The Use of Clinical Information Systems to Optimize the Care of Type II Diabetics in an Ambulatory Setting

By

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A Master’s Paper submitted to the faculty of The University of North Carolina at Chapel Hill
In partial fulfillment of the requirements for The degree of Master of Public Health in The Public Health Leadership Program.

Chapel Hill

2004
Abstract

Background

In the search to optimize care of type II diabetics, computers have become an integral part of patient care. Clinical information systems are computerized systems that are increasingly being used in the medical field.

Objective

To examine the effectiveness of computerized clinical information systems on improving both physician management processes and patient outcomes in the management of type II DM compared to usual care with no system.

Research Design and Methods

This is a systematic review of Randomized Controlled Trials (RCT), Clinical Controlled Trials (CCT), and Controlled Before and After Studies (CBA) evaluating the effectiveness of clinical information systems used by health professionals in optimizing care for type II diabetics. The MEDLINE database (1994-2004) was searched using keywords: “type II diabetes” and “primary care,” “community care,” or “outpatient care.” All articles that contained studies involving interventions in outpatient settings, directed at providers, and involving one component of computerized clinical information systems (diabetes registry, point-of-care reminder, feedback) were included in the review.

Results

A total of 6 studies met the inclusion criteria. Studies were RCTs, CCTs, or CBAs. All studies involved diabetes registries, 5 included physician feedback, and two involved computerized reminders. The quality of the studies ranged from good to poor, with only one study receiving a poor quality assessment. The clinical information systems showed marked improvement in the process of care for diabetic patients by providers. Yet, there was much less of a positive effect on actual patient outcomes.

Conclusions

Professional interventions that include clinical information systems will improve the process of care for diabetic patients. The effect of clinical information systems on patient outcomes is minimal. Longer studies in the future may reveal better patient outcomes as well as prolonged provider adherence to protocols.
**Background**

Due to increased usage of computers in outpatient medical settings, this review is intended to update the findings on the effect of clinical information systems on physician adherence to guideline recommendations and intermediate outcomes of type II diabetic patients.

**Prevalence**

Type II diabetes, considered a disease of adults, accounts for 90-95% of all diagnosed cases. The age group most affected by this disease is those who are 60 years and older. Eighteen point three percent of this population has diabetes (1). The current rates do not tell of the rapid increase in the prevalence of diabetes. As seen in a recent study, the prevalence of self reported diabetes has increased 49% in the 10 years between 1990 and 2000. The prevalence increased from 4.9% to 7.4% within the span of a decade. As of 2000 the population of diabetics 18 or older was estimated at 17 million people (5). With current rates the Census Bureau projects the population of diagnosed diabetics to reach 14.5 million by 2010 (8). The leading factor in the increasing prevalence of diabetes is the 1.3 million cases of newly diagnosed diabetes each year (5).

**Impact on morbidity and mortality**

In the year 2000, diabetes was listed as the sixth leading cause of death in the United States. Because of the many complications of diabetes, it is likely that the disease has been underreported as the cause of death. (1) The cardiovascular
complications of diabetes may be mistaken as the primary cause of death in those who are never diagnosed as having diabetes.

Due to the increased risk for atherosclerosis, diabetics have high rates of cardiovascular complications. (7) Some studies estimate the risk for cardiovascular disease between two and fourfold that of the general population (9). The resulting heart disease is the leading cause of diabetes-related death (1). Hypertension, retinopathy, nephropathy, and neuropathy are some intermediate outcomes that physicians monitor for. The incidence of blindness in diabetics is 25 times that of the rest of the population (11). Some 35% new cases of end-stage renal disease are due to diabetic nephropathy. The resulting neuropathy contributes to 50% of non-traumatic lower extremity amputations (9).

Economic costs

Due to the increasing incidence of diabetes, the increase in diabetic medications, and resulting increase in lifespan, diabetes has become a major burden on the U.S. economy. In 2002 alone, an estimated $132 billion was attributable to both medical care and lost productivity. A total of $92 billion came from direct medical expenditures. The lost work time, disability, and premature deaths associated with diabetes cost the U.S. $40 billion. Projections from the Census estimate the total cost of diabetes to rise to $156 by 2010. (6)
Current Protocol for management

Table 6—Summary of recommendations for adults with diabetes

<table>
<thead>
<tr>
<th>Glycemic control</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>&lt;7.0%*</td>
</tr>
<tr>
<td>Preprandial plasma glucose</td>
<td>90–180 mg/dL (5.0–10.0 mmol/L)</td>
</tr>
<tr>
<td>Postprandial plasma glucose</td>
<td>&lt;180 mg/dL (&lt;10.0 mmol/L)</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>&lt;130/80 mmHg</td>
</tr>
<tr>
<td>Lipid profile</td>
<td></td>
</tr>
<tr>
<td>LDL</td>
<td>&lt;100 mg/dL (&lt;2.6 mmol/L)</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>&lt;150 mg/dL (&lt;1.7 mmol/L)</td>
</tr>
<tr>
<td>HDL</td>
<td>&gt;40 mg/dL (&gt;1.1 mmol/L)</td>
</tr>
</tbody>
</table>

Key concepts in setting glycemic goals:
- Goals should be individualized
- Certain populations (children, pregnant women, and elderly) require specific considerations
- Less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia
- More stringent glycemic goals (i.e., a normal A1C, &lt;6%) may further reduce complications at the cost of increased risk of hypoglycemia (particularly in those with type 1 diabetes)
- Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals

*Reference to a metabolic range of 4.0–6.0% using a DCCT-based assay. *Postprandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes. "Current ADA/ACCF/AHA/ADA/ACCF/AHA guidelines suggest that in patients with triglycerides &gt;200 mg/dL, the "non-HDL cholesterol" total cholesterol minus HDL be utilized. The goal is 150 mg/dL (1.7). For women, it has been suggested that the HDL goal be increased by 10 mg/dL.

by expert opinion to set a level of diabetes control for physicians to try to reach.

The ADA goal for control of glycemia is HbA1C level less than 7% which is 1% above the upper limits of normal (12). Although this goal has not been proven by evidence based medicine, both the Diabetes Control and Complications Trial (DCCT) and the U.K. Prospective Diabetes Study (UKPDS) found that maintaining HbA1C levels ~7% reduces the risk for microvascular complications. The trials also indicate that a 1 percentage point reduction at any HbA1C will reduce the risk for microvascular complications by 25% to 30% (25, 26).

