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Technical Review

Number 9

Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies

Volume 2—Diabetes Mellitus Care

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to **epc@ahrq.gov.**

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The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

Structured Abstract

Objective: Care remains suboptimal for a substantial proportion of the more than 17 million patients in the United States with diabetes. This review examines strategies for improving the quality of care for adult type 2 diabetic patients, through changes in provider behavior and modifications to the organization of care.

Search Strategy and Inclusion Criteria: The researchers searched the MEDLINE® database, the Cochrane Collaboration's Effective Practice and Organisation of Care (EPOC) registry, article bibliographies, and relevant journals for experimental evaluations of quality improvement (QI) interventions involving outpatient care for adults with type 2 diabetes mellitus. The investigators included randomized or quasi-randomized controlled trials, controlled before–after studies, and interrupted time series in which at least one reported outcome involved changes in serum hemoglobin A_{1c} or a measure of provider adherence to a recommended process of care.

Data Collection and Analysis: Two reviewers independently abstracted relevant data, including classifying the components of each QI intervention as provider education, provider reminders, facilitated relay of clinical information, patient education, promotion of self-management, patient reminders, audit and feedback, organizational change, or financial incentives. Certain categories were further subdivided into major subtypes (e.g., professional meetings for provider education and disease management for organizational change). The investigators also assessed the impact of clinical information systems as a mediator for interventions of all types. They compared different QI strategies in terms of the median effects achieved for glycemic control and for a generalized measure of clinician adherence. In addition, linear regression analyses were performed using methodologic features and QI types as predictors, taking into account baseline groups differences and study size.

Main Results: Fifty-eight articles reporting a total of 66 trials met the established inclusion criteria. The most common interventions employed were organizational change in 40 trials, patient education in 28 trials, and provider education in 24 trials. Fifty-two trials involved interventions employing more than one QI strategy, with a median of 2 strategies per trial and a maximum of 5. The included trials reported a median absolute reduction in HbA_{1c} of 0.48% (interquartile range: 0.20%, 1.38%), and a median improvement in clinician adherence of 4.9% (interquartile range: 3.8%, 15.0%). Trials in the lower 2 quartiles of sample size reported substantially larger effect sizes, as did non-randomized trials, strongly suggesting the presence of publication bias, with publication of smaller non-randomized trials occurring more often when reported improvements are large. Multifaceted trials reported a median reduction in HbA_{1c} of 0.60% (interquartile range: 0.30%, 1.40%), compared to a median reduction of 0.0% (interquartile range: -0.08%, 0.16%) for trials of a single intervention ($p=0.01$). The benefit of employing more than one QI strategy appeared to persist among larger, randomized trials, but the small numbers of studies limits the reliability of this impression. The investigators did not find any specific type of QI strategy to confer unambiguous benefit. Provider education and disease management were the only strategies to approach statistical significance, compared with interventions absent these strategies.

Conclusion: The authors' analysis of quality improvement strategies for diabetes care showed no particular type of QI to have an advantage over others, but suggested that employing at least two strategies provides a greater chance of success than single-faceted interventions, in terms of improving glycemic control or provider adherence. These conclusions are limited by probable publication bias favoring smaller trials and non-randomized trials, and the confounding presence of multiple QI strategies in a given intervention, as well as important patient and provider factors, and organizational characteristics.

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Summary

Diabetes affects more than 17 million people in the United States alone. Taking into account undiagnosed cases and cases of impaired glucose tolerance, one in seven Americans either has diabetes or is at high risk for developing it. Despite a high-quality evidence base to aid providers in treating diabetes and screening for its complications, the quality of diabetes care remains less than optimal, with many patients not receiving established processes of care (such as eye and foot screening), or achieving optimal outcomes (such as controlled glycosylated hemoglobin levels).

To bring data to bear on the quality improvement opportunities cited by the Institute of Medicine (IOM) in its 2003 report, *Priority Areas for National Action: Transforming Health Care Quality*, the Agency for Healthcare Research and Quality (AHRQ) engaged the Stanford–UCSF Evidence-based Practice Center (EPC) to analyze the scientific literature on quality improvement strategies for some of the 20 disease and practice priorities named in the IOM Report. The resulting investigations focus on translating research into practice—identifying those activities that increase the rate at which practices known to be effective are applied to patient care in real world settings. In other words, the EPC research effort aims to help narrow the "quality gap" that is in large part responsible for suboptimal health care practices and outcomes. In addition to furthering the IOM's quality agenda, this analysis also has been prepared in support of the *National Healthcare Quality Report* (NHQR) (also see the *National Healthcare Disparities Report)*.

In this, the second volume of the *Closing the Quality Gap* series, the authors focused on quality improvement in the management of patients with diabetes mellitus (Type 2 diabetes), which accounts for more than 90% of diabetes cases in the U.S. Quality improvement targets included measures of disease control (e.g., serum HbA_{1c}, blood pressure) and provider adherence (e.g., serial monitoring of serum HbA_{1c}, control of hypertension, and management of other cardiovascular risk factors, as well as monitoring for nephropathy, neuropathy, and retinopathy).

The carefully designed methodology used to review the vast amount of existing quality literature on particular diseases is the result of collaborative efforts of the editorial team, in consultation with several of the undisputed experts in the field. To ensure consistency in the review, the editors developed a taxonomy of interventions that modifies several well-established classification systems, denominating the QI strategies as follows:

1. Provider reminder systems
2. Facilitated relay of clinical data to providers
3. Audit and feedback
4. Provider education
5. Patient education
6. Promotion of self-management
7. Patient reminder systems
8. Organizational change
9. Financial, regulatory or legislative incentives

For more information regarding the origins and details of the research framework developed for the *Closing the Quality Gap* series, the statistical tools and analytical processes used throughout, and the target audiences expected to benefit most from the series, please refer to *Volume 1—Series Overview and Methodology* (AHRQ Publication No. 04-0051-1).

From an original sample of 3,601 potentially relevant articles, a total of 529 articles were reviewed at the full text level. Of the 126 articles meeting criteria for complete abstraction, approximately half dealt solely with patient education or self-management; these are likely to be reviewed in a subsequent volume of the *Closing the Quality Gap* series addressing these patient-focused interventions as they apply to many chronic illnesses, and therefore were excluded from this review. (Interventions involving patient education or self-management but including at least one QI strategy directed at providers or organizational change were included in the present review.) Thus, 58 articles, reporting a total of 66 comparisons, made up the final sample of studies included in the present review.

Taken as a group, interventions in the included comparisons reported a median absolute reduction in HbA_{1c} of 0.48% (inter-quartile (IQ) range: 0.20% to 1.38%) above any reductions observed in the control groups, and a median improvement in clinician adherence of 4.9% (IQ range: 3.8% to 15.0%). Studies utilizing multiple QI strategies did appear to exert stronger effects than single-intervention studies. The 32 multifaceted trials reported a median reduction in HbA_{1c} of 0.60% (IQ range: 0.30%, 1.40%), compared to no change (-0.08%, 0.16%) in trials of single interventions (p=0.01). This finding does confirm one of the authors' *a priori* hypotheses, but nevertheless should be interpreted with caution. Given the small number of studies involved, the lesser improvements associated with single-faceted interventions might relate to the specific strategies employed in these studies, rather than any intrinsic inferiority of the single-faceted QI interventions.

The investigators did not find any individual QI strategies to be unambiguously beneficial in diabetes care. Provider education resulted in large median effects for both glycemic control and clinician adherence, but these findings were of only borderline significance even before correction for multiple comparisons. Interventions employing disease or case management strategies resulted in significantly greater median reductions in serum $HbA_{1c,}$ compared with interventions lacking any component of disease management (p=0.009), but this result would not retain statistical significance after correction for the 10-15 comparisons in the analysis. Moreover, the impact of disease management was not significant in the regression analysis, which, in contrast to the median effects analysis, adjusted for study size and baseline differences between the intervention and control groups. All other evaluated QI strategies (including the integration of a computerized clinical information system) failed to improve serum HbA_{1c} levels or clinician adherence to an appreciable extent, when analyzed quantitatively.

Even when particular QI strategies (or combinations of strategies) were associated with improved outcomes or processes, these effects exhibited a striking association with sample size and trial design. For example, among the 38 trials reporting changes in mean HbA_{1c}, those falling in the lower two quartiles of sample size reported a median absolute reduction in serum HbA_{1c} of 1.30%, whereas those falling in the upper two quartiles reported a median absolute reduction in serum HbA_{1c} of only 0.21%. A similar (though not statistically significant) relationship between sample size and study results was seen in studies of interventions targeting increased provider adherence. The reviewers also found a correlation between trial design (randomized vs. non-randomized) and the magnitude of the effect on QI targets such as provider adherence. For example, randomized trials of a variety of interventions reported a median

absolute improvement in provider adherence of 4.5% (QI range: 3.5%, 5.4%) compared with 18.0% (QI range: 17.2%, 21.0%) for non-randomized trials. Taken together, these findings support the presence of a substantial publication bias, manifested by a greater propensity of smaller studies with non-randomized designs to be published when they report large improvements, rather than small or no improvement.

Also of interest was the discovery that studies reporting provider adherence exhibited a significant association with study period, with more recent trials reporting smaller improvements (regression coefficient: -0.04; 95% CI: -0.07 to -0.21, p=0.004). This finding appears related to the fact that baseline adherence reported in both intervention and control groups improved over time, presumably reflecting the general impact of passive relevant knowledge dissemination, as well as more active QI initiatives. Whatever its etiology, this secular trend likely means that demonstrating QI impacts becomes more difficult over time, at least in the realm of diabetes care.

In summary, this review (which expands upon previous work by virtue of its scope and the use of quantitative analysis of the effect of QI strategies on key outcomes) found that multifaceted interventions may be more likely to exert positive effects on glycemic control and (to a lesser extent) provider adherence than single interventions. The investigators were unable to identify any individual QI strategy as clearly more effective than any other. The review also uncovered probable publication bias, as well as a significant diminution of effect in more recent trials.

Chapter 1. Introduction

Background

In the past decade, diabetes mellitus (DM) has reached epidemic proportions in the United States. The disease now affects more than 17 million people nationwide.[1] Include undiagnosed cases and individuals with impaired glucose tolerance, and one in every seven Americans either has diabetes, or is at high risk for developing the disease. Equally disturbing, the prevalence of diabetes has increased by 60% since 1991,[1] and there is a direct correlation with the increase in obesity over the same period.[2] As a result, diabetes is likely to pose a major public health problem for decades to come.[3]

The past decade also has played witness to major advances in diabetes care, beginning with the publication of the Diabetes Control and Complications Trial (DCCT) in 1993,[4] followed by the United Kingdom Prospective Diabetes Study (UKPDS) trials in the second half of the 1990s.[5, 6] These studies clearly demonstrated that aggressive management of hyperglycemia significantly improves quality of life, while reducing morbidity and mortality. Effective treatment strategies also have been developed for the control of diabetes' principal comorbid conditions, hyperlipidemia and hypertension,[7-9] and for the screening and early treatment of complications such as retinopathy, neuropathy, nephropathy, and foot disease.[10] Since diabetes-related complications account for more than 200,000 deaths, 82,000 amputations, 38,000 new cases of end-stage renal disease, and 12,000 cases of blindness annually, the implementation of proven screening and treatment strategies could significantly reduce morbidity and mortality.[1] Exact projections are difficult to establish, but evidence from the UKPDS trials shows that a mere one point reduction in the average hemoglobin A_{1c} (HbA_{1c}) could lead to a 25% decrease in diabetes-related deaths.[11] Morevoer, the National Committee for Quality Assurance estimates that improved glycemic control could prevent 13,600 deaths annually in the U.S. alone.[12]

The Quality Gap

Diabetes care in the U.S. consistently has failed to meet recommended quality standards. Data collected between 1988 and 1995 (derived from the Center for Disease Control's population-based Behavioral Risk Factor Surveillance System [BRFSS], as well as the National Health and Nutrition Examination [NHANES] surveys) reveal significant quality gaps in the treatment of diabetes and in screening for diabetes-related complications. Nearly one in five diabetics has poor glycemic control (HbA_{1c} level > 9.5%), more than one-third have elevated blood pressure (> 140/90 mmHg) and more than half of diabetes patients have elevated LDL-cholesterol levels (even under the more liberal National Cholesterol Education Program [NCEP-II] guidelines, with unacceptable levels defined as > 130 mg/dl.).[13] Diabetics also do not receive appropriate screening measures: only 28% receive the recommended HbA_{1c} measurements more than once yearly, while just 55% obtain annual foot examinations, and 63% submit to an annual dilated eye examination.[13] These data were collected before publication and widespread distribution of the DCCT and UKPDS results, but more recent data do not indicate significant improvement.[14] Racial and ethnic disparities persist as well. African Americans and Hispanics are significantly more likely to die of diabetes-related complications than are Caucasians,[1] while

Native Americans and other vulnerable populations suffer under a disproportionate burden of diabetes and diabetes-related morbidity and mortality.[15]

The National Committee on Quality Assurance (NCQA) used similar criteria to compile its Health Plan Employer Data Information Set (HEDIS®), the basis for its annual "State of Health Care Quality" report. The HEDIS data uses benchmarks established in 1997 by the Diabetes Quality Improvement Project, a consortium of 13 public and private organizations including the American Diabetes Association. In 2001, HEDIS data show that among patients with commercial health insurance, 37% had an HbA_{1c} greater than 9.5%, 45% had a blood pressure of over 140/90 mmHg, and 50% had LDL-cholesterol of over 130 mg/dl.[12] Process measures also revealed disconcerting lapses: 19% of diabetics did not receive HbA_{1c} measurements, 48% did not receive retinal exams, and nephropathy screenings were not conducted for 54% of diabetic patients.[12] Thus, despite the continuing advances in diabetes treatment and an increased focus on bridging quality gaps, many patients who should have adequate access to care are not receiving guideline-concordant care.

Outpatient care for diabetes exemplifies the challenges of, and opportunities for, chronic disease management. Involving patients in their own care, particularly with regard to education and self-management, can improve health outcomes, as well as the diabetic patient's quality of life.[10] However, the quality gaps that persist in the treatment and secondary prevention screening processes demonstrate the pressing need to improve medical providers' adherence to standards of care in both of these areas. Management priorities have focused traditionally on glycemic control, but control of hypertension and hyperlipidemia is of equal importance, given the high morbidity and mortality from cardiovascular disease in diabetic patients. Regular monitoring of long-term glycemic control and hyperlipidemia also should accompany traditional secondary prevention measures such as screening for retinopathy (with dialation), neuropathy (with foot exams) and nephropathy (with urine microalbuminuria); smoking cessation; as well as influenza and pneumococcal vaccination.

A prior systematic review of this topic area[16] examined articles from MEDLINE®, the Cochrane Collaboration's Effective Practice and Organisation of Care database (EPOC), and related databases. The comprehensive search strategy identified a total of 41 articles involving professional and/organizational interventions intended to improve diabetes management, though it should be noted the review has not been updated to include articles published since 1999. The results of the review suggest that multifaceted interventions and interventions involving organizational change (i.e., those involving a change in the structure or delivery of health care) could have a positive effect on key processes of care, though analysis of the identified studies was purely descriptive.

With the exception of a recent review of disease management strategies,[17] prior systematic reviews have not included any quantitative synthesis of quality improvement (QI) strategies, presumably because of study heterogeneity along multiple dimensions (e.g., trial design, study, setting, variations in definitions of "provider education," "audit and feedback," "disease management," and other labels for QI strategies), as well as relatively small numbers of trials. In this review, the authors have expanded upon the previous qualitative and systematic review of strategies to improve diabetes care[16] with the inclusion of more recent studies, and through the use of quantitative analysis to better characterize the effectiveness of particular QI strategies. They have also analyzed more general conclusions such as the relative impact of multifaceted interventions or organizational interventions versus strategies targeting only behavioral change in providers.

Settings Goals for Clinical Care vs. Performance Measurement

Recognizing the urgent need to improve the quality of diabetes care, the National Diabetes Quality Improvement Alliance (NDQIA), a consortium of prominent organizations involved with diabetic patient care and overall health care quality improvement efforts,* released updated guidelines in May, 2003.[18] The NDQIA report[18] distinguishes between targets appropriate for guiding the treatment of individual patients versus targets appropriate for measuring the performance of a clinic or larger health care delivery system (Appendix A). For instance, the NDQIA endorses the $HbA_{1c} < 7.0\%$ as the optimal target for clinical care but, for purposes of performance measurement, focuses on the percentage of patients with HbA_{1c} below 9.0%. This focus on "poor control as it pertains to performance measurement" versus "good control as it pertains to individual patient care" reflects a recognition of various factors other than quality issues that can influence the percentage of patients achieving optimal control. Further examples of this awareness include variations in the degree to which local laboratories follow guidelines for assay selection,[19] comorbid conditions, frequency and severity of hypoglycemia, and patient preferences, among other factors.

Studies included in this review have a tendency to specify the targets found in clinical guidelines as their QI goals—although this was not part of the authors' inclusion criteria. Rather, the outcomes have been structured to accommodate expected variations in QI targets. These outcomes are explained in Chapter 2, Methods.

Key Questions

In this review, the literature on quality improvement for diabetes care has been carefully synthesized in an effort to address three questions:

1. Are there QI strategies that improve physicians' treatment of diabetes and its comorbidities?
   - Can the control of hyperglycemia, hyperlipidemia, and hypertension be improved?
   - Can microvascular and macrovascular complications be prevented?

2. Are there QI strategies that improve provider adherence to recommended monitoring?
   - Which interventions improve physicians' adherence to long-term glucose monitoring, to screening for hyperlipidemia and hypertension, and to screening for complications such as retinopathy, neuropathy, and nephropathy?

3. Are there QI strategies that improve patients' adherence to treatment and self-care measures?

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* Organizations include the Agency for Healthcare Research and Quality, American Academy of Family Physicians, American Association of Clinical Endocrinologists, American College of Physicians, American Diabetes Association, American Medical Association, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, National Institute of Diabetes and Digestive and Kidney Diseases, and U.S. Department of Veterans Affairs, among others.

Although screening and prevention of diabetes have become increasingly important, these interventions lack a clear evidence base indicating a reduction in morbidity and mortality.[10] Accordingly, the authors did not address questions related to screening for diabetes in this review. (By contrast, the impact of screening for elevated blood pressure is well established, so screening interventions are included in Volume 3, the hypertension review.)

Chapter 2. Methods

Types of Quality Improvement Strategies

A variety of interventions have been tested with the goal of improving the quality of care for common clinical conditions. From the literature, a conceptual framework has been developed for the classification of quality improvement strategies (See Chapters 1-3). These interventions can target organizations, providers, patient communities, or individual patients, and have been evaluated in a wide variety of formats. For each study, reviewers described key features of the intervention in free-text format and answered a series of questions designed to characterize the intervention in terms of its component QI strategies. The taxonomy of QI strategies is defined as follows:

Provider reminders—Information tied to a specific clinical encounter, provided verbally, in writing, or by computer, that is intended to prompt the clinician to recall information (e.g., to make medication adjustments or order appropriate screening tests), or to consider performing a specific process of care. The phrase "tied to a specific clinical encounter" distinguishes reminder systems from the audit and feedback strategy, where clinicians are typically presented with summaries of their performance relative to a process or outcome of care over multiple encounters.

Facilitated relay of clinical data to providers—Clinical information collected directly from patients is relayed to the provider in situations where the data are not generally collected during a patient visit, or when collected using a means other than the existing local medical record system (e.g., transmission of a patient's home glucose level). The investigators expected there to be some overlap with the provider reminder systems strategy, but kept them separate at the abstraction stage. This was done to allow for the possibility that the data could be subsequently analyzed with and without collapsing the strategies.

Audit and feedback—Any summary of a health care provider's clinical performance or an institution's clinical performance that is reported, either publicly or confidentially, to or about the clinician or institution (e.g., the percentage of a provider's patients who have achieved or have not achieved some clinical target). The practice of benchmarking refers to the distribution of performance data from institutions or providers regarded as leaders in the field. It is considered a type of audit and feedback, so long as local data is provided in addition to the benchmark figures.

Provider education—Any intervention that includes one of the following three substrategies: educational workshops, meetings (e.g., traditional Continuing Medical Education [CME]), and lectures (live or computer-based); educational outreach visits (the use of a trained person who meets with providers in their practice settings to disseminate information intended to change the provider's practice); or the distribution of educational materials (published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications).

Patient education—Live appearance patient education, for individuals or members of a patient group or community, or via the distribution of printed or audio-visual educational materials. Only those approaches that include patient education as part of a multifaceted strategy were evaluated. Those in which patient education was the sole approach were excluded. One of

the upcoming volumes in the Closing the Quality Gap series may be used to review the topic of patient education with regard to its effect on a variety of chronic diseases, including diabetes.

Promotion of self-management—The distribution of materials (e.g., devices for glucose self-monitoring) or access to a resource that enhances the patients' ability to manage their condition, the communication of clinical test data back to the patient, or followup phone calls from the provider to the patient with recommended adjustments to care. The authors expected some overlap with the patient education and patient reminders strategies, but elected to separate the strategies at the abstraction stage. This was done to allow for the possibility that the data could be analyzed subsequently, with and without collapsing the strategies.

Patient reminders—Any effort directed toward patients that encourages them to keep appointments or adhere to other aspects of self-care.

Organizational change—Changes in the structure or delivery of care designed to improve the efficiency or breadth and depth of clinical care. These include the use of disease management or case management tactics (coordination of assessment, treatment, and arrangement for referrals by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider); other personnel or team changes; the use of telemedicine (communication and case discussion between distant health care professionals); Total Quality Management (TQM) or Continuous Quality Improvement (CQI) approaches (quality problem cycles of measurement, intervention design, implementation, and re-measurement); and changes to medical records systems or hospital information systems. Three substrategies (disease/case management, team/staffing changes, and medical records changes) also were extracted for analysis in studies that identified organizational change as one of their multiple strategies.

Financial, regulatory, or legislative incentives—Interventions with positive or negative financial incentives directed at providers (e.g., linked to adherence to some process of care or achievement of some target patient outcome). This strategy also included positive or negative financial incentives directed at patients, system-wide changes in reimbursement (e.g., capitation, prospective payment, or a shift from fee-for-service to salary pay structure), changes to provider licensure requirements, or changes to institutional accreditation requirements.

In addition to the aforementioned QI strategies, the authors had planned initially to abstract data on intervention features such as social influence (e.g., local opinion leaders[74, 75]), the involvement of top-level management, intervention designs based on a theory of behavior or organizational change,[76-78] and other potential "mediators" of intervention success.[73] Unfortunately, the identified studies rarely explored these and other potentially relevant features of intervention design.[79] Moreover, few studies considered organizational context[80] and local attitudes and beliefs,[81] so questions targeting these potential predictors of intervention success or failure were eliminated from the abstraction forms and from the analysis.

The one "mediator" that reviewers anticipated would be reported with sufficient frequency and detail was the use of clinical information systems, which was identified as a potential predictor of success in a prior review.[16, 43] For each article, therefore, the involvement of a clinical information system in the design or implementation of the intervention was recorded (regardless of QI strategy type). The potential roles identified in structured form were: identification and/or group allocation of eligible patients or providers; reminders generated by existing clinical information system; and decision support at point of care. Additional potential roles include facilitated communication between providers (e.g., generation of e-mails between members of care team); and audit data gathered from clinical information systems to design QI strategy (e.g., audit and feedback, TQM, provider education, or financial incentives).

Scope

This report focuses on quality improvement strategies that target adult patients with type 2 diabetes mellitus (DM). Type 2 diabetes accounts for 90-95% of diabetes cases in the United States. It is the sixth leading cause of death among the general U.S. population, and is the seventh leading cause of disability among adults.[1] Numerous trials in this patient population show that diabetes-related morbidity and mortality can be reduced with close adherence to treatment guidelines. Accordingly, quality improvement strategies have a tendency to focus on adult type 2 diabetics. The reviewers did not assess QI strategies for children with diabetes, due to the higher prevalence of type 1 DM (although cases of type 2 DM also are on the rise among children), as well as the unique challenges involved with the treatment of this patient population and their potential to limit the applicability of QI strategies tested in the adult population. Studies that focused exclusively on gestational diabetes also were excluded.

A wide range of interventions targeting patient behavior, individual provider behavior, and systemic problems has been researched and implemented to address these quality gaps. As documented previously, the treatment goals for diabetic patients are clear and well supported by research. Providers can avail themselves of a variety of safe and effective treatments to help patients reach these goals. Thus, the focus of this review is interventions that seek to change the methods by which organizations or providers deliver care, with the goal of improving individual patient outcomes. Studies that focused exclusively on patient behavioral changes were not included in this review, but will likely be addressed in a future series report on patient education and self-management as QI strategies for chronic illness.

Inclusion and Exclusion Criteria

The general inclusion criteria were described in the chapter on Methods, in Volume 1 of this series. Briefly, included studies are required to:

- Evaluate an intervention meeting the authors' definition for quality improvement (definitions summarized below);
- Use an experimental or quasi-experimental design – including patient or cluster randomized controlled trials (RCTs), quasi-randomized controlled trials (quasi-RCTs), controlled–before after studies (CBAs), and interrupted time series (ITS) (as defined below); and
- Report at least one measure of disease control, provider adherence, or patient compliance, (as defined below and in the abstraction forms in Appendix C), specifically related to diabetes.

Many of the abstracted outcomes relate to blood pressure control and modification of important cardiovascular risk factors (e.g., smoking cessation, weight loss). When a study reported such outcomes but did not include any measures specifically related to glycemic control or the prevention of diabetic complications (e.g., retinopathy, neuropathy, nephropathy, skin ulcers), the investigators did not include it. For instance, a study of blood pressure control in diabetics would be excluded from the present review if the *only* outcomes reported were related

to hypertension. The study would, however, be eligible for inclusion in the hypertension review (Volume 3 of this series).

Studies also were excluded when their outcomes consisted solely of provider or patient understanding, satisfaction, or self-efficacy; or solely of costs and resource use (i.e., when these outcomes were not accompanied by at least one measure of disease control, provider adherence, or patient compliance).

Included Trial Designs

Randomized trials offer the best means of isolating the effects of a given intervention, as patients in different study groups generally differ only with respect to their exposure to the treatment (i.e., other known and unknown factors affecting relevant outcomes should be distributed equally between the groups). Patient randomized trials and cluster randomized trials have been included in the review for this reason. In the former, individual patients are assigned randomly to an intervention group or a control group. Patient randomized trials represent the gold standard for health care evaluations. For trials of QI interventions, however, the advantages of patient randomized trials must be weighed against the disadvantage of contamination. Because clinicians will care for patients in both study groups, the level of care received by the control group patients may improve over the course of the trial. This could lead to an apparent null result, despite the improvement in patient outcomes occuring as a result of the intervention.[64]

Cluster randomized trials seek to avoid this contamination by allocating the intervention at the level of clinicians as individuals or groups (e.g., clinics as the unit of allocation). This approach overcomes the problems of contamination at the cost of a decreased effective sample size. Since patients within a given "cluster" receive their care at the same participating study clinic, outcomes for these patients cannot be regarded as completely independent.[65-72] The statistical correction for this violation of independence decreases the effective sample size and, as a result, the efficiency of the study. The choice of a clustered RCT versus patient RCT, therefore, depends on the magnitude of the contamination across patients that would occur under the latter design choice.[68] The authors' judgment regarding the appropriateness of the particular choice made in a given trial did not have a direct impact on their analysis, as the effective sample size was adjusted for cluster effects whenever the unit of analysis differed from the unit of treatment allocation.

Terminology to Distinguish Studies, Interventions, and Comparisons

Since the reviewed articles did not present their study data in a uniform fashion, the authors adopted the following terminology to better describe the quality improvement interventions reviewed for this volume:

When a single *study* led to multiple *publications* (articles) describing different aspects of the study, (e.g., a methods article followed later by a results paper, or several results papers) each publication was identified separately and all articles emerging from the same study were reviewed together.

A single study may include several different *study arms* (groups of subjects), with different *QI interventions* provided to the subjects in each study arm. These are often

reported in a single published article. For purposes of analysis, the researchers regarded each intervention that was studied in contrast to a control group as a separate *comparison*. For example, a single study with one control group and three different arms receiving different QI interventions (e.g., provider education and organizational change in one arm, patient reminder and organizational change in another arm, audit and feedback in a third arm), was compared with the control group, and was regarded (and listed in the Tables section) as three comparisons. When an article reported several comparisons, the reviewers performed a separate data abstraction for each comparison.

The *intervention* described in a particular study may be multifaceted, that is, it may involve more than one QI strategy. For example, the intervention may consist of a combination of provider education and provider reminders. A multifaceted intervention that was applied to a single study arm and judged against the control group was treated as a single comparison.

Literature Search and Review Process

The search strategy began with a broad electronic search of the MEDLINE® database from January 1966 to July 2003 (the specific search is shown in Appendix B). The reviewers augmented these results with a search of the Cochrane Collaboration's (EPOC) database,[20, 21] (which includes the results of extensive periodic searches of the EMBASE®, CINAHL®, and MEDLINE® databases), as well as hand searches of article bibliographies and specific journals.[22] They also performed their own MEDLINE® review because of slight differences in scope (e.g., a desire to identify articles involving patient education or self-management only, even though they may be included in a subsequent volume of this series, rather than in the present review). This step was considered a means of enhancing the completeness of the EPOC database search, in an effort to be as thorough and meticulous as possible.[* 17, 21, 23-47]

To meet the criteria for full abstraction, articles had to assess the effect of a quality improvement strategy on disease control, provider adherence, or patient adherence in adults. (Appendix C shows the structured abstraction forms used to guide these judgments.) A total of 529 articles merited full-text reviews. These involved two independent reviewers, at least one of whom was a core investigator or senior methodologist (as opposed to a trained research assistant). At the full-text level, reviewers abstracted basic information on the study design, quality improvement strategy, and variety of outcomes. (The complete full-text abstraction form also is shown in Appendix C.) All disagreements were resolved by consensus.

Publication Bias

Publication bias refers to an overestimation of effect size, and is due to the preferential publication of positive studies. Given the absence of a single, well-established analytic method for detecting or correcting the effects of publication bias,[48-50] the preferred approach to preventing this source of error is a thorough search for unpublished research.[51-53] Unfortunately,

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[*] The EPOC Web site reports a sensitivity of 92.4% for the registry's search strategy and precision of 18.5%, but the gold standard of hand searching included a fairly limited sample of journals and somewhat outdated time periods: *Medical Care* (1969-95), *BMJ* (1992-94), and full text searching from the Ovid Biomedical Core Collection all original and miscellaneous articles from *Annals of Internal Medicine*, *BMJ*, *JAMA* and *Lancet* (1995-96).

the search for unpublished quality improvement trials is complicated by a paucity of well-defined and centralized information resources. Unlike research into topics of clinical care, (e.g., determining the best drug to use in the event of heart failure or the preferred test for pulmonary embolism), there are no relevant clinical trial registries for QI strategies or pharmaceutical companies to query for unpublished data. For disease-specific reviews, as opposed to reviews of general strategies (e.g., audit and feedback,[54] provider education,[55, 56] disease management,[17] etc.), some conference proceedings related to the disease or specialty may exist. To that end, the conference proceedings of several prominent meetings in endocrinology and diabetes care were reviewed.

Another problem that may exacerbate the impact of publication bias on reviews of quality improvement studies involves the research often conducted by personnel interested in pragmatic, local quality improvement. The results of such studies may be less likely to be submitted for publication, while investigators involved in clinical research trials generally have a stronger incentive to publish. And though publication bias may occur at the level of journal acceptance, it is unlikely that investigators would opt not to submit their work anywhere, simply because the trial had a negative finding. By contrast, some quality improvement studies may be undertaken by personnel for whom quality assurance activities are a part of their job descriptions. The emphasis often is placed on measures of success in such instances, rather than on research dissemination. In effect, the incentive to publish may be particularly low when the evaluation result is negative.

One exception to the generalization regarding the dearth of sources for unpublished QI trials is the Health Care Quality Improvement Program (HCQIP) database, maintained by the U.S. Centers for Medicare & Medicaid Services (CMS).[57] This database includes descriptions of research projects conducted by Medicare Peer Review Organizations (PRO), now called Quality Improvement Organizations (QIOs). Unfortunately, the relatively unstructured format of these project narratives makes for time-intensive searches. And while recent changes to the database denied the reviewers access during the timeframe of this project, they plan to revisit the access issue for future topics in the series.

The difficulty in obtaining unpublished QI trials and vulnerability to publication bias were incentives for analyzing the studies in terms of median effect sizes. As described in greater detail in the Methods section of Volume 1, the investigators summarized their findings for a given QI type or study feature by reporting the median effect size achieved by the studies (e.g., the median effect on HbA_{1c} reported by studies sharing a specific QI strategy). Publication bias is more likely a factor in smaller, low quality studies.[52, 58-63] When the results are similar to other studies, they will have little effect on the median. When the results report larger effects for a given intervention, they will not affect the median so long as their total number is small.

Outcome Measures

Investigators targeted three broad categories of study outcomes: measures of disease control, measures of provider adherence to recommended care, and patient adherence to prescribed medications and self-care recommendations. Measures of disease control included intermediate clinical outcomes such as HbA_{1c} and blood pressure, as well as clinical endpoints such as mortality, cardiovascular events, vision loss, and amputation. Quality improvement studies generally have insufficient power to detect changes in morbidity and mortality, as such studies require large numbers of patients and lengthy observation periods.[82] Accordingly, the focus

shifted to intermediate clinical outcomes as measures of disease control, especially serum HbA_{1c} and blood pressure. HbA_{1c} levels have a well-established connection to glycemic control over time and to the prevention of important diabetic complications.[4-6, 11] Management of cardiovascular risk factors—especially control of hypertension—now is recognized for being as important to diabetic patient outcomes as glycemic control.[7] Similarly, studies that promoted provider adherence to measures shown to prevent diabetic complications also were made a priority. Serial monitoring of serum HbA_{1c}, blood pressure, and cholesterol, as well as monitoring for nephropathy (with microalbuminuria), neuropathy (by foot examinations), and retinopathy (with dilated retinal examinations) are widely accepted care practices (see Appendix A).

Guidelines for the care of diabetic patients continue to evolve, and significant changes have occurred within the last half-decade alone. While recommendations for optimal glycemic control have remained stable, new data have led to recommendations for tighter blood pressure and hyperlipidemia control.[83, 84] The NCEP-III guidelines for cholesterol management were issued in 2001, and the latest Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC-VII) recommendations for hypertension management were announced in 2003. These guidelines support an LDL-cholesterol target of < 100 mg/dl and a blood pressure target of < 130/80 mmHg, for diabetic patients. But most of the quality improvement strategy trials reviewed for this study were undertaken in years when less restrictive guidelines were in place, and therefore contain targeted goals that would be considered suboptimal by current standards. Since the focus of this review was to identify effective strategies for implementation, the investigators opted to include studies designed to improve provider adherence with the targets deemed acceptable at the time of the original study—even in those instances where they no longer were consistent with present guidelines.

Core outcomes were abstracted using a structured format, in an effort to permit quantitative analysis. For measures of disease control, the core outcome consisted of changes in serum HbA_{1c} and blood pressure. Serum lipids, creatinine, and outcomes related to retinal disease and foot ulcers also were captured, with the expectation that such outcomes were reported in too many different formats across studies to permit their inclusion in the quantitative analysis. (As mentioned previously, investigators also included clinical endpoints such as death and amputation, but expected studies to report these infrequently and to be underpowered to detect differences across study groups.) For measures of provider adherence, outcomes were captured as reported in the study, but all adherence outcomes were categorized in terms of broad categories:

- Adherence to guideline targets for frequency of glycemic control assessment (e.g., measuring HbA_{1c} at least once within a specified time period).
- Adherence to recommended screening practices for ophthalmologic complications (e.g., performance of, or referral for, dilated retinal exam).
- Adherence to recommended screening practices for renal complications (e.g., checking urine microalbumin).
- Adherence to recommended screening practices for neuropathy or foot-related complications (e.g., performance of, or referral for, foot examination).
- Adherence to treatment choices for achieving glycemic control (e.g., making specific medication choices).

- Adherence to guideline targets for managing blood pressure or cardiovascular disease.
- Adherence to recommendations for patient education or counseling regarding dietary regime, exercise, smoking, and other lifestyle factors.

For measures of provider adherence, the investigators stipulated outcomes data sourced from chart reviews, direct observations, and clinical information systems, but not from provider self-reporting. They did permit data taken from patient self-reporting, for patient adherence outcomes.

Patient outcomes were collected in a similar fashion for two broad categories: adherence to prescribed medication regimens; and for adherence to self-care practices (e.g. self-monitoring of blood glucose, recommendations for diet and exercise, and keeping appointments). In accordance with a recent systematic review of strategies designed to increase adherence to prescribed medication regimens,[46] studies were included only if they reported at least one treatment outcome in addition to measures of adherence.

For outcomes involving medication adherence, investigators also made an effort to record the method of measurement, relative to the following categories: laboratory confirmation (e.g., the detection of a drug or metabolite in blood or urine, including biochemical assays for smoking cessation); pharmacy data (e.g., filled or refilled prescriptions); specially designed dispensers that record medication use, home medication counts, office medication counts (e.g., patients bring in bottles with unused pills); patient self-report (via interview or survey). While the number of studies reporting medication outcomes was anticipated to be too few to permit the incorporation of these measurement categories into the analysis, the data was captured in preparation for the final volume in this series and the possibility that sufficient studies may be found to examine their impact across the various priority topics.

Formats for Reported Outcomes

The investigators anticipated four basic formats for reporting outcomes. Results could be reported at the provider level (e.g., mean blood pressure for patients cared for by a particular physician or group of physicians), or patient level (e.g., mean HbA_{1c} for individual patients in a particular clinic). These outcomes also could be reported as a summary measure for a group (e.g., mean blood pressure), or as the percentage of patients within a certain range (e.g., percentage of patients with $HbA_{1c} < 9.5\%$). Most studies were expected to report summary data at the patient level, as the clinical significance is more immediately evident. The full-text abstraction forms were devised to target the following measures:

- Reductions in HbA_{1c}, systolic blood pressure (SBP), and diastolic blood pressure (DBP) were reported as mean and standard deviation[†] for each study group before and after the intervention;
- Changes in adherence to a process of care were reported as the percentage of patients in each group who received the process of care before and after the intervention; changes in patient adherence to a recommended process of self-care or a medication regimen was

[†] Where standard error of the mean (SEM) was reported, we calculated the standard deviation (SD) based on SEM = SD/SQRT(N), for sample size N.

defined similarly as the percentage of patient adherence in each group at baseline and following the intervention.

Investigators also had planned to document disease control outcomes reported as a percentage of patients with HbA_{1c}, SBP, or DBP decreases within a target range. The same was true for adherence outcomes, framed as summary measures applied to providers rather than patients (e.g., in trials where clinicians were randomized, the reviewers expected some studies would report summary scores for clinicians in each group rather than for all patients within each group). So few studies reported outcomes in this manner, however, that the researchers changed their abstraction form and analytic plan to focus on outcomes reported in the formats listed previously.