The current ADA goal for blood pressure control is systolic blood pressure less than 130 mm Hg and diastolic blood pressure less than 80 mm Hg. Clinical trials do indicate that a 10mm Hg reduction in blood pressure can lead to a
decrease in mortality rate of 35%, as well as a decreased risk of micro- and macrovascular complications (27).

The goal for lipid management is as follows: lowering low density lipoprotein cholesterol (LDL-C) to less than 100 mg/dL, increasing high density lipoprotein cholesterol (HDL-C) to greater than 45 mg/dL for men and 55 mg/dL for women and lowering triglyceride levels to less than 150 mg/dL. The National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP-III) additionally sets a goal for total cholesterol levels of less than 200 mg/dL (8).

The most recent study measuring the adherence to ADA and NCEP-ATP-III guidelines by diabetic patients is the National Health and Nutrition Examination Survey of 1999-2000 (NHANES 1999-2000) revealed that only 37% of diabetics have reached the HbA1C goal of <7%. More importantly the NHANES III revealed that around 24.9% of diabetics have HbA1C levels >9%. In the fight for blood pressure control, more than 1/3 of diabetics had systolic hypertension defined as SBP >140 mm Hg; only 6.5% had diastolic hypertension >90 mm Hg. More than 23% of diabetic patients failed to reach total cholesterol goals of less than 160 mg/dL (4.2 mmol/l) despite receiving preventive care (28). Overall, a lowly 7.3% of adults with diabetes attained all three recommended goals. The NHANES 1999-2000 study showed no significant change in the amount of patients attaining targets of HbA1C or blood pressure control, yet did show a significant decrease in the amount of patients with hypercholesterolemia (8).
There are several protocols for disease management for patients with type II DM. The American Diabetic Association has laid out a protocol that is less stringent yet outlines the minimal care to satisfy adequate diabetic monitoring. Strict adherence to the guidelines has promoted excellent outcomes in glycemic, blood pressure, and cholesterol control (10). Yet despite well known benefits of following guidelines, underuse of recommended preventive care practices is common (9).

**Chronic Care Model**

In order to optimize care for diabetes as well as other chronic illnesses, Bodenheimer, et al. has created the chronic care model. This model included 4 components: Self-management support, delivery system design, decision support, and clinical information systems. Self-management support involves helping patients and their supports acquire the skills and confidence to manage their chronic illness, providing self management tools, and routinely assessing problems and accomplishments. Delivery system design creates more efficient
practice teams with a delegation of labor to separate acute care from the planned management of chronic conditions. The physician deals with acute problems while non-physician personnel can support patient self-management and arrange routine testing, and examinations. Decision support involves using evidence-based clinical practice guidelines. These guidelines are then integrated into daily practice through reminders. The model also promotes more communication between generalists and specialists without official referrals. Clinical information systems are rooted in computer technology. Computers are used for 3 primary functions:

1) reminder systems to help physicians adhere to guidelines
2) feedback on physician performance on measuring chronic illness outcomes
3) disease-specific registries that allow all data relating to the condition to go into an individual patient's registry file (13).

**Computerized Clinical Information Systems**

Medicine is one of the last leading industries to integrate computers into practice, yet many in the healthcare industry feel that computers are needed to optimize care of chronic diseases such as diabetes. Two previous systematic reviews include the examination of the effects of computerized reminders on improving management of type II DM in outpatient care (23) and (13). Renders found that computerized reminders both alone and in combination with other interventions improved process measures, yet had conflicting results in patient outcomes. Bodenheimer et. Al. used the Renders systematic review as a template to perform their own review on the process measures and patient outcomes of
interventions that were part of the chronic care model. The results suggested that clinical information systems both alone and in conjunction with other components of the chronic care model led to both positive outcomes and positive processes.

**Objective**

To examine the effectiveness of computerized clinical information systems on improving both physician management processes and patient outcomes in the management of type II DM compared to usual care with no system.

**Research Design and Methods**

**Identification of studies**

This systematic review included studies of diabetic care programs featuring the clinical information system component of Wagner, et. al. (24) chronic care model. Bodenheimer et. Al performed a similar search that included all components of the model ending in 2000. It was based on Render’s et. Al systematic review under the effective Practice and Organization of Care (EPOC) review group search strategy. The EPOC review group is part of the Cochrane Collaboration which is an international organization that performs systematic reviews of the effects of health care interventions. The same search strategy from Render’s study was used in this systematic review. The MEDLINE (1994-2004) database was searched using free-text words and key words regarding “type II diabetes” and “primary care,” “community care,” or “outpatient care.” The search results
were limited to the English language due to lack of financial resources to translate any non-English publications. This produced 522 results.

Study Selection

Studies from the search results were included in the review if they evaluated the effectiveness of computerized clinical information systems directed at healthcare professionals who care for ambulatory patients with type 2 diabetes in primary care, outpatient, or community settings. Using modifications to the Cochran Effective Practice and Organization of Care Review Group (EPOC) inclusion criteria (Renders, 2001) the included studies had to be of one of the following designs:

1) Randomized Controlled Trial (RCT): a trial in which the participants (or other units) were definitely assigned prospectively to one or two (or more) alternative forms of healthcare using a process of random allocation (e.g. random number generation, coin flips).

2) Controlled Clinical Trial (CCT): may be a trial in which participants (or other units) were:

   a) definitely assigned prospectively to one or two (or more) alternative forms of health care using a quasi-random allocation method (e.g. alternation, date of birth, patient identifier) or;
   
   b) possibly assigned prospectively to one or two (or more) alternative forms of health care using a process of random or quasi-random allocation.

3) Controlled Before and After Study (CBA): involvement of intervention and control groups other than by random process, and inclusion of a baseline period of
assessment of main outcomes. There are two minimum criteria for inclusion of CBAs in EPOC reviews:

a) Contemporaneous data collection

Pre and post intervention periods for study and control sites must be the same.

b) Appropriate choice of control site

Study and control sites must be comparable with respect to level of care, setting of care, and academic status.

4) Interrupted Time Series (ITS): change in trend attributable to the intervention. There are two minimum criteria for inclusion of ITS designs in EPOC reviews.

a) Clearly defined point in time when the intervention occurred.

The precise point in time of the intervention must be reported

b) At least three data points before and three after the intervention.

After ensuring that the article fit one of the previous study designs, the article had to fit the other inclusion criteria:

1) The intervention had to be in an outpatient setting, including but not limited to hospital based ambulatory care clinics or private practices.

2) This review is intended to study the effectiveness clinical information systems used by health care providers in optimizing care for type II diabetes. Therefore, studies that were only patient-oriented were excluded from the review.

3) The intervention had to involve one component of clinical information systems:

   a. Computerized Diabetes Registry
b. Computerized Point-of-Care Reminder

c. Computerized Feedback system to reminder

Articles included in the study also had to have an objective measurement of performance/provider behavior of health/patient outcome(s) in a clinical, not test, situation.

The inclusion criteria were applied to each article in a stepwise fashion during the abstract review. If an inclusion criterion was applicable to an abstract or could not be determined from the abstract, the next inclusion criterion was applied. This process was repeated until an article was either stricken from the review or all inclusion criteria were met. If there were still some question of the fit in the inclusion criteria at the end of the abstract review, the original article was examined to see if all inclusion criteria were met.

Data Extraction

Data extraction was performed by a single reviewer (E.B.) using an adapted version of the EPOC Data Collection Checklist (Appendix 1) (Cochrane EPOC, 2002). A second reviewer was not used due to both finance and time constraints. If finances and time allowed, a second reviewer would be incorporated into the review to independently extract the data. A third reviewer would be called upon if there was any disagreement between the primary and secondary reviewer.

Quality Criteria

The quality of eligible trials was assessed using the standard criteria described by the EPOC group (Cochrane EPOC, 2002). The following seven
standard criteria were used for the randomized controlled trials (RCTs) and controlled clinical trials (CCTs), which made up the bulk of the studies reviewed: a) concealment of allocation (protection against selection bias); b) follow-up of professionals (protection against exclusion bias); c) follow-up of patients or episodes of care; d) blinded assessment of primary outcome(s); e) baseline measurement comparability; f) reliability of primary outcome measure(s); g) protection of the control group against contamination.

Since this study was based on provider specific interventions, concealment of allocation was scored DONE if the unit of allocation was by institution, team or professional and the authors described the method of randomization such as a coin toss or a computerized randomization. Concealment was scored NOT CLEAR if there was no explicit mention of the unit of allocation or method of randomization. Concealment was scored NOT DONE if the authors reported using alternation such as reference to case record numbers, hour of day seen, day of the week or any other such approach (as in CCTs); or the allocation was altered (by investigators, professionals, or patients) in a process such as matching.

Follow-up of professionals was scored DONE if greater than 80% of the professionals in the study had recorded outcome measures. If the follow-up rate was not specified in the paper the article received a NOT CLEAR. If outcome measures were obtained for less than 80% of the provider participants in the study the article received a NOT DONE.

In order to further ensure quality of the study follow-rates of the patients within the study should also be high. Patient follow-up was scored DONE if patient outcome measures represented greater than 80% of the patients entered in
the study. The study received a NOT CLEAR if the follow-up rate was not specified in the paper. A score of NOT DONE was reserved for studies that stated a follow-up rate less than 80%.

The primary outcome(s) were defined as those outcomes related to the authors' primary hypothesis. Assessment of the outcomes had to be blinded to prevent detection bias. Blinded assessment was scored DONE if the study stated that the primary outcome variables were assessed blindly or they were objective measures, e.g. HbA1C levels. A score of NOT CLEAR was given if quality of assessment was not specified in the paper. A score of NOT DONE was given in the outcome(s) were not blindly assessed.

A quality baseline measurement insures not confounding variables were present across study groups. Quality baseline measurement was scored DONE if the provider process measures or patient outcomes were measured before the intervention and there was no considerable difference between the study and control groups. A study was given a score of NOT CLEAR if there is no report of baseline measures or it is unclear if there is a significant difference in baseline measures across the study groups. A score of NOT DONE was recorded if there are differences in baseline measures that remain after the intervention.

A study was given a score of DONE if the two or more raters of primary outcomes had a kappa greater or equal to 0.8. The score of DONE could also be given if the outcome came from an automated system, e.g. mechanized assessment of blood pressure. The score of NOT CLEAR was assigned to any paper in which reliability is not recorded in a paper that used chart extraction or
data collected by an individual. A score of NOT DONE was given to any studies with an inter-rater reliability of less than 0.8.

To protect against cross-contamination of study participants must remain separated by study arms. This is scored as DONE if allocation was done by practice, community, or groups within a practice and it is unlikely that the control population received the intervention. A score of NOT CLEAR was assigned if providers were allocated within a practice and it is possible that communication between the subjects could have occurred. A score of NOT DONE is assigned to any study in which the control group received the intervention.

Controlled before and after (CBA) designs followed slightly different quality criteria. The seven criteria were for a) baseline measurement; b) characteristic for studies using a second site as control; c) blinded assessment of primary outcome(s); d) protection against contamination; e) reliable primary outcome measures; f) follow-up of professionals; and g) follow-up of patients. All scoring for the CBAs was the same as those of RCTs and CCTs except scoring criteria b). If the characteristics of the study and control providers are similar, then a score of DONE is assigned. If the paper does not clearly have a table showing the similarities between providers, but the text does, a score of NOT CLEAR is assigned. A score of NOT DONE is given if there is no report of characteristics in the text or table, or the table shows significant differences between the study and control providers.

In order to give an overall grade for the quality of the paper, I created my own grading standard. Those studies that met six to seven criteria categories were given a grade of GOOD. Those studies that met four to five out of seven
categories were given a grade of FAIR. Those studies that completed 3 or less criteria were given a grade of POOR.

Data was extracted that contained either process measures of physician performance or patient outcomes as a result of diabetic care. Performance measures include, but are not limited, to percentage of patients with hemoglobin A1C (HbA1C) and low density lipoprotein-C (LDL-C) tests, a foot exam, and eye-exam by an eye care specialists in the previous 12 months. Patient outcome measures include, but are not limited to, mean HBA1C, LDL-C, and blood pressure levels.

Data Analysis

Data from included studies were tabulated in terms of means with standard error (SE) for patient outcomes and proportions for process measures, when possible; other data were presented as outlined in the original source. Data from each study were divided into diabetes care processes and patient outcomes when applicable. Baseline data were recorded to provide a comparable measure of the study groups. P-values tested the differences between the intervention and control groups in change in means or proportions from the baseline values. A statistically significant change was valued at $P<0.05$.

Due to the heterogeneity of interventions, study populations, settings, and reported outcomes, a pooled analysis was not possible. However a qualitative assessment of the effects of the studies was made based on the quality of the study and the magnitude and direction of the observed effects.
Results

The initial search strategy for articles yielded 530 results. Twenty-nine articles were removed for not addressing Type II Diabetes Mellitus. Another 355 articles were eliminated for not being an RCT, CCT, CBA, or ITS. Three articles were removed for not being in an outpatient setting. One hundred one studies were removed for not being a provider focused intervention. Another 31 studies were removed for not encompassing one of the components of clinical information systems. This left 11 studies available for article review. Due to time and financial constraints, any articles which could not be found either online or through the University of North Carolina Health Sciences Library were also eliminated; this number included 3 more studies. After further examination, two more studies were removed from the review, one for being in French and the other for being a planned study. This elimination scheme left 6 studies that met the inclusion criteria of this review. A flow diagram has been provided in (figure 1).