Analysis

The Median Reported Effect as a Summary Measure

In addition to descriptive and qualitative analyses, two more forms of analysis had been planned. The first involved the calculation of a "median effect" among outcomes within a given category (e.g., all provider adherence outcomes reported by a given study) so that studies exhibiting the same features could be compared in terms of a common metric. Following the method employed in a recent systematic review of strategies for guideline implementation,[85] the researchers identified in each study the adherence outcome that exhibited the median improvement attributable to the intervention. For example, if a study reported one outcome involving adherence to a guideline for checking HbA_{1c}, another related to screening for retinal disease, and a third outcome for delivery of patient education, investigators calculated the net improvement attributable to the intervention for each outcome. The net improvement in adherence was calculated as (Post-intervention adherence – Pre-intervention adherence)$_{\text{Study group}}$ - (Post-intervention adherence –Pre-intervention adherence)$_{\text{Control group}}$. Then the median value among values for the net improvement in adherence was calculated. This median value was regarded as the primary adherence outcome for that particular study.

Outcomes were not combined for measures of disease control, so the net reduction in HbA_{1c}, SBP, or DBP attributable to the intervention was reported.[‡] However, in analyzing the impact of a particular QI type or study feature (e.g., trial design), investigators did report a similar "median effect" across studies, such as the median reduction in HbA_{1c} reported by RCTs versus CBAs, or the median reduction in HbA_{1c} reported by all studies employing a given QI type.

Focusing on median effects rather than average effects helped to eliminate skewing in the summary measure, based on one or two outliers with particularly large or small effect sizes. The reviewers regarded this effect as particularly important, given the aforementioned difficulty in accounting for publication bias. They considered the calculation of a weighted median, with weighting based on sample size, in order to avoid studies with equal weights, irregardless of size. But weighted medians are not as straight forward as weighted means, especially when the aim is to preserve the original significance of the effect size (e.g., the relation to a reduction in HbA_{1c} or SBP in the units used for those outcomes). Therefore, instead of applying a variable weighting scheme, investigators examined the median effect sizes by different strata of study sample size

[‡] The net change in a disease control measure such as HbA_{1c} was calculated as (Post-intervention HbA_{1c} – Pre-intervention HbA_{1c})$_{\text{Study group}}$ – (Post-intervention HbA_{1c} – Pre-intervention HbA_{1c})$_{\text{Control group}}$.

(e.g., comparing the median effect among studies with sample sizes in the lowest quartile against those in the highest quartile, or those in the lower half versus the upper half.

A simple non-parametric assessment—the Mann-Whitney rank-sum test—was used when possible to ascertain differences in median effects.[86] Such comparisons were possible only for mutually exclusive categories (e.g., randomized versus non-randomized trials) or for all interventions with a particular QI strategy compared with all those lacking the same strategy. It was not possible, however, to compare one strategy with another because of the frequent overlap between the two groups, and the contribution of the same interventions to the two medians.

Standardization of Direction of Effect

To avoid confusion regarding the direction of effect, investigators standardized all outcomes so that a positive change would reflect improvement. Thus, all reported changes in HbA_{1c} and blood pressure are reductions, and a positive change always can be interpreted as an improvement. For adherence outcomes, the adherence target was constructed in such a way that an increase in the outcome always corresponded to an improvement. Thus, if a study reported an outcome involving the percentage of clinicians who *failed* to perform some process of care, the complementary percentage of clinicians who *succeeded* in performing the targeted process of care was used. Similarly, if a study reported an outcome involving the delivery of an undesirable process of care (e.g., prescribing a medication regarded as harmful), the complementary percentage of clinicians who *did not* perform the adverse process of care was used, so that a positive change would better indicate improvement.

Accounting for "Cluster" Effects

"Clustering" was anticipated in a substantial number of studies for which the unit of analysis and unit of allocation differ (e.g., providers or clinics randomized, but patient level outcomes analyzed). Clustering is significant in that patients within a cluster are not independent (i.e., patients at one clinic have a greater resemblance to one another than to patients at other sites, or those cared for by other providers in the trial). Unit of analysis errors do not affect point estimates for effect sizes, but they may spuriously narrow the associated confidence interval, leading to potential false-positive trial results.[65-72] To avoid the same inflation of precision in this analysis, investigators calculated an effective sample size for each study.[§] From the perspective of this analysis, the degree to which investigators acknowledged or accounted for cluster effects did not affect the analysis, forepart from the fact that investigators who did consider cluster effects in the design or analysis of the trial were more likely to report data such as the number of providers randomized, rather than just the total numbers of patients in each group. They also were more likely to provide more technical details, such as values for the intra-cluster coefficient (ICC). Because so few studies reported ICC values,[87-89] the reviewers used values derived from published estimates.[67] (Appendix F shows the calculation of effective sample sizes and presents sensitivity analyses based on the range of published ICC values.)

[§] Effective N = (km) / (1 + (m-1)r) where k is the number of clusters and m is the number of observations per cluster and r is the intra-cluster coefficient. When r = 0, then N = km. When r = 1, then N = k.[65-72]

Regression Analysis

For the more involved quantitative analyses—meta-regression analysis of included studies—investigators used a more conventional measure of effect size, defined as the difference between the means of the intervention and control arms divided by the pooled estimate of the within group standard deviation.** These formal effect sizes, and the above median effect measures, were constructed in such a way that a positive result always reflected improvement (e.g., a positive reduction in average HbA_{1c} or a positive improvement in adherence).

Specifically, regression models were constructed using the pre-intervention effect size (ES_{Pre}) as a predictor variable. Initially, each methodologic feature or QI strategy was modeled with ES_{Pre} to evaluate its effect on the post-intervention effect size (ES_{Post}). Investigators subsequently developed multivariate models, using multiple components as an individual feature's covariates, in order to independently assess the effect of an individual feature after adjustment for other components. This model assumed no important interactions between types of QI strategies, provider factors, or other potential predictors. This assumption may be overly simplistic, but it was considered reasonable in the context of this exploratory analysis.

Linear regression was carried out as $Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2$, with $X_1 = ES_{pre}$ and the dependent variable, Y, corresponding to the outcome of interest—a measure of disease control such as HbA_{1c} or the "summary adherence" outcome described above, in which the value for each study corresponds to the adherence outcome with the median effect among the outcomes reported by the study. ES_{pre} was retained as a predictor in all analyses because of expected baseline differences between the study and control groups and their role as important covariates, even when these differences did not meet conventional thresholds for statistical significance. This point is discussed in detail in the analysis of trials reporting changes in a target measurement rather than single endpoints (Volume 1, Chapter 2: Methods).

Briefly, investigators often assume that if a study is randomized, baseline values of the outcome of interest (e.g., baseline HbA_{1c} in the control and study groups) can be handled in the manner of basic demographic and clinical features reported typically as subject characteristics in a "Table 1." Despite the common practice of reporting p-values in a "Table 1," assessing baseline differences is philosophically unsound. If randomization has been carried out appropriately, any observed differences have, by definition, occurred on the basis of chance.[90-94] More importantly, even when baseline differences do not have p-values below 0.05, such differences may nevertheless exert significant effects on the observed results.[90-94] If the correlation is low (less than approximately 0.3), using change score from the baseline value will add variation, so the followup score is more likely to show a significant result. Conversely, if the correlation is high (greater than approximately 0.6) using only the followup score will lose information and the change score is more likely to prove significant.[95]

Only four studies[96-99] (including one excluded at Stage 3) reported average change scores per patient (e.g., post-intervention HbA_{1c} – pre-intervention HbA_{1c}) accompanied by a value for the standard deviation of the change score. These four studies contributed two values each (one per

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** Effect size = $(\bar{X}_I - \bar{X}_C) / S_p$ where $\bar{X}_I$ is the mean for the intervention group, $\bar{X}_C$ is the mean for the control group and S_p is the pooled within groups standard deviation, which is calculated from:

$S_p^2 = ((N_I - 1) S_I^2 + (N_C - 1) S_C^2) / (N_I + N_C - 2)$. N_I and N_C are the intervention and control sample sizes and S_I and S_C are the intervention and control standard deviations.

study group), permitting estimation of the correlation between baseline and followup values according to the equation: $SDx\text{-}y = SD_x^2 + SD_y^2 - 2*SD_x*SD_y*\rho$, where ρ represents the correlation between the pre- and post-intervention measurements. The calculated values for ρ had a median of 0.64 [inter-quartile (IQ) range: 0.50,0.72]. Given this range of values for correlation within groups, baseline differences between the study groups were considered a necessary predictor in the regression analyses.

Multiple Comparisons and *A Priori* Hypotheses

Meta-regression analysis amounts to studying the epidemiology of a population of trials. In other words, despite the experimental nature of the trial, this analysis is essentially observational. Moreover, the number of trials (in the range of 10 to 60, depending on the QI strategy and outcome being reported), while reasonable for a conventional meta-analysis addressing a focused question (Is Treatment A superior to Treatment B?) with one or two potential confounding variables, is relatively small for an analysis with at least 10 to 15 potential variables of interest. As outlined in Table 4 of Volume 1, Chapter 2, in this series, potential predictors of intervention success or failure include features of trial methodology, the setting in which the trial occurred, attitudes of clinicians towards the QI target, organizational support for the intervention, and many other potential predictors. Investigators were unable to adequately incorporate some of these into this analysis, while others proved too elusive to be abstracted in a consistent and accurate manner.

Given the aforementioned considerations and the sheer number of comparisons considered in the analysis, any significant findings should be regarded as exploratory and solely for the purpose of generating hypotheses, regardless of adjustments to the threshold for statistical significance. In this context, more important than the actual correction is the degree to which significant findings relate to an *a priori* hypothesis. In the case of this review, the only specific hypotheses were as follows:

- **Trial design may have a significant impact on results, with randomized trials expected to show lesser effect sizes**

  Despite the epistemological superiority of randomized trials, the magnitude of bias introduced by well-conducted non-randomized trials and other observational research is surprisingly modest. Moreover, the direction and magnitude of bias do not appear to be consistent (i.e., observational studies may under-or over-estimate true effects to varying extents).[100-102] It should be noted, however, that comparisons of results from randomized and non-randomized trials have been used for clinical efficacy research, not for quality improvement research. The significance of this distinction is that potential confounders are far better known for the former, based on the results of previous clinical research and a much greater understanding of the relevant pathophysiology, than exists for our understanding of behavioral change, organizational theory, etc.

  Thus, QI trials may be more susceptible to confounding by unknown variables, both at the level of trial design and analysis. For this reason, the investigators expected study design to exert an influence on the results of QI studies. They had no hypothesis about the direction of this effect, apart from the likelihood that publication bias would exert a greater influence on non-randomized trials, and that the positive trials would be over-

represented among the non-randomized trials to a greater degree than the randomized trials.

- **Study period may be an important predictor, but the authors had no hypothesis about the direction of effect**

  There are three reasons for which the study period was considered a potential predictor or confounder: showing an effect might have become more difficult over time if care has improved in response to previous QI studies (higher baseline adherence, as might occur over time, was in fact associated with smaller effects in the recent update of the Cochrane review of audit and feedback[54]); study design has probably improved with time, as may be the case for intervention design (e.g., the type and number of QI strategies employed); regardless of baseline adherence, QI targets may have become harder to achieve because what counts as adherence has changed (e.g., guidelines recommend lower target levels for serum HbA_{1c}, blood pressure, lipids) and the newer targets are generally more difficult to achieve.

  These factors could exert an influence opposite that of the effect, so the investigators had no hypothesis regarding the net impact of study period on QI trial results.

- **Number of QI strategies**

  The number of QI strategies employed is at least as important as the choice of strategies (e.g., multifaceted interventions are more likely to succeed than interventions using a single QI strategy[103]). Two recent reviews—one of strategies to promote guideline implementation[85] and one on audit and feedback as a QI strategy[54]—have called into question the widely held view that multifaceted strategies are superior to single-faceted ones. The authors considered this hypothesis worthy of examination, in terms of its practical value to those engaged in QI work and research, and the likelihood that this review would involve sufficient data to address the question. (By contrast, the researchers expected relatively small numbers of studies for any particular QI type.)

Chapter 3. Results

Search Yield and Results of Article Review Process

Figure 1 depicts the article search and review process, with the results at each step. The MEDLINE® search using PubMed® yielded a total of 3,601 citations. Searching the EPOC database produced an additional 104 articles deemed relevant for full abstraction, of which 12 articles[104-115] reporting 16 trials, met full inclusion criteria. (Conversely, the MEDLINE® search identified 10 articles[82, 87, 89, 116-122] evaluating 11 trials, which were not indexed in the EPOC database.) The manual search yielded an additional 77 articles, though only two of these[23, 24] met the inclusion criteria for this review.[††]

A total of 529 articles merited full-text review. Of these, 139 were deemed "not a quality improvement or not an evaluation" and were excluded. This relatively large number of articles outside the scope of the review reflects the fact that 97 of the citations contained no abstract, and so they could not be screened out at Stages 1 or 2. Other reasons for exclusion after full text review included: excluded topic (22 articles); study design failed to meet the criteria for RCTs, quasi-RCTs, CBAs, or ITS (176 articles); no eligible outcomes (42 articles); duplicate or overlapping articles (14 articles); publication prior to 1980 (three articles); and other reasons (six articles), including one abstract not yet published or available as a manuscript from the authors.[123] One published article could not be obtained.[124, 125] (Figure 1 identifies all six of the articles excluded as "other," and Appendix G lists all citations excluded after the full text review, along with reasons for the exclusions.)

As shown in Figure 1, a total of 126 articles merited full abstraction. The intervention in 68 of these articles consisted solely of patient education or promotion of self-management. These articles are listed in Appendix D and their results will likely be analyzed in another volume of this series that focuses on patient education and self-management. Those articles involving patient education in combination with other interventions were included in the present review. The study sample for the review consisted of 58 articles, reporting a total of 66 comparisons (Table 1).

Features of the Included Studies

Demographics. Table 1 displays the included 66 trials, along with descriptions of the trials with regard to setting, design, and QI strategies. (Appendix E presents structured summaries of the results for each of these studies.) Roughly half (29 articles reporting 34 comparisons) were published in the 1990s, [88, 96, 97, 106, 108-110, 115, 116, 120, 122, 126-144] while 24 articles (reporting 26 comparisons) were published in 2000 or later.[82, 87, 89, 98, 104, 107, 112-114, 117-119, 121, 145-155] Only five articles (reporting six comparisons) were published in the 1980s.[105, 111, 156-158] Roughly half of the comparisons (36 studies; 55% overall) were conducted in the United States. Twelve studies [82, 87, 104, 126, 129, 130, 134, 140, 142-144, 154] (involving 13 comparisons) selected patients with poor glycemic control, poor adherence to medications or clinic attendance, the presence of specific

[††] The relatively low yield of the manual search likely reflects the existing contribution of hand searching to the EPOC registry. Also, a substantial number of articles identified by the manual search involved patient education or self-management only. While they did not meet inclusion criteria for the present review, they will likely meet criteria for inclusion in a forthcoming volume of this Series focusing on patient education and self-management.

comorbid conditions (e.g., hypertension, hyperlipidemia, coronary artery disease, obesity, tobacco use), or advanced illness (e.g., specific and previously documented diabetic complications such as nephropathy, neuropathy, or retinopathy).

Many studies omitted key data elements. For instance, among the 33 studies reporting mean reductions in HbA_{1c}, 10 articles (reporting 12 comparisons) did not provide standard deviations or standard errors of the mean,[88, 89, 112, 121, 137, 141, 143, 152, 153, 157] and four studies provided no baseline HbA_{1c} values for either study group.[88, 107, 120, 156] Similarly, among the 26 studies reporting at least one measure of provider adherence, nine articles (reporting 10 comparisons) included no baseline values for any of the adherence outcomes.[110, 111, 119, 120, 122, 127, 130, 154, 155]

Methodologic features. Forty seven (71%) of the included trials had a randomized design,[82, 87-89, 97, 98, 104, 106, 107, 110, 112, 114-117, 121, 126-133, 135, 136, 139, 140, 143-150, 152-157] while one used a quasi-randomized design,[96] and another 18 were controlled before–after studies.[105, 108, 109, 111, 113, 118-120, 122, 134, 137, 138, 141, 142, 151, 158] The investigators identified numerous uncontrolled before–after studies, but none of these met the adopted EPOC criteria for inclusion as a time series, which mandates data from at least three time points in the pre- and post-intervention periods.[159] Thirty-five of the included trials involved clustering (i.e., unit of analysis differed from unit of allocation[‡‡]).[87-89, 96, 105, 107-110, 113-115, 119, 121, 122, 129, 132, 137, 138, 141, 145, 147-149, 151-153, 155, 157, 158] The number of clustered units per trial ranged from a low of one clinic, team, or firm per study group[96, 109, 114, 119, 137, 153] to a high of 247 (with clinicians as the unit of allocation).[149] Only three clustered trials reported ICC values.[87-89] One of these studies[87] reported ICC values for each of the seven adherence outcomes identified in the study. These values ranged from 0.02 to 0.33, and the researchers used the median (0.18) to calculate the effective sample size for the adherence outcomes in this study. The additional two studies reported ICC values for measures of disease control. In one case,[88] the ICC = 0.045 and 0.047. The other[89] used a value of 0.07 in performing the power calculation, though the rationale for choosing this number was unclear. Since the remaining studies did not report ICC values, the investigators assigned values based on data from the literature.[67]

Reported outcomes. The included studies reported a wide range of specific outcomes, with 51 studies reporting at least one measure of disease control and 26 reporting at least one measure of provider adherence. Only nine studies meeting the inclusion criteria (which required studies to report at least one measure of disease control or provider adherence) reported patient adherence outcomes. Thirty eight studies reported changes in serum HbA_{1c} in the format of mean and standard deviation for each study group, while 13 studies reported other measures related to changes in serum HbA_{1c} (e.g., the percentage of patients with serum HbA_{1c} falling within a certain range). Twenty-one studies reported an outcome involving blood pressure control, although only 15 reported the mean systolic or diastolic blood pressure, and just eight reported sufficient information to permit quantitative analysis (i.e., a standard deviation in at least one of the measurement periods for each study group and mean values from both periods).

Because of the variety of adherence outcomes, the investigators focused the analysis on a summary measure of provider adherence. As described in the Methods section, they calculated for each study the net change attributable to the intervention for all adherence outcomes reported and then used the outcome with the median effect as the data contributed by that study for this

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[‡‡] Cluster trials allocate participants at one level (e.g. providers randomized to intervention or control group), but collect and analyze data at the level of individual patients or clinical encounters. Analyzing such studies at the patient level produces so-called unit of analysis errors [160] unless investigators adjust for correlation within each cluster. As described in Methods and illustrated in Appendix F, we calculated an "effective sample size" to adjust for clustering effects whenever the unit of analysis and unit of study group allocation were not the same.

summary adherence measure. (Although nine studies included outcomes related to patient adherence, they exhibited little overlap in terms of the type of adherence outcome reported or the QI strategies employed. Consequently, patient adherence outcomes were not included in the present analysis.)

Provider adherence outcomes were reported in 26 studies, however only 17 had sufficient data to permit quantitative analysis. Adherence outcomes related to appropriate monitoring of serum HbA_{1c} in 19 comparisons, management of hypertension or coronary artery disease in 14 studies, and to monitoring of laboratory values other than serum HbA_{1c} or glucose in 20 comparisons (e.g., serum lipids, urine microalbumin). Thirteen studies reported adherence outcomes related to screening for diabetic complications of the foot, and 14 studies measured provider adherence in connection with screening for ophthalmologic complications.

Among the disease control outcomes, the analysis focused on changes in serum HbA_{1c} (results for studies reporting usable data on changes in blood pressure are shown in Appendix E, Table E2). All outcomes were standardized so that a positive number for any change (or for any coefficient in the regression analysis) corresponds to an improvement, while a negative value reflects an undesirable change. As described previously, all outcomes involving changes in mean serum HbA_{1c} refer to the net reduction in serum HbA_{1c} (i.e., the intervention was associated with a positive reduction in HbA_{1c}, as desired). Adherence outcomes also were standardized so that adherence was measured in terms of the desired process in such a way that positive changes always reflect an improvement in care.

Types and numbers of quality improvement strategies. As shown in Table 2a, the most common type of QI intervention fell into the broad category of organizational change (40 comparisons including 24 RCTs), followed by patient education (28 comparisons, 23 RCTs), and provider education (24 comparisons including 16 RCTs). Apart from studies[161-164] of incentives directed at patients for the purpose of reinforcing patient education or self-care, only one study[131] evaluated financial incentives. (These other studies[161-164] will be included in the forthcoming volume of QI strategies focused on patient education and self-management.) The investigators reported results for the specific QI strategies, including analyses collapsing some of the categories with clear overlap (e.g., patient education, promotion of self-management, and patient reminders).

Table 2b depicts the number of different QI strategies examined per study. Fourteen studies evaluated single-component interventions. Fifty-two trials involved interventions employing more than one of the nine QI strategies in the taxonomy, with five being the maximum number of strategies involved in any single intervention.[117, 133, 148, 150, 157]

The median number of QI strategies per intervention was two. Though not a QI strategy *per se*, the researchers also abstracted information on the role played by clinical information systems in the trials.

Analysis by Outcome Measures

Trial design was a significant negative predictor of effect size for both outcomes (i.e., trials with a randomized design reported smaller improvements in glycemic control, and for provider adherence). For studies reporting impacts on glycemic control, sample size also exhibited a significant inverse correlation with the magnitude of effect (i.e., the larger studies showed smaller reductions). This inverse correlation persisted among the randomized trials and suggested an independent effect of sample size, rather than confounding due to a tendency of

larger trials to have a randomized design. Consequently, the tables showing the associations between QI strategies and targeted outcomes are stratified generally by sample size for glycemic control, and by study design for both outcomes.

Publication bias, to be discussed below, provides the most likely explanation for the striking patterns shown in the tables stratifying reported results by sample size and by trial design. Thus, in addition to illustrating the magnitude of the relationships between effect sizes and study features, the tables also summarize the likely effect sizes of each QI type based on the subset of studies with the least apparent bias.

Effect of QI Strategies on Glycemic Control

Table 3a shows the median reductions in serum HbA_{1c} achieved by interventions employing different QI strategies. Among the 38 comparisons with sufficient data regarding changes in mean serum HbA_{1c} in the study and control groups, the median effect on serum HbA_{1c} was an absolute reduction of 0.48% (IQ range: 0.20%, 1.38%). For specific QI strategies, trials that included provider education (alone or in combination with other QI strategies) had the highest median effect, with a median absolute decrease in serum HbA_{1c} equal to 1.10% (IQ range: 0.56%, 1.50%). Trials that included promotion of self-management showed the lowest median reduction in serum HbA_{1c} (0.40%; IQ range: 0.20%, 0.60%).

Stratifying the results by study sample size shows that the larger studies reported generally smaller effects. For instance, the 10 trials in the lowest quartile of sample size reported a median reduction in serum HbA_{1c} of 1.35% (IQ range: 0.81%, 1.73%), while the 10 trials in the highest quartile reported a median reduction of only 0.10% (IQ range: 0.10%, 0.33%). Similarly, the 19 trials falling in the lower two quartiles of sample size reported a median reduction in serum HbA_{1c} of 1.30% (IQ range: 0.41%, 1.49%), while the 19 trials in the upper two quartiles reported a median reduction of only 0.21% (IQ range: 0.10%, 0.55%). As shown in Table 3a, this pattern was consistent for all but one of the QI strategies. (Provider reminders represent the one exception, as reported reductions in serum HbA_{1c} were approximately equivalent for studies in the upper and lower quartiles of sample size.)

Table 7a confirms the inverse relationship suggested by visual inspection as statistically significant. Specifically, the Spearman rank correlation coefficient for the relationship between sample size and improvement in serum HbA_{1c} was -0.46 (95% CI: –0.09, –0.72; p=0.02). This relationship does not appear to reflect confounding based on trial design, as the same correlation existed among randomized trials (Spearman correlation coefficient = –0.48; 95% CI: -0.03,-0.77; p=0.04).

The relationship between sample size and reported effects strongly suggests publication bias, such that smaller studies reporting negative or less impressive results are not as likely to be published. For this reason, the authors have presented the results for impacts on glycemic control stratified by quartiles of sample size wherever possible. (The issue of publication bias is explored further in the Discussion section.)

Effect of QI Strategies on Provider Adherence

Table 3b exhibits the median improvements in the summary measure of provider adherence achieved by interventions employing the various QI strategies. Among the 17 trials with sufficient data regarding changes in provider adherence, the achieved median effect was an attributable 4.9% increase in adherence (IQ range: 3.8%, 15.0%). Self-management appears to have the largest median effect in Table 3b, but this result reflects a single study[152] in which the intervention also included components of patient education and organizational change. (The issue of other interventions as a potential confounding presence is addressed in the analysis of specific QI types.)

Apart from self-management, the largest median effects on provider adherence were associated with provider education and audit and feedback. Among the 11 trials with some component of provider education, either alone or in combination with other QI strategies, the median increase in adherence was 5.6% (IQ range: 4.15%, 17.2%). Nine trials utilizing audit and feedback also achieved a 5.6% median increase in adherence (IQ range: 3.4%, 16.4%).

Visual inspection of Table 3b suggests no striking variation in the effect sizes across quartiles of sample size, and Table 7a confirms the correlation to be smaller than for studies reporting changes in serum HbA_{1c} and lacking in statistical significance (Spearman correlation coefficient = –0.22; 95% CI: 0.29, –0.63; p=0.4). However, trial design was a highly significant predictor in the regression analysis (p=0.0008; Table 7a). Based on the mean post-intervention differences between the study and control groups, the parameter estimate of –0.30 for the impact of trial design implies that randomization generally decreased the improvement in provider adherence associated with an intervention by 15.3% (see text accompanying Table 7a).

Table 4a bears out this relationship by showing the median effects associated with randomized and non-randomized trials, both overall and for each QI strategy. For those studies detailing impacts on glycemic control, RCTs reported a median reduction in serum HbA_{1c} of 0.39% compared with 1.40% for non-randomized trials, and this difference was statistically significant (p=0.008 for Mann-Whitney test; Table 7c). This difference diminished only slightly with the restriction of the analysis to trials in the upper two quartiles of sample size (p=0.03; data not shown). Table 4b bears out the persistence of a relationship between sample size and magnitude of reductions in serum $HbA_{1c,}$ even among randomized trials.

Effect of the Number of QI Strategies per Intervention

Trials utilizing combinations of QI strategies were more likely to exert a positive effect. The six trials involving single-faceted interventions had no overall effect on glycemic control (Table 5a). The median reduction in serum HbA_{1c} reported by these trials was 0.00 (IQ range: –0.08, 0.16) (i.e., some studies reported *increases* in serum HbA_{1c}). By contrast, the 32 trials involving interventions with at least two strategies reported a median absolute reduction in serum HbA_{1c} of 0.60% (IQ range: 0.30%, 1.40%). The Mann-Whitney test comparing these median effects was statistically significant at p=0.01 (Table 7c). The difference diminished only slightly when the analysis was restricted to trials in the upper two quartiles of sample size (p=0.03; data not shown).

The relationship between number of QI strategies and magnitude of effect was slightly weaker for provider adherence (Table 5b). The 14 trials involving interventions with at least two QI strategies were associated with a median increase in provider adherence of 5.3% (IQ range:

4.5%,16.1%) compared with the three single-faceted trials, which reported a median increase in adherence of 3.0% (IQ range: 2.0%,3.5%). The Mann-Whitney test for this comparison suggests rejection of the null hypothesis (p=0.04; Table 7c), that these two medians are the same. This p-value would not withstand correction for multiple comparisons, but the beneficial impact of multifaceted interventions was one of our *a priori* hypotheses (as described in the Methods section).

For trials reporting impacts on glycemic control, the apparent superiority of interventions with more than one QI strategy persisted when the analysis was restricted to randomized trials (Table 6). The 23 randomized comparisons of interventions involving at least two distinct QI strategies reported a median reduction in serum HbA_{1c} of 0.41% (IQ range: 0.25%, 0.94%) attributable to the intervention, as opposed to 0.00% (IQ range: −0.10%, 0.00%) for the five randomized comparisons involving single-faceted interventions. Even with the relatively small number of studies involved, these medians are unlikely to be drawn from the same population (p=0.008 for Mann-Whitney test). Among trials in the upper two quartiles of sample size, interventions with at least two strategies retained their association with greater median reduction in serum HbA_{1c}, though the difference between the medians was less striking (p=0.01; Table 7c). The greater impact of interventions with at least two QI types persisted even when the analysis was restricted to interventions involving organizational change, which would generally be regarded as more complex and more intense than other QI types. In other words, even in studies of single-faceted interventions employing a form of organizational change as the sole QI strategy, the addition of at least one more strategy was found to increase the overall effect (0.71% vs. 0.05% median reduction in serum HbA_{1c}; p=0.002).

The investigators further explored the relationship between number of QI strategies and magnitude of effects using an alternate classification scheme in which important subtypes of provider education and organizational change were treated as their own category. Specifically, the broad category of provider education was replaced by three categories—workshops or meetings,[55] distribution of educational materials,[165] and educational outreach[56]—and organizational change was replaced by four strategies—disease or case management,[17] changes to team structure or personnel, modification of medical records systems, and "other organizational change." This alternate classification scheme resembles that used in the Cochrane review of QI interventions for diabetes care,[16] and is more consistent with other reviews focusing on these specific strategies.[17, 55, 56, 165]

Under this alternate classification of the QI strategies, five studies still were catagorized as single-faceted,[104, 112, 116, 121, 127] but the median number of strategies increased from two to three and the maximum number of strategies increased from five to six.[153, 157] Appendix H (Tables H4a-c) presents the same relationships discussed above and shown in Tables 5a, 5b, and 6, but using the results of this alternate classification in which major substrategies are promoted to their own category of QI strategy (Tables H4a, H4b, and H4c). The relationship between increased numbers of QI strategies and magnitude of effects appears somewhat stronger for studies reporting impacts on glycemic control. Though the analysis is not shown, the Mann-Whitney test of the difference in median effects between single and multifaceted interventions using the alternate classification scheme had greater significance (p=0.005).

Analysis by Type of QI Strategy

Visual inspection of Tables 3a, 3b, and 4a suggests no striking differences among the various QI strategies. However, studies that included provider education or audit and feedback, alone or in combination with other strategies, were among those associated with the largest effects on both outcomes. The effects also exhibited less erosion with stratification by sample size or by trial design.

Tables 8a through 11b show the median effects on glycemic control and provider adherence for specific QI strategies. These tables attempt to address several particular limitations inherent to this analysis:

1. Several of the nine major QI strategies in our taxonomy may include substrategies that are sufficiently distinct to warrant their own category. To address this heterogeneity within some of the QI strategies, the tables of specific QI strategies compare specific substrategies to the overall set of QI strategies—not just other strategies within the same category. For example, "disease management" is compared with all other interventions, and not just interventions designated as "organizational change." Similarly, educational meetings are compared with all other strategies, not just those designated as having some component of provider education. (Provider education and organizational change are analyzed in this manner in Tables 8a, 8b, and 11a, 11b, respectively.)

2. Several of the categories currently defined as separate QI strategies may overlap with other QI strategies such that they might reasonably have been designated a substrategy within those categories (e.g., patient education might subsume promotion of self-management or even patient reminders; provider reminders might subsume facilitated relay of clinical data to providers). Tables 9a and 9b address this issue for patient education by presenting median effects for various ways of collapsing patient education, self-management, and patient reminders. Tables 10a and 10b present similar analyses for provider reminders and the facilitated relay of clinical data.

3. The apparent benefit of any particular strategy is confounded by the presence of other strategies in the same intervention. Comparing interventions with a particular strategy to those interventions with no such component provides some estimate of the attributable effect of a given strategy (e.g., the median effect of all studies with provider education versus the median effect of all interventions with no component of provider education). Nevertheless, no definitive statements can be made about the effects of individual QI strategies because most studies used more than one strategy. The researchers also performed linear regression as a means of assessing the relative benefits of a particular QI strategy.

Provider Education

Interventions with some component of provider education, alone or in combination with other QI strategies, produced significantly larger improvements in glycemic control. Such interventions had a median absolute reduction in serum HbA_{1c} of 1.10% (IQ range: 0.56%,1.50%), compared with 0.40% (IQ range: 0.10%, 1.08%) for interventions with no provider education component. The Mann-Whitney test suggests that these two medians are

unlikely to be equivalent (p=0.02; Table 7c). But since the impact of provider education does not have a specific relation to any of the *a priori* hypotheses, this p-value would have to be adjusted for multiple hypothesis testing, in which case it would lose its significance (p= 0.2-0.3 if the number of comparisons were taken to be 10-15).

Visual inspection of Table 8a gives the impression that the greater effects associated with interventions having some component of provider education, compared with those with no such component, persisted among larger studies (1.50% median reduction in serum HbA_{1c} vs. 0.20%). This comparison loses its significance, however, even without adjusting for multiple hypothesis testing (p=0.30 for Mann-Whitney test). Restriction of the analysis to RCTs also results in loss of significance (p=0.06 before adjustment for multiple comparisons), despite the persistent appearance of a larger effect in Table 8b.

Interventions involving provider education also reported greater improvements in provider adherence than did interventions without any educational component for providers. But the relative difference was less striking than for glycemic control, and it diminished when the analysis was restricted to RCTs (Table 8b). Interestingly, provider education also was the only QI strategy to have even borderline significance in the regression analysis (Table 7b), with a coefficient of 0.25 (95% CI: 0.00, 0.51%; p = 0.05). At the same time, a specific benefit for provider education did not relate to any of the *a priori* hypotheses, so this p-value requires adjustment for multiple comparisons and would remove the appearance of a significant result.

As acknowledged in the preceding section, the designation of "provider education" as a single category—including components as diverse as workshops and conferences, educational outreach, and distribution of printed materials—is somewhat arbitrary. These components were compared to the overall set of QI strategies, and not just to other strategies with some element of provider education, as if educational meetings and dissemination of educational materials were regarded as their own categories. Using this more general approach to the comparisons (Tables 8a and 8b), interventions with educational meetings or workshops appeared more effective than interventions without them. This also is true of interventions involving the distribution of educational materials, compared with those lacking the distributed materials component (p=0.03 and p=0.06, respectively). Only one study of educational outreach reported effect on glycemic control in a format compatible with this analysis, preventing meaningful comparisons with interventions lacking educational outreach.

Putting aside the issue of multiple hypothesis testing, the small numbers of studies make confounding by the presence of other interventions a significant possibility. The one study of educational materials, for example, that fell in the upper two quartiles of sample size involved a fairly intensive case management intervention.[109] There is no way to assess the impact attributable to the component involving educational materials.

Confounding by the presence of other interventions is still quite probable, even with larger numbers of comparisons. Across all sample sizes, for instance, eight comparisons[89, 96, 109, 115, 153, 157] evaluated interventions involving educational materials distributed to providers. These comparisons reported a median reduction in serum HbA_{1c} of 0.91% (IQ range: 0.52%,1.48%) compared with 0.40% (IQ range: 0.1%, 1.25%) for the 30 interventions involving no distribution of educational materials. The eight comparisons with interventions including educational materials involved problem-based learning in one trial judged to involve no other QI strategies,[96] a multifaceted intervention including components of audit and feedback and disease/case management in addition to provider education,[153] and patient reminders and disease or case management in addition to provider education.[109] Other comparisons included elements of

patient education, patient reminders, and provider reminders in addition to provider education,[157] a Web-based decision support tool,[89] and an intensive, multifaceted intervention including benchmarking, computerized decision support, and frequent interaction with participating patients and providers.[135] Thus, even among these eight interventions involving the distribution of educational materials and also reporting an effect on glycemic control, the apparent benefit of educational material actually might reflect the benefits of the other intervention components involved.

Patient Education, Promotion of Self-management, and Patient Reminders

Tables 9a and 9b present the median effects on glycemic control and provider adherence for patient education, promotion of self-management, and patient reminders, alone or in combination with other QI strategies. The 18 trials involving patient education achieved a median reduction in HbA_{1c} of 0.70% (IQ range: 0.34%, 1.45%), compared with the median reduction of 0.39% (IQ range: 0.10%, 0.81%) seen in the 20 studies with no patient education component (Mann-Whitney p=0.08). The regression analysis detected no significant effect for patient education, in terms of glycemic control or the summary measure of provider adherence.

The investigators were unable to detect any important effects in the analysis for self-management or patient reminders. Collapsing the patient education, patient reminders and promotion of self-management strategies into a single, broad category added nine more studies but left the median effect relatively unchanged at 0.8% (IQ range: 0.33%, 1.44%). Moreover, self-management and patient reminders—separately or as a collapsed category—produced roughly the same median effects as interventions without any of these QI strategy components.

Provider Reminders and Facilitated Relay of Clinical Data

Among comparisons of all sizes, neither provider reminders nor facilitated relay of clinical data to providers achieved results substantially different from all other QI strategies, or all comparisons without any component of either of these strategies (Table 10a). Among larger studies, both strategies achieved marginally increased reductions in serum HbA_{1c} compared to interventions without these strategies, but this benefit disappeared for RCTs (Table 10b). Neither strategy produced any apparent benefit for provider adherence beyond what was achieved by all other strategies, and by all interventions without components of either of these two strategies.

Audit and Feedback

The five trials utilizing audit and feedback[137, 145, 153, 157] reported a median reduction in HbA_{1c} of 0.71% (IQ range: 0.41%, 1.40%), compared with 0.47% (IQ range: 0.20%, 1.30%) for trials absent audit and feedback—though these medians are unlikely be different (p=0.5 for Mann-Whitney test). The improvement in provider adherence seen with audit and feedback (median improvement of 5.6% [IQ range: 3.4%, 16.4%]) also was superior to that achieved by interventions without any audit and feedback component (median improvement of 4.5% [IQ range: 4.0%, 5.1%]), though this difference also was non-significant (p=0.4).

The results for audit and feedback also may illustrate another form of publication bias related to quality of reporting, rather than sample size or trial design. Of the five comparisons (reported in four publications[137, 145, 153, 157]) evaluating the impact on glycemic control of an intervention involving audit and feedback, four comparisons[137, 153, 157] reported no standard deviations for any of the reported serum HbA_{1c} group means. (Consequently, the regression coefficient shown in Table 7b reflects the comparison of the post-intervention effect size for a single study of audit and feedback[145] with the 26 other comparisons involving no component of audit and feedback). The single comparison that provided sufficient data to warrant inclusion in the regression analysis reported a net reduction in serum HbA_{1c} attributable to the intervention of only 0.10% (from this single study), which appears significantly lower than the median reduction of 0.47% (95% CI: 0.24%, 0.99%) associated with all studies lacking any component of audit and feedback.

The researchers were unable to adequately capture any objective measure of "intensity" for audit and feedback (or any QI strategy), and therefore did not adjust for any such measure in the analysis. Consequently, it is possible that the single trial of audit and feedback included in the regression analysis was a particularly low intensity form of this general strategy and/or the 26 interventions with no audit and feedback component involved some high intensity versions of QI strategies other than feedback. The former possibility appears unlikely, as the aforementioned comparison of audit and feedback[145] also involved a computerized decision support system used to guide physicians in matters of diagnostics, history recording, the physical exam, additional tests, and treatment, as well as providing recommendations for key management decisions. Nevertheless, any inferences regarding the relative benefit (or lack thereof) of audit and feedback, compared with the merits of other QI strategies, would be highly speculative given only one (or even five[137, 145, 153, 157]) trials as a basis for comparison.

Organizational Change

Organizational changes were present in 27 of the 38 comparisons reporting changes in mean serum HbA_{1c}, but the investigators were able to calculate a value for the summary measure of provider adherence in only six of the 17 trials (Tables 11a and 11b). While organizational change as a broad category had little apparent impact on glycemic control, it was the disease or case management and changes to the existing medical record system (e.g., implementation of a specialized diabetes patient registry, or a more general electronic medical record) strategies that achieved median reductions in serum HbA_{1c} notably greater than the interventions absent these strategies. This appeared to be the case across the entire sample of studies and in the subset of interventions that included some component of organizational change. For changes to the medical record (e.g., implementation of a clinical information system), the five studies classified as implementing this type of organizational change reported a median reduction in serum HbA_{1c} of 1.40% (IQ range: 1.40%, 1.90%), compared with a median reduction of 0.40% (IQ range: 0.10%, 0.80%) for the 33 trials with no such component. This comparison was judged significant after the Mann-Whitney test was applied to the two medians (p=0.007; Table 7c), however the five trials involving this type of organizational change all appeared in the lower two quartiles of sample size (Table 11a).

The comparison of the median effects associated with interventions involving disease management and those interventions without any such component appeared to have a significant impact on the median reduction in serum HbA_{1c} (p=0.009; Table 7c). But this appearance of

statistical significance would not endure an adjustment for multiple hypothesis testing (given the 10-15 basic comparisons made). It should be noted that a trend towards a significant difference persisted among non-randomized trials in the upper two quartiles of sample size (p=0.003), although less so among randomized trials (p=0.06 without adjusting for multiple comparisons).

Adding disease management to an intervention was associated with less substantial incremental improvement in provider adherence (Table 11b). Because of the inverse associations with trial design and study period (discussed below), the researchers repeated the regression analysis of the impact of disease management with inclusion of trial design and study year as predictors. This analysis, however, left the parameter estimate and associated confidence interval relatively unchanged (data not shown). That disease management had little impact on provider adherence is perhaps to be expected, given the focus on structured followup and patient management, rather than aspects of provider behavior.

Only one trial examined changes to the medical record with provider adherence, and it reported less improvement than did studies without this intervention component. Changes to team personnel or structure produced unimpressive effects on glycemic control. Only two studies employed this intervention component and also reported provider adherence. The single RCT did achieve a larger improvement in generalized provider adherence than the 13 RCTs without changes to team structure or personnel, while the non-randomized trial did not (Table 11b).

Additional Analyses–Clinical Information Systems

Clinical information system is a broad term encompassing systems performing a wide variety of functions. A general feature that serves to distinguish clinical information systems from administrative information systems is that the former require data entry or data retrieval by clinicians at the point of care.[166] The researchers identified interventions using a clinical information system for any of the following purposes: trial participant identification or enrollment, provider reminder delivery, clinical decision support, provider-to-provider communications enhancements, or clinical performance auditing.

As shown in Tables 12a and 12b, 20 trials (30%) involved some role for a clinical information system, though this role was limited to identifying or enrolling eligible participants in 6 of the trials.[121, 129, 133, 143, 152, 155] Interventions that used a clinical information system in at least one such capacity achieved greater reductions in glycemic control than did interventions in which this component played no role (Table 12a). The difference, however, was not statistically significant (p=0.10 for Mann-Whitney test; Table 7c), even without adjustment for multiple comparisons. Moreover, even the appearance of a benefit for interventions with some role for a clinical information system diminished substantially in larger studies and those with a randomized design (Tables 12a and 12b).

The roles listed above clearly have the potential to differ widely in their effect (e.g., provision of decision support, versus mere identification of eligible participants in the intervention). At the same time, focusing on the specific roles for this intervention suggested no apparent benefit for decision support, auditing clinical performance, or any of the other roles examined (Tables 12a and 12b).

Effects of Study Setting and Methodologic Features

Study Setting

Table 7a shows relationships between key study outcomes and country (e.g., U.S. versus non-U.S.), study period (i.e., the midpoint of the observation period for the trial), and patient selection. Patient selection refers to any explicit efforts to enrich the study population for more complex patients, defined in terms of comorbid conditions, presence of diabetic complications, problems with treatment adherence, or poor access to care (e.g., uninsured patients).

The only statistically significant finding among these relationships is a negative correlation between study period and provider adherence, meaning that more recent trials had a tendency toward smaller improvements in adherence (p= 0.004). The relatively low p-value would retain conventional statistical significance, even with correction for as many as 15 comparisons. More important, this finding relates to one of the investigators' *a priori* hypotheses. As stated in Methods section (Page 24), one reason for entertaining this hypothesis was that baseline adherence might have improved in response to past QI efforts, making further improvement more difficult. The mean baseline adherence in control and intervention groups across all studies was 51 ±18%. Although not depicted in Table 7a, baseline adherence did exhibit a substantial positive correlation with study period, with a Spearman rank correlation of 0.6 (p=0.006).

Methodologic Features

The most striking finding in Table 7a is the highly significant negative correlation between use of a randomized design and the generalized measure of provider adherence, with randomization reducing the effect size by roughly 30% (p=0.0007). Again, this p value would retain its statistical significance with adjustment for multiple comparisons. Moreover, this was another of the researchers' *a priori* hypotheses. As there were only three non-randomized trials reporting impacts on provider adherence,[105, 108, 113] this statistical significance reflects a striking difference in effect size. As shown in Table 6, these three non-randomized trials reported a median improvement in provider adherence of 18% (IQ range: 17.2%, 21.0%), compared with a median of 4.5% (IQ range: 3.5%, 5.4%) for the 14 randomized comparisons.

A substantial negative correlation also existed between sample size and effect size (i.e., larger studies tended to show smaller effects), further confirming the trend toward larger effects for smaller studies seen in Tables 3-12. Also, as shown in Table 7a, the rank correlation coefficients for this relationship were -0.46 (p=0.02) and -0.22 (p=0.4) for glycemic control and provider adherence, respectively. While of smaller magnitude, the correlation for provider adherence still is noteworthy. (The statistically non-significant result likely reflects the small number of studies reporting this outcome.) Also, though not shown in Table 7a, the inverse correlation between sample size and effect size changed very little among RCTs alone. Only six of the RCTs had a cluster design, so the p-value lost statistical significance, but the magnitude of the correlation increased overall (Spearman rank correlation coefficient = -0.54; p=0.3).

Chapter 4. Discussion

Effectiveness of QI Strategies

This investigation determined that QI interventions provided small-to-modest improvements in glycemic control and provider adherence. Taken as a whole, the interventions studied in the 66 included comparisons reported a median absolute reduction in serum HbA_{1c} of 0.48% (IQ range: 0.20%, 1.38%) and median absolute increase in provider adherence of 4.9% (IQ range: 3.8%, 15.0%) above any improvements observed from "usual care." The researchers also found that interventions involving more than one QI strategy resulted in a greater benefit than did interventions using a single strategy. This difference achieved statistical significance, but nevertheless should be interpreted with caution, as the small number of single-faceted interventions in the review makes confounding by other factors (e.g., the intensity of these single interventions, as well as various patient, provider, and organizational characteristics) a substantial possibility. Disease management and changes to the existing medical record system (e.g., implementation of a specialized patient registry, or a more generalized clinical information system) were associated with trend toward larger improvements in glycemic control, but these relationships were not pre-specified as hypotheses. Moreover, they would not withstand correction for multiple comparisons in this largely exploratory analysis, and were less pronounced in RCTs.

The findings should be interpreted cautiously for several reasons. First, the reviewers found that larger and more rigorously designed trials found a smaller benefit than did smaller or less rigorously designed trials. As discussed below, this finding strongly suggests the presence of publication bias. Second, most interventions involved multiple QI strategies, thus limiting assessments of the intrinsic benefit for any particular QI strategy. Finally, this review considered only QI studies regarding diabetes. QI studies related to other diseases are relevant in understanding the usefulness of specific QI strategies, as discussed in further detail below. Because of the importance of potential publication bias, the discussion will begin with this topic.

Publication Bias

The researchers found a significant inverse correlation between trial design and the magnitude of reported improvements in provider adherence, and, to a lesser extent, glycemic control (i.e., comparisons employing a randomized design reported significantly smaller improvements). Whereas non-randomized trials reported a median absolute improvement in provider adherence of 18.0% (IQ range: 17.2%, 21.0%), randomized trials reported a median improvement of only 4.5% (IQ range: 3.5%, 5.4%). The Spearman correlation coefficient was significant for both outcomes, but the investigators also tested the impact of trial design in a regression model adjusted for baseline differences between the control and intervention groups, as well as weighting by sample size, to ensure that this did not reflect baseline imbalances in study groups (which would occur more commonly in non-randomized trials). This analysis eliminated the significant relationship between trial design and glycemic control, but the relationship remained highly significant for provider adherence. On average, the improvement in provider adherence observed in randomized trials was 14.3% less than that observed in non-randomized trials ($p=0.001$).

For studies of glycemic control, the relationship to trial design was less clear-cut, but a striking inverse relationship existed with sample size. Among the 38 comparisons reporting changes in mean glycemic control, those falling in the lowest quartile of sample size reported a median reduction in serum HbA_{1c} of 1.35% (IQ range: 0.81%, 1.73%), whereas those in the highest quartile reported a median reduction of only 0.10% (IQ range: 0.10%, 0.33%). This inverse relationship between sample size and observed impact on glycemic control was statistically significant (Spearman rank correlation coefficient = −0.39, 95% CI: −0.01, −0.67; p= 0.04).[§§] These findings strongly suggest substantial publication bias operating at the level of sample size and trial design, such that publication of smaller studies with non-randomized designs occurs more often when reported improvements are large, than when the improvements are small or negative.

Correction for multiple hypothesis testing might give the appearance of chance association for some of these relationships. However, the results of these hypothesis tests also must be considered in the context of the prior probability or expectation that such associations might well exist. As discussed in the Methods section, publication bias is likely to affect this review, at least to the same extent that it exists for meta-analyses of clinical research—if not to a greater extent. Sample size and trial design are the two most often identified factors playing a role in publication bias. Thus, the detection of an inverse relationship between either study size or trial design and the magnitude of reported effect is more plausibly regarded as a confirmation of publication bias, than as a chance association due to multiple comparisons.

Benefit of Multifaceted Interventions

Despite the associations of effect size with sample size and trial design, certain findings appear to reflect more than just the effects of publication bias. In particular, interventions having at least two component QI strategies were associated with median effects significantly larger than were single-faceted interventions. The 32 comparisons involving interventions with at least two strategies reported a median reduction in serum HbA_{1c} of 0.60% (95% CI: 0.30%, 1.40%) compared with a median reduction of 0.00% (IQ range: -0.08%, 0.16%). These medians are unlikely to be equivalent, given the Mann-Whitney test result of p=0.01. The significance of this difference further increased (p=0.005) when the investigators reclassified interventions using a scheme similar to other authors, in which the major substrategies of provider education and organizational change were treated as their own categories. These results might be considered of borderline significance, given the multiple hypotheses explored in the analysis, except that this hypothesis differed from the others in its role as one of three *a priori* hypotheses.

Nevertheless, this finding will require further exploration. Other reviews have reached conflicting conclusions regarding the relative impact of adding more QI strategies, irrespective of their content.[16, 54, 85, 103] As with the analysis of specific QI types, the apparent impacts of a particular number of strategies (even the simple distinction between single- and multifaceted) is confounded by the distribution of the particular QI types across interventions. The authors cannot rule out the possibility that the one or two strategies with the largest, true underlying effects happen to be included in strategies that incorporated more QI components. Further confounding

[§§] This inverse correlation persisted with restriction among randomized trials and even among randomized trials without clustering effects (Spearman = 0.415; p=0.07). The loss of statistical significance for the second subset presumably reflects the decreased number of studies.

undoubtedly occurs as a result of non-random relationships between the adoption of more complex interventions and characteristics related to the local proponents of the intervention and/or the organizational milieu. For example, more complex interventions may occur more commonly in institutions with a greater commitment to quality improvement, which might affect support from senior management, availability of resources, and attitudes of participants, among other potential predictors of intervention success.

Uncertain Benefit for Specific QI Strategies

Disease management was the only strategy to exhibit an impact on median effects on glycemic control that approached a level of significance such that it would withstand correction for multiple hypothesis testing. Even without such adjustment, however, this apparent effect was diminished somewhat by a focus on larger trials and diminished substantially by restricting the analysis to randomized trials. Moreover, the regression analysis adjusting for baseline group imbalances and weighting by sample size yielded a non-significant result for disease management as a predictor of improved glycemic control.

A recent and systematic review of disease management strategies reported significant beneficial effects on measures of disease control such as the authors examined.[17] This comprehensive and well-conducted review had the advantage of cutting across multiple conditions (in contrast to this review of diabetes, and another systematic review focused on disease management for heart failure patients[167]). The recent crosscutting review,[17] however, did not take into account cluster effects.[168] Nor did it adjust for baseline differences between intervention and control groups. As outlined in the Methods section and reviewed elsewhere at length, the adoption of a randomized design does not preclude the need to adjust for baseline differences likely to impact the outcome of interest, even when these baseline differences do not appear significant.[90-94]

Among other individual QI strategies, trials using provider education achieved the highest absolute reduction in HbA_{1c} and had a significant Mann-Whitney comparison test, versus trials without provider education. Provider education also was the only strategy to emerge as a significant predictor for improved provider adherence in regression analysis. As outlined above, however, these results were found to lose their significance if adjusted for multiple comparison testing.

Little Benefit from Existing Clinical Information Systems

Apart from the implementation of a new clinical information system (which was treated as a type of organizational change), the investigators further assessed the potential impact of existing clinical information systems performing any of five specific roles. Thirty percent of the included interventions involved some role for a clinical information system, and these interventions reported greater median improvement in glycemic control than did interventions without any role for a clinical information system. This difference was not statistically significant, however, ($p=0.10$ for Mann-Whitney test even without adjustment for multiple comparisons) and shifting the focus to larger studies and those with a randomized design diminished substantially the appearance of a benefit for interventions with some role for a clinical information system.

Clinical information systems also had no apparent additional effect on provider adherence, compared with interventions without any role for an information system.

Focusing on specific roles for clinical information systems suggested no incremental benefit for any particular informatics function (e.g., decision support, auditing clinical performance, reminder systems). It should be noted that these findings reflect very small numbers of studies. The disappointing findings, however, also should be considered in light of likely confounding factors, which could inflate reported effects. For instance, the presence of sophisticated information systems is likely to be associated with the presence of other factors plausibly associated with successful interventions (e.g., greater financial resources, increased institutional investment in QI). Furthermore, while other reviews have found evidence supporting the impact of decision support systems,[33, 169] it is noteworthy that the most recent and possibly best-designed study assessing the impact of a clinical information system in outpatient management of chronic illnesses showed no beneficial impact on processes of care or any patient outcome for asthma or chronic angina.[170] The same investigators are likely to publish the results of a similar trial focused specifically on diabetes care in the near future,[171] which will add substantially to the evidence addressing this topic.

Of course, the absence of a demonstrable benefit does not prove a lack of benefit, and there are sound *a priori* reasons to believe that changes to existing medical record systems (e.g., a clinical information system deployment) might confer some benefit in diabetes care. In addition to the non-significance of this result, however, it is worth noting that evaluations of clinical information systems involve a special type of publication bias, insomuch as systems with failed[172-174] or unsatisfactory[175] implementations generally are excluded from evaluations of the of the intervention benefits, even though these implementations consume significant QI resources.

Comparison with Previous Review of this Topic

In the previous Cochrane review of this topic,[16] all included trials were judged to have more than one QI strategy, permitting no direct comparison of single and multifaceted interventions. (The authors inferred a benefit from multifaceted interventions based on the general finding of positive effects for the various multifaceted interventions evaluated.) The researchers involved with this review regarded 14 trials as having a single QI strategy, nine of which were published after the last substantive update to the Cochrane review.[89, 104, 112, 114, 116, 119, 121, 147, 155] The multiple QI strategies designation given to the remaining five studies by the Cochrane reviewers reflected differences in taxonomy in several instances. For instance, educational meetings and distribution of educational materials were considered separate strategies, rather than substrategies within the broader category of patient education. In other cases, however, there appears to have been a difference in judgment between the present reviewers and those involved with the previous study. Nevertheless, when the present investigators employed a taxonomy more akin to that used in the Cochrane review (in which major substrategies of provider education and organizational change were treated as their own categories), multifaceted interventions showed a median reduction in serum HbA_{1c} of significantly greater magnitude than that reported by single strategy interventions (0.58% vs. 0.05%; p=0.005).

The Cochrane review also included a study[176] as an interrupted time series that the present investigators regarded as a simple before–after study and therefore excluded it. Re-review of these studies might produce consensus, but this disagreement further reinforces the notion that

catagorizing design attributes for trials can be challenging and requires interpretation based on limited descriptions.

The Cochrane review[16] of this topic suggested that multifaceted interventions carried benefit, and cited organizational changes (including computerized patient tracking systems and structured recall of patients) as particularly worthwhile interventions. The present review lends greater credence to the benefit of multifaceted interventions, as the Cochrane review included no single faceted interventions and performed no quantitative analysis. Thus, the benefit of multifaceted interventions was inferred simply from the qualitative impression of benefit derived from the included studies, without any comparison to single-faceted interventions.

Limitations

An important limitation of this review arises from the studies themselves, and underscores the need for more rigorously designed studies of quality improvement interventions. The limitation can be split into two categories: issues specifically related to the design and interpretation of research in quality improvement[64, 79, 177, 178] and problems with respect to the optimal design and reporting of health care research in general. Examples of the second category include a failure to report baseline data for the outcomes of interest, data omissions such as sample sizes or standard deviations, and inappropriate choices of statistical tests. Examples of the first category—problems more specifically related to quality improvement—highlight important gaps in the literature. They include limited descriptions of the interventions themselves, such that many interventions could not be categorized except in the most general terms (e.g., "provider education" or "disease management"), nor replicated by other investigators; omissions of important information regarding factors likely to affect intervention success or failure (e.g., the degree of institutional support, the availability of ancillary administrative resources, the attitudes of participants towards the intervention, or the perceived quality target). Another factor hampering quality improvement research is the lack of grounding in a theoretical understanding of how to effect change at the level of individual behavior or organizational culture and structure (see Chapter 3). For instance, the vast majority of studies provided no answer to the most basic question of why a particular QI strategy was selected to address a given problem (e.g., why provider education and not, say, audit and feedback—or vice versa). Choices regarding the format for delivering the selected QI strategy similarly received little to no attention. Some of this information is challenging to collect or quantify (e.g., degree of institutional support), but other types of data (e.g., attitudes of participants) could be collected and may prove helpful in determining why some QI interventions succeed while others fail.

The lack of theoretic grounding for many QI interventions is in stark contrast to the clinical research (see Chapter 3). By the time a clinical intervention reaches the stage of evaluation in a randomized trial, a substantial body of research (both basic scientific and epidemiologic) generally exists and lends credence to the hypothesis that the intervention will benefit patients. as A number of theoretic models of behavioral or organizational change so exist, as noted in Chapter 2, but their usefulness and applicability to QI interventions in health care has not been well studied. Improving the state of evidence regarding QI interventions will require commensurate improvements in the preliminary research leading up to the design or selection of a particular intervention.

Despite the aforementioned general concerns regarding the methodology and underpinnings of many QI intervention evaluations, it is possible that beneficial interventions already exist and that our analysis has failed to identify their benefits relative to other interventions or usual care. It is worth noting in this regard that the investigators' analysis suggested a modest but statistically significant correlation between study period and baseline provider adherence (i.e., more recent studies tended to report higher baseline adherence). This suggests quality improvement has occured and, perhaps more importantly, that achieving the same rate of improvement may become more difficult with time. The decision to pursue further improvements with respect to any given target depends on a number of factors: the effectiveness of the targeted process of care (e.g., how well tight control works to prevent diabetic complications); the effectiveness of strategies for promoting further changes in patient or provider behavior; the costs associated with the targeted quality gap; and the costs of interventions attempting to narrow this gap.[179]

The small number of studies in certain areas also is likely to limit our ability to detect true benefits for QI strategies. Although this review is the largest study of this particular topic area to date, the number of studies for a particular QI strategy assessing specific outcomes was generally 10 or fewer. When possible, the investigators performed regression analysis and also nonparametric tests to assess for differences between medians. Given the small number of studies in some groups, however, the possibility that small effects may have gone undetected cannot be ignored.

In an attempt to increase the number of studies providing data for the quantitative analysis, the researchers focused on glycemic control (measured by serum HbA_{1c}) as the sole measure of disease control. Thus, they were unable to capture the impacts of the interventions on other important aspects of diabetes-related morbidity, such as cardiovascular disease. A QI strategy producing even a modest impact on blood pressure control or hyperlipidemia could confer substantial benefits to patients. In fact, one of the most comprehensive studies in the sample[82] demonstrated a reduction in cardiovascular mortality, while reporting no significant reduction in HbA_{1c} for intervention patients compared with patients receiving usual care. Thus, in the absence of markedly positive effects for any single strategy, a crosscutting strategy that has modest individual effects on glycemic control, hypertension, and hyperlipidemia could result in a significant benefit for diabetic patients.

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Figure 1: Search Strategy and article review process

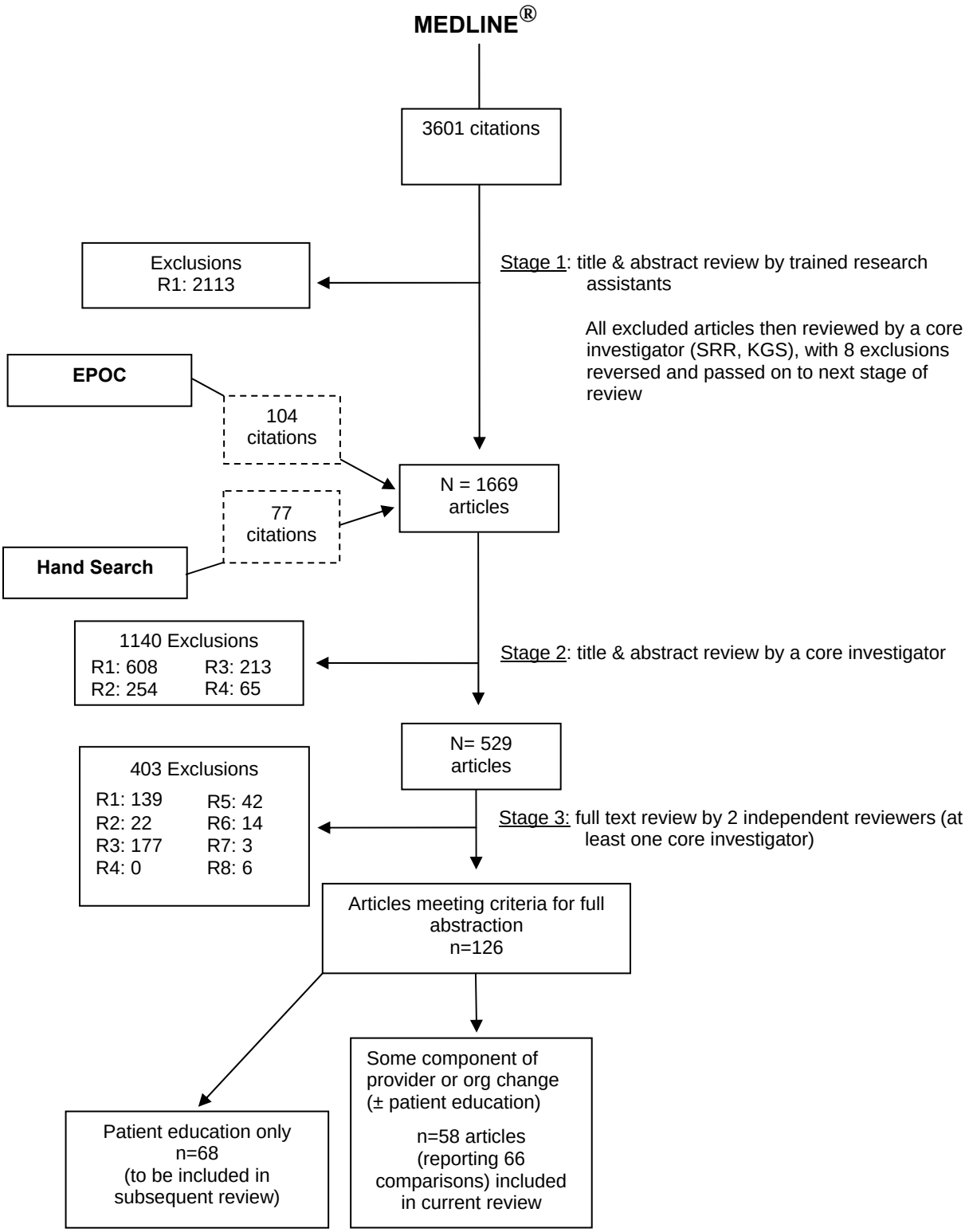

Figure 1 Legend

EPOC = Cochrane Effective Practice and Organization of Care database, described above, contains the results of extensive electronic searches of multiple large bibliographic databases, as well as hand searching of key journals. The 104 citations indicated above as contributed by EPOC do not include the 241 additional citations in EPOC already identified by the PubMed search.

Hand searching conducted for this project involved scanning bibliographies of all articles included at Stage 4 and the bibliographies of all systematic reviews and meta-analyses related to QI strategies in diabetes. When no systematic review existed for a given topic, we searched the bibliographies of traditional (narrative) review articles, editorials, and news items that appeared to describe QI studies involving outpatient diabetic care.

Reasons for Exclusion

R1 = not QI or not an evaluation

R2 = excluded topic: interventions restricted to diabetes in pregnancy, Type I Diabetes Mellitus, diabetes in children/adolescents, screening for new diagnoses of diabetes, preventing diabetes in high risk patients, hospital care

R3 = study design below Level 2 (i.e. does not meet criteria for RCT, quasi-RCT, CBA, or ITS)

R4 = unrelated to diabetes care (e.g., QI article retrieved by broad search but related to a different chronic illness)

R5 = no eligible outcomes

R6 = duplicate article (in some cases the article may have only partially overlapped with another report of the same study; in general the earlier or smaller the two publications was excluded, but reviewed with the other article in case it contained any additional information.)

R7 = study published prior to 1980

R8 = other; included one abstract not yet published or available as a manuscript from authors[1]; one cross-over trial with an inadequate wash out period and insufficient information to allow inclusion of the part of the trial by itself[2]; one study without clear documentation of the number of patients involved[3]; one study with data that appeared to contain several errors relating to the eligible outcomes[4]; one publication we were unable to obtain[5]; and one which described a QI strategy for eye screening of diabetics in rural areas that did not fit into any of our analytic categories.[6]

Figure 1 References

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Table 1. Summary features of included studies

Setting	Study period (duration)	Study Design (Number of Patients)	QI strategies employed*	Outcomes reported†
2 endocrinology clinics (Canada)[1]	--- (3 months)	RCT (42)	Self-Mx, Facil Relay	Dz: HbA1c, other
2 clinics, (unspecified US city)[2]	--- (6 months)	CBA (117)	Self-Mx, Facil relay, Org change	Dz: HbA1c, other
2 clinics (unspecified US city)[2]	--- (6 months)	CBA (87)	Self-Mx, Facil relay, Org change	Dz: HbA1c, other
2 large clinics (Jacksonville, FL)[3]	--- (1 year)	RCT (138)	Patient Ed, Facil relay, Org change	Dz: other Adhere: other
2 clinics, Baystate Medical Center (Springfield, MA)[4]	1995-1996 (15 months)	Quasi-RCT (144, 2 firms)	Prvdr Ed	Dz: HbA1c
6 group practices (United Kingdom)[5]	--- (2 years)	CBA (242, 6 practices)	Pt Remind, Prvdr Ed, Facil relay, Org change	Dz: HbA1c
Individual GP offices and a public hospital outpatient clinic (Netherlands)[6]	1994 (1 year)	CBA (275, 32 providers)	Facil relay, Org change	Dz: HbA1c
Massachusetts General Hospital Diabetes Center (Boston, MA)[7]	--- (1 year)	RCT (201)	Facil relay	Dz: HbA1c
Medical U. of South Carolina Adult Primary Care Center (Charleston, SC)[8]	2001 (6 months)	RCT (120)	Patient Ed, Org change	Adhere: other

* Pt Remind – patient reminder, Prvdr Remind – provider reminder, Org change – organizational change, Self-Mx — self-management, Facil Relay — facilitated relay of clinical data to providers, Patient Ed — patient education, Prvdr Ed — provider education, Audit & Fdbck — audit and feedback to provider Financial — financial or regulatory intervention

† Dz: measure of disease control; hemoglobin A1c (HbA1c), blood pressure (BP); other.
Adhere: measure of provideradherence to guideline or recommendation for measurement of HbA1c (labeled simply HbA1c), management of hypertension or coronary artery disease (HTN/CAD); screening or referral for detection of complications involving the foot or eye (foot/eye); other: patient education/counseling measurement of other lab value
Pat comp: patient compliance

Table 1. Summary features of included studies (continued)

Diabetes outpatient clinic (Australia)[9]	1998-1999 (1 year)	RCT (73)	Org change	Dz: HbA1c
Medicaid program (Hennepin County, MN)[10]	--- (1 year)	RCT (96)	Financial	Pat comp
Diabetes foot clinic (Lithuania)[11]	1995-1997 (2 years)	CBA (145)	Patient Ed, Org change	Dz: other
28 general practices (Netherlands)[12]	1989-1995 (6 years)	CBA (505, 28 providers)	Patient Ed, Self-Mx, Facil relay, Org change	Dz: HbA1c, BP, other
6 primary care centers (Florida)[13]	--- (2 years)	CBA (1029, 6 practices)	Prvdr Ed, Org change	Adhere: HTN/CAD, Foot/Eye, other
24 non-training general practices (United Kingdom)[14]	1993 (1 year)	RCT (24 practices)	Prvdr Ed, Audit & Fdbck	Adhere: HbA1c, HTN/CAD, Foot/Eye, other
Diabetes centers (Minnesota, Florida, Colorado)[15]	1992-1993 (6 months)	RCT (247)	Patient Ed, Self-Mx, Org change	Dz: HbA1c
124 general practices (The Netherlands)[16]	1996-1999 (3 years)	RCT (1431, 124 practices)	Prvdr Ed, Audit & Fdbck	Adhere: HTN/CAD, Foot/Eye, other
Diabetes clinic (Denmark)[17, 18†]	1993-2001 (9 years)	RCT (160)	Patient Ed, Org change	Dz: HbA1c, BP, other
University-affiliated family practice clinic (unspecified US city)[19]	--- (6 months)	RCT (67)	Patient Ed, Prvdr Ed	Dz: HbA1c
2 primary care clinics (unspecified US city)[20]	--- (3 months)	RCT (200)	Patient Ed, Self-Mx, Org change	Dz: HbA1c, other
Specialized diabetic service (Netherlands)[21]	--- (1 year)	RCT (246, 15 practices)	Patient Ed, Facil relay, Org change	Dz: HbA1c, BP, other

Table 1. Summary features of included studies (continued)

10 primary care practices (Germany)[22]	1993 (8 months)	CBA (403, 17 providers)	Prvdr Ed, Audit & Fdbck	Adhere: HbA1c, HTN/CAD, Foot/Eye, other Pat comp
Hospital diabetic clinic and GP offices (United Kingdom)[23]	--- (5 years)	RCT (200)	Prvdr Ed, Org change	Dz: HbA1c
29 general practices (Norway)[24]	--- (21 months)	RCT (1034, 17 practices)	Prvdr Remind, Audit & Fdbck	Dz: HbA1c, BP Adhere: HbA1c, HTN/CAD, other
U. of Washington Family Medical Center (Seattle, WA)[25]	1998-1999 (14 months)	RCT (109, 2 firms)	Prvdr Ed, Audit & Fdbck, Org change	Dz: HbA1c, BP
Royal Prince Alfred Hospital Diabetes Clinic (Australia)[26]	--- (1 year)	RCT (137)	Org change	Dz: HbA1c, BP, other Adhere: HbA1c, HTN/CAD, other Pat comp
Royal Prince Alfred Hospital Diabetes Clinic (Australia)[26]	--- (1 year)	RCT (134)	Self-Mx, Pt Remind, Prvdr Remind, Org change	Dz: HbA1c, BP, other Adhere: HbA1c, HTN/CAD, other Pat comp
General practices (Great Britain)[27]	1988-1990 (31 months)	RCT (181)	Pt Remind, Facil relay	Dz: HbA1c, other
University-affiliated outpatient clinic (unspecified US city)[28]	--- (4 months)	RCT (45)	Patient Ed, Org change	Dz: HbA1c, other
Ambulatory Care Quality Improvement Project (Alabama)[29]	1996-1998 (25 months)	RCT (1931, 70 providers)	Audit & Fdbck	Adhere: HbA1c, Foot/Eye
Cedars Sinai Medical Center (Los Angeles, CA)[30]	1994-1995 (1 year)	RCT (360, 43 practice teams)	Patient Ed, Prvdr Ed	Dz: HbA1c, BP, other
5 outpatient practices in a university-based training program[31]	1998-1999 (1 year)	RCT (497, 44 providers)	Audit & Fdbck	Adhere: other

Table 1. Summary features of included studies (continued)

2 clinics (unspecified California city)[32]	--- (1 year)	CBA (2 practices)	Pt Remind, Prvdr Ed, Org change	Dz: HbA1c, other
14 independent physician offices (unspecified California city)[32]	--- (1 year)	CBA (2 practices)	Pt Remind, Prvdr Ed, Org change	Dz: HbA1c, other
Diabetes education program (unspecified US city)[33]	1998-1999 (6 months)	RCT (150)	Patient Ed, Self-Mx, Pt Remind, Prvdr Remind, Facil relay	Dz: HbA1c, BP, other
Choa Chu Kang polyclinic (Singapore)[34]	2000-2001 (7 months)	CBA (211)	Patient Ed, Prvdr Remind, Org change	Dz: HbA1c, BP
Academic general medicine practice, Regenstrief Health Center (Indianapolis, Indiana)[35]	1989-1991 (2 years)	RCT (396, 4 firms)	Patient Ed, Pt Remind, Prvdr Ed, Prvdr Remind	Dz: other, Pat comp
Duke Family Medicine Center (North Carolina)[36]	1993-1994 (6 months)	RCT (58 providers)	Prvdr Remind	Adhere: HbA1c, HTN/CAD, Foot/Eye, other
General medicine clinic, Indiana University Medical Center[37]	1978-1982 (3 years)	RCT (260, 13 firms)	Prvdr Ed, Prvdr Remind, Audit & Fdbck	Dz: HbA1c, BP, other
General medicine clinic, Indiana University Medical Center[37]	1978-1982 (3 years)	RCT (273, 14 firms)	Patient Ed, Pt Remind, Prvdr Ed, Prvdr Remind, Audit & Fdbck	Dz: HbA1c, BP, other
21 primary healthcare sites (Australia)[38]	1999-2000 (13 months)	RCT (727, 21 practices)	Pt Remind, Prvdr Ed, Prvdr Remind, Audit & Fdbck, Org change	Dz: other Adhere: HbA1c, HTN/CAD, Foot/Eye, other
Hospital-based Adult Medicine Clinic (unspecified US city)[39]	1998-1999 (1 year)	RCT (598, 2 firms)	Prvdr Ed, Prvdr Remind	Dz: HbA1c, BP, other Adhere: HbA1c, HTN/CAD, Foot/Eye, other
2 clinics (unspecified Midwest US city)[40]	1993-1995 (21 months)	CBA (267, 2 practices)	Patient Ed, Audit & Fdbck, Org change	Dz: HbA1c, other

Table 1. Summary features of included studies (continued)

Endocrinology dept. tertiary care hospital (South Korea)[41]	2000-2001 (3 months)	RCT (50)	Patient Ed, Facil relay	Dz: HbA1c, other
311 general practices (Denmark)[42]	1989-1995 (6 years)	RCT (1263, 484 providers)	Patient Ed, Prvdr Ed, Prvdr Remind, Audit & Fdbck	Dz: other
2 primary health-care centers (Sweden)[43]	1993-1994 (1 year)	CBA (408, 2 practices)	Org change	Adhere: HbA1c, HTN/CAD, Foot/Eye, other Pat Comp
16 teaching-hospital affiliated primary care practices (Boston, Massachusetts)[44]	--- (30 months)	CBA (16 practices)	Audit & Fdbck, Org change	Adhere: other
2 general medicine clinics (unspecified US city)[45]	--- (1 year)	RCT (148)	Patient Ed, Self-Mx, Facil relay, Org change	Dz: HbA1c, other Pat comp
4 university-affiliated VA clinics (unspecified US city)[46]	--- (1 year)	RCT (292)	Patient Ed, Self-Mx, Pt Remind, Facil relay, Org change	Dz: HbA1c, other
Diabetes clinic, Vrije Universiteit Medical Center (The Netherlands)[47]	1997-1999 (20 months)	RCT (400)	Org change	Dz: HbA1c
9 primary health centers (United Arab Emirates)[48]	--- (18 months)	CBA (219, 9 practices)	Patient Ed, Prvdr Ed, Facil relay, Org change	Dz: BP, other
General practices (The Netherlands)[49]	1992-1997 (5 years)	CBA (478, 27 providers)	Prvdr Ed, Facil relay, Audit & Fdbck	Dz: other Adhere: HbA1c, HTN/CAD, other
3 Turku area podiatry clinics (Finland)[50]	--- (1 year)	RCT (530)	Patient Ed, Org change	Dz: other Pat comp
Pleasanton facility, Kaiser Permanente Medical Care Program (N. California)[51]	1995-1997 (6 months)	RCT (185)	Patient Ed, Pt Remind, Org change	Dz: HbA1c Pat comp

Table 1. Summary features of included studies (continued)

Sub-specialty diabetes clinic (unspecified US city)[52]	1996 (3 months)	CBA (82)	Org change	Dz: HbA1c, BP Adhere: HbA1c, Foot/Eye, other
Division of Community Internal Medicine, Mayo Clinic (Minnesota)[53]	2000-2001 (6 months)	RCT (727, 29 providers)	Org change	Dz: HbA1c, other Adhere: HbA1c, other
Division of Community Internal Medicine, Mayo Clinic (Minnesota)[53]	2000-2001 (6 months)	RCT (752, 29 providers)	Pt Remind, Org change	Dz: HbA1c, other Adhere: HbA1c, other
Diabetes clinic (Canada)[54]	--- (6 months)	RCT (46)	Patient Ed, Facil relay, Org change	Dz: HbA1c
General practices (England)[55]	--- (16 months)	CBA (218)	Org change	Dz: other Adhere: HbA1c
35 primary care practices (Seattle, Washington)[56]	--- (1 year)	RCT (707, 35 practices)	Patient Ed, Self-Mx, Org change	Dz: HbA1c, other Adhere: Foot/Eye, other
2 community health centers (unspecified Northeast US city)[57]	--- (1 year)	RCT (400, 2 practices)	Prvdr Ed	Adhere: HbA1c, Foot/Eye, other
2 community health centers (unspecified Northeast US city)[57]	--- (1 year)	RCT (400, 2 practices)	Patient Ed, Prvdr Ed	Adhere: HbA1c, Foot/Eye, other
Australia[58]	--- (6 months)	RCT (265, 160 providers)	Prvdr Ed, Audit & Fdbck	Adhere: HbA1c, HTN/CAD, Foot/Eye, other
Australia[58]	--- (6 months)	RCT (256, 160 providers)	Prvdr Ed, Audit & Fdbck	Adhere: HbA1c, HTN/CAD, Foot/Eye, other
General medical clinic, Durham Dept of VA Medical Center (North Carolina)[59]	--- (1 year)	RCT (275)	Patient Ed, Self-Mx, Pt Remind, Facil relay, Org change	Dz: HbA1c, other