A rather equal distribution of study types were represented in the included studies. Two of the six studies were EPOC Criteria approved randomized controlled trials; two were clinical controlled trials; and 2 were controlled before and after studies.

In 5 of the 6 studies (15-19,) the interventions and process measurements were based on clinical guidelines for the management of type II diabetes. One study (19) was based on the American Diabetic Association guidelines for
management of hyperglyceridemia, hypertension, and hyperlipidemia; two (15, 16) were based on national guidelines, one (16) was based on local guidelines, and one study (18) did not record the source of the guidelines.

Computerized reminders were the intervention in 2 studies (17, 20). Often it was in combination with the other two clinical information systems components. Based on the results computerized reminders seem to have a positive effect on physician process measures related to type II DM care, and a positive effect on patient outcomes.

Physician feedback was the primary intervention in five out of six studies (15-19). Although this was also found in combination with the other components of clinical information systems, it was never the sole intervention in any study. Based on the results physician feedback seems to have a positive effect on physician process measures related to type II DM care, and a positive effect on patient outcomes.

Registries were included in the intervention in veritably all of the studies (15-20). Oftentimes registries were used in conjunction with specialist and other health care professional communication with the primary care providers. Based on the results diabetic patient registries seem to have a positive effect on physician process measures related to type II DM care, and a positive effect on patient outcomes. However, the broad use of a combination of the components of clinical information systems makes positive outcomes and process measures attributable to a specific component difficult.
Meigs, et. al. 2003

Meigs et. al. performed a randomized controlled trial examining both patient outcomes and diabetes management after application of a web-based information management/clinical decision support tool, which included both patient-specific registries and feedback based on national guidelines for diabetes, hyperlipidemia, and hypertension. No involuntary reminders were included in this study. Based on EPOC quality criteria, this study was performed in an adequate manner. However, a score of NOT DONE was given to the baseline measurement because there was a significant difference in the amount of foot examinations per year between the study and control groups at both baseline and in change from baseline. Even though the physicians included in the study remained throughout the entire study period, they only used the diabetes management application (DMA) during 42% of scheduled visits. The authors did note that a secondary "treatment received" analysis did produce similar effects as the intention-to-treat analysis, which underlines the effectiveness of the DMA. The Meigs study received an overall quality rating of GOOD with 6 out of 7 quality criteria met.

In regards to patient outcomes as the result of the DMA, the system showed only a negative effect on mean systolic blood pressure levels. All other patient outcomes were nonsignificant. There was no significant change in patient proportions reaching guideline recommended levels of HbA1C<7%, LDL-C <130mg/dl, or blood pressure <130/85 as compared with the control group. There was also no significant change in mean HbA1C, mean LDL-C, and mean diastolic
blood pressure. The glycemic control did show an increase in the intervention group and decrease in the control group.

Process measures improved with the intervention. There was a significant improvement in the mean number of HbA1C tests per year, the mean number of LDL-C tests per year, and the percentage of patients receiving at least one foot examination in the past 12 months. In the measure of patients receiving a foot examination, 82% of the control group and 65.5% of the intervention group received one in the past 12 months at baseline. The significant change in the intervention group is likely attributable to the upper threshold of care of the control group.

Grant, et. al. 2003

Grant, et. al. performed a controlled before and after study examining the effects of population based feedback on the processes of care for type II diabetics. One hundred forty-nine patients with the highest HbA1C and cholesterol levels at one primary care sight were selected for intervention of e-mail recommendations based on ADA guidelines to the patients’ PCP. Another site, matched in a 1:1 ratio within 5 years of age, 0.5% HbA1C, and 10 mg/dl total cholesterol, served as the control group.

Because Grant, et. al. performed a controlled before and after study, selection bias is inherent in the fact that the investigators chose the control population. However, matching by the patient outcomes of interest may have decreased some of the bias. Baseline characteristics of the patient populations were DONE in a proper fashion. There were no significant differences between intervention and
control patient populations. Baseline measurement of providers showed that there were substantial differences across the study groups. Physicians at the intervention site had significantly less amount of training, 12.9 years (SD 7.0), than those of the control site, 22.9 years (SD 10.0), p-value <0.0001. They also performed less cholesterol checks in the previous year per patient 1.1 (SD 0.9) vs. 1.3 (SD 1.0), respectively, p-value = 0.04. Because the results of tests and testing rates were recorded on an electronic medical record (EMR,) there was adequate protection against selection bias and reliable measurement of primary outcomes. Due to the fact the control site was a completely separate practice, there was no potential for contamination. Follow up of professionals was adequate, but follow up of patients was not properly performed. Only 74% of the patients were seen during the 3-month follow up period. Grant received an overall quality rating of FAIR with 5 out of 7 quality criteria being met.

Recommendations made by the population manager to the physicians were either for repeat testing (of HbA1C, blood pressure, or cholesterol), or change in therapy (for glycemic, blood pressure, or cholesterol control.) There was a significant difference in percentage of total recommendations followed between intervention (59%) and control sites (45%), (p = 0.2). However there was no significant difference in percentage of recommendations when the recommendations were analyzed by repeat testing or changes in therapy. These results show that there is a significant change in adherence to evidence-based guidelines with the implementation of population based feedback. However due to the rather short follow-up period of 3 months, this study does not tell if adherence is maintained throughout the care of such a chronic disease.
Olivarius, et. al., 2003

Olivarius, et. al. performed a randomized controlled trial involving regular follow-up and individualized goal setting of patients supported by prompting of doctors, clinical guidelines, feedback, and continuing medical education in the treatment of type II diabetes. Therefore, actual use of clinical information systems is but a small part of this intervention. This large study included 311 practices and 474 providers in Denmark in a study that lasted 48 months.