Table 2a. Number and design of included studies for each quality improvement strategy

QI strategy	Randomized Controlled Trial	Controlled Before-After Study	Total
Provider education	14 publications [4, 14, 16, 19, 23, 25, 30, 35, 37-39, 42, 57, 58] (16 comparisons)	6 publications [5, 13, 22, 32, 48, 49] (8 comparisons)	20 publications (24 comparisons)
Provider reminders	8 publications [24, 33, 35-39, 42] (10 comparisons)	1 publication[34] (1 comparison)	9 publications (11 comparisons)
Facilitated Relay of clinical data	11 publications [1, 3, 7, 21, 27, 33, 41, 45, 46, 54, 59] (11 comparisons)	6 publications [2, 5, 6, 12, 48, 49] (6 comparisons)	17 publications (17 comparisons)
Patient education	20 publications [3, 8, 15, 17, 19-21, 28, 30, 33, 35, 41, 42, 45, 46, 50, 51, 54, 56, 59] (23 comparisons)	5 publications [11, 12, 34, 40, 48] (5 comparisons)	25 publications (28 comparisons)
Promotion of self-Management	8 publications [1, 15, 20, 33, 45, 46, 56, 59] (10 comparisons)	2 publications [2, 12] (3 comparisons)	10 publications (13 comparisons)
Patient reminders	8 publications [27, 33, 35, 38, 45, 51, 59, 60] (10 comparisons)	2 publications[15, 32] (3 comparisons)	10 publications (13 comparisons)
Audit and feedback	10 publications [14, 16, 24, 25, 29, 31, 37, 38, 42, 58] (11 comparisons)	4 publications [22, 40, 44, 49] (4 comparisons)	14 publications (15 comparisons)
Organizational change	21 publications [3, 8, 9, 15, 17, 20, 21, 23, 25, 26, 28, 38, 45-47, 50, 51, 53, 54, 56, 59] (24 comparisons)	14 publications [2, 5, 6, 11-13, 32, 34, 40, 43, 44, 48, 52, 55] (16 comparisons)	35 publications (40 comparisons)
Financial Incentives	1 (publication)[10] (1 comparison)	0	1 publication (1 comparison)
Total	42 publications (48 comparisons)	16 publications (18 comparisons)	58 publications (66 comparisons)

Table 2b. Number of quality improvement strategies per study intervention

Number of QI types in intervention	Number of comparisons Citations		
	Randomized	**Non-Randomized**	**Total**
Single QI type	11[4, 7, 9, 10, 26, 29, 31, 36, 47,53, 57]	3[43, 52, 55]	14
Multiple (total)	37[1, 3, 8, 14-17, 19-21, 23-28, 30, 33, 35, 37-39, 41, 42,45, 46, 50, 51, 53, 54, 56-59]	15[2, 5, 6, 11-13, 22, 32, 34, 40, 44, 48, 49]	52
2 QI strategies	18[1, 8, 14, 16, 17, 19, 23, 24, 27, 28, 30, 39, 41, 50, 53, 57, 58]	5[6, 11, 13, 22, 44]	23
3 QI strategies	10[3, 15, 20, 21, 25, 37, 51, 54, 56]	7[2, 5, 32, 34, 40, 49]	17
4 QI strategies	4[26, 35, 42, 46]	3[15, 12, 48]	7
5 QI strategies	5[33, 37, 38, 45, 59]	0	5

Table 3a. Association between type of quality improvement strategy and glycemic control stratified by study sample size*

	Median Reduction in HbA_{1c} [inter-quartile range]† N=Number of comparisons				
	All Comparisons	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All QI types	0.48 [0.20, 1.38] N=38	1.35 [0.81, 1.73] N=10	1.30 [0.41, 1.49] N=19	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
Provider Education	1.1 [0.56, 1.5] N=9	1.10 [0.71, 1.50] N=5	1.29 [0.67, 1.60] N=8	0.37 - - - - N=1	0.37 - - - - N=1
Provider Reminders	0.41 [0.34, 0.97] N=7	N=0	0.41 [0.36, 0.94] N=3	0.42 [0.3 0, 0.85] N=4	0.24 [0.10, 0.40] N=2
Facilitated relay	0.48 [0.33, 1.38] N=14	1.30 [0.85, 1.55] N=3	1.40 [0.85, 1.60] N=7	0.30 [0.21, 0.48] N=7	0.35 [0.18, 0.53] N=4
Patient Education	0.70 [0.34, 1.45] N=18	1.50 [1.40, 1.80] N=5	1.49 [1.42, 1.73] N=6	0.48 [0.20, 0.60] N=12	0.35 [0.17, 0.53] N=4
Self-management	0.40 [0.20, 0.60] N=13	0.40 - - - - N=1	0.90 [0.38, 1.40] N=4	0.30 [0.20, 0.50] N=9	0.35 [0.17, 0.53] N=4
Patient reminders	0.60 [0.35, 1.29] N=11	1.95 [1.10, 2.80] N=2	1.29 [0.57, 1.79] N=6	0.47 [0.20, 0.60] N=5	0.20 [0.15, 0.40] N=3
Audit & feedback	0.71 [0.41, 1.40] N=5	1.06 [0.70, 1.40] N=2	1.06 [0.63, 1.42] N=4	0.10 - - - - N=1	0.10 - - - - N=1
Organizational Change	0.60 [0.10, 1.35] N=27	1.35 [1.15, 2.00] N=6	1.35 [0.61, 1.53] N=12	0.20 [0.10, 0.60] N=15	0.10 [0.08, 0.27] N=8

This table shows the median effect on serum HbA1c for all studies in which the intervention involved a given QI type. This was calculated as follows. For each study, we calculated the net change in serum HbA_{1c} attributable to the intervention as:

Net ΔHbA_{1c} (Post-intervention HbA_{1c} – Pre-intervention $HbA_{1c})_{Study\ group}$ - (Post-intervention HbA_{1c} –Pre-intervention $HbA_{1c})_{Control\ group}$.

The median value was then obtained from the values of Net ΔHbA_{1c} for the studies involving a given QI type or quartile of sample size.

* Sample size stratifications for HbA1c: 1st quartile=69, median=123, 3rd quartile=226

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles

Table 3b. Association between improvements in provider adherence* and type of quality improvement strategy stratified by study sample size†

	Median Improvement in provider adherence [inter-quartile range]‡ N=Number of comparisons				
	All Comparisons	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All QI types	4.8 [3.8, 15.0] N=17	4.5 [2.8, 11.4] N=3	10.6 [4.6, 17.6] N=6	4.5 [3.6, 5.8] N=11	4.2 [3.7, 5.2] N=8
Provider Education	5.6 [4.15, 17.2] N=11	4.5 [2.8, 11.4] N=3	16.4 [4.5, 18.0] N=5	5.3 [4.1, 12.7] N=6	5.3 [4.7, 8.0] N=4
Provider Reminders	3.4 [2.2, 3.6] N=3	- - - - N=0	- - - - N=0	3.4 [2.2, 3.6] N=3	3.6 [3.4, 3.8] N=2
Facilitated Relay	4.85 - - - - N=1	- - - - N=0	4.85 - - - - N=1	- - - - N=0	- - - - N=0
Patient Education	4.9 [4.7, 5.4] N=3	4.5 - - - - N=1	4.7 [4.5, 4.9] N=2	6.0 - - - - N=1	- - - - N=0
Self-Management	6.0 - - - - N=1	- - - - N=0	- - - - N=0	6.0 - - - - N=1	- - - - N=0
Patient Reminders	2.8 [1.0, 4.5] N=2	N=0	N=0	2.8 [1.0, 4.5] N=2	4.5 - - - - N=1
Audit & Feedback	5.6 [3.4, 16.4] N=9	18.3 - - - - N=1	17.4 [16.4, 18.3] N=2	5.0 [3.2, 10.3] N=7	5.0 [3.4, 5.6] N=5
Organizational Change	4.7 [4.1, 5.7] N=6	4.9 - - - - N=1	11.4 [4.9, 18.0] N=2	4.3 [3.3, 4.9] N=4	4.3 [4.0, 4.5] N=2

* For each comparison, the general provider adherence outcome captured the adherence outcome with the median effect size reported by that study. For example, if a study reported one adherence outcome involving checking HbA1c, another relating to referral for screening for retinal disease and another for delivery of patient education, each of these outcomes would have an effect size calculated and the one with the median effect size would contribute the generic adherence outcome for that study.

† Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226

‡ When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 4a. Associations between improvements in glycemic control and provider adherence stratified by trial design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
	All Comparisons	RCT	Non-RCT†	All Comparisons	RCT	Non-RCT†
All QI types	0.48 [0.20, 1.38] N=38	0.39 [0.10, 0.73] N=28	1.40 [0.70, 1.78] N=10	4.9 [3.8, 15.0] N=17	4.5 [3.5, 5.4] N=14	18.0 [17.2, 21.0] N=3
Provider Education	1.1 [0.56, 1.5] N=9	0.71 [0.41, 1.47] N=5	1.50 [0.97, 2.13] N=4	5.6 [4.2, 17.2] N=11	4.8 [3.1, 8.0] N=8	18.0 [17.2, 21.0] N=3
Provider Reminders	0.41 [0.34, 0.97] N=7	0.39 [0.32, 0.45] N=6	1.99 - - - - N=1	3.4 [2.2, 3.6] N=3	3.4 [2.2, 3.6] N=3	- - - - N=0
Facilitated relay	0.48 [0.33, 1.38] N=14	0.40 [0.30, 0.60] N=9	1.40 [0.50, 1.40] N=5	4.9 - - - - N=1	4.9 - - - - N=1	- - - - N=0
Patient Education	0.70 [0.34, 1.45] N=18	0.60 [0.25, 1.39] N=15	1.40 [0.95, 1.70] N=3	4.9 [4.7, 5.4] N=3	4.9 [4.7, 5.4] N=3	- - - - N=0
Self-management	0.40 [0.20, 0.60] N=13	0.30 [0.20, 0.45] N=10	1.40 [0.95, 1.40] N=3	6.0 - - - - N=1	6.0 - - - - N=1	- - - - N=0
Patient reminders	0.60 [0.35, 1.29] N=11	0.43 [0.28, 0.72] N=8	1.90 [1.50, 2.35] N=3	2.8 [1.0, 4.5] N=2	2.8 [1.0, 4.5] N=2	- - - - N=0
Audit & feedback	0.71 [0.41, 1.40] N=5	0.56 [0.33, 0.90] N=4	1.40 - - - - N=1	5.6 [3.4, 16.4] N=9	5.0 [3.2, 10.3] N=7	20.2 [16.4, 23.9] N=2*
Organizational Change	0.60 [0.10, 1.35] N=27	0.25 [0.03, 0.68] N=18	1.4 [1.1, 1.9] N=9	4.7 [4.1, 5.7] N=6	4.5 [4.0, 4.9] N=5	18.0 - - - - N=1

* When N=2, square brackets show the actual results of each study rather than interpolated inter-quartile range.

† Non-RCT included 16 controlled before-after studies and 1 quasi-randomized trial.

Table 4b. Impacts on glycemic control and provider adherence stratified by trial design and sample size*

		All sizes	Comparisons with sample size in lowest quartile	Comparisons with sample size in lower 2 quartiles	Comparisons with sample size in upper 2 quartiles	Comparisons with sample size in highest quartile
Median reduction in serum HbA_{1c} (%) [inter-quartile range†] N=Number of comparisons	**All trial designs**	0.48 [0.20, 1.38] N=38	1.35 [0.81, 1.73] N=10	1.30 [0.41, 1.49] N=19	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
	RCTs only	0.39 [0.10, 0.73] N=28	1.40 [0.86, 1.73] N=6	0.56 [0.37, 1.48] N=12	0.21 [0.10, 0.50] N=16	0.10 [0.08, 0.24] N=8
	Non-RCTs	1.40 [0.70, 1.78] N=10	1.25 [0.97, 1.75] N=4	1.40 [1.25, 1.65] N=7	0.50 [0.30, 1.25] N=3	0.30 [0.10, 0.50] N=2
Median Improvement in provider adherence (%) [inter-quartile range]‡ N=Number of comparisons	**All trial designs**	4.8 [3.8, 15.0] N=17	4.5 [2.8, 11.4] N=3	10.6 [4.6, 17.6] N=6	4.5 [3.6, 5.8] N=11	4.2 [3.7, 5.2] N=8
	RCTs	4.5 [3.5, 5.5] N=14	4.5 [2.8, 11.4] N=3	4.7 [3.6, 8.2] N=4	4.3 [3.5, 5.5] N=10	4.3 [3.7, 5.2] N=8
	Non-RCTs	18.0 [17.2, 21.0] N=3	N=0	17.2 [16.4, 18.0] N=2	23.9 - - - - N=1	N=0

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† Sample size stratification for adherence outcomes: 1st quartile=55, median=164, 3rd quartile=229.

‡ When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 5a. Association between improvement in glycemic control and number of quality improvement strategies stratified by study sample size*

	Median Reduction in HbA_{1c} [inter-quartile range] N=Number of comparisons				
Number of QI Strategies†	**All Comparisons**	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
Any number of strategies	0.48 [0.20, 1.38] N=38	1.35 [0.81,1.73] N=10	1.30 [0.41, 1.49] N=19	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
1 strategy only	0.00 [-0.08,‡ 0.16] N=6	0.56 - - - - N=1	0.10 [-0.15,‡ 0.23] N=3	0.00 [0.00, 0.11] N=3	0.00 [0.00, 0.00] N=2§
≥ 2 strategies	0.60 [0.30, 1.40] N= 32	1.40 [1.10, 1.80] N=9	1.40 [0.63, 1.58] N=16	0.34 [0.10, 0.60] N=16	0.15 [0.10, 0.40] N=8
≥ 3 strategies	0.66 [0.33, 1. 40] N=22	1.30 [1.10, 1.40] N=5	1.40 [0.91, 1.44] N=11	0.47 [0.20, 0.60] N=11	0.35 [0.17, 0.53] N=4
≥ 4 strategies	0.48 [0.30, 0.82] N=8	N=0	1.47 [0.89, 1.69] N=3	0.47 [0.30, 0.50] N=5	0.50 [0.35, 0.55] N=3
5 strategies**	0.53 [0.40, 0.82] N=4	N=0	1.47 - - - - N=1	0.47 [0.33, 0.53] N=3	0.40 [0.20, 0.60] N=2§

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226

† The median number of strategies was 2, with 16 studies involving 2 of fewer strategies and 22 employing 3 or more.

‡ All changes were standardized to reflect reductions. Thus, the negative sign here indicates an *increase* in serum HbA_{1c}.

§ When N=2, the numbers in square brackets reflect the results for each of the two studies rather than the interquartile range.

** No study involved an intervention with more than 5 QI types. Using the alternate taxonomy shown in Table 1 (Appendix H) in which substrategies of provider education and organizational change are treated as distinct categories, 2 studies reported interventions involving 6 strategies.[140,146]

Table 5b. Association between improvement in provider adherence and number of quality improvement strategies stratified by study sample size*

Number of QI Strategies	Median Improvement in Provider Adherence (%) [inter-quartile range]† N=Number of comparisons				
	All Comparisons	Comparisons with sample size in lowest quartile	Comparisons with sample size in lower 2 quartiles	Comparisons with sample size in upper 2 quartiles	Comparisons with sample size in highest quartile
Any number (for comparison purposes)	4.8 [3.8, 15.0] N=17	4.5 [2.8, 11.4] N=3	10.6 [4.6, 17.6] N=6	4.5 [3.6, 5.8] N=11	4.2 [3.7, 5.2] N=8
1 strategy only	3.0 [2.0,3.5] N=3	1.0 ---- N=1	1.0 ---- N=1	3.5 [3.0, 4.0] N=2	3.5 [3.0, 4.0] N=2
≥ 2 strategies	5.3 [4.5, 16.1] N=14	11.4 [4.5, 18.3] N=2	16.4 [4.9, 18.0] N=5	5.0 [3.8, 6.0] N=9	4.8 [4.0, 5.5] N=6
≥ 3 strategies	4.9 [2.9, 5.4] N=3	N=0	4.9 ---- N=1	3.5 [1.0, 6.0] N=2	N=0
≥ 4 strategies	1.0 ---- N=1	N=0	N=0	1.0 ---- N=1	N=0
5 strategies‡	1.0 ---- N=1	N=0	N=0	1.0 ---- N=1	N=0

* Sample size stratification for adherence outcomes: 1st quartile=55, median=164, 3rd quartile=229

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

‡ No study involved an intervention with more than 5 QI types.

Table 6. Associations between number of quality improvement strategies and improvements in glycemic control and provider adherence stratified by trial design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
	All Comparisons	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
Any number (for comparison purposes)	0.48 [0.20, 1.38] N=38	0.39 [0.10, 0.73] N=28	1.4 [0.70, 1.78] N=10	4.9 [3.8, 15.0] N=17	4.5 [3.5, 5.4] N=14	18.0 [17.2, 21.0] N=3
Single strategy only	0.00 [-0.08†, 0.16] N=6	0.00 [-0.10, 0.00] N=5	0.56 ---- N=1	3.0 [2.0, 3.5] N=3	3.0 [2.0, 3.5] N=3	N=0
≥ 2 strategies	0.60 [0.30, 1.40] N=32	0.41 [0.25, 0.94] N=23	1.40 [1.10, 1.90] N=9	5.3 [4.5, 16.1] N=14	4.9 [4.2, 5.8] N=11	18.0 [17.2, 21.0] N=3
≥ 3 strategies	0.66 [0.33, 1. 40] N=22	0.44 [0.22, 0.68] N=14	1.40 [1.33, 1.92] N=8	4.9 [2.9, 5.4] N=3	4.9 [2.9, 5.4] N=3	N=0
≥ 4 strategies	0.48 [0.30, 0.82] N=8	0.39 [0.30, 0.57] N=6	1.20 [0.50, 1.90] N=2	1.0 ---- N=1	1.0 ---- N=1	N=0
5 strategies‡	0.53 [0.40, 0.82] N=4	0.53 [0.40, 0.82] N=4	N=0	1.0 ---- N=1	1.0 ---- N=1	N=0

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

† All changes were standardized to reflect reductions. Thus, the negative sign here indicates an *increase* in serum HbA_{1c}.

‡ No study involved an intervention with more than 5 QI types.

Table 7a. Regression results for impact of general study features on glycemic control and provider adherence

Study attribute or Methodological feature	HbA_{1c} (27 studies*)	Median adherence Outcome (17 studies)
	Regression Coefficient for prediction of lowered HbA_{1c} [95%CI; p value]	Regression coefficient for prediction of increased adherence [95%CI; p value]
Country (U.S. vs. non-U.S.)	0.16 [-0.38, 0.70; p=0.5]	-0.05 [0.24, -0.33; p=0.7]
Study Period	- 0.008 [-0.08, 0.06; p=0.8]	-0.04 [-0.02, -0.07; 0.004]
Patient selection†	0.16 [-0.48, 0.81; p=0.6]	-0.18 [0.21, -0.63; p=0.3]
Sample Size‡	-0.46 [-0.09,-0.72; p=0.02]	-0.22 [0.29, -0.63; p=0.4]
Randomization	-0.15 [-0.69, 0.70; p=0.7]	-0.48 [-0.23, -0.72; p=0.001]
Adequate concealment of allocation	-0.15 [-0.90, 0.60; p=0.7]	-0.22 [0.09, -0.53; p=0.2]
Units of analysis same as unit of treatment allocation	-0.02 [-0.68, 0.64; p=0.95]	-0.15 [0.44, -0.74; p=0.6]
Patient blinding§	0.17 [-0.67, 1.01; p=0.68]	0.18 [0.61, -0.24; p=0.4]

* N=27 rather than 38, as in the previous tables showing median effects for studies involving impacts on mean HbA_{1c}, because 11 studies did not report data required to include them in the regression analysis (e.g., standard deviations for the reported means).

† "Patient selection" refers to the explicit selection of patients with more advanced disease (e.g., longer duration or presence of major complications), greater prevalence of co-morbid conditions, poor adherence, or decreased access to care.

‡ The data shown for sample size reflects the Spearman rank correlation coefficient for effective sample size and the Net reduction in HbA_{1c}, the same outcome used in all of the median effects Tables. This outcome was defined as:

Net reduction in HbA1c = $(\text{Post-intervention } HbA_{1c} - \text{Pre-intervention } HbA_{1c})_{\text{Study group}} - (\text{Post-intervention } HbA_{1c} - \text{Pre-intervention } HbA_{1c})_{\text{Control group}}$.

This outcome was used in place of post-intervention effect size, as the strong inverse correlation would largely reflect the inclusion of sample size in the calculation of effect size.

§ Blinding was judged to be present when the subjects were unaware of study group assignment. In studies in which providers were randomized and patient level data was abstracted from medical records, patient blinding was coded as present.

Table 7b. Regression results for impacts of quality improvement strategies by strategy type and by the number of strategies per intervention*

QI Strategy	Reduction in Serum HbA_{1c} (27 studies) Regression Coefficient [95%CI; p value]	Improvement in Provider Adherence (17 studies) Regression Coefficient [95%CI; p value]
Provider education	0.34 [-0.37, 1.05; p=0.33]	0.25 [0.00, 0.51; p = 0.05]
Patient education	0.21 [-0.31, 0.74; p=0.4]	-0.01 [0.37, -0.40; p=0.9]
Self-management	- 0.23 [-0.58, 0.53; p=0.93]	-0.19 [0.39, -0.78; p=0.5]
Patient reminders	0.04 [-0.58, 0.66; p=0.98]	-0.13 [0.30, -0.56; p=0.5]
Provider reminders	-0.42 [-1.15, 0.31; p=0.25]	-0.27 [0.07, -0.60; p = 0.1]
Facilitated relay	0.20 [-0.33, 0.73; p=0.44]	-0.15 [0.44, -0.74; p = 0.6]
Audit and feedback	- 0.57 [-1.94, 0.81; p=0.40]	0.00 - - - -
Organizational change	-0.05 [-0.63, 0.52; p=0.85]	-0.04 [0.25, -0.33; p = 0.8]
Disease management	0.49 [-0.19, 1.19; p=0.15]	-0.15 [0.44, -0.74; p=0.6]
Change to medical records system	0.17 [-0.67, 1.01; p=0.69]	-0.13 [0.47, -0.73; p=0.6]
Personnel or team changes	-0.39 [-0.95, 0.17; p=17]	0.23 [-0.18, 0.64; p=0.2]

* It is important to note that the regression models aimed to evaluate the *relative* effectiveness of different intervention components and the impact of study features such as trial design and study period. Consequently, a negative coefficient does not imply "harm" or that the intervention was worse than "usual care." Rather, a negative result means simply that the average effect associated with, for instance, the presence of provider reminders (which has a negative coefficient in the analysis of both outcomes) was less than the average effects associated with interventions lacking this feature (i.e., studies without provider reminders reported larger effect sizes, not that provider reminders were harmful).

Table 7c. Significance tests (Mann-Whitney) for median effects associated with selected methodologic features and QI strategies

	Median Reduction in HbA_{1c} (38 studies)			Median Increase in Provider adherence (17 studies)		
		Median effect (%) [95% CI]	P value for comparison*		Median effect (%) [95% CI]	P value for comparison
Study design	**RCT (n = 28)**	0.39 [0.20, 0.60]	0.008	**RCT (n = 14)**	4.5 [3.3, 5.7]	0.02
	Non-RCT (n = 10)	1.40 [0.52, 1.96]		**Non-RCT (n = 3)**	18.0 [16.4, 23.9]	
Sample size	**Upper 2 quartiles**	0.20 [0.10, 0.57]	0.005	**Upper 2 quartiles**	4.4 [2.4, 18.8]	0.7
	Lower 2 quartiles	1.20 [0.42, 1.46]		**Lower 2 quartiles**	4.9 [1.0, 18.3]	
Number of QI strategies	**Single (n = 6)**	0.00 [-0.19, 0.53]	0.01 [0.005]†	**Single (n = 3)**	3.0% [1.0, 4.0%]	0.04
	Multiple (n = 32)	0.60 [0.40, 1.3]		**Multiple (n = 14)**	5.3 [4.4, 16.7]	
Provider Education	**Yes (n=9)**	1.1 [0.42, 1.87]	0.02	**Yes (n=11)**	5.6 [3.0, 18.1]	0.2
	No (n = 29)	0.4 [0.17, 0.66]		**No (n = 6)**	4.3 [3.0, 5.9]	
Disease Manag.	**Yes (n=8)**	1.09 [0.67, 2.25]	0.009	**Yes (n=1)**	4.9 - - - -	1.0
	No (n=30)	0.39 [0.20, 0.55]		**No (n=16)**	4.8 [3.6, 15.7]	
Change to medical records system	**Yes (n=5)**	1.40 [1.10, 2.80]	0.007	**Yes (n=1)**	1.0 - - - -	0.1
	No (n=33)	0.40 [0.20, 0.60]		**No (n=16)**	5.0 [3.9, 15.7]	
Role for clinical information system‡	**Yes (n=20)**	0.90 [0.37, 1.40]	0.1 [0.46]	**Yes (n=5)**	4.0 [3.4, 6.0]	0.3
	No (n=18)	0.35 [0.20, 0.59]		**No (n=12)**	5.3 [3.2, 17.9]	

* P value represents two-sample Wilcoxon rank-sum (Mann-Whitney) test of hypothesis that the two medians being compared are equal.

† Result if the alternate classification scheme shown in Appendix H is used. In this scheme, major substrategies of organizational change (e.g., Disease Management) and provider education (e.g., educational outreach and professional meetings) are treated as their own categories.

‡ Focusing on specific roles for clinical information systems resulted in higher p-values (e.g., p=0.26 for interventions with some form of computerized decision support compared to all interventions without decision support.

Table 8a. Association between improvements in glycemic control and specific substrategies of provider education stratified by study sample size*

	Median improvement in HbA_{1c} [inter-quartile range] † N=Number of comparisons				
Type of provider education	**All Comparisons**	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All QI types	0.48 [0.20, 1.38] N=38	1.35 [0.60, 1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
Any form of provider education	1.1 [0.56, 1.5] N=9	1.10 [0.71, 1.50] N=5	1.29 [0.67, 1.60] N=8	0.37 - - - - N=1	0.37 - - - - N=1
No form of provider education	0.40 [0.1, 1.08] N=29	1.40 [1.30, 1.80] N=5	1.30 [0.35, 1.40] N=11	0.21 [0.10, 0.58] N=18	0.10 [0.10, 0.20] N=9
Meetings/workshops	1.1 [0.64, 1.69] N=7	0.91 [0.67, 1.53] N=4	1.10 [0.64, 1.69] N=7	N=0	N=0
No meetings or workshops	0.4 [0.1, 1.19] N=31	1.45 [1.33, 1.73] N=6	1.35 [0.47, 1.43] N=12	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
No meetings or workshops (has provider education)	0.94 [0.4, 1.5] N=2	1.5 ---- N=1	1.5 ---- N=1	0.37 ---- N=1	0.37 ---- N=1
Educational materials	0.91 [0.52, 1.48] N=8	1.10 [0.71, 1.50] N=5	1.10 [0.64, 1.49] N=7	0.37 ---- N=1	0.37 ---- N=1
No educational materials	0.4 [0.1, 1.25] N=30	1.40 [1.30, 1.80] N=5	1.35 [0.37, 1.50] N=12	0.21 [0.10, 0.58] N=18	0.10 [0.10, 0.20] N=9
No educational materials (has provider education)	1.9 ---- N=1	N=0	1.9 ---- N=1	N=0	N=0
Educational outreach	0.71 ---- N=1	0.71 ---- N=1	0.71 ---- N=1	N=0	N=0
No educational outreach	0.47 [0.20, 1.4] N=37	1.40 [1.10, 1.80] N=9	1.35 [0.40, 1.49] N=18	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
No educational outreach (has provider education)	1.29 [0.52, 1.60] N=8	1.30 [0.97, 1.83] N=4	1.47 [0.83, 1.70] N=7	0.37 ---- N=1	0.37 ---- N=1

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 8b. Association between improvements in glycemic control and specific substrategies of provider education stratified by study design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
Type of provider education	**All Comparisons**	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
All QI types	0.48 [0.20, 1.38] N=38	0.39 [0.10, 0.73] N=28	1.4 [0.70, 1.78] N=10	4.85 [3.8,15.03] N=17	4.5 [3.5, 5.45] N=14	18.0 [17.2, 20.95] N=3
Provider education	1.10 [0.56, 1.50] N=9	0.71 [0.41, 1.47] N=5	1.5 [0.97, 2.13] N=4	5.6 [4.2, 17.2] N=11	4.8 [3.1, 8.0] N=8	18.0 [17.2, 21.0] N=3
No provider education	0.40 [0.10, 1.08] N=29	0.3 [0.10, 0.60] N=23	1.40 [0.73, 1.40] N=6	4.3 [3.5, 4.8] N=6	4.3 [3.5, 4.8] N=6	---- N=0
Meetings/workshops	1.10 [0.64, 1.69] N=7	0.71 [0.56, 1.09] N=3	1.50 [0.97, 2.13] N=4	10.7 [3.6, 18.1] N=8	4.50 [1.0, 5.0] N=5	18.0 [17.2, 21.0] N=3
No meetings or workshops	0.40 [0.10, 1.19] N=31	0.30 [0.10, 0.6] N=25	1.40 [0.73, 1.4] N=6	4.50 [3.8, 5.6] N=9	4.50 [3.8, 5.6] N=9	---- N=0
No meetings or workshops (has provider education)	0.94 [0.40, 1.5] N=2	0.94 [0.40, 1.5] N=2	---- N=0	5.6 [4.7, 10.3] N=3	5.6 [4.7, 10.3] N=3	---- N=0
Educational materials	0.91 [0.52, 1.48] N=8	0.71 [0.41, 1.47] N=5	1.10 [0.83, 1.95] N=3	5.6 [4.2, 16.5] N=7	4.5 [3.8, 5.6] N=5	21.0 [18.0, 23.9] N=2
No educational materials	0.40 [0.10, 1.25] N=30	0.30 [0.10, 0.60] N=23	1.40 [0.95, 1.65] N=7	4.7 [3.5, 5.8] N=10	4.5 [3.4, 5.0] N=9	16.4 ---- N=1
No educational materials (has provider education)	1.9 ---- N=1	---- N=0	1.9 ---- N=1	10.7 [4.0, 16.9] N=4	5.0 [3.0, 11.7] N=3	16.4 ---- N=1
Educational outreach	0.71 ---- N=1	0.71 ---- N=1	 N=0	5.6 [4.8, 16.5] N=7	5.3 [4.6, 12.7] N=6	18.0 ---- N=1
No educational outreach	0.47 [0.20, 1.4] N=37	0.37 [0.10, 0.70] N=27	1.40 [0.70, 1.78] N=10	4.3 [3.5, 5.7] N=10	3.9 [3.3, 4.6] N=8	20.2 [16.4, 23.9] N=2
No educational outreach (has provider education)	1.29 [0.52, 1.60] N=8	0.94 [0.40, 1.48] N=4	1.50 [0.97, 2.13] N=4	10.1 [3.1, 18.3] N=4	2.4 [1.0, 3.8] N=2	20.2 [16.4, 23.9] N=2

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 9a. Association between improvements in glycemic control and specific substrategies of patient education stratified by sample size*

	Median improvement in HbA1c [inter-quartile range]† N=Number of comparisons				
Type of patient education	**All Comparisons**	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All QI types	0.48 [0.20, 1.38] N=38	1.35 [0.60, 1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
Patient education	0.70 [0.34, 1.45] N=18	1.50 [1.40, 1.80] N=5	1.49 [1.42, 1.73] N=6	0.48 [0.20, 0.60] N=12	0.35 [0.17, 0.53] N=4
No patient education	0.39 [0.1, 0.81] N=20	0.71 [0.56, 1.10] N=5	0.56 [0.40, 1.40] N=13	0.10 [0.05, 0.16] N=7	0.10 [0.03, 0.10] N=6
Patient Education, self-management, or patient reminders	0.8 [0.35, 1.44] N=27	1.45 [1.25, 1.90] N=8	1.40 [1.15, 1.73] N=14	0.47 [0.20, 0.60] N=13	0.20 [0.10, 0.50] N=5
None of above	0.10 [0.0, 0.39] N=11	0.64 [0.60, 0.70] N=2	0.41 [0.10, 0.56] N=5	0.10 [0.03, 0.18] N=6	0.10 [0.00, 0.10] N=5
Self-management or patient reminders	0.48 [0.28, 1.18] N=20	1.10 [0.75, 1.95] N=3	1.40 [0.40, 1.47] N=9	0.30 [0.15, 0.55] N=11	0.20 [0.10, 0.50] N=5
No Self-management or patient reminders	0.49 [0.1, 1.38] N=18	1.40 [1.01, 1.65] N=7	1.01 [0.45, 1.48] N=10	0.16 [0.08, 0.48] N=8	0.10 [0.00, 0.10] N=5
Self-management	0.4 [0.2, 0.6] N=13	0.40 ---- N=1	0.90 [0.38, 1.40] N=4	0.30 [0.20, 0.50] N=9	0.35 [0.17, 0.53] N=4
No self-management	0.71 [0.1, 1.47] N=25	1.40 [1.10, 1.80] N=9	1.30 [0.49, 1.65] N=15	0.16 [0.10, 0.69] N=10	0.10 [0.03, 0.10] N=6
Patient reminders	0.60 [0.35, 1.29] N=11	1.95 [1.10, 2.80] N=2	1.29 [0.57, 1.79] N=6	0.47 [0.20, 0.60] N=5	0.20 [0.15, 0.40] N=3
No patient reminders	0.41 [0.1, 1.35] N=27	1.35 [0.67, 1.58] N=8	1.30 [0.41, 1.40] N=13	0.21 [0.10, 0.47] N=14	0.10 [0.05, 0.24] N=7

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 9b. Association between improvements in glycemic control and specific substrategies of patient education stratified by study design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
Type of patient education	**All Comparisons**	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
All QI types	0.48 [0.2, 1.38] N=38	0.39 [0.1, 0.73] N=28	1.4 [0.7, 1.78] N=10	4.85 [3.8, 15.03] N=17	4.5 [3.5, 5.45] N=14	18.0 [17.2, 20.95] N=3
Patient education (Broad†)	0.8 [0.35, 1.44] N=27	0.47 [0.25, 1.19] N=19	1.4 [1.33, 1.92] N=8	4.5 [4.5, 4.9] N=5	4.5 [4.5, 4.9] N=5	---- N=0
No Patient education (Broad)	0.10 [0.0, 0.39] N=11	0.1 [0.0, 0.37] N=9	0.33 [0.10, 0.60] N=2	5.3 [3.7, 16.8] N=12	4.0 [3.4, 5.6] N=9	18.0 [17.2, 21.0] N=3
Self-management or patient reminders	0.48 [0.28, 1.18] N=20	0.35 [0.2, 0.57] N=14	1.4 [1.18, 1.78] N=6	4.5 [2.8, 5.3] N=3	4.5 [2.8, 5.3] N=3	---- N=0
No Self-management or patient reminders	0.49 [0.1, 1.38] N=18	0.39 [0.03, 1.18] N=14	0.98 [0.45, 1.55] N=4	4.9 [3.9, 16.1] N=14	4.5 [3.6, 5.3] N=11	18.0 [17.2, 21.0] N=3
Patient education	0.7 [0.34, 1.45] N=18	0.6 [0.25, 1.39] N=15	1.4 [0.95, 1.7] N=3	4.9 [4.7, 5.4] N=3	4.9 [4.7, 5.4] N=3	---- N=0
No Patient education	0.39 [0.1,0.81] N=20	0.21 [0.0,0.4] N=13	1.4 [0.83,1.65] N=7	4.8 [3.5,16.1] N=14	4.0 [3.2,5.3] N=11	18.0 [17.2,21.0] N=3
Self-management	0.4 [0.2, 0.6] N=13	0.3 [0.2, 0.45] N=10	1.4 [0.95, 1.4] N=3	6.0 ---- N=1	6.0 ---- N=1	---- N=0
No self-management	0.71 [0.1, 1.47] N=25	0.4 [0.1, 1.25] N=18	1.4 [0.83, 1.95] N=7	4.7 [3.7, 15.4] N=16	4.5 [3.4, 5.0] N=13	18.0 [17.2, 21.0] N=3
Patient reminders	0.60 [0.35, 1.29] N=11	0.43 [0.28, 0.72] N=8	1.90 [1.5, 2.35] N=3	2.75 [1.0, 4.5] N=2	2.75 [1.0, 4.5] N=2	---- N=0
No patient reminders	0.41 [0.1, 1.35] N=27	0.34 [0.08, 0.73] N=20	1.4 [0.53, 1.4] N=7	5.0 [3.9, 15.7] N=15	4.7 [3.7, 5.7] N=12	18.0 [17.2, 21.0] N=3

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 10a. Association between improvements in glycemic control and specific substrategies of provider reminder stratified by sample size*

	Median improvement in HbA1c [inter-quartile range]† N=Number of comparisons				
Type of provider reminder	**All Comparisons**	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All QI types	0.48 [0.20, 1.38] N=38	1.35 [0.60, 1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
Provider reminder or facilitated relay	0.44 [0.3, 1.4] N=20	1.30 [0.85, 1.55] N=3	1.35 [0.40, 1.45] N=10	0.34 [0.20, 0.49] N=10	0.29 [0.13, 0.47] N=6
Neither provider reminder nor facilitated relay	0.58 [0.03, 1.1] N=18	1.40 [0.91, 1.85] N=7	1.10 [0.56, 1.50] N=9	0.10 [0.00, 0.60] N=9	0.05 [0.00, 0.10] N=4
Provider reminder	0.41 [0.34, 0.97] N=7	N=0	0.41 [0.36, 0.94] N=3	0.42 [0.3 0, 0.85] N=4	0.24 [0.10, 0.40] N=2
No provider reminder	0.56 [0.15, 1.35] N=31	1.35 [0.81, 1.73] N=10	1.35 [0.52, 1.58] N=16	0.20 [0.10, 0.55] N=15	0.10 [0.08, 0.27] N=8
Facilitated relay	0.48 [0.33, 1.38] N=14	1.30 [0.85, 1.55] N=3	1.40 [0.85, 1.60] N=7	0.30 [0.21, 0.48] N=7	0.35 [0.18, 0.53] N=4
No facilitated relay	0.49 [0.1, 1.18] N=24	1.40 [0.91, 1.85] N=7	0.91 [0.38, 1.48] N=12	0.15 [0.08, 0.65] N=12	0.10 [0.10, 0.30] N=6