This study was strongly performed by EPOC quality standards. Allocation was adequately concealed by stratification and then randomization by random numbers into two groups. Only 10 (2%) of the 484 practitioners who volunteered dropped out of the trial after randomization, thus protecting against any exclusion bias. Yet, outcomes were not attained for 31% of patients that met the study’s inclusion criteria. A great majority (23%) of those patients died before completion of the intervention; the others died before the completion of follow-up (2%), withdrew consent (3%), or was lost to follow-up (3%). Detection bias for the outcome was prevented by using computerized assays. The only in which reliability was not clear was for retinopathy. A separate group of ophthalmologists performed the eye exam and there is no recording of inter-rater reliability. At baseline there were no significant differences across study groups for process measures or patient outcomes. Because the clinicians were randomized by practice it is unlikely that there was any contamination in the study. With 6 out of 7 quality criteria met, Olivarius received an overall quality rating of GOOD.
The multi-faceted intervention had a positive overall effect on outcome. The intermediary marker levels of median fasting plasma glucose (7.9 mm/l vs. 8.7 mm/l, p = 0.0007); median HbA1C % (8.5 vs. 9.0, p<0.0001); and percent of patients with glycosuria (22 vs. 37, p<0.0001) were all significantly improved by the intervention. There was no substantial effect on mean total cholesterol levels, fasting triglyceride levels, or serum creatinine levels. There were significantly less patients with albuminuria >15mg/l (22.5% vs. 30.8%, p = 0.04). There were no significant decreases in the major endpoints of diabetes with respect to overall mortality, diabetic retinopathy, myocardial infarction, stroke, peripheral neuropathy, or amputation at the p <0.05 level.

The intervention tested by Olivarius et. al. also showed improvement in process measures. Due to the intense management at the primary care site, less patients had to be referred to a diabetes clinic (17% vs. 26%, p=0.009). There was also an increase in the median amount of diabetic related consultations per year for each patient (4 (interquartile range 3-6) vs. 4 (interquartile range 2-6), p<0.0001). The number of hospital admissions was the same in each group.

Vaughan and Potts, 1996

Vaughan and Potts performed a clinical controlled trial involving a decision support system with reminders that can be applied to a computer. Reminders are based upon hyperglycemia treatment methods, the patient’s current state of glycemic control, trend of glycemic control, current BMI, and weight changes. This trial tests if such an intervention will improve diabetic control if used by a
primary care nurse. General practices within the United Kingdom were divided into an intervention and control group, matching for size, geographical area, and standards of existing diabetes care.

This article achieved 3 out of 7 of the EPOC quality criteria for a clinical controlled trial, which made it a POOR study. Because the study did not have a randomization scheme protection against selection bias was not strong. There was no mention of follow-up rates of the professionals involved in the study. The article also failed to mention how the study was narrowed to 228 total patients. Although it did mention some exclusion criteria, the study failed to mention patients who dropped out or were lost to follow-up. Because all HbA1C measurements are objective values protection against detection bias can be maintained, and the primary outcome of HbA1C level is reliable. Baseline measurements and comparisons between study and control groups did state similar weights and treatment regimen, yet failed to compare baseline HbA1C levels. Because all control patients were seen at clinics other than the intervention clinic, contamination is unlikely. Beyond EPOC Criteria, the Vaughan study was poorly written. Without a baseline measure of HbA1C values for each of the groups, it is impossible to follow the data that they claim. Also, values given in the results section of the test do not correspond to the results given in the data table. Because the ruleset study excluded patient with serious coexisting diseases such as cardiac and renal failure, the ruleset itself cannot be applied to these patients.

Despite its many limitations, the Vaughan study found that the intervention led to an increased proportion of patients with HbA1C values <7.5% (88% vs.
63%, p<0.05). Although a process measure was performed in the study, a lack of statistical significance measure excludes it from being reported in this review.

de Sonnaville, et. al., 1997

de Sonnaville, et. al. performed a clinical controlled trial examining the effects of a structured care program for type II diabetics that involved a laboratory with facilities to visit patients at home, a computerized patient register and recall system, a wide-angle retinal camera, a dietician, diabetes nurse educator, a podiatrist, and a diabetologist available 24 hours per day. The study group contained 22 general practitioners, while the control group contained six. These two groups were not matched for any characteristics.

This study was fairly performed by EPOC standards. Five out of seven EPOC quality criteria were reached in the study, which made it FAIR. The lack of either randomization or matching greatly decreases the strength of the study. It is not known whether one group of physicians had greater experience dealing with diabetic patients, and therefore having a patient population that had better glycemic control. All 28 professionals did participate in the follow-up to the intervention. The study failed at assuring optimal follow-up of the study and control patients. Some 23.1% of the intervention patients dropped out during the 2 years of follow up. Another 33.3% of the control population dropped out during the follow up period. All outcomes were performed by computer assays, therefore detection bias was avoided. Baseline measurements of outcomes were performed, which yielded significantly more men, a higher fasting glucose and a
higher systolic blood pressure in the control group. Because the outcome measures were objective measures of diabetes, the primary outcome measures were deemed reliable. Contamination was avoided by allocating the intervention and control to different practices within Amsterdam.

Sonnaville revealed a significant improvement in patient outcomes as the result of this intervention that included a computerized patient register and recall system. This system showed marked results in the area of glycemic control. Mean fasting plasma glucose of the intervention group was improved significantly over that of the control group. Fasting plasma glucose went from 8.9 ± 2.5 to 8.1 ± 2.5 mmol/l in the study group while it went from 9.6± 3.4 to 9.8 ± 2.9 mmol/l in the control group (p=0.004). Mean HbA1C (%) produced similar findings when intervention went from 7.4 ± 1.6 to 7.0 ± 1.3% and control went from 7.4 to 7.6% (p=0.004). The percentage of patients with an HbA1C <7.5% followed the same trend of the previous measures of glucose control with the proportion improving from 43.4 to 54.3% in the study group and regressing from 54.4 to 44.1% in the control group (p=0.008). The total cholesterol level changed in a similar fashion as the glucose control markers in that the intervention group improved while the study group progressively worsened, 6.1 ± 1.3 to 5.8 ± 1.1 and 5.9 ± 1.0 and 5.9 ± 1.0 mmol/l respectively (p=0.002). There was no significant improvement as a result of the intervention for all other diabetic outcomes.

Branger, et. al., 1997

Branger, et. al. performed the second controlled before and after study (1-year) in the review. This study examined the effects of an electronic communication
network combined with a patient registry and reminders on the patient outcomes and the management of type II diabetes mellitus. The computerized system tested allows the physician to inspect and record clinical data during the patient encounter then reminds the physician to compose a message for communication with other providers for the patient. The 20 general practitioners who referred the highest number of patients to a diabetic consultant were selected to the intervention group, while the remaining 12 providers were allocated to the control group. The intervention providers were given the inter-physician communication module while the control physicians continued with their usual care for patients.

Branger’s study met 4 out of 7 quality criteria for EPOC reviews which made it a FAIR study. Proper baseline measurement was not done during this study. There were more type I diabetics in the control population (43%) than in the intervention (29%). This creates a problem in trying to compare patient outcomes due to the risk of hypoglycemia in type I diabetics. Characteristics of the study and control providers were similar yet not clear due to a lack of data table comparing the providers in each group. Each group had an average of 12 contacts per patient per year in 1993 and 14 contacts per patient per year in 1994. Since the outcomes and process measures were taken from the electronic data interchange (EDI), there was adequate protection against detection bias. Since the EDI was only equipped in study practices, contamination of the study was highly unlikely. The automated system recording outcomes ensured reliability of the outcomes. There were no drop-outs for professionals or patients, thereby fulfilling the last two EPOC criteria.
Only one measure of patient outcomes was performed in this trial. HbA1C was not significantly changed as a result of the intervention. The baseline mean values for intervention and control were 7.0 and 6.6%, respectively. The mean difference after the follow-up period was -0.12 ± 0.36 and -0.21 ± 0.19%, respectively, (p=0.68).

Use of the intervention led to an increase in several process measures for diabetes. The amount of tests for kidney function was not significantly improved. This included both serum creatinine levels and proteinuria. There was no significant increase in ophthalmologist assessments either. Glucose control significantly improved as the result of the intervention. Both HbA1C and fructosamine level tests per patient per year increased at a significant level, p=0.003 and p=0.01, respectively. Checks for hypertension were also improved, p=0.000. Hyperlipidemia control became more important as well. Cholesterol and triglyceride assessments were also increased, p=0.03 and p=0.02, respectively. Due to the link between weight and glucose control, frequent analysis of weight is important. Weight checks were increased significantly due to the EDI, p=0.000.

**Discussion**

This review was performed to identify components of clinical information systems (CIS) that improved care for type II diabetics by either better control over outcomes or optimization of management. Although several studies exist that address clinical information systems and their use for diabetes-self management, this review focused on CIS that was created for provider use. In addition to
randomized controlled trials, studies with controlled before and after and clinical controlled trials that fulfilled the EPOC group methodological and quality criteria, met the review's inclusion criteria, and were published between 1994 and 2004 were included. A total of 6 studies were therefore included in this review.

Electronic registries were used throughout each of the studies involved in the review. Because it is a constant throughout all interventions, this cannot be directly attributed to making an impact on diabetes care. However, without the use of diabetic registries within electronic medical records, the other two components of clinical information systems can not exist. Thus, I can conclude that the combination of patient specific registries combined with other aspects of clinical information systems improves both patient outcomes and the process of care.

Computerized reminders were used in two of the six studies. One study received an overall quality rating of GOOD while the other received a rating of FAIR. These two studies found a positive effect on process measures through the use of computerized reminders combined with other interventions. Results suggest that the number of diabetes specific laboratory tests increase with the use of reminders. This improved care translates into optimization of primary care management of diabetes, which is suggested by a decrease in percentage of patients treated in a diabetes clinic each year.

Feedback to physicians allows physicians to gauge their performance based on treatment goals. These treatment goals are usually outlined by evidence based guidelines for improving diabetes care (20). Five out of six studies incorporated
physician feedback into their intervention. The percentage of patients having good control (HbA1C < 7.0%) seems to improve with the use of feedback on physician performance. Two studies showed a positive effect while one study showed no effect. Only one study addressed the effect of feedback on the other measures of good diabetic control (BP < 130/85 mmHg and LDL-C < 130 mg/dl). It showed no significant effect on the percentage of patients reaching these goals.

Feedback has been proven to positively affect process measures (21). Computerized feedback seems to have the same effect. One of the stronger studies showed an increased number of HbA1C and LDL-C tests performed per patient per year. The same study also showed an increased likelihood of getting a foot examination. These early interventions have the potential of decreasing some endpoint outcomes of diabetes, yet there is no clearly defined relationship.

Limitations of the review

The fact that most of the studies included in the involved other interventions outside of the use of clinical information systems must be emphasized. Due to the multitude of additional interventions, any potential effect of clinical information systems on both diabetic outcomes and processes of care is diminished. In one study clinical information systems were used to support other main interventions such as population management (15). Improvement in outcomes cannot be attributed to computer information systems alone, yet they do play a significant part in optimizing patient care.
The small number of studies is another limitation to this review. This is due in large part to the time commitment of the study and lack of monetary resources. Oftentimes, two or more reviewers perform vast searches on multiple databases, because these projects are funded by federal grants and private organizations. With a lack of such financial resources, this systematic review was carried out on only one database, MEDLINE (1994-2004). Due to the progressive use of computers in outpatient medicine, some of the most recent research may not have been catalogued in MEDLINE when the review was performed. The lack of monetary resources also limited the ability to identify unpublished studies.

The methodological quality of the included studies was often limited. Although there were two studies rated as good by the EPOC quality criteria, even these studies had their limitations. One study failed to ensure that there were no baseline differences that might alter the post-intervention statistics (15). The other failed to ensure >80% follow up of the patients (17). The most common limitations to the individual studies included lack of concealment of allocation, lack of physician follow-up, patient follow-up and proper baseline measurements.

**Generalizability**

Due to fairly strict inclusion criteria of the individual studies, application of the results of this review can be applied only to the care of type II diabetic patients that have no other severe co-morbidities. The studies were also performed in various national and regional settings. Nations other than the United States have both different patient demographics and different health care systems. Because the non-white population is so small in Europe, being of this group was
often an exclusion criterion. Therefore, it is difficult to apply some results to the American Diaspora. The different health care systems create differences in training of physicians. If one nation already puts more emphasis on structured care for diabetes, the impact of CIS may be diminished. Thus, generalizations from this review should be done with some reservations.

Implications for future research

The results have shown that although CIS may not be sufficient to optimize care for type II diabetes, but it is necessary. The use of computer systems streamlines the delivery of care for complex diseases such as diabetes. It allows for better communication between professionals, which translate in more continuity of care.

In this review only 3 out of the 6 studies recorded both patient outcomes and physician process measures. Patient outcomes have long been benchmarks for judging quality of care, yet the activity of physicians is also a good indicator. Without process measures, the implementation rate of needed interventions would be overlooked. Therefore, both process measures and patient outcomes should be incorporated in future research.