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 10b. Association between improvements in glycemic control and specific substrategies of provider reminder stratified by trial design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
Type of provider reminder	**All Comparisons**	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
All QI types	0.48 [0.2, 1.38] N=38	0.39 [0.1, 0.73] N=28	1.4 [0.7, 1.78] N=10	4.85 [3.8, 15.03] N=17	4.5 [3.5, 5.45] N=14	18.0 [17.2, 20.95] N=3
Provider reminder or racilitated relay	0.44 [0.3, 1.4] N=20	0.4 [0.3, 0.57] N=14	1.4 [0.73, 1.78] N=6	3.6 [2.8, 4.1] N=4	3.6 [2.8, 4.1] N=4	---- N=0
Neither provider reminder nor facilitated relay	0.58 [0.03, 1.1] N=18	0.15 [0.0, 0.78] N=14	1.25 [0.97, 1.75] N=4	5.6 [4.5, 16.4] N=13	4.8 [4.1, 5.9] N=10	18.0 [17.2, 21.0] N=3
Provider reminder	0.41 [0.34, 0.97] N=7	0.39 [0.32, 0.45] N=6	1.99 ---- N=1	3.4 [2.2, 3.6] N=3	3.4 [2.2, 3.6] N=3	---- N=0
No provider reminder	0.56 [0.15, 1.35] N=31	0.35 [0.1, 0.78] N=22	1.4 [0.56, 1.4] N=9	5.3 [4.5, 16.1] N=14	4.9 [4.3, 5.8] N=11	18.0 [17.2, 21.0] N=3
Facilitated relay	0.48 [0.33, 1.38] N=14	0.4 [0.3, 0.6] N=9	1.4 [0.5, 1.4] N=5	4.9 ---- N=1	4.9 ---- N=1	---- N=0
No facilitated relay	0.49 [0.1, 1.18] N=24	0.3 [0.05, 0.76] N=19	1.4 [1.1, 1.99] N=5	4.8 [3.7, 15.4] N=16	4.5 [3.4, 5.6] N=13	18.0 [17.2, 21.0] N=3

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 11a. Association between improvements in glycemic control and specific substrategies of organizational change stratified by study sample size*

	Median improvement in HbA1c [inter-quartile range]† N=Number of comparisons				
Type of organizational change	**All comparisons**	**Bottom quartile for sample size**	**Bottom two quartiles for sample size**	**Top two quartiles for sample size**	**Top quartile for sample size**
All QI types	0.48 [0.20, 1.38] N=38	1.35 [0.60, 1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
All types of organizational change	0.60 [0.10, 1.35] N=27	1.35 [1.15, 2.0] N=6	1.35 [0.61, 1.53] N=12	0.20 [0.10, 0.60] N=15	0.10 [0.08, 0.27] N=8
No organizational change	0.41 [0.39, 1.02] N=11	1.03 [0.52, 1.58] N=4	0.56 [0.41, 1.49] N=7	0.29 [0.18, 0.40] N=4	0.24 [0.10, 0.37] N=2
Disease/case management	1.09 [0.78, 1.55] N=8	1.25 [1.0, 1.75] N=4	1.25 [1.0, 1.75] N=4	0.94 [0.75, 1.31] N=4	0.60 ---- N=1
No disease/case management	0.39 [0.10, 1.13] N=30	1.40 [0.75, 1.73] N=6	1.35 [0.40, 1.49] N=15	0.20 [0.10, 0.34] N=15	0.10 [0.10, 0.20] N=9
No disease/case management (has org change)	0.20 [0.05, 0.95] N=19	1.75 [1.30, 2.20] N=2	1.35 [0.20, 1.53] N=8	0.10 [0.05, 0.25] N=11	0.10 [0.05, 0.15] N=7
Team/staffing changes	0.30 [0.12, 0.68] N=14	1.30 [1.01, 1.75] N=3	0.71 [0.30, 1.30] N=5	0.20 [0.10, 0.50] N=9	0.15 [0.07, 0.27] N=4
No team/staffing changes	0.58 [0.33, 1.42] N=24	1.40 [0.83, 1.65] N=7	1.40 [0.45, 1.49] N=14	0.29 [0.10, 0.57] N=10	0.10 [0.10, 0.30] N=6
No team/staffing changes (has org change)	1.10 [0.10, 1.40] N=13	1.40 [1.25, 2.10] N=3	1.40 [1.25, 1.65] N=7	0.35 [0.10, 0.75] N=6	0.10 [0.08, 0.23] N=4
Medical record changes	1.40 [1.40, 1.9] N=5	1.95 [1.10, 2.80] N=2	1.40 [1.40, 1.90] N=5	N=0	N=0
No medical record changes	0.4 [0.1, 0.8] N=33	1.35 [0.67, 1.58] N=8	0.64 [0.40, 1.45] N=14	0.21 [0.10, 0.55] N=19	0.10 [0.10, 0.33] N=10
No medical record changes (has org change)	0.30 [0.10, 0.78] N=22	1.35 [1.15, 1.60] N=4	0.71 [0.10, 1.35] N=7	0.20 [0.10, 0.60] N=15	0.10 [0.08, 0.27] N=8

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 11b. Association between improvements in glycemic control and specific substrategies of organizational change stratified by study design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
Type of organizational change	**All Comparisons**	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
All QI types	0.48 [0.20, 1.38] N=38	0.39 [0.1, 0.73] N=28	1.4 [1.1, 1.78] N=10	4.85 [3.8, 15.03] N=17	4.5 [3.5, 5.45] N=14	18.0 [17.2, 20.95] N=3
All types of organizational change	0.60 [0.10, 1.35] N=27	0.25 [0.03, 0.68] N=18	1.4 [1.1, 1.9] N=9	4.7 [4.1, 5.7] N=6	4.5 [4.0, 4.9] N=5	18.0 ---- N=1
No organizational change	0.41 [0.39, 1.02] N=11	0.41 [0.38, 1.22] N=10	0.56 ---- N=1	5.0 [3.6, 15.7] N=11	4.5 [3.4, 5.6] N=9	20.2 [16.4, 23.9] N=2
Disease/case management	1.09 [0.78, 1.55] N=8	0.76 [0.68, 0.87] N=4	1.7 [1.33, 2.19] N=4	4.9 ---- N=1	4.9 ---- N=1	N=0
No disease/case management	0.39 [0.10, 1.13] N=30	0.3 [0.1, 0.5] N=24	0.98 [0.52, 1.4] N=6	4.8 [3.7, 15.4] N=16	4.5 [3.4, 5.6] N=13	18.0 [17.2, 21.0] N=3
No disease/case management (has organizational change)	0.20 [0.05, 0.95] N=19	0.15 [0.0, 0.30] N=14	1.40 [0.50, 1.40] N=5	4.5 [4.0, 6.0] N=5	4.3 [3.3, 4.9] N=4	18.0 ---- N=1
Team/staffing changes	0.30 [0.12, 0.68] N=14	0.3 [0.1, 0.71] N=13	0.5 ---- N=1	12.0 [6.0, 18.0] N=2	6.0 ---- N=1	18.0 ---- N=1
No team/staffing changes	0.58 [0.33, 1.42] N=24	0.4 [0.16, 0.7] N=15	1.4 [1.1, 1.9] N=9	4.5 [3.6, 10.3] N=15	4.5 [3.4, 5.0] N=13	20.2 [16.4, 23.9] N=2
No team/staffing changes (has organizational change)	1.10 [0.10, 1.40] N=13	0.10 [0.0, 0.60] N=5	1.40 [1.33, 1.92] N=8	4.3 [3.3, 4.6] N=4	4.3 [3.3, 4.6] N=4	N=0
Medical record changes	1.40 [1.40, 1.9] N=5	N=0	1.40 [1.40, 1.9] N=5	1.0 ---- N=1	1.0 ---- N=1	N=0
No medical record changes	0.4 [0.1, 0.8] N=33	0.39 [0.1, 0.73] N=28	0.56 [0.5, 1.4] N=5	4.9 [4.0, 15.4] N=16	4.5 [3.8, 5.6] N=13	18.0 [17.2, 21.0] N=3
No medical record changes (has organizational change)	0.30 [0.10, 0.78] N=22	0.25 [0.03, 0.68] N=18	0.95 [0.40, 1.55] N=4	4.9 [4.5, 6.0] N=5	4.7 [4.4, 5.1] N=4	18.0 ---- N=1

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 12a. Association between improvements in glycemic control and various roles for clinical information systems stratified by quartiles of sample size*

	Median improvement in HbA1c [inter-quartile range]† N=Number of comparisons				
Type of role for clinical information system‡	**All Comparisons**	**Comparisons with sample size in lowest quartile**	**Comparisons with sample size in lower 2 quartiles**	**Comparisons with sample size in upper 2 quartiles**	**Comparisons with sample size in highest quartile**
All Comparisons	0.48 [0.20, 1.38] N=38	1.35 [0.60, 1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
Any role	0.9 [0.3, 1.42] N=20	1.40 [1.10, 1.50] N=5	1.40 [0.91, 1.49] N=11	0.10 [0.10, 0.60] N=9	0.10 [0.10, 0.24] N=7
No role	0.35 [0.2, 0.59] N=18	1.30 [0.56, 1.80] N=5	0.48 [0.20, 1.43] N=8	0.26 [0.20, 0.49] N=10	0.20 [0.10, 0.35] N=3
Identification of eligible participants	0.35 [0.1, 0.96] N=6	1.40 ---- N=1	1.40 ---- N=1	0.10 [0.10, 0.60] N=5	0.10 [0.08, 0.23] N=4
No identification of eligible participants	0.48 [0.21, 1.4] N=32	1.30 [0.710, 1.80] N=9	1.20 [0.40, 1.49] N=18	0.26 [0.13, 0.49] N=14	0.15 [0.10, 0.33] N=6
No identification of eligible participants, but has some other role for an information system	1.25 [0.40, 1.49] N=14	1.40 [1.00, 1.83] N=4	1.40 [0.81, 1.49] N=10	0.24 [0.10, 0.78] N=4	0.10 [0.10, 0.24] N=3
Reminder system	0.71 [0.39, 1.69] N=11	1.10 [0.91, 1.95] N=3	1.10 [0.56, 1.69] N=7	0.24 [0.10, 1.78] N=4	0.1 [0.1, 0.24] N=3
No reminder system	0.47 [0.15, 1.19] N=27	1.40 [0.93, 1.65] N=7	1.35 [0.38, 1.43] N=12	0.21 [0.10, 0.55] N=15	0.10 [0.05, 0.35] N=7
No reminder system, but has some other role for an information system	1.08 [0.10, 1.40] N=9	1.45 [1.40, 1.50] N=2	1.40 [1.40, 1.43] N=4	0.10 [0.10, 0.60] N=5	0.10 [0.08, 0.23] N=4
Computerized decision support system (CDSS)	1.1 [0.37, 1.99] N=5	1.95 [1.10, 2.80] N=2	1.95 [1.10, 2.80] N=2	0.37 [0.24, 1.18] N=3	0.24 [0.1, 0.40] N=2

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

† When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

‡ In addition to the roles shown in the table, we had included "facilitated communication between providers," but only 1 study, in which the intervention involved an electronic communication designed to enhance shared care between primary care providers and specialists, exhibited this feature.[129]

Table 12a (continued). Association between improvements in glycemic control and various roles for clinical information systems stratified by quartiles of sample size*

No CDSS	0.47 [0.2, 1.30] N=33	1.35 [0.67, 1.58] N=8	1.30 [0.40, 1.47] N=17	0.21 [0.10, 0.53] N=16	0.10 [0.08, 0.27] N=8
No CDSS, but has some other role for an information system	0.71 [0.25, 1.40] N=15	1.40 [1.06, 1.45] N=3	1.40 [0.71, 1.47] N=9	0.10 [0.10, 0.48] N=6	0.10 [0.10, 0.10] N=5
Audit system	1.4 [0.75, 1.45] N=3	1.45 [1.40, 1.50] N=2	1.45 [1.40, 1.50] N=2	1.0 ---- N=1	1.0 ---- N=1
No Audit system	0.47 [0.2, 1.2] N=35	1.20 [0.67, 1.90] N=8	1.10 [0.40, 1.47] N=17	0.26 [0.10, 0.58] N=18	0.10 [0.10, 0.37] N=9
No Audit system, but includes other role for information system	0.71 [0.37, 1.40] N=17	1.10 [0.91, 1.95] N=3	1.40 [0.71, 1.47] N=9	0.24 [0.10, 0.72] N=8	0.10 [0.10, 0.30] N=6

* Sample size stratification for HbA1c: 1st quartile=69, median=123, 3rd quartile=226.

Table 12b. Association between improvements in provider adherence and glycemic control for various roles for clinical information systems stratified by trial design

	Median Reduction in HbA_{1c} [inter-quartile range]* N=Number of comparisons			Median Improvement in provider adherence [inter-quartile range]* N=Number of comparisons		
Type of clinical information system	**All Comparisons**	**RCT**	**Non-RCT**	**All Comparisons**	**RCT**	**Non-RCT**
All Comparisons	0.48 [0.20, 1.38] N=38	0.39 [0.1, 0.73] N=28	1.4 [1.1, 1.78] N=10	4.85 [3.8, 15.03] N=17	4.5 [3.5, 5.45] N=14	18.0 [17.2, 20.95] N=3
Any clinical information system	0.9 [0.3, 1.42] N=20	0.4 [0.1, 0.8] N=12	1.4 [1.33, 1.92] N=8	4.0 [3.8, 4.5] N=5	4.0 [3.8, 4.5] N=5	---- N=0
No clinical information system (CIS)	0.35 [0.2, 0.59] N=18	0.3 [0.15, 0.65] N=16	0.53 [0.5, 0.56] N=2	5.3 [4.1, 16.8] N=12	4.9 [3.0, 5.6] N=9	18.0 [17.2, 21.0] N=3
Identification of eligible participants	0.35 [0.1, 0.96] N=6	0.1 [0.1, 0.6] N=5	1.4 ---- N=1	4.5 [4.3, 5.3] N=3	4.5 [4.3, 5.3] N=3	---- N=0
No identification of eligible participants	0.48 [0.21, 1.4] N=32	0.4 [0.2, 0.76] N=23	1.4 [0.56, 1.9] N=9	4.9 [3.5, 16.1] N=14	4.5 [3.2, 5.3] N=11	18.0 [17.2, 21.0] N=3
No identification of eligible participants (but has CIS)	1.25 [0.40, 1.49] N=14	0.41 [0.39, 1.09] N=7	1.40 [1.25, 1.95] N=7	3.6 [3.4, 3.8] N=2	3.6 [3.4, 3.8] N=2	---- N=0
Reminder system	0.71 [0.39, 1.69] N=11	0.4 [0.24, 0.56] N=7	1.95 [1.7, 2.19] N=4	3.8 [3.6, 4.2] N=3	3.8 [3.6, 4.2] N=3	---- N=0
No reminder system	0.47 [0.15, 1.19] N=27	0.3 [0.1, 0.8] N=21	0.98 [0.52, 1.4] N=6	5.3 [4.1, 16.1] N=14	4.9 [3.5, 5.8] N=11	18.0 [17.2, 21.0] N=3
No reminder system (but has CIS)	1.08 [0.10, 1.40] N=9	0.60 [0.10, 1.08] N=5	1.40 [1.08, 1.40] N=4	5.0 [4.0, 6.0] N=2	5.0 [4.0, 6.0] N=2	---- N=0
Computerized decision support system (CDSS)	1.1 [0.37, 1.99] N=5	0.24 [0.1, 0.37] N=2	1.99 [1.55, 2.4] N=3	3.6 [3.4, 3.8] N=2	3.6 [3.4, 3.8] N=2	---- N=0
No CDSS	0.47 [0.2, 1.30] N=33	0.4 [0.12, 0.78] N=26	1.4 [0.53, 1.4] N=7	5.0 [4.3, 15.7] N=15	4.7 [3.8, 5.7] N=12	18.0 [17.2, 21.0] N=3

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table 12b (continued). Association between improvements in provider adherence and glycemic control for various roles for clinical information systems stratified by trial design*

No CDSS (but has CIS)	0.71 [0.25, 1.40] N=15	0.51 [0.17, 0.99] N=10	1.40 [1.40, 1.40] N=5	4.5 [4.3, 5.3] N=3	4.5 [4.3, 5.3] N=3	---- N=0
Audit system	1.4 [0.75, 1.45] N=3	0.8 [0.1, 1.5] N=2	1.4 ---- N=1	3.4 ---- N=1	3.4 ---- N=1	---- N=0
No Audit system	0.47 [0.2, 1.2] N=35	0.39 [0.12, 0.68] N=26	1.4 [0.56, 1.9] N=9	4.9 [4.0, 15.4] N=16	4.5 [3.8, 5.6] N=13	18.0 [17.2, 21.0] N=3
No Audit system (but has CIS)	0.71 [0.37, 1.40] N=17	0.40 [0.17, 0.68] N=10	1.40 [1.25, 1.95] N=7	4.3 [4.0, 4.9] N=4	4.3 [4.0, 4.9] N=4	---- N=0

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

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Appendix A. Comparison of recommended goals for clinical practice vs. targets for performance measurement

	Goal for clinical practice	Target for performance measurement	Comment
Adequacy of Glycemic Control	"good control": $HbA_{1c} \leq$ 7.0% ADA[1]	Proportion of patients with "poor control": ▪ $HbA_{1c} \geq$ 9% NDQIA[2] ▪ $HbA_{1c} \geq$ 9.5%)[3]	Many factors effect the appropriateness of HbA_{1c} < 7% as a fixed goal for a clinic or health care system to achieve (e.g., frequency of hypoglycemia, comorbid conditions, patient preferences), hence the focus on percentage of patients with "poor control" (≥ 9%) for purposes of performance measurement
Blood pressure control	< 130/80 mmHg	$\leq$ 140/90 mmHg	Similarly, system-wide reports of BP control focus on percentage of patients with poor control ($\geq$ 140/90 mmHg)
Lipid control	LDL-C $\leq$ 100 mg/dl (2.6 mmol/l) Triglycerides $\leq$ 150 mg/dl (1.7 mmol/l) HDL $\leq$ 40 mg/dl (1.1 mmol/l)	LDL-C $\leq$ 130 mg/dl	Elevated LDL-cholesterol is most strongly correlated with increased risk of cardiovascular disease. Again, optimal goal of 100 mg/dl may not be attainable for numerous reasons.
Frequency of assessing HbA_{1c}	≥ 2 times/year for patients meeting treatment goals;[1] ≥ 4 times/year patients not meeting treatment goals[1]	$\geq$ 1 HbA_{1c} test/year (NDQIA,[2] HEDIS®[3])	Yearly measurements of HbA_{1c} are correlated with actual lower HbA_{1c} levels.
Frequency of assessing lipids	> 1 complete lipid panel/year[1]	$\geq$ 1 LDL-C measurement/year (NDQIA,[2] HEDIS[3])	
Urine protein screening	$\geq$1 test for urine microalbumin/year[1]	$\geq$ 1 test for urine microalbumin/year (NDQIA,[2] HEDIS[3])	Receives only an "E" recommendation from ADA ("Expert consensus or clinical practice") for type 2 diabetic patients.
Eye examination	$\geq$1 dilated retinal examination/year[1]	$\geq$ 1 dilated retinal examination/year (or every other year if low risk)	"Low risk": non-insulin-requiring, HbA_{1c} < 8%, no prior evidence of retinopathy
Foot examination	$\geq$ 1 complete foot exam/year (including sensory exam with microfilament)[1]	$\geq$ 1 foot examination of any kind	
Smoking cessation	Advise all smokers to quit; smoking cessation as part of routine diabetic care[1]	Percentage of patients whose smoking status was ascertained and documented annually	

Patient education	No formal recommendation	No formal recommendation	

ADA – American Diabetes Association; NDQIA – National Diabetes Quality Improvement Alliance; HEDIS - Health Plan Employer Data and Information Set. The HEDIS measure is actually a composite measures for "comprehensive diabetes care" consisting of the specific measurements show in the table.

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Appendix B. MEDLINE search for diabetes quality improvement articles

Search	Search String	Citations *
#1 *targets QI strategies that tend to be multi-factorial using relevant MeSH terms and title words*	Disease Management [mh] OR Patient Care Planning [mh] OR Patient-Centered Care [mh] OR Primary Health Care [mh] OR Progressive Patient Care [mh] OR Critical Pathways [mh] OR Delivery of Health Care, Integrated [mh] OR Health Services Accessibility [mh] OR Managed Care Programs [mh] OR Product Line Management [mh] OR Patient Care Team [mh] OR Patient-Centered Care [mh] OR Behavior Control [mh] OR Counseling [mh] OR Health Promotion [mh] OR Patient Compliance [mh] OR After-Hours Care [mh] OR ((coordination [ti] OR coordinated [ti] OR Multifactorial [ti] OR Multi-factorial [ti] OR Multicomponent [ti] OR Multi-component [ti] OR multidisciplinary [ti] OR multi-disciplinary [ti] OR interdisciplinary [ti] OR inter-disciplinary [ti] OR integrated [ti] OR community-based [ti] OR organized [ti]) AND (care [ti] OR approach [ti] OR intervention [ti] OR strategy [ti] OR strategies [ti] OR management [ti] OR managing [ti] OR center* [ti] OR clinic*[ti])) OR Organization and Administration [mh]	682,850
#2 *targets TQM and CQI*	Total Quality Management [mh] OR Quality control [mh] OR TQM [ti] OR CQI [ti] OR (quality [ti] AND (continuous [ti] OR total [ti]) AND (management [ti] OR improvement [ti]))	28,079
#3 *targets provider education*	Education, Continuing [mh] OR (Education [ti] AND Continuing [ti] AND (medical [ti] OR professional* [ti] OR nursing [ti] OR physician* [ti] OR nurse* [ti])) OR (outreach [ti] AND (visit*[ti] OR educational [ti]) OR (academic [ti] AND detailing [ti]))	35,275
#4 *targets diffusion of innovation*	Diffusion of Innovation [mh] OR (Diffusion [ti] AND (Innovation [ti] OR technology [ti]))	4,887
#5 *targets audit & feedback, reminder systems, and financial incentives*	Medical audit [mh] OR ((Audit [ti] OR feedback [ti] OR compliance [ti] OR adherence [ti] OR training [ti]) AND (improvement* [ti] OR improving [ti] OR improves [ti] OR improve [ti] OR guideline* [ti] OR practice* [ti] OR medical [ti] OR provider* [ti] OR physician* [ti] OR nurse* [ti] OR clinician* [ti] OR practice guidelines [mh] OR academic [ti] OR visit* [ti])) OR Reminder Systems [mh] OR Reminder* [ti] OR ((financial [ti] OR economic [ti] OR physician* [ti] OR patient*) AND incentive* [ti]) OR Reimbursement Mechanisms [mh]	36,788
#6	Medical Informatics [mh] OR computer [ti] OR (decision [ti] AND support [ti]) OR	306,619

targets informatics and telemedicine	Telemedicine[mh] OR Telemedicine [ti] OR telecommunication* [ti] OR Internet [mh] OR web [ti] OR modem [ti] OR telephone* [ti] OR telephone [mh]	
#7 *combines #1-7 for overall set of articles relating to QI*	#1 OR #2 OR #3 OR #4 OR #5 OR #6	988,084
#8 *combines overall QI search key terms for articles involving diabetes*	#7 AND (Diabetes Mellitus [mh] OR diabetes [ti] OR diabetic [ti] OR glycemic [ti] OR glycaemic [ti] OR sugar* [ti])	9,956
#9 *identifies subset of #9 likely to involve original research or systematic reviews*	#8 AND (systematic review search string^ OR original research string†)	3,992
#10	#9 Limit to English	3,575
#11	#10 Limit to publication since 1980	3,460
#12	#11 BUTNOT (editorial [pt] OR comment [pt] OR letter [pt])	3,348
#13 *additional yield of journal search*	(#8 AND Journal Search String §) BUTNOT (#9 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	294
#14 *additional yield of author search*	(#8 AND author search**) BUTNOT (#13 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	29
Total	#12 or #13 or #14	**3,601** references total

* Numbers of citations reflect search results from July 8, 2003

^ ((meta-analysis [pt] OR meta-analysis [tw] OR metanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti] OR Decision Support Techniques [mh]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti]))) BUTNOT (case report [mh] OR case* [ti] OR report [ti] OR editorial [pt] OR comment [pt] OR letter [pt]) → 38,850 MEDLINE records

† Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR impact [ti] OR effectiveness [ti] OR Evaluation [ti] OR Studies [ti] OR study [ti] Comparative [ti] OR Feasibility [ti] OR Program [ti] OR Design [ti] OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh] —> 2,550,756 MEDLINE records

§ N Engl J Med [ta] OR JAMA [ta] OR Ann Intern Med [ta] OR Am J Med [ta] OR Arch Intern Med [ta] OR J Gen Intern Med [ta] OR BMJ [ta] OR Lancet [ta] OR CMAJ [ta] OR Clin Invest Med [ta] OR Arch Fam Med [ta] OR J Fam Pract [ta] OR Fam Pract [ta] OR Ann Med [ta] OR Br J Gen Pract [ta] OR J Intern Med [ta] OR Med J Aust [ta] OR South Med J [ta] OR West J Med [ta] OR Aust N Z J Med [ta] OR Med Care [ta] OR Health Serv Res [ta] OR Inquiry [ta] OR Milbank Q [ta] OR Health Aff (Millwood) [ta] OR Health Care Financ Rev [ta] OR Med Care Res Rev [ta] OR eff clin pract [ta] OR eval health prof [ta] OR Jt Comm J Qual Improv [ta] OR Qual Saf Health Care [ta] OR Int J Qual Health Care [mh] OR Qual Health Care [ta] OR Qual Health Res [ta] OR Rep Med Guidel Outcomes Res [ta] OR Am J Manag Care [ta] OR Am J Med Qual [ta] OR J Contin Educ Health Prof [ta] OR Prev Med [ta] OR Am J Prev Med [ta] OR Patient Educ Couns [ta] OR Ann Behav Med [ta] OR Diabetes Educ [ta] OR Endocrinology [ta] OR J Clin Endocrinol Metab [ta] OR Diabet Med [ta] OR Diabetes Care [ta] OR Diabetes Res Clin Pract [ta] OR Exp Clin Endocrinol Diabetes [ta] OR J Pediatr Endocrinol Metab [ta]

** The author search could not be exhaustive, but, after completion of the initial search, we identified authors who appeared in multiple trials or prominent review articles and searched for publications listing any of them as authors (list available on request)

Appendix C. Abstraction forms for screening and full-text review

Stage 1

1. Does the article report or evaluate the results of an intervention (whether performed by the investigators or not)?
   - o Yes
   - o No ***{exclusion}***
   - o Can't Tell ***{promotion to Stage 2}***

2. Does the article involve quality improvement or a QI strategy?
   - o Yes - involves quality improvement or a QI strategy
   - o Yes - systematic review of evaluations of a QI strategy
   - o No ***{exclusion}***
   - o Can't Tell ***{promotion to Stage 2}***

Stage 2

1. Should this article proceed to article abstraction stage for this topic?
   - o Yes - evaluates a QI strategy involving diabetes
   - o No - focused on diabetes in pregnancy, Type I DM or children only, screening for/preventing diabetes, hospital care only ***{exclusion}***
   - o No - off topic (use textbox to indicate if involves other EPC topics) ***{exclusion}***
   - o No - not an evaluation or not QI ***{exclusion}***
   - o Can't tell - need article ***{promotion to Stage 3}***
   - o No - but useful background article ***{exclusion}***

2. What type of study design was used?
   - o RCT or quasi-RCT
   - o CBA* or ITS **
   - o Cohort study; before-after or time series not meeting CBA* or ITS** definitions ***{exclusion}***
   - o Observational (e.g., cross-section, case-control) ***{exclusion}***
   - o Can't tell (need article) ***{promotion to Stage 3}***
   - o Systematic review or meta-analysis ***{exclusion}***
   - o Economic or decision analysis, modeling ***{exclusion}***
   - o Non-research (commentary, review, news) ***{exclusion}***
   - o Qualitative research (e.g., focus groups) ***{exclusion}***
   - o Guideline or consensus statement ***{exclusion}***

* Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgment that control represents a comparable group or setting

** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND at least three time points both before and after

Note: At this stage of triage, if there is a reasonable chance article is a clinical trial, CBA or ITS, err on the side of inclusion at that level. Stricter criteria can be applied more reliably at next stage of abstraction using full text of article. Similarly, if there is a reasonable chance article is a systematic review, designate it as such so article can be pulled.

Stage 3

1. Does this article merit abstraction at Stage 3?
   - o Yes
   - o No – not QI or not an evaluation of a QI strategy ***{exclusion}***
   - o No – study design below Level 2 ***{exclusion}***
   - o No - excluded topic (focused only on pregnancy, hospital care, Type I DM, or screening) ***{exclusion}***

- o No – no eligible outcomes* ***{exclusion}***
- o No - publication prior to 1980 (select only if no other exclusionary answer applies) ***{exclusion}***
- o No- other ***{exclusion}***

* Eligible outcomes include measures of disease control, provider adherence, or patient compliance. Excluded are: measures of provider or patient understanding, satisfaction, self-efficacy; costs and resource use. Also excluded are articles reporting no outcomes specifically related to diabetes (e.g. smoking only). Also excluded is provider adherence measured exclusively by provider self-report.

2. Does this article present data overlapping with another article?
   - o Exclude this article as a duplicate publication (identify included citation being duplicated) ***{exclusion}***
   - o Include this article, but obtain listed citation to help with abstraction (e.g., separate methods paper; identify required citation)
   - o No or N/A

3. What category of study question is addressed by the article?
   - o Can screening for or awareness of diabetes be improved?
   - o Can provider treatment of diabetes be improved? (e.g., increased adherence to recommended care)
   - o Can patient glycemic control or diabetic complications be improved
   - o Can patient compliance, education or self management be improved?
   - o Not sure or Other (describe)
   - o N/A

4. Describe the QI strategy used and its salient features.

5. Did the QI strategy involve a provider reminder system* or facilitated relay of clinical data ** back to providers?
   - o Chart based reminder system* for providers
   - o Computer based reminder* or decision support for providers
   - o Facilitated relay of clinical data to providers**
   - o Not sure
   - o No or N/A

* Patient or provider encounter specific information, provided verbally, on paper or on a computer screen, which is intended to prompt provider to recall information (e.g., the last time the patient had a HbA1c checked and its value, the last time the patient underwent screening colonoscopy and the result)

** Clinical information collected directly from patients and given to the provider using some format other than the conventional chart system

6. Did the QI strategy involve provider audit and feedback*?
   - o feedback to individual provider (state if confidential)
   - o feedback about clinic or practice performance only
   - o Public reporting of performance data (state if individual data or data for a group or institution)
   - o Benchmarking**
   - o Not sure or other
   - o No or N/A

* Any summary of clinical performance of health care over a specified period of time. E.g., the percentage of a provider's patients who have achieved or have not achieved some clinical target (e.g., BP or HbA1c in certain range), have or have not been offered some diagnostic test. **Benchmarking refers to the provision of performance data from institutions or providers regarded as "leaders in the field." These data provide targets for other providers and institutions to emulate.

7. Did the QI strategy involve provider education?
   - o Educational workshops, meetings (e.g., traditional CME), lectures (live or computer based)

- o Educational outreach visits (Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice)
- o Distribution of educational materials (Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications)
- o Not sure or other
- o No or N/A

8. Did the QI strategy involve patient education or promote self-management?
- o In-person patient education individually or as a part of a group or community
- o Distribution of printed or audio-visual educational materials
- o Patient reminders (e.g., to keep appointments or comply with other aspect of care)
- o Provision of clinical data back to the patient (e.g., your most recent HbA1c or lipid panel was such and such)
- o Distribution of materials or access to a resource that enhances patients' ability to manage their condition
- o Not sure or other
- o No or N/A

9. Did the QI strategy involve organizational change?
- o Case management, disease management --coordination of assessment, treatment and arrangement for referrals by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider
- o Adding new members to team (e.g., adding a diabetes nurse, clinical pharmacist, or nutritionist to clinic) or creating multidisciplinary teams (creation of a new team of health professionals of different disciplines or additions of new members to the team who work together to care for patients)
- o Communication and case discussion between distant health professionals (e.g., telemedicine)
- o TQM/CQI - cycles of measurement of quality problems, design of interventions, implementation and re-measurement
- o Changes in medical records systems -- e.g. changing from paper to computerised records, patient tracking systems
- o Revision of professional roles ('professional substitution', 'boundary encroachment') - the shifting of roles among health professionals (e.g., nurse midwives providing obstetrical care)
- o Increased staffing without changes in roles (e.g., adding more nurses)
- o Not sure or other
- o No or N/A

10. Did the QI strategy involve financial, regulatory or legislative incentives or actions?
- o Positive or negative financial incentives directed at providers
- o Positive or negative financial incentives directed at patients
- o System-wide changes in reimbursement (e.g., capitation, prospective payment, shift from fee for service to salary)
- o Changes to provider licensure requirements
- o Changes to institutional accreditation requirements
- o Not sure or other
- o No or N/A

11. Did a clinical information system play a role in design or implementation of intervention (regardless of QI strategy type)?
- o Identification and/or group allocation of eligible patients or providers
- o Reminders generated by existing clinical information system
- o Decision support at point of care (e.g., for provider order entry)
- o Facilitated communication between providers (e.g., generated emails between members of care team)
- o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
- o Not sure or Other
- o No or N/A

12. Who or what was targeted by the intervention?
- o Patients

- o Providers (i.e., individual clinicians)
- o Ambulatory clinics or practices
- o Inpatient units or hospitals
- o Public health systems, healthcare delivery systems, policy makers
- o Not sure or Other
- o N/A

13. Among the target group, what was the number of participants? (i.e., study size)

14. What type of study design was used?
    - o RCT or quasi-RCT
    - o CBA* or ITS**
    - o Cohort study, retrospective before-after, or time series not meeting ITS definition** ***{exclusion}***
    - o Not sure or other
    - o N/A

* Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgement that control represents a comparable group or setting

** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND at least three time points both before and after

15. What were the outcome types?
    - o Measure of disease control (clinical outcomes, HbA1c, glucose control, lipids)
    - o Provider adherence (adherence to a guideline or recommended practice)
    - o Patient compliance
    - o Patient or provider understanding, self-efficacy, empowerment
    - o Not sure or other
    - o N/A

16. What specific measures of disease control were used?
    - o Serum glucose values (mean or percent of patients in certain range)
    - o HbA1c (mean or percent of patients in certain range)
    - o Cardiovascular risk factor modification (hyperlipidemia, hypertension, smoking cessation)
    - o Microvascular complications (retinopathy, neuropathy, microalbuminuria, foot ulcers)
    - o Macrovascular complications (MI, stroke, renal failure, amputation)
    - o Not sure or other
    - o None or N/A

17. For studies reporting measures of clinician adherence, what specific measures were used?
    - o Adherence to guideline targets for assessment of glycemic control (e.g., measuring HbA1c at certain intervals)
    - o Adherence to recommended screening practices for ophthalmologic complications (e.g., performance of or referral for dilated retinal exam)
    - o Adherence to recommended screening practices for renal complications (e.g., checking urine microalbumin)
    - o Adherence to recommended screening practices for neuropathy or foot complications (e.g., performance of or referral for foot examination)
    - o Adherence to treatment choices for achieving glycemic control (e.g., medication choices)
    - o Adherence to guideline targets for managing blood pressure or cardiovascular disease
    - o Adherence to recommendations for patient education or counseling re: diet, exercise, smoking, or other lifestyle factors
    - o Not sure or other
    - o N/A

18. For studies reporting measures of patient compliance, how was compliance assessed?
    - o Laboratory confirmation (e.g., detection of drug or metabolite in blood or urine; including biochemical assays for smoking cessation
    - o Pharmacy data (e.g., filled or refilled prescriptions)
    - o Specially designed dispensers that record medication use

- o Home medication counts
- o Office medication counts (e.g., patients bring in bottles with unused pills)
- o Patient self report (via interview or survey)
- o Not sure or other
- o N/A

19. Use textbox to state any important study features or concerns not captured above.

20. Does the study intervention primarily consist of patient education or promotion of self-management?
- o Yes: there are no QI strategies other than patient education/promotion of self-management OR either of two criteria below is met* ***{exclusion}***
- o No: provider or organizational change represented an intrinsic feature of the intervention
- o Not sure

* Criteria for classifying intervention as primarily patient education:

1) other strategies served only as vehicles for promoting education/self-management (e.g., adding a new team member whose sole job as to provide patient education, providing financial incentives for patients to comply with targets of patient educational program, training providers about how to deliver more effective patient education.)

2) non-patient education strategies were delivered to control group and not just intervention group (e.g., study of patient education intervention in which all providers received "facilitated relay of clinical information, " decision support or any other management aide that is common to all providers or all organizations caring for patients in the study, not just those in intervention group.

Stage 4

1. Does abstraction of this study require information from methods or results reported in other citations (see Q2, Stage 3)
- o Yes (specify)
- o No

2. Does the article report data for more than one comparison (i.e., should it be abstracted as more than one study)?
- o Yes (specify which comparison is being abstracted here and which others will be abstracted elsewhere)
- o No

A) Study Setting and Participants

3. In what country did the study take place?
- o US only
- o non-US (specify)

4. Were the dates of the study period reported?
- o Yes - give dates as exactly as indicated in paper
- o No - indicate duration of study in month or years if reported

5. In what setting did the study intervention take place?
- o Primary care clinic
- o Specialist clinic (e.g. diabetes or endocrinology practice)
- o Community
- o Multiple or Other (describe)
- o Not stated or not clear

6. Were INCLUDED patients selected on the basis of any of the following?

- o Poor compliance with medications or clinic attendance (describe)
- o Poor glycemic control (describe)
- o Presence of specific comorbid conditions or illnesses (specify/describe -- e.g., HTN, hyperlipidemia, coronary artery disease, obesity, tobacco use)
- o Presence of specific diabetic complications (specify/describe -- e.g., renal failure, albuminuria, neuropathy, retinopathy)
- o Other (explain)
- o None of above
- o Not applicable (no patient involvement in study - e.g., study of provider-based intervention and provider outcomes only).

7. What type of care was provided to the control population?
- o No intervention or usual care
- o Some form of low intensity intervention (describe)
- o No true control - just two or more different types of intervention (discuss with other reviewers; study may need to be excluded)

B) Study Design

8. What was the study design?
- o Randomized trial - state method of randomization if described and any descriptive phrases (e.g. "randomly assigned")
- o Quasi randomized trial - state basis for treatment allocation (e.g. alternating patients, calendar date, eve or odd identification numbers)
- o Controlled before-after study

9. Did the study have a cross over design? (Patients randomized to a sequence of interventions such as treatment A followed by treatment B in one group and treatment B followed by treatment A in the other group).
- o Yes (describe)
- o No
- o Not sure - clarify with other reviewers before proceeding

10. What was the unit of randomization or treatment allocation?
- o Patient
- o Episode of care
- o Clinic day
- o Provider
- o Practice
- o Firm (describe)
- o Institution
- o Community
- o Other

11. For the unit of treatment allocation (above), state sample size in each group (If sample size differs for outcomes, detail differences in "Not stated or not clear" text box):
- o control group
- o intervention group
- o Not stated or not clear (explain)

12. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient outcomes analyzed), state sample size in each group: (Use text box for "Not applicable" if sample size for any outcomes reported is different-give details)
- o control group
- o intervention group
- o Not stated or not clear
- o Not applicable (unit of analysis same as unit of treatment allocation above)

13. If unit of analysis differed from unit of treatment allocation, did authors acknowledge this issue and/or make appropriate adjustments?
- o Yes (describe)
- o No
- o Not applicable (unit of analysis did not differ from unit of treatment allocation)

14. Was there adequate concealment of treatment allocation?
- o Yes -(unit of allocation was institution, team or professional and any random process explicitly described, e.g. use of random number tables, OR unit of allocation was patient or episode of care and some form of centralized randomization scheme or sealed, opaque, serially numbered envelopes used)
- o Not clear (only partially meets above criteria) or not stated - specify which
- o No - inadequate concealment (enrollment of patients in alternation or through use of even/odd identifying numbers OR unit of allocation was patient or episode of care and reported use of any allocation process that is entirely transparent before assignment (e.g., open list of random numbers) OR allocation was altered by investigators, professionals or patients)

15. Were patients blind to intervention/treatment allocation?
- o Yes
- o No
- o Not sure (explain)
- o Not applicable (patients not actively involved in study - e.g., provider-focused intervention with patient level data obtained retrospectively from charts)

16. Were providers blind to intervention/treatment allocation?
- o Yes
- o No
- o Not sure (explain)
- o Not applicable - (explain)

17. Do any methodologic aspects of the study design not captured above seriously undermine appropriateness of inclusion?
- o Yes (explain)
- o No (use text box to document any non-fatal, but still noteworthy methodological features)

C) Quality Improvement Attributes of Intervention

18. Did the study intervention involve PATIENT Education?
- o Yes (describe what was taught, where it occurred, duration and frequency of sessions)
- o No

19. Did the intervention include access to a resource or provision of a device that promoted Patient Self-Management? (Patient reminder systems are addressed below in Q40, so do not answer yes here on basis of patient reminders.)
- o Yes (describe)
- o No

20. Did the intervention involve a PATIENT REMINDER system?
- o Yes (specify target of reminder - appointments, compliance with meds or recommendations for self-care)
- o No

21. Did the intervention involve PROVIDER education?
- o Yes (describe nature of education, who administered the education, how often did it occur, etc)
- o No

22. Did the intervention involve a PROVIDER REMINDER system? (Facilitated relay of clinical data is addressed below , so do not answer yes solely on that basis.)
- o Yes (describe content of reminders and how delivered)
- o No

23. Did the intervention involve Facilitated Relay of clinical information to providers?
- o Yes (describe type of information - e.g., recent glucose or HbA1c, and method of relaying information)
- o No

24. Did the intervention involve provider AUDIT and FEEDBACK?
- o Yes (describe what was fed back, how often, etc)
- o No

25. Did the intervention involve ORGANIZATIONAL Change (e.g., disease or case management, creation of multidisciplinary teams or expansion of professional roles, TQM/CQI, telemedicine, change in medical record system)?
- o Yes
- o No

26. If the intervention involved Disease Management or Case Management, which of the following apply?
- o Intervention specifically described as involving "case management" or "disease management"
- o Someone other than physician actively participated in ongoing patient management using guidelines or systematic approach to care (protocols/algorithms to guide practitioner and patient decisions in specific clinical circumstances (specify type of person playing role of case manager)
- o Person or system actively tracked, scheduled and coordinated patients' appointments
- o Other basis for describing intervention as disease/case management (describe)
- o Not applicable - no component of disease/case management

27. Did intervention involve changes to make up of healthcare team or roles of providers?
- o Yes - Creation of multidisciplinary team, addition of new team member, expansion of roles, automatic referral for periodic visit with specific provider type (e.g., podiatrist or opthalmologist)
- o Revision/expansion of roles or "shared care" (e.g., nurse or pharmacist operated actively managed medications without consulting physician)
- o Other (describe)
- o No changes to team/personnel

28. Did the intervention involve changes to medical records systems?
- o Change from paper to computerised records
- o Implementation of computerized provider order entry (CPOE)
- o New patient tracking system
- o Other (describe)
- o Not applicable - No change to medical record system

29. Did intervention involve any type of organizational change not captured by above questions?
- o Yes (describe)
- o No

30. Did a clinical information system play a role in design or implementation of intervention (see Q11 at Stage 3)?
- o Identification and/or group allocation of eligible patients or providers
- o Reminders generated by existing clinical information system
- o Decision support at point of care (e.g., for provider order entry)
- o Facilitated communication between providers (e.g., generated emails between members of care team)
- o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
- o Other
- o No role for a clinical information system

D) Results

31. For unit of treatment allocation (e.g., clinics, providers, patients), were results reported for at least 80% of participants?
- o Yes (state %)
- o No (state %)
- o Not stated

32. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient level outcomes analyzed), were results reported for at least 80% of participants?
- o Yes (state %)
- o No (state %)
- o Not stated or not clear
- o Not applicable (unit of analysis same as unit of treatment allocation)

Measures of Disease Control

33. Did the study report outcomes involving measures of disease control?
- o Yes
- o No

34. Did one measure of disease control involve HbA1c reported as mean and standard deviation in intervention and control groups?
- o Yes
- o No

35. For the outcome of disease control involving mean HbA1c, provide the following information for patients in CONTROL group; indicate not reported by typing "NR"
- o Mean HbA1c before intervention
- o Standard deviation for HbA1c before intervention
- o Mean HbA1c after intervention
- o Standard deviation for HbA1c after intervention
- o Mean difference between pre- and post-intervention HbA1c values
- o Standard deviation for difference between pre- and post-intervention HbA1c values
- o Not applicable (no measure of HbA1c)

36. For the outcome of disease control involving mean HbA1c, provide the following information for INTERVENTION group; indicate not reported by typing "NR"
- o Mean HbA1c value before intervention
- o Standard deviation for HbA1c before intervention
- o Mean HbA1c value after intervention
- o Standard deviation for HbA1c after intervention
- o Mean difference between pre- and post-intervention HbA1c values
- o Standard deviation for difference between pre- and post-intervention HbA1c values
- o Not applicable (no measure of HbA1c)

37. Did study report any measures of disease control involving HbA1c outcomes not captured above (e.g. median HbA1c or % of patients with HbA1c in certain range)?
- o Yes (describe)
- o No

38. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in CONTROL group (indicate not reported by typing NR)
- o pre-intervention SBP (state mean and standard deviation)
- o post-intervention SBP (state mean and standard deviation)
- o difference between pre- and post-intervention values (state mean and SD)
- o Not applicable - no disease control outcomes involving SBP as mean and SD

39. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)
- o pre-intervention SBP (state mean and SD)

- o post-intervention SBP (state mean and SD)
- o difference between pre- and post-intervention values (state mean and SD)
- o Not applicable - no disease control outcome involving SBP as mean and SD

40. For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in the CONTROL group (indicate not reported by typing NR)
- o pre-intervention DBP (state mean and SD)
- o post-intervention DBP (state mean and SD)
- o difference between pre- and post-intervention values (state mean and SD)
- o Not applicable - no disease control outcome involving DBP as mean and SD

41. For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)
- o pre-intervention DBP (state mean and SD)
- o post-intervention DBP (state mean and SD)
- o difference between pre- and post-intervention values (state mean and SD)
- o Not applicable - no disease control outcome involving DBP and mean and SD

42. Did study report any measures of disease control involving blood pressure outcomes not captured above (e.g. median SBP/DBP or % patients with BP in certain range)?
- o Yes (describe)
- o No

43. Indicate results for measures of disease control no captured above:
- o Serum blood glucose
- o Other CV risk factor (e.g. total cholesterol, HDL-C, LDL-C, triglyceride, lipid, smoking, weight)
- o Microalbuminuria or renal failure
- o Other microvascular complications (e.g. foot lesions, retinopathy, neuropathy)
- o Clinical outcomes (e.g. mortality, MI, stroke, amputation)
- o Other (explain)
- o Not applicable - no other outcomes of disease control

Measures of clinician adherence

44. Did the study report outcomes related to clinician adherence?
- o Yes
- o No - none reported or none in usable form (explain)

Adherence to Guidelines for Assessing Glycemic Control using HbA1c

45. Did one of the outcomes of clinician adherence involve proportion of patient with HbA1c measured at least once during certain time period?
- o Yes (specify definition)
- o No or not reported in usable form (explain)

46. For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with HbA1c checked according to stated definition); indicate not reported by typing NR
- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving measurement of HbA1c in this format

47. For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for intervention group:
- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving measurement of HbA1c in this format

48. Did study report any outcomes of clinician adherence involving checking HbA1c that are not captured above?

- o Yes (describe; give results)
- o No

Adherence to Other Guidelines Involving Performance of Laboratory Tests

49. Did the article report outcomes for change in clinician adherence to a guideline for obtaining any lab measurements other than HbA1c?

- o Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention; use Excel to calculate and save file)
- o No - none reported or none in usable form

50. For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with other lab values checked according to stated definition); indicate not reported by typing NR

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving measurement of other lab values in this format

51. For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for intervention group:

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving measurement of other lab values in this format

52. Were there any adherence outcomes for obtaining lab measurements not captured above? (If you had to choose outcome with median effect, use textbox for “Yes” answer to list the other adherence outcomes.)

- o Yes (list)
- o No

Adherence to Guidelines for Assessment or Management of Hypertension and/or Coronary Artery Disease

53. Did the article report outcomes for change in clinician adherence to a guideline for assessment or management of HTN and/or CAD?

- o Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention; use Excel to calculate and save file)
- o No - none reported or none in usable form

54. For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with stated guideline performed); indicate not reported by typing NR

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format

55. For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for intervention group:

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format

56. Were there any adherence outcomes for assessment or management of HTN and/OR CAD not captured above? (If you had to choose outcome with median effect, use textbox for “Yes” answer to list the other adherence outcomes.)

- o Yes (list)
- o No

Adherence to Guidelines for Assessment of Diabetic Complications Involving the Eye or Foot

57. Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of foot exam?

- o Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention; use Excel to calculate and save file)
- o No - none reported or none in usable form

58. For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with feet checked according to stated definition); indicate not reported by typing NR

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving referral for or performance of foot exam in this format

59. For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for intervention group:

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving referral for or performance of foot exam in this format

60. Were there any adherence outcomes for referral for or performance of foot exam not captured above? (If you had to choose outcome with median effect, use textbox for “Yes” answer to list the other adherence outcomes.)

- o Yes (describe)
- o No

61. Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of eye exam?

- o Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention; use Excel to calculate and save file)
- o No - none reported or none in usable form

62. For the adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with eyes checked according to stated definition); indicate not reported by typing NR

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving referral for or performance of eye exam in this format

63. For adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for intervention group:

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving referral for or performance of eye exam in this format

64. Were there any adherence outcomes for referral for or performance of eye exam not captured above? (If you had to choose outcome with median effect, use textbox for “Yes” answer to list the other adherence outcomes.)

- o Yes (describe)
- o No

Adherence to Guidelines for Patient Counseling or Delivery of Patient Education

65. Did the article report outcomes for change in clinician adherence to a guideline for patient counseling or delivering of patient education?

- o Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention; use Excel to calculate and save file)
- o No - none reported or none in usable form

66. For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group counseled or educated according to stated definition); indicate not reported by typing NR

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving patient education or counseling in this format

67. For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for intervention group:

- o pre-intervention adherence (% patients)
- o post-intervention adherence (% patients)
- o difference between pre- and post-intervention values (% patients)
- o Not applicable - no adherence outcome involving patient education or counseling in this format

68. Were there any adherence outcomes for patient education or counseling not captured above? (If you had to choose outcome with median effect, use textbox for “Yes” answer to list the other adherence outcomes.)

- o Yes
- o No

69. Did the article report outcomes for change in clinician adherence to any OTHER guideline?

- o Yes (describe and give results)
- o No

Patient compliance outcomes

70. Describe results for any outcomes involving patient compliance

- o Compliance with self-care measures (e.g. self-monitoring of blood glucose), complying with diet or exercise, keeping appointments
- o Compliance with medications
- o Other (describe)
- o No patient compliance outcomes
- o Not sure (explain)

71. Use textbox to state any important study features or results not captured above.

72. Has a senior reviewer checked this Stage 4 abstraction?

- o Yes - completely (indicate which senior reviewer)
- o Partially (indicate where re-review was left off, i.e. question #)
- o No (indicate any important questions/comments for senior reviewer)
- o Not applicable (first reviewer is a senior reviewer)

Appendix D. Articles excluded solely on the basis that intervention focused only on patient education or promotion of self-management

1. Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care.* 1995;18:943-949.

2. Barth R, Campbell LV, Allen S, Jupp JJ, Chisholm DJ. Intensive education improves knowledge, compliance, and foot problems in type 2 diabetes. *Diabet Med.* 1991;8:111-117.

3. Boehm S, Schlenk EA, Raleigh E, Ronis D. Behavioral analysis and behavioral strategies to improve self-management of type II diabetes. *Clin Nurs Res.* 1993;2:327-344.

4. Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care.* 2002;25:259-268.

5. Cooper HC, Booth K, Gill G, IN. Patients' perspectives on diabetes health care education. *Health Education Research.* 2003;18:191-206.

6. Corbett CF, IN. A randomized pilot study of improving foot care in home health patients with iabetes. *Diabetes Educator.* 2003;29:273-282.

7. Domenech MI, Assad D, Mazzei ME, Kronsbein P, Gagliardino JJ. Evaluation of the effectiveness of an ambulatory teaching/treatment programme for non-insulin dependent (type 2) diabetic patients. *Acta Diabetol.* 1995;32:143-147.

8. Estey AL, Tan MH, Mann K. Follow-up intervention: its effect on compliance behavior to a diabetes regimen. *Diabetes Educ.* 1990;16:291-295.

9. Gilliland SS, Azen SP, Perez GE, Carter JS. Strong in body and spirit: lifestyle intervention for Native American adults with diabetes in New Mexico. *Diabetes Care.* 2002;25:78-83.

10. Glasgow RE, Toobert DJ, Hampson SE, Strycker LA. Implementation, generalization and long-term results of the "choosing well" diabetes self-management intervention. *Patient Educ Couns.* 2002;48:115-122.

11. Goldhaber-Fiebert JD, Goldhaber-Fiebert SN, Tristan ML, Nathan DM. Randomized controlled community-based nutrition and exercise intervention improves glycemia and cardiovascular risk factors in type 2 diabetic patients in rural Costa Rica. *Diabetes Care.* 2003;26:24-29.

12. Greenfield S, Kaplan SH, Ware JE, Jr., Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med.* 1988;3:448-457.

13. Halbert RJ, Leung KM, Nichol JM, Legorreta AP. Effect of multiple patient reminders in improving diabetic retinopathy screening. A randomized trial. *Diabetes Care.* 1999;22:752-755.

14. Hendricks LE, Hendricks RT. The effect of diabetes self-management education with frequent follow-up on the health outcomes of African American men. *Diabetes Educ.* 2000;26:995-1002.

15. Hiss RG, Gillard ML, Armbruster BA, McClure LA. Comprehensive evaluation of community-based diabetic patients: effect of feedback to patients and their physicians: a randomized controlled trial. *Diabetes Care.* 2001;24:690-694.

16. Hopper SV, Miller JP, Birge C, Swift J. A randomized study of the impact of home health aides on diabetic control and utilization patterns. *Am J Public Health.* 1984;74:600-602.

17. Pieber. Evaluation of a structured teaching and treatment programme for type2 diabetes in general ractice in a rural area of Austria. *Diabetes Medicine.* 1995;112:349-354.

18. Krier BP, Parker RD, Grayson D, Byrd G. Effect of diabetes education on glucose control. *J La State Med Soc.* 1999;151:86-92.

19. Lafata JE, Baker AM, Divine GW, McCarthy BD, Xi H. The use of computerized birthday greeting reminders in the management of diabetes. *J Gen Intern Med.* 2002;17:521-530.

20. Lo R, Lo B, Wells E, Chard M, Hathaway J. The development and evaluation of a computer-aided diabetes education program. *Aust J Adv Nurs.* 1996;13:19-27.

21. Lustman PJ, Griffith LS, Freedland KE, Kissel SS, Clouse RE. Cognitive behavior therapy for depression in type 2 diabetes mellitus. A randomized, controlled trial. *Ann Intern Med.*

1998;129:613-621.

22. Malone JM, Snyder M, Anderson G, Bernhard VM, Holloway GA, Jr., Bunt TJ. Prevention of amputation by diabetic education. *American Journal of Surgery.* 1989;158:520-523.

23. McCabe CJ, Stevenson RC, Dolan AM. Evaluation of a diabetic foot screening and protection rogramme. *Diabet Med.* 1998;15:80-84.

24. Mulrow C, Bailey S, Sonksen PH, Slavin B. Evaluation of an Audiovisual Diabetes Education rogram: negative results of a randomized trial of patients with non-insulin-dependent diabetes mellitus. *J Gen Intern Med.* 1987;2:215-219.

25. Noel PH, Larme AC, Meyer J, Marsh G, Correa A, Pugh JA. Patient choice in diabetes education curriculum. Nutritional versus standard content for type 2 diabetes. *Diabetes Care.* 1998;21:896-901.

26. Pill R, Stott NC, Rollnick SR, Rees M. A randomized controlled trial of an intervention designed to mprove the care given in general practice to Type II diabetic patients: patient outcomes and professional ability to change behaviour. *Fam Pract.* 1998;15:229-235.

27. Rabkin SW, Boyko E, Wilson A, Streja DA. A randomized clinical trial comparing behavior modification and individual counseling in the nutritional therapy of non-insulin-dependent diabetes mellitus: comparison of the effect on blood sugar, body weight, and serum lipids. *Diabetes Care.* 1983;6:50-56.

28. Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J.* 1999;92:667-672.

29. Rutten G, van Eijk J, de Nobel E, Beek M, van der Velden H. Feasibility and effects of a diabetes type II protocol with blood glucose self-monitoring in general practice. *Fam Pract.* 1990;7:273-278.

30. Samaras K, Ashwell S, Mackintosh AM, Fleury AC, Campbell LV, Chisholm DJ. Will older sedentary people with non-insulin-dependent diabetes mellitus start exercising? A health promotion model. *Diabetes Res Clin Pract.* 1997;37:121-128.

31. Schwedes U, Siebolds M, Mertes G. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care.* 2002;25:1928-1932.

32. Shandro MT, Pick ME, Gruninger A, Ryan EA, IN. Diabetes care: interventions in the community. *Diabetes Care.* 2002;25:941-942.

33. Skaer TL, Sclar DA, Markowski DJ, Won JK. Effect of value-added utilities on prescription refill compliance and Medicaid health care expenditures--a study of patients with non-insulin-dependent diabetes mellitus. *J Clin Pharm Ther.* 1993;18:295-299.

34. Smith DM, Weinberger M, Katz BP. A controlled trial to increase office visits and reduce hospitalizations of diabetic patients. *J Gen Intern Med.* 1987;2:232-238.

35. Smith DE, Heckemeyer CM, Kratt PP, Mason DA. Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM. A pilot study. *Diabetes Care.* 1997;20:52-54.

36. Surwit RS, van Tilburg MA, Zucker N, et al. Stress management improves long-term glycemic control in type 2 diabetes. *Diabetes Care.* 2002;25:30-34.

37. Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia.* 2002;45:1231-1239.

38. Tsang MW, Mok M, Kam G, et al. Improvement in diabetes control with a monitoring system based on a hand-held, touch-screen electronic diary. *J Telemed Telecare.* 2001;7:47-50.

39. Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults--the effect of a posteducational follow-up program. *Diabetes Educator.* 1993;19:25-30.

40. Werdier D, Jesdinsky HJ, Helmich P. A randomized, controlled study on the effect of diabetes counseling in the offices of 12 general practitioners. *Rev Epidemiol Sante Publique.* 1984;32:225-229.

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Appendix E. Summary of results for each included study

Table E1. Main results for glycemic control and provider adherence

Study details	Intervention	Provider adherence outcomes	Disease control outcomes	Patient adherence
Ahring, 1992[1]	**Intervention group:** Patients transmitted fingerstick readings by telephone system automatically to provider (SMx, FR) **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 11.2 ± 1.8→10.2 ± 1.2 **Intervention:** 10.6 ± 2.8 → 9.2 ± 1.1	
			Other outcomes: serum blood glucose, weight	
Albisser, 1996[2]	**Comparison 1:** **Intervention group:** Patients reported HbA1c values, symptoms, life changes to automated system, received medication/other advice; providers received feedback of patient status (SMx, FR, OC/medrcrd) **Control group:** Registered for, but did not use automated system		**Disease control 1:** HbA1c **Control:** 10.2 ± 1.4→10.3 ± 1.3 **Intervention:** 10.1 ± 1.5→8.8 ± 1.4	
			Other outcomes: weight	
	Comparison 2: **Intervention group:** Patients reported HbA1c values, symptoms, life changes to automated system, received medication/other advice; providers received feedback of patient status (SMx, FR, OC/medrcrd) **Control group:** Registered for, but did not use automated system		**Disease control 1:** HbA1c **Control:** 8.2 ± 1.9→8.6 ± 1.7 **Intervention:** 8.9 ± 1.7→7.9 ± 1.2	
			Other outcomes: weight	
Aubert, 1998[3]	**Intervention group:** Nurse case management supervised by GP, telephone reminders to patient, diabetes education (PtE, FR, OC/DxMx) **Control group:** Diabetes education only	**Other outcomes:** % patients with dipstick test in past year, % patients with protein/microalbumin test in past year	**Other outcomes:** median HbA1c, median SBP, median DBP, fasting blood glucose, total cholesterol, HDL-C, LDL-C, triglycerides, weight	
Benjamin, 1999[4]	**Intervention group:** Providers developed and implemented clinical practice guidelines based on problem-		**Disease control:** HbA1c **Control:** 9.21 ± 2.3→9.15 ± 2.3 **Intervention:** 9.3 ± 2.4 →8.68	

	based learning (PvE) **Control group:** no intervention/usual care		± 2.1	
Boucher, 1987[5]	**Intervention group:** Diabetes support service gave lists of patients requiring tests to provider, provider education in examination for diabetic fundi (PtR, PvE, FR, OC/medrcrd) **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 12.6 ± 3.2→12.5 ± 2.6 **Intervention:** 13.4 ± 2.9→11.4 ± 2.3	
Branger, 1998[6]	**Intervention group:** Physicians equipped with electronic communication system to facilitate communication between PCP and specialist (FR, OC/other) **Control group:** All providers had electronic patient records		**Disease control:** HbA1c **Control:** 6.6 ± NR→ 6.5 ± NR **Intervention:** 7.0 ± NR→ 6.8 ± NR	
Cagliero, 1999[7]	**Intervention group:** Patients had HbA1c measured with benchtop analyzer with results immediately available to provider during visit (FR) **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 8.49 ± 1.59→ 8.3 ± NR **Intervention:** 8.67 ± 1.79→ 8.27 ± NR	
Clancy, 2003[8]	**Intervention group:** Patients had group instead of individual physician visits consisting of education and one-on-one consult (PtE, OC/DxMx/team) **Control group:** no intervention/usual care	**Other outcome:** adherence to 8 out of 10 diabetes guidelines		
Clifford, 2002[9]	**Intervention group:** Pharmacist monitored patients and made treatment decisions, consulted with MD (OC/DxMx **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 8.5 ± 1.6→8.1 ± 1.6 **Intervention:** 8.4 ± 1.4→8.2 ± 1.5	
Coffey, 1995[10]	**Intervention group:** Patients on managed care plan **Control group:** Traditional fee-for-service plan			**Patient compliance:** % patients compliant with home monitoring **Control:** 60%→63% **Intervention:** 63%→60% **Net difference:** -6%
Dargis,	**Intervention group:** Patients		**Other outcomes:** recurrent	

1999[11]	received foot care in specialty clinic, special footwear, foot care education (PtE, OC/team) **Control group:** one time foot consult with education/advice		foot ulcers, amputations	
de Sonnaville, 1997[12]	**Intervention group:** Diabetes support service provides GP with consult of podiatrist, diabetologist, and diabetes nurse educator; lab measurements at patient home; retinal camera (PtE, SMx, FR, OC/team) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 7.6 ± 1.9→7.6 ± 1.5 **Intervention:** 7.5 ± 1.7→7.0 ± 1.3	
			Disease control 2: SBP **Control:** 158.2 ± 23.5→ 155.3 ± 22.9 **Intervention:** 147.2 ± 21.7→ 147.7 ± 23.5	
			Disease control 2: DBP **Control:** 88.9 ± 11.7→ 85.3 ± 11.4 **Intervention:** 87.7 ± 10.4→ 83.0 ± 12.6	
			Other outcomes: fasting blood glucose, BMI, total chol, HDL-chol, triglycerides, % smokers	
Deeb, 1988[13]	**Intervention group:** Providers attended diabetes education seminars, had quarterly consults with outside leaders, received printed education modules (PvE, OC/team) **Control group:** no intervention/usual care	**Adherence measure:** % patients with BP measured in past year **Control:** 99%→99% **Intervention:** 100%→100% **Net difference:** 0%		
		Adherence measure: % patients with lower-extremity exam in past year **Control:** 27%→41% **Intervention:** 66%→94% **Net difference:** -6%		
		Other outcomes: % patients with urinalaysis, lower-extremity history, referral for retinopathy exam, retinopathy history, and retinopathy exam in past year		
Feder, 1995[14]	**Intervention group:** Diabetes	**Adherence measure:** %		

	care guidelines introduced, followed by provider audit and feedback as follow-up (PvE, Aud) **Control group:** Providers received guidelines on asthma, not diabetes	patients with HbA1c record **Control:** 20.6%→30% **Intervention:** 24.8%→48.1% **Net difference:** +13.9%		
		Adherence measure: % patients with BP record **Control:** 66.1%→58.3% **Intervention:** 69%→79.5% **Net difference:** +18.3%		
		Adherence measure: % patients with foot exam record **Control:** 28.3%→27.2% **Intervention:** 31.4%→51.8% **Net difference:** +21.5%		
		Adherence measure: % patients with funduscopy record **Control:** 19.4%→20% **Intervention:** 20.5%→38.1% **Net difference:** +17%		
		Other outcomes: % patients with record of blood glucose and weight		
Franz, 1995[15]	**Comparison 1** **Intervention group:** Patients received diet therapy with dietitian who made recommendations to PCP on medical therapy (PtE, SMx, OC/team) **Control group:** Patients had one meeting with dietitian to discuss diet goals and advice		**Disease control :** HbA1c **Control:** 8.3 ± 1.7→8.1 ± 1.7 **Intervention:** 8.1 ± 1.6→7.7 ± 1.2	
	Comparison 2 **Intervention group:** Patients received diet therapy with dietitian who made recommendations to PCP on medical therapy (PtE, SMx, OC/team) **Control group:** Patients had one meeting with dietitian to discuss diet goals and advice		**Disease control :** HbA1c **Control:** 8.2 ± 2.2→6.8 ± 1.3 **Intervention:** 8.8 ± 1.9→6.8 ± 1.0	
Frijling, 2002[16]	**Intervention group:** Providers received didactic education and audit and feedback to improve compliance with care	**Adherence measure:** % patients with BP record in last year **Control:** 89%→92%		

	guidelines (PvE, Aud) **Control group:** no intervention/usual care	**Intervention:** 91%→94% **Net difference:** -1%		
		Adherence measure: % patients with foot exam record in last year **Control:** 30%→39% **Intervention:** 24%→43% **Net difference:** +10%		
		Adherence measure: % patients with eye exam record in last year **Control:** 69%→67% **Intervention:** 61%→70% **Net difference:** +11%		
		Other outcomes: % patients with discussion of body weight control		
Gaede, 2003[17, 18]*	**Intervention group:** Intensive treatment with stepwise implementation of behaviour modification and pharmacologic therapy, dietary and exercise counselling (PtE, OC/DxMx) **Control group:** All patients received individual diabetic dietary advice		**Disease control 1:** HbA1c (mean and SE) **Control:** 8.8 ± 1.7→9.0 ± NR **Intervention:** 8.4 ± 1.6→7.8 ± NR	
			Disease control 2: SBP **Control:** 149 ± 19→ 146 ± NR **Intervention:** 146 ± 20→ 132 ± NR	
			Disease control 2: DBP **Control:** 86 ± 11→ 78 ± NR **Intervention:** 85 ± 10→ 73 ± NR	
			Other outcomes: urinary AER, triglycerides, total cholesterol, GFR	
Ginsberg, 1996[19]	**Intervention group:** Providers trained in Staged Diabetes Management (benchmarking, flowcharts for decision-making, evaluation, feedback to community); patients received education (PtE, PvE) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 10.3 ± 2.1→10.4 ± 2.1 **Intervention:** 10.2 ± 2.8→8.8 ± 0.7	

Glasgow, 1996[20]	**Intervention group:** Brief, computer-based assessment of dietary compliance. Patients received dietary advice, one-on-one counselling, a video and 2 follow-up calls (PtE, SMx, OC/team) **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 7.9 ± NR→7.7 ± NR **Intervention:** 7.8 ± NR → 7.6 ± NR	
			Other outcomes: serum blood glucose	
Groeneveld, 2001[21]	**Intervention group:** Patients followed-up with structured diabetes care service including education, testing and advice to PCPs on drug therapy (PtE, FR, OC/DxMx) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 7.5 ± 1.8 (post) **Intervention:** 7.1 ± 1.2 (post)	
			Disease control 2: SBP **Control:** 149 ± 24→ 143 ± 21 **Intervention:** 137 ± 21→ 135 ± 18	
			Disease control 2: DBP **Control:** 86 ± 9.7→ 82 ± 9 **Intervention:** 91 ± 9→ 90 ± 8	
			Other outcomes: serum blood glucose, total cholesterol, weight, creatinine	
Hartmann, 1995[22]	**Intervention group:** Providers participated in a series of structured peer-review groups focused on diabetes patient records, didactic education and role-play (PvE, Aud) **Control group:** Providers had same type of group session only once	**Adherence measure:** % patients with at least one HbA1c record per quarter **Control:** 24.4%→32.3% **Intervention:** 27.6%→26.8% **Net difference:** -8.7%		**Patient compliance:** % patients with documentation of glucose self-mx at least once per quarter **Control:** 21.3%→17.1% **Intervention:** 7.9%→11.3% **Net difference:** +7.6%
		Adherence measure: % patients with record of fundoscopy and foot exam with tuning fork **Control:** 1.2%→0.6% **Intervention:** 20.5%→20.5% **Net difference: +**0.6%		

		Adherence measure: % patients with record of fundoscopy at least once per year **Control:** 5.5%→13.4% **Intervention:** 8.4%→32.2% **Net difference: +**15.9%		
		Other outcomes: % patients with pallaesthesia at least once per year, % patients with documentation of triglycerides, HDL-C and total chol, weight and BP, albumin, serum creatinine at least once per year, blood glucose at least once per quarter		
Hayes, 1984[23]	**Intervention group:** Patients received care from a GP instead of a diabetes specialist clinic, GPs received printed care guidelines (PvE, OC/team) **Control group:** no intervention/usual care (diabetes specialist clinic)		**Disease control:** HbA1c **Control:** 9.5 ± 1.77 (post) **Intervention:** 10.4 ± 1.73 (post)	
Hetlevik, 2000[24]	**Intervention group:** Computerized support system provided physician with treatment, test, and referral recommendations; providers received feedback of missing tests at 6 month intervals (PvR, Aud) **Control group:** no intervention/usual care	**Adherence measure:** % patients with record of HbA1c during study period **Control:** 77.6%→81.2% **Intervention:** 72.5%→79.5% **Net difference: +**3.4%	**Disease control 1:** HbA1c **Control:** 8.2 ± 1.8→ 7.9 ± 1.6 **Intervention:** 8.2 ± 1.8→ 7.8 ± 1.6	
		Adherence measure: % patients with record of BP during study period **Control:** 77.4%→81.5% **Intervention:** 78.2%→81.3% **Net difference:** -1%	**Disease control 2:** SBP **Control:** 151.7 ± 21.3→ 152.7 ± 19 **Intervention:** 152.5 ± 21.6→ 151.5 ± 22.1	
		Other outcomes: % patients with record of cholesterol during study period	**Disease control 3:** DBP **Control:** 85.1 ± 10.1→ 85.3 ± 9.9 **Intervention:** 84.5 ± 10→ 82.8 ± 10.6	
Hirsch, 2002[25]	**Intervention group:** Provider intervention: reminders for tests, diabetes management guidelines, didactic teaching, feedback of HbA1c levels, pharmacist case		**Disease control 1:** HbA1c **Control:** 7.57 ± NR→ 8.2 ± NR **Intervention:** 7.64 ± NR→	

	management, access to endocrinologist (PvE, Aud, OC/DxMx, team) **Control group:** Providers received reminders to test HbA1c		7.56 ± NR	
			Disease control 2: SBP **Control:** 134 ± NR→ 137.1 ± NR **Intervention:** 135 ± NR→ 133.8 ± NR	
			Disease control 3: DBP **Control:** 80 ± NR→ 79.19 ± NR **Intervention:** 79 ± NR→ 75.21 ± NR	
Hoskins, 1993[26]	**Comparison 1** **Intervention group:** GP received one time letter requesting adherence to recommended management protocol, and measurement of HbA1c, BP, weight (OC/other) **Control group:** All patients received 3-6 mo education before intervention.	**Adherence measure:** % HbA1c results received from GP out of number of know GP attendances **Control:** 98.4% post-intervention **Intervention:** 45.6 % post-intervention	**Disease control 1:** HbA1c **Control:** 8.9 ± 2.5→ 7.3 ± 1.6 **Intervention:** 8.4 ± 2.6→ 6.9 ± 1.3	**Patient compliance:** % patients attended visit 3 (out of 3) to their GP during study period **Control:** 53% **Intervention:** 35%
		Adherence measure: % weight measurements received from GP out of number of know GP attendances **Control:** 98.3% post-intervention **Intervention:** 70.6 % post-intervention	**Disease control 2:** SBP **Control:** 150 ± 23→ 133 ± 19 **Intervention:** 148 ± 23→ 136 ± 14	
		Adherence measure: % BP measurements received from GP out of number of know GP attendances **Control:** 92.7% post-intervention **Intervention:** 89.7 % post-intervention	**Disease control 3:** DBP **Control:** 90 ± 13→ 81 ± 13 **Intervention:** 90 ± 15→ 80 ± 11	
			Other outcomes: weight	
	Comparison 2	**Adherence measure:** %	**Disease control 1:** HbA1c	**Patient**

	Intervention group: Shared care between patient, GP, clinic. Nurse liaised btw patient and GP, reminded GP of measurements. Patient received copy of management protocol (SMx, PtR, PvR, OC/team/other) **Control group:** All patients received 3-6 mo education before intervention.	HbA1c results received from GP out of number of know GP attendances **Control:** 98.4% post-intervention **Intervention:** 66 % post-intervention	**Control:** 8.9 ± 2.5→ 7.3 ± 1.6 **Intervention:** 8.5 ± 2.2→ 6.6 ± 1.6	**compliance:** % patients attended visit 3 (out of 3) to their GP during study period **Control:** 53% **Intervention:** 72%
		Adherence measure: % weight measurements received from GP out of number of know GP attendances **Control:** 98.3% post-intervention **Intervention:** 93.5 % post-intervention	**Disease control 2:** SBP **Control:** 150 ± 23→ 133 ± 19 **Intervention:** 145 ± 24→ 130 ± 25	
		Adherence measure: % BP measurements received from GP out of number of know GP attendances **Control:** 92.7% post-intervention **Intervention:** 94.8 % post-intervention	**Disease control 3:** DBP **Control:** 90 ± 13→ 81 ± 13 **Intervention:** 88 ± 13→ 81 ± 11	
			Other outcomes: weight	
Hurwitz, 1993[27]	**Intervention group:** Patients received computer-generated reminders to get blood and urine tests done. Results relayed to providers, appointments made as necessary (PtR, FR) **Control group:** usual care with specialist		**Disease control:** HbA1c **Control:** 10.3 ± 2.3→ 10.6 ± 2.5 **Intervention:** 10.4 ± 2.5→ 10.3 ± 2.3	
			Other outcomes: serum blood glucose, % mortality	
Jaber, 1996[28]	**Intervention group:** Pharmacist was responsible for medication adjustments and provided education, dietary and exercise counselling (PtE, Oc/team) **Control group:** no intervention/usual care		**Disease control :** HbA1c **Control:** 12.2 ± 3.5→ 12.1 ± 3.7 **Intervention:** 11.5 ± 2.9→ 9.2 ± 2.1	
			Other outcomes: serum blood glucose	

Kiefe, 2001[29]	**Intervention group:** Providers had QI education and audit and feedback, as well as "achievable benchmarks" for specific processes of care (Aud) **Control group:** Provider education and audit and feedback	**Adherence measure:** % patients with at least one HbA1c in 18-month period **Control:** 35%→65% **Intervention:** 31%→70% **Net difference:** +9%		
		Adherence measure: % patients with at least one foot exam in 18-month period **Control:** 32%→45% **Intervention:** 46%→61% **Net difference:** +2%		
Kinmonth, 1998[30]	**Intervention group:** Providers received training in patient-centered care as well as materials to give to patients (PtE, PvE) **Control group:** Limited training on use of guidelines and patient materials		**Disease control 1:** HbA1c **Control:** 7.17 ± NR (post) **Intervention:** 7.07 ± NR (post)	
			Disease control 2: SBP **Control:** 141.5 ± NR→ 142.8 ± NR **Intervention:** 144.1 ± NR→ 144.3 ± NR	
			Disease control 3: DBP **Control:** 83.7 ± NR→ 87.2 ± NR **Intervention:** 85.5 ± NR→ 89 ± NR	
			Other outcomes: total cholesterol, BMI, % smoking	
Kogan, 2003[31]	**Intervention group:** Residents received report card of individual and group disease management performance and brief discussion with faculty (Aud) **Control group:** no intervention/usual care	**Other outcomes: %** overall diabetes management (pneumovax, flu shot, creatinine, microalbumin, appropriate use of ACE-inhibitors, dilated eye exam, foot exam, lipid screening, lipid management, HbA1c, diet, exercise) recorded in chart		
Legorreta, 1996[32]	**Comparison 1** **Intervention group:** Nurse case managed patients using		**Disease control:** HbA1c **Control:** 8.3 ± 2.6→ 9.1 ± NR **Intervention:** 8.9 ± 2.1→ 6.9	

	protocols for management. Computer information system generated reminders and algorithms for medication adjustment. Diabetologist available for consult (PtR, PvE, OC/DxMx/medrcrd/other) **Control group:** no intervention/usual care		± NR	
			Other outcomes: LDL-cholesterol	
	Comparison 2 **Intervention group:** Nurse case managed patients using protocols for management. Computer information system generated reminders and algorithms for medication adjustment. Diabetologist available for consult (PtR, PvE, OC/DxMx/medrcrd/other) **Control group:** no intervention/usual care		**Disease control:** HbA1c **Control:** 8.6 ± 2.0→ 8.4 ± NR **Intervention:** 10.3 ± 2.5→ 9.0 ± NR	
			Other outcomes: LDL-cholesterol	
Levetan, 2002[33]	**Intervention group:** Patients received a wall poster and wallet card containing current lab values and goals, as well as postcards with reminders. Providers received lab values as well (PtE, SMx, PtR, PvR, FR) **Control group:** All patients had finished 3 month diabetes education before enrolment in study		**Disease control 1:** HbA1c **Control:** 8.39 ± 2.03→ 7.79 ± 1.91 **Intervention:** 8.85 ± 2.48→ 7.78 ± 2.22	
			Other outcomes: % patients with HbA1c in range, HDL-chol, LDL-chol	
Lim, 2002[34]	**Intervention group:** Case management with PCP, case manager, podiatrist, dietitian. Patients received education and reminders. Providers received reminders for testing/referral (PtE, PvR, OC/DxMx) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 8.28 ± 1.94→ 8.28 ± 1.69 **Intervention:** 9.81 ± 2.22→ 7.82 ± 1.75	
			Disease control 2: SBP **Control:** 138.9 ± 19.3→	

			136.8 ± 18.5 **Intervention:** 142.1 ± 16.4→ 134.2 ± 10.1	
			Disease control 3: DBP **Control:** 80.8 ± 8.9→ 79.1 ± 8.41 **Intervention:** 82.8 ± 10.3→ 80.5 ± 7.8	
			Other outcomes: % patients with HbA1c in range, % patients with BP in range	
Litzelman, 1993[35]	**Intervention group:** Patients received education on foot care and reminders by phone and mail to continue foot care. Provider received reminders in chart to educate patient and perform foot care (PtE, PtR, PvE, PvR) **Control group:** no intervention/usual care		**Other outcomes:** % patients with serious foot lesions	
Lobach, 1997[36]	**Intervention group:** Computerized system of guidelines provided physicians with reminders for tests/referrals (PvR) **Control group:** no intervention/usual care	**Adherence measure:** % provider compliance with chronic glycemia monitoring **Control:** 52.8% (post) **Intervention:** 57.4% (post)		
		Adherence measure: % provider compliance with cholesterol level determination **Control:** 13.4% (post) **Intervention:** 43.7% (post)		
		Adherence measure: % provider compliance with foot exam **Control:** 30% (post) **Intervention:** 55.6% (post)		
		Adherence measure: % provider compliance with opthalmologic exam **Control:** 3.2% (post) **Intervention:** 18.8% (post)		
		Other outcomes: % provider compliance with urine protein		

		determination		
Mazzuca, 1986[37]	**Comparison 1** **Intervention group:** Providers had one didactic session with three problem-oriented follow-up sessions, distribution of guidelines, access to specialist, computer-generated guideline reminders (PvE, PvR, Aud) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 10.19 ± NR→ 10.74 ± NR **Intervention:** 10.51 ± NR→ 10.65 ± NR	
			Disease control 2: SBP **Control:** 137.2 ± NR→ 144.9 ± NR **Intervention:** 142.5 ± NR→ 146.4 ± NR	
			Disease control 3: DBP **Control:** 81.4 ± NR→ 85.2 ± NR **Intervention:** 83.1± NR→ 83.4 ± NR	
			Other outcomes: serum creatinine, fasting blood glucose	
	Comparison 2 **Intervention group:** Providers had one didactic session with three problem-oriented follow-up sessions, distribution of guidelines, access to specialist, computer-generated guideline reminders; patients had didactic sessions and dietary education (PtE, PtR, PvE, PvR, Aud) **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 10.19 ± NR→ 10.74 ± NR **Intervention:** 11.34 ± NR→ 10.42 ± NR	
			Disease control 2: SBP **Control:** 137.2 ± NR→ 144.9 ± NR **Intervention:** 140.4 ± NR→ 145 ± NR	
			Disease control 3: DBP **Control:** 81.4 ± NR→ 85.2 ± NR **Intervention:** 81.8± NR→	

			81.3 ± NR	
			Other outcomes: serum creatinine, fasting blood glucose	
McDermott, 2001[38]	**Intervention group:** Visit to clinic by outreach team (diabetologist, nutritionist, podiatrist, diabetes healthcare worker), reminder and recall system (PtR, PvE, PvR, Aud, OC/medrcrd) **Control group:** Outreach team visits, audit of past clinician adherence guidelines	**Adherence measure:** % patients with HbA1c check in past 6 mo. **Control:** 60%→62% **Intervention:** 70%→73% **Net difference:** +1%	**Other outcomes:** % patients with HbA1c in range, % patients with BP in range	
		Adherence measure: % patients with BP check in past 6 mo. **Control:** 64%→57% **Intervention:** 76%→65% **Net difference:** -4%		
		Adherence measure: % patients with foot check in past year **Control:** 52%→55% **Intervention:** 60%→72% **Net difference:** +9%		
		Adherence measure: % patients with opthalmologist check in past year **Control:** 18%→22% **Intervention:** 21%→25% **Net difference:** 0%		
		Other outcomes: % patients with serum creatinine past yr, lipids past yr, urinary ACR past yr		
Meigs, 2003[39]	**Intervention group:** Providers given access to web-based system of clinical information and care recommendations for individual patients to be used during visit (PvE, PvR) **Control group:** no intervention/usual care	**Adherence measure:** % patients with at least one HbA1c in past year **Control:** 88%→87% **Intervention:** 86%→87.6% **Net difference:** -2.6%	**Disease control 1:** HbA1c (mean and SE) **Control:** 8.1 ± 0.1→ 8.24 ± NR **Intervention:** 8.4 ± 0.1→ 8.17 ± NR	
		Adherence measure: % patients with at least one BP in past year **Control:** 98.6%→97.2% **Intervention:** 97.4%→98.4%	**Disease control 2:** SBP **Control:** 136.9± 1.2→ 134.7± NR **Intervention:** 138.1 ± 1.2→ 138.9 ± NR	

		Net difference: +0.4%		
		Adherence measure: % patients with at least one foot exam in past year **Control:** 82.1%→81.4% **Intervention:** 65.5%→75.3% **Net difference:** +10.5%	**Disease control 3:** DBP **Control:** 76.4 ± 0.6→ 75.6 ± NR **Intervention:** 78.3± 0.6→ 79.1± NR	
		Adherence measure: % patients with at least one eye exam in past year **Control:** 41.2%→42.9% **Intervention:** 29.3%→34.8% **Net difference:** +3.8%	**Other outcomes:** % patients with HbA1c and BP in range, LDL-chol	
		Other outcomes: % patients with at least on LDL-chol in past year		
O'Connor, 1996[40]	**Intervention group:** Continuous quality improvement program of: audit and feedback, patient education by RN, nurse responsibility for care of poorly controlled diabetics (PtE, Aud, OC/DxMx) **Control group:** no intervention/usual care		**Disease control:** HbA1c (mean ± SE) **Control:** 8.4 ± 0.19→ 8.8 ± 0.17 **Intervention:** 8.9 ± 0.22→ 7.9 ± 0.17	
			Other outcomes: % patients with HbA1c in range	
Oh, 2003[41]	**Intervention group:** Patients received regular telephone calls to monitor glucose and diet and make medication adjustments. Changes and data relayed to MD (PtE, FR) **Control group:** no intervention, usual care		**Disease control:** HbA1c **Control:** 8.4 ± 1.0→ 9.0 ± 1.2 **Intervention:** 8.9 ± 1.2→ 7.7 ± 1.0	
			Other outcomes: FBG, 2-hr post prandial BG, BMI	
Olivarius, 2001[42]	**Intervention group:** Providers prompted to see patients every 3 months and follow care guidelines, received annual guideline seminar and audit and feedback of individual patient status (PtE, PvE, PvR, Aud) **Control group:** no intervention/usual care		**Other outcomes:** % patients with HbA1c and BP in range, MI, stroke, amputation, retinopathy, neuropathy, angina pectoris, microalbuminuria, smoking; mean/median total cholesterol, triglycerides, serum blood glucose, serum creatinine	
Ovhed, 2000[43]	**Intervention group:** Patients care for primary by RN using care guidelines (OC/team/other)	**Adherence measure:** % patients with record of HbA1c during study year **Control:** 36% post-		**Patient compliance:** % patients with record of urine and

	Control group: no intervention/usual care	intervention **Intervention:** 97% post-intervention		blood glucose self-measurement during study year
		Adherence measures (HTN/CAD): % patients with record of body weight, cholesterol, TG, BP in study year		
		Adherence measure: % patients with fundus photo during study year **Control:** 47% **Intervention:** 73%		
		Other outcome: % patients with FBG record during study year		
Palmer, 1985[44]	**Intervention group:** Provider quality assurance training and audit and feedback of selected cases (Aud, OC/other) **Control group:** no intervention/usual care	**Other outcomes:** % follow-up of abnormal glucose levels		
Piette, 2000[45]	**Intervention group:** Automated telephone system for patient reporting of blood glucose, symptoms, self-care behaviours. Results relayed from nurse to physician, nurse follow-up to patient by phone (PtE, SMx, FR, OC/team **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 8.6 ± 1.8→ 8.3 ± 1.9 **Intervention:** 8.8 ± 1.8→ 8.2 ± 1.9	
			Other outcomes: % patients with HbA1c in a range, serum glucose	
Piette, 2001[46]	**Intervention group:** Automated telephone system for patient reporting of blood glucose, symptoms, self-care behaviours. Results relayed from nurse to physician, nurse follow-up to patient by phone (PtE, SMx, PtR, FR, OC/team **Control group:** no intervention/usual care		**Disease control 1:** HbA1c **Control:** 8.1 ± 1.7→ 8.2 ± 0.1 (SEM) **Intervention:** 8.2 ± 1.7→ 8.1 ± 0.1 (SEM)	
			Other outcomes: % patients with HbA1c in a range, serum glucose	
Pouwer, 2001[47]	**Intervention group:** Patients monitored twice by diabetes nurse specialist and survey for psychological wellbeing,		**Disease control:** HbA1c **Control:** 7.8 ± NR→ 7.7 ± NR **Intervention:** 7.8 ± NR→ 7.7	

	referred to psychologist if appropriate (OC/other) **Control group:** Patients had two meetings with diabetes nurse specialist.		± NR	
Reed, 2001[48]	**Intervention group:** 3 diabetes care clinics created, used to introduce care guidelines; patients given education and clinical data cards to bring to appointments; provider education and access to hospital-based specialists (PtE, PvE, FR, OC/team/medrcrd) **Control group:** no intervention/usual care		**Disease control 1:** SBP **Control:** 133.7 ± 19→ 131.3 ± 16.6 **Intervention:** 129.2 ± 18.8→ 126.5 ± 16.4	
			Disease control 2: DBP **Control:** 82.6 ± 9.5→ 81.1 ± 9.1 **Intervention:** 79.4 ± 8.6→ 80.9 ± 8.7	
Renders, 2001[49]	**Intervention group:** Providers received clinical guideline education, audit and feedback and relay of data from central monitoring visit (PvE, FR, Aud) **Control group:** annual visit with resulting data sent to GPs	**Adherence measure:** % patients with HbA1c at least once per year **Control:** 15.6%→29.3% **Intervention:** 34.9%→75.5% **Net difference:** +26.9%	**Other outcomes:** % patients with HbA1c and BP in range, total cholesterol, HDL-cholesterol, triglycerides, BMI	
		Other outcomes: % patients with at least one urine albumin, serum creatinine, triglycerides, total cholesterol, HDL-chol, blood pressure measurements per year, % patients with weight measurements and diabetes visits 4 per year		
Ronnemaa, 1997[50]	**Intervention group:** Patients received foot education and primary prevention from podiatrist (PtE, OC/team) **Control group:** Patients received written information on foot care and preventive practices		**Other outcomes:** % patients with: callosities in calcaneal region and other regions, corns, ingrown toenails, other nail disorders, inability to spread out toes, inability to flex toes	**Patient compliance:** foot self-care score (out of 12) **Control:** 5.3 ± 2.6→ 6.0 ± 2.5 **Intervention:** 5.4 ± 2.8→ 7.0 ± 3.2
Sadur, 1999[51]	**Intervention group:** Multidisciplinary care team of diabetologist, RN educator, pharmacist, dietitian,		**Disease control:** HbA1c **Control:** 9.55 ± NR→ 9.33 ± NR	**Patient compliance:** % patients monitoring BG at home

	behaviourist. Patients received education, foot care, counselling, feedback (PtE, PtR, OC/DxMx/team) **Control group:** no intervention/usual care		**Intervention:** 9.48 ± NR→ 8.18 ± NR	**Control:** 93.4%→93.6% **Intervention:** 90%→97.5%
Smith, 1998[52]	**Intervention group:** Physicians entered clinical data into electronic system during patient visit (OC/medrcrd) **Control group:** no intervention/usual care	**Adherence measure:** % patients with 4 HbA1c measurements per yr **Control:** 51.2% post **Intervention:** 76.9% post	**Disease control 1:** HbA1c **Control:** 10.2 ± 1.9 post **Intervention:** 9.7 ± 1.7 post	
		Adherence measure: % patients with dilated eye exam in past yr **Control:** 65.1% post **Intervention:** 64.1% post	**Disease control 2:** SBP **Control:** 140.9 ± 19.6 post **Intervention:** 138.3 ± 16.9 post	
		Other outcomes: % patients with measurement of urinary microalbumin, lipid profile in past year; % patients with diabetes self-mx and diet education; % smoking patients with advice to quit	**Disease control 2:** DBP **Control:** 93.6 ± 25 post **Intervention:** 80.6 ± 9.6	
Stroebel, 2002[53]	**Comparison 1** **Intervention group:** 20-minute physician meeting every 2 months to remind to use Hot Lists of patients needing test (OC/other) **Control group:** Academic detailing and "hot list" of patients not in compliance	**Adherence measure:** % patients with HbA1c in 6 months **Control:** 77%→74% **Intervention:** 74%→76% **Net difference:** 5%	**Disease control:** HbA1c (mean ± SE) **Control:** 8.1 ± 1.8→ 8.0 ± 1.8 **Intervention:** 8.3 ± 2→ 8.2 ± 2	
		Other outcomes: % patients with LDL-chol in last year	**Other outcomes:** % patients with HbA1c and BP in a range, LDL-Chol	
	Comparison 1 **Intervention group:** 20-minute physician meeting every 2 months to remind to use Hot Lists of patients needing test and reminders to patients on Hot Lists to make appointments (PtR, OC/other) **Control group:** Academic detailing and "hot list" of patients not in compliance	**Adherence measure:** % patients with HbA1c in 6 months **Control:** 77%→74% **Intervention:** 79%→78% **Net difference:** 2%	**Disease control:** HbA1c (mean ± SE) **Control:** 8.1 ± 1.8→ 8.0 ± 1.8 **Intervention:** 8.1 ± 2→ 7.9 ± 1.8	
		Other outcomes: % patients with LDL-chol in last year	**Other outcomes:** % patients with HbA1c and BP in a range, LDL-Chol	
Thompson, 1999[54]	**Intervention group:** Patients received 3x weekly calls from		**Disease control:** HbA1c	

	RN who adjusted insulin and reviewed with MD (PtE, FR, OC/team) **Control group:** no intervention/usual care		**Control:** 9.4 ± 0.8→ 8.9 ± 1.0 **Intervention:** 9.6 ± 1.0→ 7.8 ± 0.8	
Vaughan, 1996[55]	**Intervention group:** Patients were treated by RN using paper algorithms for medication adjustment (OC/team) **Control group:** no intervention/usual care	**Adherence measure:** % patients with HbA1c performed **Control:** 79% post **Intervention:** 100% post	**Other outcomes:** % patients with HbA1c in a range	
Wagner, 2001[56]	**Intervention group:** Patients received care (MD visit, RN visit, pharmacist visit, group education) at chronic care clinic (PtE, SMx, OC/team) **Control group:** no intervention/usual care	**Adherence measure:** % patients with foot exam in past year **Control:** 80.8% post **Intervention:** 87.7% post	**Disease control:** HbA1c **Control:** 7.4 ± NR→ 7.9 ± NR **Intervention:** 7.5 ± NR→ 7.9 ± NR	
		Adherence measure: % patients with retinal eye exam in past year **Control:** 62.2%→63.5% **Intervention:** 60.6%→67.9% **Net difference:** +6%	**Other outcomes:** total cholesterol	
		Other outcomes: % patients with microalbumin test in past year		
Walker, 2001[57]	**Comparison 1** **Intervention group:** Providers had one time problem-based learning education program, printed guidelines, follow-up (PvE) **Control group:** Clinic was sent printed care guidelines with no follow-up	**Adherence measure:** % patients with at least one record of HbA1c **Control:** 44%→63% **Intervention:** 53%→73% **Net difference:** +1%		
		Adherence measure: % patients with document of foot exam **Control:** 22%→50% **Intervention:** 53%→76% **Net difference:** -5%		
		Adherence measure: % patients with documented DFE or referral for DFE **Control:** 37%→33% **Intervention:** 21%→38%		

		Net difference: +21%		
		Other outcomes: % patients with at least one serum creatinine record		
	Comparison 2 **Intervention group:** Providers had one time problem-based learning education program, printed guidelines, follow-up; clinic received printed patient guides to disseminate (PtE, PvE) **Control group:** Clinic was sent printed care guidelines with no follow-up	**Adherence measure:** % patients with at least one record of HbA1c **Control:** 44%→63% **Intervention:** 40%→44% **Net difference:** -15%		
		Adherence measure: % patients with document of foot exam **Control:** 22%→50% **Intervention:** 46%→58% **Net difference:** -16%		
		Adherence measure: % patients with documented DFE or referral for DFE **Control:** 37%→33% **Intervention:** 19%→55% **Net difference:** +40%		
		Other outcomes: % patients with at least one serum creatinine record		
Ward, 1996[58]	**Comparison 1** **Intervention group:** Providers received feedback of their care records compared to the whole group and checklists of guidelines; providers had interview with a GP regarding care guidelines (PvE, Aud) **Control group:** Providers received feedback of their care records compared to the whole group and checklists of guidelines	**Adherence measure:** % patients with one HbA1c per 8 months **Control:** 46.7%→40.7% **Intervention:** 36.9%→54.6% **Net difference:** +23.7%		
		Adherence measure: % patients with record of eye exam or referral to opthalmologist annually		

		Control: 29.6%→31.1% **Intervention:** 23.1%→42.3% **Net difference:** +17.7%		
		Other outcomes: % patients with record of urine and blood glucose (2 per 8 mo); urine protein, urine nitrite, creatinine, total cholesterol, triglycerides (1 per 8 mo); blood pressure, weight, foot reflex exam, feet pulses, feet sensation, nails (annually); alcohol inquiry and advice, diet, exercise, smoking, vaginitis/impotence advice		
	Comparison 2 **Intervention group:** Providers received feedback of their care records compared to the whole group and checklists of guidelines; providers had interview with a nurse regarding care guidelines (PvE, Aud) **Control group:** Providers received feedback of their care records compared to the whole group and checklists of guidelines	**Adherence measure:** % patients with one HbA1c per 8 months **Control:** 46.7%→40.7% **Intervention:** 28.9%→44.6% **Net difference:** +21.7%		
		Adherence measure: % patients with record of eye exam or referral to opthalmologist annually **Control:** 29.6%→31.1% **Intervention:** 19.8%→40.5% **Net difference:** +19.2%		
		Other outcomes: % patients with record of urine and blood glucose (2 per 8 mo); urine protein, urine nitrite, creatinine, total cholesterol, triglycerides (1 per 8 mo); blood pressure, weight, foot reflex exam, feet pulses, feet sensation, nails (annually); alcohol inquiry and advice, diet, exercise, smoking, vaginitis/impotence advice		
Weinberger, 1995[59]	**Intervention group:** Nurse performed patient education, medication counselling, liaison to MD by telephone contact with patients (PtE,		**Disease control:** HbA1c **Control:** 10.7 ± 3.4→ 11.1 ± 2.4 **Intervention:** 10.7 ± 3.3→	

	SMx, PtR, FR, OC/DxMx) **Control group:** no intervention/usual care		10.5 ± 2.7	
			Other outcomes: serum blood glucose, total cholesterol, LDL-C, HDL-C, triglycerides	

*Results reported come from both articles.

Table E2. Main results for blood pressure

Setting	Study period (duration)	Study Design* (Number of Patients)	QI strategies employed ^	Systolic blood pressure results
28 general practices (Netherlands)[12]	1989-1995 (6 years)	CBA (505, 28 providers)	Patient Ed, Self-Mx, Facil relay, Org change	Control: 158.2±23.5 → 155.3±22.9 Intervention: 147.2±21.7 → 147.7±23.5
Diabetes clinic (Denmark)[17, 18†]	1993-2001 (9 years)	RCT (160)	Patient Ed, Org change	Control: 149±19 → 146±NR Intervention: 146±20 → 132±NR
Specialized diabetic service (Netherlands)[21]	--- (1 year)	RCT (246, 15 practices)	Patient Ed, Facil relay, Org change	Control: 149±24 → 143±21 Intervention: 137±21 → 135±18
29 general practices (Norway)[24]	--- (21 months)	RCT (1034, 17 practices)	Prvdr Remind, Audit & Fdbck	Control: 151.7±21.3 → 152.7±19 Intervention: 152.5±21.6 → 151.5±22.1
U. of Washington Family Medical Center (Seattle, WA)[25]	1998-1999 (14 months)	RCT (109, 2 firms)	Prvdr Ed, Audit & Fdbck, Org change	Control: 134±NR → 137.1±NR Intervention: 135±NR → 133.8±NR
Royal Prince Alfred Hospital Diabetes Clinic (Australia)[26]	--- (1 year)	RCT (137)	Org change	Control: 150±23 → 133±19 Intervention: 148±23 → 136±14
Royal Prince Alfred Hospital Diabetes Clinic (Australia)[26]	--- (1 year)	RCT (134)	Self-Mx, Pt Remind, Prvdr Remind, Org change	Control: 150±23 → 133±19 Intervention: 145±24 → 130±25
Cedars Sinai Medical Center (Los Angeles, CA)[30]	1994-1995 (1 year)	RCT (360, 43 practice teams)	Patient Ed, Prvdr Ed	Control: 141.5±NR → 142.8±NR Intervention: 144.1±NR → 144.3±NR
Diabetes education program	1998-1999	RCT	Patient Ed, Self-Mx, Pt Remind,	Control: 143±NR → NR±NR

(unspecified US city)[33]	(6 months)	(150)	Prvdr Remind, Facil relay	Intervention: 142±NR → NR±NR
Choa Chu Kang polyclinic (Singapore)[34]	2000-2001 (7 months)	CBA (211)	Patient Ed, Prvdr Remind, Org change	Control: 138.9±19.3 → 136.8±18.5 Intervention: 142.1±16.4 → 134.2±10.1
General medicine clinic, Indiana University Medical Center[37]	1978-1982 (3 years)	RCT (260, 13 firms)	Prvdr Ed, Prvdr Remind, Audit & Fdbck	Control: 137.2±NR → 144.9±NR Intervention: 142.5±NR → 146.4±NR
General medicine clinic, Indiana University Medical Center[37]	1978-1982 (3 years)	RCT (273, 14 firms)	Patient Ed, Pt Remind, Prvdr Ed, Prvdr Remind, Audit & Fdbck	Control: 137.2±NR → 144.9±NR Intervention: 140.4±NR → 145±NR
Hospital-based Adult Medicine Clinic (unspecified US city)[39]	1998-1999 (1 year)	RCT (598, 2 firms)	Prvdr Ed, Prvdr Remind	Control: 136.9±NR → 134.7±NR Intervention: 138.1±NR → 138.9±NR
9 primary health centers (United Arab Emirates)[48]	--- (18 months)	CBA (219, 9 practices)	Patient Ed, Prvdr Ed, Facil relay, Org change	Control: 133.7±19 → 131.3±16.6 Intervention: 129.2±18.8 → 126.5±16.4
Sub-specialty diabetes clinic (unspecified US city)[52]	1996 (3 months)	CBA (82)	Org change	Control: NR±NR → 140.9±19.6 Intervention: NR±NR → 138.3±16.9

* RCT – randomized controlled trial; CBA – controlled before after comparison.

^ Pt Remind – patient reminder, Prvdr Remind – provider reminder, Org change – organizational change, Self-Mx — self-management, Facil Relay — facilitated relay of clinical data to providers, Patient Ed — patient education, Prvdr Ed — provider education, Audit & Fdbck — audit and feedback to provider Financial — financial or regulatory intervention

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Gen Intern Med. Feb 1995;10(2):59-66:**PtEd, SelfMx, PtRmndr, FcltdRly, OrgChng/DxMx:clin information\ID:Dz/HbA1c/other**

Appendix F. Calculation of effective sample sizes for trials with clustering

A substantial number of studies exhibited "clustering," in that the units of analysis were patient level outcomes but the unit of allocation had been clusters of patients (e.g., randomization involved providers or clinics). The significance of clustering is that patients within a cluster are not independent – i.e., patients at one clinic have greater resemblance to each other than to patients at other sites or cared for by other providers in the trial. Unit of analysis errors do not affect point estimates for effect sizes, but they may spuriously narrow the associated confidence interval, potentially leading to a false-positive result in a trial.[1-8] To avoid the same inflation of precision in our analysis, we calculated an effective sample size* for each study. Importantly, from the point of view of our analysis, the degree to which investigators acknowledged or accounted for cluster effects did not affect our analysis, except in so far as investigators who did consider cluster effects in the design or analysis of the trial were more likely to report data such as the number of providers randomized, rather than just the total numbers of patients in each group, as well as provide more technical details, such as values for the intra-cluster coefficient (ICC). [9-11]

The table below compares the effective and originally reported sample sizes for effective sample sizes. Only values at baseline in the control and intervention groups are shown, but the same calculations were carried out for reported sample sizes in the post-intervention period for all study groups. Because so few studies reported ICC values,[9-11] we imputed values based on published estimates. Specifically, we used ICC=0.03 for the HbA1c outcome and ICC=0.10 for measures of provider adherence, based no the midpoints of published values for process and outcome measures in primary care settings. [3] As a sensitivity analysis, we re-ran the effective sample size calculations and regression analyses with the upper bounds of these ranges (ICC=0.10 and ICC=0.33, for outcome and process measures, respectively), with no substantial impacts no the results.

Table F1. Reported vs. effective sample sizes for clustered studies evaluating reduction in HbA_{1c}

	No. of clusters	Reported N (patients)	Effective N (patients)	Percent reduction (%)
Benjamin 1999[12]	2	106	46	57
Boucher 1997[13]	6	183	105	43
Olivarius 2001[14]	484	874	857	2
de Sonnaville 1997[15]	28	563	376	33
Frijling 2002[9]	123	1430	1128	21
Groeneveld 2001[16]	15	224	165	26
Hetlevik 2000[17]	30	733	452	38
Hirsch 2002[18]	2	109	46	58
Kiefe 2001[19]	84	1352	974	28
Kinmonth 1998[10]	42	240	197	18
Kogan 2003[20]	44	283	249	12
Litzelman 1993[21]	4	353	111	69
Mazzuca 1986[22]	13	127	104	18
McDermott 2001[23]	21	678	380	44

Meigs 2003[11]	66	598	377	37
O'Connor 1996[24]	2	241	60	75
Ovhed 2000[25]	2	394	66	83
Reed 2001[26]	9	189	123	35
Renders 2001[27]	27	389	291	25
Wagner 2001[28]	34	609	425	30
Walker 2001[29]	2	345	65	81
Deeb 1988[30]	6	636	173	73
Feder 1995[31]	24	21	21	0
Legorreta 1996[32]	2	205	58	72
Hartmann 1995[33]	17	376	246	35
Walker 2001[29]	2	345	65	81
Legorreta 1996[32]	2	185	55	70
Branger 1999[34]	32	275	227	17
Mazzuca 1986[22]	14	120	101	16

* Effective N equals sample size adjusted for presence of clustering. It was calculated as $N_{Effective} = (k*m) / (1 + (m-1)*r)$, where 'k 'is the number of clusters, 'm' is the number of patients per cluster, and 'r' is the intracluster coefficient (ICC). When r = 0, then $N_{Effective} = k*m$ (i.e., the reported sample size). When r = 1, then $N_{Effective} = k$ (i.e., the number of clusters) [1-8]

Appendix F References

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Appendix G. Articles excluded at the level of full-text review

	Citation	Reason for Exclusion
1.	Selected methods for the management of diabetes mellitus. *Ann Intern Med* 1983; 99:272-4.	Not an evaluation of a QI intervention
2.	Impact of policy and procedure changes on hospital days among diabetic nursing-home residents--Colorado. *MMWR Morb Mortal Wkly Rep* 1984; 33:621-4, 629.	Study design did not meet criteria for RCT, CBA, or ITS
3.	Private practitioners, public health join forces in unique diabetes program. *Urban Health* 1985; 14:23-7, 46-8.	Not an evaluation of a QI intervention
4.	Leads from the MMWR. Improving eye care for persons with diabetes mellitus--Michigan. *JAMA* 1985; 254:3293-4.	Not an evaluation of a QI intervention
5.	Community-based exercise intervention--the Zuni Diabetes Project. *MMWR Morb Mortal Wkly Rep* 1987; 36:661-4.	Study design did not meet criteria for RCT, CBA, or ITS
6.	Leads from the MMWR. Demonstration to improve care practices for diabetic patients in primary care centers--Florida. *JAMA* 1987; 257:1580-1.	Study design did not meet criteria for RCT, CBA, or ITS
7.	Program reimburses pharmacists who counsel patients on glyburide product. *Am J Hosp Pharm* 1992; 49:2645-6.	Not an evaluation of a QI intervention
8.	Integrated care for diabetes: clinical, psychosocial, and economic evaluation. Diabetes Integrated Care Evaluation Team. *BMJ* 1994; 308:1208-12.	Other*
9.	Longitudinal electronic records for diabetic patients. Part II: Clinical aspects. *J Clin Comput* 1995; 22:1-36.	Study design did not meet criteria for RCT, CBA, or ITS/outcomes
10.	Longitudinal electronic records for diabetic patients. Part I: Clinical aspects. *J Clin Comput* 1995; 22:1-88.	Study design did not meet criteria for RCT, CBA, or ITS/outcomes
11.	National Standards for Diabetes Self-Management Education Programs. Task Force to Revise the National Standards. *Diabetes Care* 1995; 18:141-3.	Not an evaluation of a QI intervention
12.	From the Centers for Disease Control and Prevention. Availability of diabetes information on the Internet. *JAMA* 1997; 278:1565.	Not an evaluation of a QI intervention

13.	From the Centers for Disease Control and Prevention. National Diabetes Awareness Month--November 1997. *JAMA* 1997; 278:1564.	Not an evaluation of a QI intervention
14.	Putting primary care guidelines into practice. *Med Manag Netw* 1998; 6:1-5.	Study design did not meet criteria for RCT, CBA, or ITS
15.	Disease management program improves diabetes outcomes, curbs hospital costs, utilization. *Health Care Cost Reengineering Rep* 1998; 3:42-5.	Not an evaluation of a QI intervention
16.	Innovative touchscreen-driven solution for diabetics. *Health Manag Technol* 1999; 20:20-1.	Not an evaluation of a QI intervention
17.	Pilot study proves CM's effectiveness. *Hosp Case Manag* 2000; 8:17-9.	Study design did not meet criteria for RCT, CBA, or ITS
18.	Compliance and combinations. *Diabetes Obes Metab* 2001; 3:383-4.	Not an evaluation of a QI intervention
19.	'Behavior change' is centerpiece of new DM approach for diabetics. *Dis Manag Advis* 2001; 7:118-21, 113.	Not an evaluation of a QI intervention
20.	Diabetes education program in Bulgaria. *Patient Educ Couns* 2001; 43:111-4.	No eligible outcomes
21.	In-house diabetes program delivers on a 'shoestring' budget. *Dis Manag Advis* 2002; 8:181-5, 177.	Not an evaluation of a QI intervention
22.	The Translating Research Into Action for Diabetes (TRIAD) study: a multicenter study of diabetes in managed care. *Diabetes Care* 2002; 25:386-9.	No eligible outcomes
23.	From the Centers for Disease Control and Prevention. Preventive-care practices among persons with diabetes--United States, 1995 and 2001. *JAMA* 2002; 288:2814-5.	Study design did not meet criteria for RCT, CBA, or ITS
24.	Incentive program focuses physicians on improving outcomes. *Perform Improv Advis* 2003; 7:49-54.	Study design did not meet criteria for RCT, CBA, or ITS
25.	Abourizk NN, O'Connor PJ, Crabtree BF, Schnatz JD. An outpatient model of integrated diabetes treatment and education: functional, metabolic, and knowledge outcomes. *Diabetes Educ* 1994; 20:416-21.	Study design did not meet criteria for RCT, CBA, or ITS
26.	Achtmeyer CE, Payne TH, Anawalt BD. Computer order entry system	Excluded topic (hospital care only)

	decreased use of sliding scale insulin regimens. *Methods Inf Med* 2002; 41:277-81.	
27.	Ackerman SJ. Benefits of preventive programs in eye care are visible on the bottom line. A new nationwide effort to improve eye care for people with diabetes gets backing from a study on the cost-effectiveness of screening for retinopathy. *Diabetes Care* 1992; 15:580-1.	Not an evaluation of a QI intervention
28.	Adams CE, Biggerstaff N. Reduced resource utilization through standardized outcome-focused care plans. *J Nurs Adm* 1995; 25:43-50.	No eligible outcomes
29.	Adamson TE, Gullion DS. Assessment of 8 continuing medical education. *Diabetes Care* 1986; 9:11-16.	Study design did not meet criteria for RCT, CBA, or ITS
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33.	Albisser AM. Clinical studies with home glucose clamping. *Ann Endocrinol (Paris)* 2001; 62:11-8.	Study design did not meet criteria for RCT, CBA, or ITS
34.	Allanach EJ, Allanach BC. Diabetes teaching follow-up compliance: a quality assurance evaluation. *Mil Med* 1984; 149:73-5.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
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36.	Anderson RM, Zimbelman L, Green J, Saunders JT, Pohl S. The development of a competency-based interdisciplinary clinical training program in diabetes. *Diabetes Educ* 1986:200-3.	Not an evaluation of a QI intervention

37.	Anderson RM, Funnell MM, Barr PA, Dedrick RF, Davis WK. Learning to empower patients. Results of professional education program for diabetes educators. *Diabetes Care* 1991; 14:584-90.	No eligible outcomes
38.	Anderson RM, Funnell MM, Butler PM, Arnold MS, Fitzgerald JT, Feste CC. Patient empowerment. Results of a randomized controlled trial. *Diabetes Care* 1995; 18:943-9.	Patient education or self-management only
39.	Ardron M, MacFarlane IA, Robinson C, van Heyningen C, Calverley PM. Anti-smoking advice for young diabetic smokers: is it a waste of breath? *Diabet Med* 1988; 5:667-70.	Excluded topic (smoking cessation)/No eligible outcomes
40.	Arlen D, Harkless L, Frykberg R, Garcia I. Skilled nursing facility units. Preliminary screening of geriatric infections. *J Am Podiatr Med Assoc* 1990; 80:385-92.	Not an evaluation of a QI intervention
41.	Assal. Patient education as the basis for diabetes care in clinical practice and research. *Diabetologia* 1985; 283:602-603.	Study design did not meet criteria for RCT, CBA, or ITS
42.	Bacon GE, Ladu C, Shein HE, Rucknagel DL. Evaluation of glycosylated hemoglobin in the management of young patients with insulin-dependent diabetes mellitus. *J Adolesc Health Care* 1986; 7:187-90.	Excluded topic (Type 1 diabetes only)
43.	Baker SB, Vallbona C, Pavlik V, et al. A diabetes control program in a public health care setting. *Public Health Rep* 1993; 108:595-605.	Study design did not meet criteria for RCT, CBA, or ITS
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46.	Balik B, Moynihan PM, Haig B. Community-based diabetes education: an outreach program. *Diabetes Educ* 1985; 11:19-23.	Not an evaluation of a QI intervention
47.	Barrera M, Jr., Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support?: An experimental trial of approaches for supporting diabetes	No eligible outcomes

	self-management. *Am J Community Psychol* 2002; 30:637-54.	
48.	Bartel J. A comprehensive diabetes education program. *Nurs Manage* 1992; 23:74-6.	Not an evaluation of a QI intervention
49.	Barth R, Campbell LV, Allen S, Jupp JJ, Chisholm DJ. Intensive education improves knowledge, compliance, and foot problems in type 2 diabetes. *Diabet Med* 1991; 8:111-7.	Patient education or self-management only
50.	Bashook PG. Clinical assessment: a state-of-the-art review. *Diabetes Educ* 1985; 11 Suppl:30-6.	Not an evaluation of a QI intervention
51.	Beaven DW, Scott RS, Brown LJ. Diabetes care--a continuing challenge. *Aust N Z J Med* 1988; 18:297-301.	Not an evaluation of a QI intervention
52.	Beck MJ, Evans BJ, Quarry-Horn JL, Kerrigan JR. Type 2 diabetes mellitus: issues for the medical care of pediatric and adult patients. *South Med J* 2002; 95:992-1000.	Not an evaluation of a QI intervention
53.	Bell R, Norman M, Lamb B, Holliday J, Leggett-Frazier N. Assessing the effectiveness of a clinical fellowship on diabetes in enhancing diabetes care in North Carolina. *Diabetes Educ* 2000; 26:41-2, 53-4, 57.	No eligible outcomes
54.	Bellazzi R, Riva A, Montani S, et al. Application report: preliminary evaluation of the T-IDDM project in Pavia. *Stud Health Technol Inform* 1999; 68:99-101.	Not an evaluation of a QI intervention
55.	Bender AP, Sprafka JM, Jagger H, Wannamaker J, Muckala KH. Evaluation of the effect of record source on the profiles of patients with diabetes mellitus in Wadena, Minnesota. *Minn Med* 1983; 66:383-7.	Not an evaluation of a QI intervention
56.	Ben-Noun L. Poorly controlled diabetes in the elderly. *Practitioner* 1989; 233:14, 16.	Not an evaluation of a QI intervention /No eligible outcomes
57.	Berger A. Action on clinical audit: progress report 2. *BMJ* 1998; 317:880-1.	Not an evaluation of a QI intervention /No eligible outcomes
58.	Berkowitz KJ, Anderson LA, Panayioto RM, Ziemer DC, Gallina DL. Mini-residency on diabetes care for healthcare providers: enhanced knowledge and attitudes with unexpected challenges to assessing behavior change. *Diabetes Educ* 1998; 24:143-4, 149-50.	No eligible outcomes

59.	Bessman AN. Comparison of medical care in nurse clinician and physician clinics in medical school affiliated hospitals. *Journal of Chronic Diseases* 1974; 27:115-125.	Study design did not meet criteria for RCT, CBA, or ITS
60.	Birke JA, Horswell R, Patout CA, Jr., Chen SL. The impact of a staged management approach to diabetes foot care in the Louisiana public hospital system. *J La State Med Soc* 2003; 155:37-42.	Study design did not meet criteria for RCT, CBA, or ITS
61.	Blonde L, Guthrie R, Testa M, et al. Diabetes management by a team of diabetes nurse educators, endocrinologists and primary care physicians in a managed care setting [abstract]. *Book/Association for Health Services Research*; 16:318-319.	Other ^
62.	Bloomgarden, et al. Randomized, controlled trial of diabetic patient education: improved knowledge without improved metabolic status. *Diabetes Care* 1987; 10:263.	Patient education or self-management only
63.	Bloomgarden ZT. International Diabetes Federation meeting, 1997. Neuropathy, information technology, cost of diabetes care, and epidemiology. *Diabetes Care* 1998; 21:1198-202.	Not an evaluation of a QI intervention
64.	Blum A. Sugar 'n' spice-- 'n' public relations. *Med J Aust* 1982; 2:16-9.	Not an evaluation of a QI intervention
65.	Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA* 2002; 288:1909-14.	Not an evaluation of a QI intervention
66.	Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA* 2002; 288:1775-9.	Study design did not meet criteria for RCT, CBA, or ITS
67.	Boehm S, Schlenk EA, Raleigh E, Ronis D. Behavioral analysis and behavioral strategies to improve self-management of type II diabetes. *Clin Nurs Res* 1993; 2:327-44.	Patient education or self-management only
68.	Bohannon NJ, Zilbergeld B, Bullard DG, Stoklosa JM. Treatable impotence in diabetic patients. *West J Med* 1982; 136:6-10.	Not an evaluation of a QI intervention /No eligible outcomes
69.	Boswell EJ, Pichert JW, Penha ML. Negotiating independent practice in diabetes education. *Diabetes Educ* 1992; 18:288, 290.	Not an evaluation of a QI intervention /No eligible outcomes
70.	Bowyer NK. A primary care team approach to the prevention of ocular complications of diabetes: a program review. *J Am Optom Assoc* 1997; 68:233-42.	Study design did not meet criteria for RCT, CBA, or ITS

71.	Boyd AF, Hartzema AG. Computerized monitoring protocols as a pharmaceutical care practice enhancement: a conceptual illustration using diabetes mellitus. *Ann Pharmacother* 1993; 27:963-6.	Not an evaluation of a QI intervention
72.	Branger PJ, van 't Hooft A, van der Wouden JC, Duisterhout JS, van Bemmel JH. dup Shared care for diabetes: supporting communication between primary and secondary care. *Medinfo* 1998; 9 Pt 1:412-6. (Duplication/overlap of included article †)	Overlaps with or duplicates another article that was included
73.	Brooks RJ, Legoretta AP, Silver AL, Fabius RJ, Krakovitz J. Implementing guidelines for eye care of diabetic patients: results from an HMO intervention study. *American Journal of Managed Care* 1996; 2:365-369.	Study design did not meet criteria for RCT, CBA, or ITS
74.	Brouard N, Mounier F, Schaub C. Ocular lesions of diabetic retinopathy: a computer documentation by correspondence factor analysis. *Med Inform (Lond)* 1981; 6:235-7.	Not an evaluation of a QI intervention
75.	Brown SA, Hedges LV. Predicting metabolic control in diabetes: a pilot study using meta-analysis to estimate a linear model. *Nurs Res* 1994; 43:362-8.	Not an evaluation of a QI intervention /No eligible outcomes
76.	Brown SA, Hanis CL. A community-based, culturally sensitive education and group-support intervention for Mexican Americans with NIDDM: a pilot study of efficacy. *Diabetes Educ* 1995; 21:203-10.	Study design did not meet criteria for RCT, CBA, or ITS
77.	Brown SA, Upchurch S, Anding R, Winter M, Ramirez G. Promoting weight loss in type II diabetes. *Diabetes Care* 1996; 19:613-24.	Not an evaluation of a QI intervention
78.	Brown SA, Hanis CL. Culturally competent diabetes education for Mexican Americans: the Starr County Study. *Diabetes Educ* 1999; 25:226-36. (Duplicate/overlap of article #80 from this table)	Overlaps with or duplicates another article that was included
79.	Brown JB, Nichols GA, Glauber HS. Case-control study of 10 years of comprehensive diabetes care. *West J Med* 2000; 172:85-90.	Study design did not meet criteria for RCT, CBA, or ITS
80.	Brown SA, Garcia AA, Kouzekanani K, Hanis CL. Culturally competent diabetes self-management education for Mexican Americans: the Starr County border health initiative. *Diabetes Care* 2002; 25:259-68.	Patient education or self-management only
81.	Bruckner M, Mangan M, Godin S, Pogach L. Project LEAP of New Jersey: lower extremity amputation prevention in persons with type 2	Study design did not meet criteria for RCT, CBA, or ITS

	diabetes. *Am J Manag Care* 1999; 5:609-16.	
82.	Burden ML, Woghiren O, Burden AC. Diabetes in African Caribbean, and Indo-Asian ethnic minority people. *J R Coll Physicians Lond* 2000; 34:343-6.	Not an evaluation of a QI intervention
83.	Burnett S, Hurwitz B, Davey C, et al. The implementation of prompted retinal screening for diabetic eye disease by accredited optometrists in an inner-city district of North London: a quality of care study. *Diabet Med* 1998; 15 Suppl 3:S38-43.	Study design did not meet criteria for RCT, CBA, or ITS
84.	Burton WN, Connerty CM, IN. Worksite-based diabetes disease management program. *Disease Management, 5(1):1-8, 2002 Spring.(20 ref) JC CP* 2002:1-8.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
85.	Calvo CB, Rubinstein A. Influence of new evidence on prescription patterns. *J Am Board Fam Pract* 2002; 15:457-62.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
86.	Campbell LV, Chisholm DJ, Barth R. Evaluation of the benefits of a diabetes education programme. *Diabetes Educ* 1984; 10 SPEC NO:46-7.	Study design did not meet criteria for RCT, CBA, or ITS
87.	Campbell RK. Pharmaceutical services for patients with diabetes. Module 1. Professional and economic impact of diabetes on pharmacy practice. *Am Pharm* 1986; NS26:suppl 1-8.	Not an evaluation of a QI intervention /No eligible outcomes
88.	Campbell, et al. The relative effectiveness of educational and behavioral instruction programs for patients with NIDDM: a randomized trial. *Diabetes Educ* 1996; 22:379.	Patient education or self-management only
89.	Campbell TM, Stamm PL, Johnson JR. Improving drug use in a capitated program for the poor. *Am J Health Syst Pharm* 1997; 54:2449-50.	Not an evaluation of a QI intervention
90.	Campbell R, Pound P, Pope C, et al. Evaluating meta-ethnography: a synthesis of qualitative research on lay experiences of diabetes and diabetes care. *Social Science & Medicine* 2003; 56:671-684.	Not an evaluation of a QI intervention
91.	Canga N, De Irala J, Vara E, Duaso MJ, Ferrer A, Martinez-Gonzalez MA. Intervention study for smoking cessation in diabetic patients: a randomized controlled trial in both clinical and primary care settings. *Diabetes Care* 2000; 23:1455-60.	Not an evaluation of a QI intervention /No eligible outcomes

92.	Carlson A, Rosenqvist U. Locally developed plans for quality diabetes care: Worker and consumer participation in the public healthcare system. *Health Educ Res* 1990; 5:41.	Not an evaluation of a QI intervention /No eligible outcomes
93.	Carlson A, Rosenqvist U. Diabetes care organization, process, and patient outcomes: effects of a diabetes control program. *Diabetes Educ* 1991; 17:42-8.	No eligible outcomes
94.	Carney T, Helliwell C. Effect of structured postgraduate medical education on the care of patients with diabetes. *Br J Gen Pract* 1995; 45:149-51.	Study design did not meet criteria for RCT, CBA, or ITS
95.	Carter IR, Nash C, Ridgway A. On any Saturday--a practical model for diabetes education. *J Natl Med Assoc* 2002; 94:67-72.	Study design did not meet criteria for RCT, CBA, or ITS
96.	Cherry JC, Moffatt TP, Rodriguez C, Dryden K. Diabetes disease management program for an indigent population empowered by telemedicine technology. *Diabetes Technol Ther* 2002; 4:783-91.	Study design did not meet criteria for RCT, CBA, or ITS
97.	Chicoye L, Roethel CR, Hatch MH, Wesolowski W. Diabetes care management: a managed care approach. *Wmj* 1998; 97:32-4.	Study design did not meet criteria for RCT, CBA, or ITS
98.	Chiou ST, Lin HD, Yu NC, et al. An initial assessment of the feasibility and effectiveness of implementing diabetes shared care system in Taiwan--some experiences from I-Lan County. *Diabetes Res Clin Pract* 2001; 54 Suppl 1:S67-73.	Study design did not meet criteria for RCT, CBA, or ITS
99.	Clancy DE, Cope DW, Magruder KM, et al. Evaluating group visits in an uninsured or inadequately insured patient population with uncontrolled type 2 diabetes. *Diabetes Educator.* 2003; 29:292-302.	No eligible outcomes
100.	Clark CM, Jr., Chin MH, Davis SN, et al. Incorporating the results of diabetes research into clinical practice: celebrating 25 years of diabetes research and training center translation research. *Diabetes Care* 2001; 24:2134-42.	Not an evaluation of a QI intervention
101.	Clark CM, Jr., Snyder JW, Meek RL, Stutz LM, Parkin CG. A systematic approach to risk stratification and intervention within a managed care environment improves diabetes outcomes and patient satisfaction. *Diabetes Care* 2001; 24:1079-86.	Study design did not meet criteria for RCT, CBA, or ITS
102.	Clarke J, Crawford A, Nash DB. Evaluation of a Comprehensive Diabetes Disease Management Program: Progress in the Stuggle for	Study design did not meet criteria for

	Sustained Behavior Change. *Disease Management* 2002; 5:77.	RCT, CBA, or ITS/No eligible outcomes
103.	Coid DR, Duncan C, Carmichael C, McLeod J, Campbell IW. Evaluation of a Fife 'Novopen' clinic held within a diabetes patient education centre. *Health Bull (Edinb)* 1990; 48:243-8.	Study design did not meet criteria for RCT, CBA, or ITS
104.	Constance A, Crawford K, Hare J, et al. MDON: a network of community partnerships. *Fam Community Health* 2002; 25:52-60.	Study design did not meet criteria for RCT, CBA, or ITS
105.	Cook S, Cohen RM. Evaluating a workshop model for improving diabetes patient education programs: is it really successful? *Diabetes Educ* 1986; 12:48-50.	Study design did not meet criteria for RCT, CBA, or ITS
106.	Cook GB. A computer program for teaching and auditing patients' knowledge of diabetes. *Diabetes Educ* 1987; 13:306-8.	Not an evaluation of a QI intervention
107.	Cook CB, Ziemer DC, El-Kebbi IM, et al. Diabetes in urban African-Americans. XVI. Overcoming clinical inertia improves glycemic control in patients with type 2 diabetes. *Diabetes Care* 1999; 22:1494-500.	Study design did not meet criteria for RCT, CBA, or ITS
108.	Cooper HC, Booth K, Gill G, IN. Patients' perspectives on diabetes health care education. *Health Education Research* 2003; 18:191-206.	Patient education or self-management only
109.	Corbett CF, IN. A randomized pilot study of improving foot care in home health patients with diabetes. *Diabetes Educator.* 2003; 29:273-282.	Patient education or self-management only
110.	Corkery, et al. Effect of a bicultural community health worker on completion of diabetes education in a Hispanic population. *Diabetes Care* 1997; 20:254.	Patient education or self-management only
111.	Courtney L, Gordon M, Romer L. A clinical path for adult diabetes. *Diabetes Educ* 1997; 23:664-71.	Study design did not meet criteria for RCT, CBA, or ITS
112.	Crane M, Werber B. Critical pathway approach to diabetic pedal infections in a multidisciplinary setting. *J Foot Ankle Surg* 1999; 38:30-3; discussion 82-3.	Excluded topic (in-patient care only)
113.	Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc (Wash)* 2003; 43:173-84.	Study design did not meet criteria for RCT, CBA, or ITS
114.	Cranor CW, Christensen DB. The Asheville Project: factors associated with outcomes of a community pharmacy diabetes care program. *J*	Study design did not meet criteria for

	Am Pharm Assoc (Wash) 2003; 43:160-72.	RCT, CBA, or ITS
115.	Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc (Wash)* 2003; 43:149-59.	Study design did not meet criteria for RCT, CBA, or ITS
116.	Crawford MJ, Rutter D, Manley C, et al. Systematic review of involving patients in the planning and development of health care. *BMJ* 2002; 325:1263.	design
117.	Cretin S, Farley DO, Dolter KJ, Nicholas W. Evaluating an integrated approach to clinical quality improvement: clinical guidelines, quality measurement, and supportive system design. *Med Care* 2001; 39:II70-84.	Excluded topic (unrelated to diabetes)/No eligible outcomes
118.	Cummings DM, Morrissey S, Barondes MJ, Rogers L, Gustke S. Screening for diabetic retinopathy in rural areas: the potential of telemedicine. *J Rural Health* 2001; 17:25-31.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
119.	Czech MS. A mastery learning program for self blood glucose monitoring. *Diabetes Educ* 1984; 10:27-30.	Not an evaluation of a QI intervention
120.	Dally DL, Dahar W, Scott A, Roblin D, Khoury AT. The impact of a health education program targeting patients with high visit rates in a managed care organization. *Am J Health Promot* 2002; 17:101-11.	No eligible outcomes
121.	Daniel M, Green LW, Marion SA, et al. Effectiveness of community-directed diabetes prevention and control in a rural Aboriginal population in British Columbia, Canada. *Soc Sci Med* 1999; 48:815-32.	Patient education or self-management only
122.	Dans PE, King TM. An office of medical practice evaluation: what is it and why have one? *QRB Qual Rev Bull* 1986; 12:320-5.	Not an evaluation of a QI intervention
123.	Davidson JK, Delcher HK, Englund A. Spin-off cost/benefits of expanded nutritional care. *Journal of the American Dietetic Association* 1979; 75:250-257.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
124.	Davidson MB, Morgan R, Bales B, Pearce MA, Crane M, Graham B. The establishment of a reimbursable diabetes education program. *Diabetes Educ* 1982; 8:31-3, 38.	Study design did not meet criteria for RCT, CBA, or ITS
125.	Davidson. The impact of managed care on the care of diabetes	Not an evaluation of a QI intervention

	patients. *Diabetes Spectrum* 1996; 9:169-90.	
126.	Davis ED, Beckman JS, Harris NL, Howe JD, Steele RM. Implementing a nursing care quality program to improve diabetes patient education. *J Nurs Care Qual* 1992; 6:67-77.	No eligible outcomes
127.	Day JL, Humphreys H, Alban-Davies H. Problems of comprehensive shared diabetes care. *Br Med J (Clin Res Ed)* 1987; 294:1590-2.	Study design did not meet criteria for RCT, CBA, or ITS
128.	Day JL, Johnson P, Rayman G, Walker R. The feasibility of a potentially 'ideal' system of integrated diabetes care and education based on a day centre. *Diabet Med* 1988; 5:70-5.	Study design did not meet criteria for RCT, CBA, or ITS
129.	Day JL, Metcalfe J, Johnson P. Benefits provided by an integrated education and clinical diabetes centre: a follow-up study. *Diabet Med* 1992; 9:855-9.	Study design did not meet criteria for RCT, CBA, or ITS
130.	de Grauw WJ, van Gerwen WH, van de Lisdonk EH, van den Hoogen HJ, van den Bosch WJ, van Weel C. Outcomes of audit-enhanced monitoring of patients with type 2 diabetes. *J Fam Pract* 2002; 51:459-64.	Study design did not meet criteria for RCT, CBA, or ITS
131.	de Weerdt I, Visser AP, Kok GJ, de Weerdt O, van der Veen EA. Randomized controlled multicentre evaluation of an education programme for insulin-treated diabetic patients: effects on metabolic control, quality of life, and costs of therapy. *Diabet Med* 1991; 8:338-45.	Patient education or self-management only
132.	Deichmann RE, Castello E, Horswell R, Friday KE. Improvements in diabetic care as measured by HbA1c after a physician education project. *Diabetes Care* 1999; 22:1612-6.	Study design did not meet criteria for RCT, CBA, or ITS
133.	D'Eramo-Melkus GA, Wylie-Rosett J, Hagan JA. Metabolic impact of education in NIDDM. *Diabetes Care* 1992; 15:864-9.	Patient education or self-management only
134.	Diehl AK, Sugarek NJ, Bauer RL. Medication compliance in non-insulin-dependent diabetes: a randomized comparison of chlorpropamide and insulin. *Diabetes Care* 1985; 8:219-23.	Not an evaluation of a QI intervention
135.	Dimmick SL, Burgiss SG, Robbins S, Black D, Jarnagin B, Anders M. Outcomes of an integrated telehealth network demonstration project. *Telemed J E Health* 2003; 9:13-23.	Study design did not meet criteria for RCT, CBA, or ITS

136.	Domenech MI, Assad D, Mazzei ME, Kronsbein P, Gagliardino JJ. Evaluation of the effectiveness of an ambulatory teaching/treatment programme for non-insulin dependent (type 2) diabetic patients. *Acta Diabetol* 1995; 32:143-7.	Patient education or self-management only
137.	Domurat ES. Diabetes managed care and clinical outcomes: the Harbor City, California Kaiser Permanente diabetes care system. *Am J Manag Care* 1999; 5:1299-307.	Not an evaluation of a QI intervention
138.	Donohoe ME, Fletton JA, Hook A, et al. Improving foot care for people with diabetes mellitus--a randomized controlled trial of an integrated care approach. *Diabet Med* 2000; 17:581-7.	No eligible outcomes
139.	Dornan C, Fowler G, Mann JI, Markus A, Thorogood M. A community study of diabetes in Oxfordshire. *J R Coll Gen Pract* 1983; 33:151-5.	Not an evaluation of a QI intervention
140.	Drapin L. I/S component crucial to diabetes management program. *Health Manag Technol* 1995; 16:30, 32.	Not an evaluation of a QI intervention
141.	Dunn SM, Beeney LJ, Hoskins PL, Turtle JR. Knowledge and attitude change as predictors of metabolic improvement in diabetes education. *Soc Sci Med* 1990; 31:1135-41.	Study design did not meet criteria for RCT, CBA, or ITS
142.	Eakin EG, Bull SS, Glasgow RE, Mason M. Reaching those most in need: a review of diabetes self-management interventions in disadvantaged populations. *Diabetes Metab Res Rev* 2002; 18:26-35.	Study design did not meet criteria for RCT, CBA, or ITS
143.	Edmonds. Improved survival of the diabetic foot: the role of the specialised foot clinic. *QJ Med* 1986; 60:763.	Study design did not meet criteria for RCT, CBA, or ITS
144.	Edmonds M, Bauer M, Osborn S, et al. Using the Vista 350 telephone to communicate the results of home monitoring of diabetes mellitus to a central database and to provide feedback. *Int J Med Inf* 1998; 51:117-25.	Excluded topic (Type 1 diabetes only)/No eligible outcomes
145.	Engelman KK, Ellerbeck EF, Totten B. Improving systems for preventive care via academic detailing by students. *Acad Med* 2001; 76:565-6.	Study design did not meet criteria for RCT, CBA, or ITS
146.	Erdman DM, Cook CB, Greenlund KJ, et al. The impact of outpatient diabetes management on serum lipids in urban African-Americans with type 2 diabetes. *Diabetes Care* 2002; 25:9-15.	Study design did not meet criteria for RCT, CBA, or ITS

147.	Estey AL, Tan MH, Mann K. Follow-up intervention: its effect on compliance behavior to a diabetes regimen. *Diabetes Educ* 1990; 16:291-5.	Patient education or self-management only
148.	Falkenberg, et al. Problem oriented participatory education in the guidance of adults with non-insulin-treated type-II diabetes mellitus. *Scand J Prim Health Care* 1986; 4:157.	Patient education or self-management only
149.	Felig P, Bergman M. Intensive ambulatory treatment of insulin-dependent diabetes. *Ann Intern Med* 1982; 97:225-30.	Not an evaluation of a QI intervention
150.	Fernando DJ, Perera SD. The work of a diabetes clinic: an audit. *Ceylon Med J* 1994; 39:138-9.	Study design did not meet criteria for RCT, CBA, or ITS
151.	Filippi A, Sabatini A, Badioli L, et al. Effects of an Automated Electronic Reminder in Changing the Antiplatelet Drug-Prescribing Behavior Among Italian General Practitioners in Diabetic Patients: An intervention trial. *Diabetes Care* 2003; 26:1497-500.	No eligible outcomes
152.	Fox CH, Mahoney MC. Improving diabetes preventive care in a family practice residency program: a case study in continuous quality improvement. *Fam Med* 1998; 30:441-5.	Study design did not meet criteria for RCT, CBA, or ITS
153.	Frame. Computer based vs manual health maintenence tracking: a controlled trial. *Arch Fam Med* 1994; 3:581.	Excluded topic (unrelated to diabetes)/No eligible outcomes
154.	Franz MJ, Splett PL, Monk A, et al. Cost-effectiveness of medical nutrition therapy provided by dietitians for persons with non-insulin-dependent diabetes mellitus [see comments]. *Journal of the American Dietetic Association* 1995; 95:1018-1024. (Duplicate/overlap of included article [§])	Overlaps with or duplicates another article that was included
155.	Friedman N. Diabetes and managed care: the Lovelace Health System's Episode of Care Program. *Manag Care Q* 1996; 4:43-9.	Not an evaluation of a QI intervention
156.	Friedman NM, Gleeson JM, Kent MJ, Foris M, Rodriguez DJ, Cypress M. Management of diabetes mellitus in the Lovelace Health Systems' EPISODES OF CARE program. *Eff Clin Pract* 1998; 1:5-11.	Study design did not meet criteria for RCT, CBA, or ITS
157.	Friedman RH. Automated telephone conversations to assess health behavior and deliver behavioral interventions. *J Med Syst* 1998; 22:95-102.	Not an evaluation of a QI intervention /No eligible outcomes

158.	Friedrich MJ. Enhancing diabetes care in a low-income, high-risk population. *JAMA* 2000; 283:467-8.	Not an evaluation of a QI intervention
159.	Funnell MM, Arnold MS, Fogler J, Merritt JH, Anderson LA. Participation in a diabetes education and care program: experience from the diabetes care for older adults project. *Diabetes Educ* 1998; 24:163-7.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
160.	Fuqua L. Marketing and diabetes education: "a harmonious chorus". *Diabetes Educ* 1989; 15:210-3.	Not an evaluation of a QI intervention
161.	Gaede P, Vedel P, Parving HH, Pedersen O. Intensified multifactorial intervention in patients with type 2 diabetes mellitus and microalbuminuria: the Steno type 2 randomised study. *Lancet* 1999; 353:617-22. (Duplicate/overlap of included article**)	Overlaps with or duplicates another article that was included
162.	Gagliardino JJ, Etchegoyen G. A model educational program for people with type 2 diabetes: a cooperative Latin American implementation study (PEDNID-LA). *Diabetes Care* 2001; 24:1001-7.	Study design did not meet criteria for RCT, CBA, or ITS
163.	Gary TL, Genkinger JM, Guallar E, Peyrot M, Brancati FL. Meta-analysis of randomized educational behavioral interventions in type 2 diabetes. *Diabetes Educ* 2003; 29:488-501.	Study design did not meet criteria for RCT, CBA, or ITS
164.	Gegick CG, Altheimer MD, Kissling GE. Benefits of computerized outcome analysis in diabetes management. *Endocr Pract* 2000; 6:253-9.	Study design did not meet criteria for RCT, CBA, or ITS
165.	Genev NM, McGill M, Hoskins PL, et al. Continuing diabetes education by telephone. *Diabet Med* 1990; 7:920-1.	No eligible outcomes
166.	Gerstein HC, Reddy SS, Dawson KG, Yale JF, Shannon S, Norman G. A controlled evaluation of a national continuing medical education programme designed to improve family physicians' implementation of diabetes-specific clinical practice guidelines. *Diabet Med* 1999; 16:964-9.	No eligible outcomes
167.	Ghosh S, Aronow WS. Utilization of lipid-lowering drugs in elderly persons with increased serum low-density lipoprotein cholesterol associated with coronary artery disease, symptomatic peripheral arterial disease, prior stroke, or diabetes mellitus before and after an educational program on dyslipidemia treatment. *J Gerontol A Biol Sci*	Study design did not meet criteria for RCT, CBA, or ITS

	Med Sci 2003; 58:M432-5.	
168.	Gibbins RL, Saunders J. Develop diabetic care in general practice. *BMJ* 1988; 297:187-9.	Not an evaluation of a QI intervention
169.	Gilden, et al. Diabetes support groups improve health care of older diabetic patients. *J Am Geriatr Soc* 1992; 40:147.	Patient education or self-management only
170.	Gilliland SS, Azen SP, Perez GE, Carter JS. Strong in body and spirit: lifestyle intervention for Native American adults with diabetes in New Mexico. *Diabetes Care* 2002; 25:78-83.	Patient education or self-management only
171.	Ginsberg BH, Tan MH, Mazze R, Bergelson A. Staged diabetes management: computerizing a disease state management program. *J Med Syst* 1998; 22:77-87.	Not an evaluation of a QI intervention
172.	Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnelly J. Improving self-care among older patients with type II diabetes: the "Sixty Something..." Study. *Patient Educ Couns* 1992; 19:61-74.	Patient education or self-management only
173.	Glasgow RE, Toobert DJ. Brief, computer-assisted diabetes dietary self-management counseling: effects on behavior, physiologic outcomes, and quality of life. *Med Care* 2000; 38:1062-73. (Duplicate/overlap of article #174 from this table)	Overlaps with or duplicates another article that was included
174.	Glasgow RE, Toobert DJ, Hampson SE, Strycker LA. Implementation, generalization and long-term results of the "choosing well" diabetes self-management intervention. *Patient Educ Couns* 2002; 48:115-22.	Patient education or self-management only
175.	Glasgow RE, Funnell MM, Bonomi AE, Davis C, Beckham V, Wagner EH. Self-management aspects of the improving chronic illness care breakthrough series: implementation with diabetes and heart failure teams. *Ann Behav Med* 2002; 24:80-7.	Study design did not meet criteria for RCT, CBA, or ITS
176.	Gleeson. Diabetes mellitus: disease management in a multispecialty group practice. *Dis Manag Health Outcomes* 1999; 5:63.	Not an evaluation of a QI intervention
177.	Goldberg HI, Neighbor WE, Hirsch IB, Cheadle AD, Ramsey SD, Gore E. Evidence-based management: using serial firm trials to improve diabetes care quality. *Jt Comm J Qual Improv* 2002; 28:155-66.	Study design did not meet criteria for RCT, CBA, or ITS
178.	Goldhaber-Fiebert JD, Goldhaber-Fiebert SN, Tristan ML, Nathan DM.	Patient education or self-management

	Randomized controlled community-based nutrition and exercise intervention improves glycemia and cardiovascular risk factors in type 2 diabetic patients in rural Costa Rica. *Diabetes Care* 2003; 26:24-9.	only
179.	Gomez EJ, Hernando ME, Garcia A, et al. Telemedicine as a tool for intensive management of diabetes: the DIABTel experience. *Comput Methods Programs Biomed* 2002; 69:163-77.	Excluded topic (Type 1 diabetes only)
180.	Goodman RM, Liburd LC, Green-Phillips A. The formation of a complex community program for diabetes control: lessons learned from a case study of Project DIRECT. *J Public Health Manag Pract* 2001; 7:19-29.	Study design did not meet criteria for RCT, CBA, or ITS
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189.	Griffin S, Kinmonth AL. Diabetes care: the effectiveness of systems for routine surveillance for people with diabetes. *Cochrane Database Syst Rev* 2000:CD000541.	Not an evaluation of a QI intervention
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198.	Hawkins, et al. Evaluation of a clinical pharmacist in caring for hypertensive and diabetic patients. *American Journal of Hospital Pharmacy* 1979; 36:1321.	Not an evaluation of a QI intervention
199.	Hawkins DW. Clinical pharmacy functions in ambulatory patient care. *J Clin Pharmacol* 1981; 21:245-50.	Not an evaluation of a QI intervention
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215.	Howorka K, Pumprla J, Wagner-Nosiska D, Grillmayr H, Schlusche C, Schabmann A. Empowering diabetes out-patients with structured education: short-term and long-term effects of functional insulin treatment on perceived control over diabetes. *J Psychosom Res* 2000; 48:37-44.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
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217.	Humphry J, Jameson LM, Beckham S. Overcoming social and cultural barriers to care for patients with diabetes. *West J Med* 1997; 167:138-44.	Study design did not meet criteria for RCT, CBA, or ITS
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220.	Ivey JM, Ehle J. Establishing unit-based glucose monitoring. *Diabetes Educ* 1988; 14:487-91.	Study design did not meet criteria for RCT, CBA, or ITS
221.	Izquierdo PEKSMJKRP-S, Weinstock RS. A comparison of diabetes education administered through telemedicine versus in person. *Diabetes Care* 2003; 26:1002-7.	Patient education or self-management only
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	behavior change. *Diabetes Educ* 2000; 26:230-2, 234, 240 passim.	RCT, CBA, or ITS
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243.	Kiechle FL. The impact of continuous glucose monitoring on hospital point-of-care testing programs. *Diabetes Technol Ther* 2001; 3:647-50.	Not an evaluation of a QI intervention

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249.	Kleschen MZ, Holbrook J, Rothbaum AK, Stringer RA, McInerney MJ, Helgerson SD. Improving the pneumococcal immunization rate for patients with diabetes in a managed care population: a simple intervention with a rapid effect. *Jt Comm J Qual Improv* 2000; 26:538-46.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
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255.	Kronsbein, et al. Evaluation of a structured treatment and teaching programme on non-insulin dependent diabetes. *Lancet* 1988; 2:1407.	Patient education or self-management only
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258.	Laron Z, Faiman G, Flexer Z, Rapaport M. Use of a computer program in the treatment and education of young diabetics. *Acta Paediatr Jpn* 1987; 29:378-84.	Study design did not meet criteria for RCT, CBA, or ITS
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260.	Lee SJ, Sicari C, Harper CA, et al. Examination compliance and screening for diabetic retinopathy: a 2-year follow-up study. *Clin Experiment Ophthalmol* 2000; 28:149-52.	Study design did not meet criteria for RCT, CBA, or ITS
261.	Lee SJ, McCarty CA, Taylor HR, Keeffe JE. Costs of mobile screening for diabetic retinopathy: a practical framework for rural populations. *Aust J Rural Health* 2001; 9:186-92.	Study design did not meet criteria for RCT, CBA, or ITS
262.	Leese GP, Ahmed S, Newton RW, et al. Use of mobile screening unit for diabetic retinopathy in rural and urban areas. *BMJ* 1993; 306:187-9.	Study design did not meet criteria for RCT, CBA, or ITS
263.	Leichter SB, Hernandez C, Harvill C, Rice G. The Kentucky Diabetes Control Program and the feasibility of the pyramidal model for public health intervention in diabetes mellitus. *Diabetes Educ* 1988; 14:218-22.	Study design did not meet criteria for RCT, CBA, or ITS
264.	Lenz ER, Mundinger MO, Hopkins SC, Lin SX, Smolowitz JL. Diabetes care processes and outcomes in patients treated by nurse practitioners or physicians. *Diabetes Educ* 2002; 28:590-8.	Not an evaluation of a QI intervention

265.	Leonard B, Leonard C, Wilson R. Zuni Diabetes Project. *Public Health Rep* 1986; 101:282-8.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
266.	Levenson D. Benchmarking project spurs better guideline adherence. *Rep Med Guidel Outcomes Res* 2001; 12:5-7.	Not an evaluation of a QI intervention /Excluded topic (unrelated to diabetes)
267.	Lewis D, Nath C. Feasibility of a kiosk-based patient education system in a busy outpatient clinic setting. *Diabetes Educ* 1997; 23:577-81, 585-6.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
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270.	Lorenz RA, Pichert JW, Enns SJ, Hanson SL. Impact of organizational interventions on the delivery of patient education in a diabetes clinic. *Patient Educ Couns* 1986; 8:115-23.	No eligible outcomes
271.	Lorenz RA. Training health professionals to improve the effectiveness of patient education programs. *Diabetes Educ* 1986:204-9.	Not an evaluation of a QI intervention /No eligible outcomes
272.	Lurie N, Ward NB, Shapiro MF, Brook RH. Termination from Medi-Cal--does it affect health? *N Engl J Med* 1984; 311:480-4.	Not an evaluation of a QI intervention
273.	Lustman PJ, Griffith LS, Freedland KE, Kissel SS, Clouse RE. Cognitive behavior therapy for depression in type 2 diabetes mellitus. A randomized, controlled trial. *Ann Intern Med* 1998; 129:613-21.	Patient education or self-management only
274.	Luz C. National campaign yields positive results for patients with diabetes. *Healthplan* 2002; 43:50-1.	Not an evaluation of a QI intervention
275.	Maislos M, Weisman D, Sherf M. Western Negev Mobile Diabetes Care Program: a model for interdisciplinary diabetes care in a semi-rural setting. *Acta Diabetol* 2002; 39:49-53.	Study design did not meet criteria for RCT, CBA, or ITS
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278.	Mancino JM, Rhia LC, McHattie K. Comparison of type 2 diabetes medical nutrition therapy to practice guidelines in a community health system. *J Am Diet Assoc* 2002; 102:1129-31.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
279.	Marrero. Increasing the use of intensified managment of diabetes: an education program for physicians. *The Journal of Continuing Education in the Health Professions* 1991; 11:283.	Study design did not meet criteria for RCT, CBA, or ITS/Excluded topic (Type 1 diabetes only)
280.	Marrero DG, Vandagriff JL, Kronz K, et al. Using telecommunication technology to manage children with diabetes: the Computer-Linked Outpatient Clinic (CLOC) Study. *Diabetes Educ* 1995; 21:313-9.	Excluded topic (Children/adolescents only)
281.	Marshall CL, Bluestein M, Briere E, et al. Improving outpatient diabetes management through a collaboration of six competing, capitated Medicare managed care plans. *American Journal of Medical Quality* 2000; 15:65-71.	Study design did not meet criteria for RCT, CBA, or ITS
282.	Martin EE. Organising a practice. Problem identification, disease management, and audit. *Br Med J (Clin Res Ed)* 1982; 285:265-6.	Study design did not meet criteria for RCT, CBA, or ITS
283.	Martin DA, McNeal B, Kronenfeld JJ, Wheeler FC. The impact of professional education on nursing behavior in the practice setting. *J Contin Educ Nurs* 1986; 17:40-2.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible No eligible outcomes
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286.	Mazzuca SA, Moorman NH, Wheeler ML, et al. The diabetes education study: a controlled trial of the effects of diabetes patient education. *Diabetes Care* 1986; 9:1-10.***	Patient education or self-management only
287.	Mazzuca SA, Vinicor F, Cohen SJ, et al. The Diabetes Education Study: a controlled trial of the effects of intensive instruction of internal	Other ^^^

	medicine residents on the management of diabetes mellitus. *J Gen Intern Med* 1988; 3:1-8.	
288.	McCabe CJ, Stevenson RC, Dolan AM. Evaluation of a diabetic foot screening and protection programme. *Diabet Med* 1998; 15:80-4.	Patient education or self-management only
289.	McCulloch DK, Mitchell RD, Ambler J, Tattersall RB. Influence of imaginative teaching of diet on compliance and metabolic control in insulin dependent diabetes. *Br Med J (Clin Res Ed)* 1983; 287:1858-61.	Excluded topic (Type 1 diabetes only)
290.	McDonald CJ. Use of a computer to detect and respond to clinical events: its effect on clinician behavior. *Annals of Internal Medicine* 1976; 84:162-167.	Publication prior to 1980
291.	McDonald CJ, Hui SL, Smith DM, et al. Reminders to physicians from an introspective computer medical record. A two-year randomized trial. *Ann Intern Med* 1984; 100:130-8.	Excluded topic (unrelated to diabetes)/No eligible No eligible outcomes
292.	McKay HG, King D, Eakin EG, Seeley JR, Glasgow RE. The diabetes network internet-based physical activity intervention: a randomized pilot study. *Diabetes Care* 2001; 24:1328-34.	No eligible outcomes
293.	McKenna M, Dolan M, Loughlin T, et al. Evaluation of impact on diabetic control of increased surveillance, and of human and U-100 insulins. *Ir J Med Sci* 1987; 156:347-52.	Excluded topic (Type 1 diabetes only)
294.	McMahon LM, Longabaugh R, Desrosiers M, Kriebel GW, Jr. Management of physical problems in a psychiatric hospital: a study of problem-oriented patient care. *QRB Qual Rev Bull* 1981; 7:13-9.	No eligible outcomes
295.	McNabb WL, Cook S, Fischer B, Quinn MT, Haas L. Dissemination of a continuing education program in diabetes to health care professionals. *Diabetes Educ* 1994; 20:35-40.	Not an evaluation of a QI intervention /No eligible No eligible outcomes
296.	McNally PG, MacIver DH, Jowett NI, Hearnshaw JR. Hypoglycaemia in insulin dependent diabetics: is advice heeded? *Br Med J (Clin Res Ed)* 1987; 294:1655-6.	Study design did not meet criteria for RCT, CBA, or ITS
297.	Michael P. Impact and components of the Medicare MNT benefit. *J Am Diet Assoc* 2001; 101:1140-1.	Not an evaluation of a QI intervention
298.	Mitchell. Does primary medical practitioner involvement with a	Study design did not meet criteria for

	specialist team improve patient outcomes? A systematic review. *Br J Gen Pract* 2002; 52:934.	RCT, CBA, or ITS No eligible outcomes
299.	Montani S, Bellazzi R, Quaglini S, d'Annunzio G. Meta-analysis of the effect of the use of computer-based systems on the metabolic control of patients with diabetes mellitus. *Diabetes Technol Ther* 2001; 3:347-56.	Study design did not meet criteria for RCT, CBA, or ITS
300.	Moore K, Mengel M. Expanding the team: the use of volunteers in a diabetes education program. *Diabetes Educ* 2002; 28:554-8, 560, 562.	Not an evaluation of a QI intervention
301.	Morrison N, Dooley J. The Sioux Lookout Diabetes Program: diabetes prevention and management in northwestern Ontario. *Int J Circumpolar Health* 1998; 57 Suppl 1:364-9.	Study design did not meet criteria for RCT, CBA, or ITS
302.	Most RS, Gross AM, Davidson PC, Richardson P. The accuracy of glucose monitoring by diabetic individuals in their home setting. *Diabetes Educ* 1986; 12:24-7.	Study design did not meet criteria for RCT, CBA, or ITS
303.	Muhlhauser I, Berger M. Diabetes education and insulin therapy: when will they ever learn? *J Intern Med* 1993; 233:321-6.	Not an evaluation of a QI intervention
304.	Mulcahy K, Peeples M, Tomky D, Weaver T. National Diabetes Education Outcomes System: application to practice. *Diabetes Educ* 2000; 26:957-64.	Study design did not meet criteria for RCT, CBA, or ITS
305.	Mulrow C, Bailey S, Sonksen PH, Slavin B. Evaluation of an Audiovisual Diabetes Education Program: negative results of a randomized trial of patients with non-insulin-dependent diabetes mellitus. *J Gen Intern Med* 1987; 2:215-9.	Patient education or self-management only
306.	Munro N, Felton A, McIntosh C. Is multidisciplinary learning effective among those caring for people with diabetes? *Diabet Med* 2002; 19:799-803.	Not an evaluation of a QI intervention
307.	Narayan KM, Hoskin M, Kozak D, et al. Randomized clinical trial of lifestyle interventions in Pima Indians: a pilot study. *Diabet Med* 1998; 15:66-72.	Excluded topic (normoglycemic patients)
308.	New JP, Hollis S, Campbell F, et al. Measuring clinical performance and outcomes from diabetes information systems: an observational study. *Diabetologia* 2000; 43:836-43.	Study design did not meet criteria for RCT, CBA, or ITS

309.	Nilasena DS, Lincoln MJ. A computer-generated reminder system improves physician compliance with diabetes preventive care guidelines. *Proc Annu Symp Comput Appl Med Care* 1995:640-5.	Other †††
310.	Nodhturft VL, MacMullen JA. Standardized nursing care plans... the effect of care plans on documentation of diabetic nursing care. *Nursing Management (Chicago.)* 1982; 13:33-6, 40-2.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
311.	Noel PH, Larme AC, Meyer J, Marsh G, Correa A, Pugh JA. Patient choice in diabetes education curriculum. Nutritional versus standard content for type 2 diabetes. *Diabetes Care* 1998; 21:896-901.	Patient education or self-management only
312.	Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 2001; 24:561-87.	Study design did not meet criteria for RCT, CBA, or ITS
313.	Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care* 2002; 25:1159-71.	Study design did not meet criteria for RCT, CBA, or ITS
314.	Norris SL, Nichols PJ, Caspersen CJ, et al. The effectiveness of disease and case management for people with diabetes. A systematic review. *Am J Prev Med