Due to the rapid progression of computer technology, and the rapid pace of medical practice, physicians may find adjustment to new computer systems difficult. Qualitative assessments of physician level barriers to use of CIS should be included in future studies. The feedback from providers indicating the aspects of CIS that make practice easier and more difficult should assist in optimizing more user friendly systems. Because the physician-patient relationship is so
crucial to improved care for chronic diseases, qualitative research should also involve patients to assess any barriers CIS promotes between patient and provider.

Longer research studies should be implemented to determine the long term effectiveness of the use of CIS when incorporated into structured care. The longest follow-up period in this review was only 4 years. A majority of the studies in this review addressed intermediary outcomes that are merely predictors of endpoint outcomes. A longer study that measures endpoint outcomes such as overall mortality, myocardial infarctions, kidney failure, blindness, and amputations, will better judge the long term benefits of CIS. These longer research projects can also be used to determine if use of clinical information systems leads to prolonged adherence to guidelines by physicians.

Results: 530 articles

- Article Addresses Type II DM.
  - YES 501 Articles
  - NO 29 Articles

- Article is an RCT, CCT, CBA or ITS.
  - YES 146 Articles
  - NO 355 Articles

- Study is performed in an outpatient setting.
  - YES 143 Articles
  - NO 3 Articles

- Intervention is provider focused.
  - YES 42 Articles
  - NO 101 Articles

- Intervention involves clinical information system component.
  - YES 11 Articles
  - NO 31 Articles

- Article found in UNC Health Sciences Library.
  - YES 8 Articles
  - NO 3 Articles

- Article is written in the English Language.
  - YES 7 Articles
  - NO 1 Article

- Study has been completed.
  - YES 6 Articles
  - NO 1 Article
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Design</th>
<th>Intervention</th>
<th>Setting</th>
<th>Follow-up (months)</th>
<th>Quality Criteria*</th>
<th>Results</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sonnaville</td>
<td>1997 (18)</td>
<td>CCT</td>
<td>i) computerized patient register and recall system</td>
<td>Netherlands general practice</td>
<td>24</td>
<td>a) NOT DONE</td>
<td></td>
<td>patient (+) study quality (FAIR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b) 561</td>
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<td>c) unknown</td>
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</tr>
<tr>
<td>Branger,</td>
<td>1999 (19)</td>
<td>CBA</td>
<td>i) computerized registry with electronic communications module</td>
<td>Netherlands general practice</td>
<td>12</td>
<td>a) NOT DONE</td>
<td></td>
<td>patient (0) study quality (FAIR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>b) 275</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient outcomes</th>
<th>Intervention Baseline/Δ</th>
<th>Control Baseline/Δ</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean FPG (mmol/l)</td>
<td>8.9(2.5)/-0.8</td>
<td>9.6(3.4)/+0.2</td>
<td>0.004</td>
</tr>
<tr>
<td>Mean HbA1C (%Hb)</td>
<td>7.4(1.5)/-0.4</td>
<td>7.4/+0.2</td>
<td>0.004</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.7(4.5)/+0.3</td>
<td>26.8(4.0)/-0.3</td>
<td>0.000</td>
</tr>
<tr>
<td>HbA1C &lt;7.0%</td>
<td>43.4%/+10.9%</td>
<td>54.4%/-10.3%</td>
<td>0.013</td>
</tr>
<tr>
<td>Tot Chol (mmol/l)</td>
<td>6.1(1.3)/-0.3</td>
<td>5.9(1.0)/0.00</td>
<td>0.002</td>
</tr>
<tr>
<td>HDL Chol(mmol/l)</td>
<td>1.2(0.3)/-0.05</td>
<td>1.14(0.35)/-0.0</td>
<td>0.40</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>2.12(1.64)/-0.16</td>
<td>2.01(1.46)/+0.02</td>
<td>0.12</td>
</tr>
<tr>
<td>Mean SBP (mmHg)</td>
<td>145.9(20.9)/+0.8</td>
<td>155.4(24.0)/-0.1</td>
<td>0.70</td>
</tr>
<tr>
<td>Mean DBP (mmHg)</td>
<td>87.4(10.6)/-4.4</td>
<td>88.6(11.4)/-3.5</td>
<td>0.59</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process Measures</th>
<th>Intervention Baseline/Δ</th>
<th>Control Baseline/Δ</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ave. Creatinine/yr</td>
<td>0.2/+0.3</td>
<td>0.2/+0.2</td>
<td>NS</td>
</tr>
<tr>
<td>Ave. Proteinuria/pt/yr</td>
<td>0.1/0.0</td>
<td>0.2/+0.3</td>
<td>NS</td>
</tr>
<tr>
<td>Ave. Opth. consult/pt/yr</td>
<td>0.2/0.3</td>
<td>0.3/+0.0</td>
<td>NS</td>
</tr>
<tr>
<td>Glucose level/pt/yr</td>
<td>1.0/+0.9</td>
<td>1.6/+0.2</td>
<td>NS</td>
</tr>
<tr>
<td>HbA1C level/pt/yr</td>
<td>0.0/+0.8</td>
<td>0.0/+0.2</td>
<td>0.003</td>
</tr>
<tr>
<td>Blood Pressure/pt/yr</td>
<td>0.6/+1.3</td>
<td>1.3/+0.1</td>
<td>0.03</td>
</tr>
<tr>
<td>Triglyceride level/pt/yr</td>
<td>0.6/+0.2</td>
<td>0.0/+0.1</td>
<td>0.02</td>
</tr>
<tr>
<td>Weight/pt/yr</td>
<td>0.2/+1.8</td>
<td>0.2/+0.3</td>
<td>0.000</td>
</tr>
</tbody>
</table>

* Quality Criteria is as follows: RCT/CCT a) consealment of allocation (protection against selection bias), b) follow-up of professionals (protection against exclusion bias), c) follow-up of patient or episodes of care, d) blinded assessment of 1° outcome(s) (protection against detection bias), e) baseline measurement, f) reliable 1° outcome measure(s), g) protection against contamination; CBA a) baseline measurement, b) characteristics for studies using second site as control, c) blinded assessment of primary outcome(s), d) protection against contamination, e) reliable primary outcome measure(s), f) follow-up of professionals, g) follow-up of patients; 1 Baseline characteristic difference, p < 0.05;
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Design</th>
<th>Intervention</th>
<th>Patient outcomes</th>
<th>Intervention</th>
<th>Control</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olivarius,</td>
<td>2001</td>
<td>RCT</td>
<td>i) regular follow-up and goal-setting supported by prompting of doctors, clinical guidelines, feedback, and CME</td>
<td>a) Number of providers</td>
<td>a) DONE</td>
<td>b) DONE</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>b) Number of patients</td>
<td>c) NOT DONE</td>
<td>d) DONE</td>
<td>0.55</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>c) Number of practices</td>
<td>e) DONE</td>
<td>f) DONE</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Setting</td>
<td>g) DONE</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Follow-up (months)</td>
<td>48</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Quality Criteria*</td>
<td>a) Overall mortality</td>
<td>216/649(33.3%)</td>
<td>208/614(33.9%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>b) Albuminuria ≥ 15mg/L</td>
<td>56/249(22.5%)</td>
<td>72/234(30.8%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>c) Diabetic Retinopathy</td>
<td>43/358(12.0%)</td>
<td>45/330(13.8%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>d) Myocardial Infarction</td>
<td>15/437(3.4%)</td>
<td>18/383(4.6%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>e) Stroke</td>
<td>18/446(4%)</td>
<td>16/405(4%)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>f) Periph. Neuropathy</td>
<td>69/376(18.4%)</td>
<td>69/406(21%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>g) Angina Pectoris</td>
<td>22/371(5.9%)</td>
<td>23/346(6.7%)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>h) Amputation</td>
<td>2/459(0.44%)</td>
<td>4/414(0.97%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>i) Median FPG (mmol/l)</td>
<td>13.8/-5.9</td>
<td>13.7/-5.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>j) Median HbA1C (%Hb)</td>
<td>10.2/-1.7</td>
<td>10.2/-1.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>k) Med. Tot. chol (mmol)</td>
<td>6.2/-0.2</td>
<td>6.2/-0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>l) Med. Triglyceride (mmol/l)</td>
<td>2.03/-0.25</td>
<td>1.98/-0.09</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>m) Med. Serum Creatinine (mmol/l)</td>
<td>90/-1</td>
<td>88/+3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>n) Median SBP (mmHg)</td>
<td>150/-5</td>
<td>148/+2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>o) Median DBP (mmHg)</td>
<td>85/-5</td>
<td>85/-1</td>
</tr>
</tbody>
</table>

| Vaughan,   | 1996 | CCT    | i) computerized decision support system with ruleset reminders based on pt. registry | a) Number of providers | a) NOT DONE | b) NOT DONE | <0.005 |
|------------|------|--------|                                              | b) Number of patients | c) NOT CLEAR | d) NOT CLEAR | 0.79 |
|            |      |        |                                              | c) Number of practices | e) NOT CLEAR | f) NOT CLEAR |         |
|            |      |        |                                              | Setting | g) NOT CLEAR |             |         |
|            |      |        |                                              | Follow-up (months) |             |             |         |
|            |      |        |                                              | Quality Criteria* |             |             |         |
|            |      |        |                                              | a) No. of Hosp. Admits since dx | 1 (0.3) | 1 (0.3) | 0.79 |
|            |      |        |                                              | b) Medical Consults/yr | 4 (3-6) | 4 (2-6) | <0.0001 |
|            |      |        |                                              | c) No. of patients with HbA1C <7.5% | 90/102(88%) | 73/116(63%) | 0.0005 |

* Quality Criteria is as follows: RCT/CCT a) concealment of allocation (protection against selection bias), b) follow-up of professionals (protection against exclusion bias), c) follow-up of patients or episodes of care, d) blinded assessment of 1° outcome(s) (protection against detection bias), e) baseline measurement, f) reliable 1° outcome measure(s), g) protection against contamination; CBA a) baseline measurement, b) characteristics for studies using second site as control, c) blinded assessment of primary outcome(s), d) protection against contamination, e) reliable primary outcome measure(s), f) follow-up of professionals, g) follow-up of patients; † Baseline characteristic difference, p < 0.05;
Table 1. Intervention versus control

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Design</th>
<th>Intervention group</th>
<th>Number of providers</th>
<th>Number of practices</th>
<th>Setting</th>
<th>Follow-up (months)</th>
<th>Quality Criteria*</th>
<th>Patient outcomes</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meigs,</td>
<td>2003 (14)</td>
<td>RCT</td>
<td>i) voluntary, web-based feedback, individualized patient registries</td>
<td>a) 66</td>
<td>c) 1</td>
<td>hospital-based</td>
<td>12</td>
<td>a) DONE</td>
<td>(0) HbA1C&lt;7%</td>
<td>21.7% ± 1.7%</td>
<td>26.6% ± 2.8%</td>
</tr>
</tbody>
</table>

| Grant, | 2003 (15) | CCT | i) diabetes registries, recommendations on via email | a) 59 | b) 258 | academic | 3 | a) DONE | (0) Mean LDL-C <130mg/dl | 54.8% ± 20.3% | 63.5% ± 10.5% | 0.5 |
|        |        |      | b) 8 | academic | affiliated | nurse | practitioners |    | b) NOT DONE | (0) Mean LDL-C (mg/dl) | 126.7(3.1) ± 14.7 | 122.1(3.2) ± 9.4 | 0.3 |
|        |        |      | c) 7 | community | center | working |    | c) DONE | (0) BP <130/85 mmHg | 25.4% ± 14% | 29.6% ± 2.2% | 0.8 |
|        |        |      | d) 6 | health |    |    |    | d) NOT DONE | (0) Mean DBP (mmHg) | 78.3(0.6) ± 1.8 | 76.4(0.6) ± 0.8 | 0.8 |

| Process Measures | | | (process) | (results) |
| (0) 1+HBA1C past 12 mo | 86.0% ± 1.6% | 88.0% ± 1.0% | 0.3 |
| (0) 1+LDL-C past 12 mo | 54.8% ± 7.2% | 57.4% ± 3.4% | 0.5 |
| (0) 1+BP past 12 mo | 97.5% ± 1.0% | 98.6% ± 1.4% | 0.3 |
| (0) 1+eye past 12 mo | 29.3% ± 5.6% | 41.2% ± 1.7% | 0.5 |
| (0) 1+foot past 12 mo | 65.5% ± 9.6% | 82.1% ± 0.7% | 0.003 |

* Quality Criteria is as follows: RCT/CCT a) concealment of allocation (protection against selection bias), b) follow-up of professionals (protection against exclusion bias), c) follow-up of patients or episodes of care, d) blinded assessment of 1st outcome(s) (protection against detection bias), e) baseline measurement, f) reliable 1st outcome measure(s), g) protection against contamination; CBA a) baseline measurement, b) characteristics for studies using second site as control, c) blinded assessment of primary outcome(s), d) protection against contamination, e) reliable primary outcome measure(s), f) follow-up of professionals, g) follow-up of patients; † Baseline characteristic difference, p < 0.05;
Reference: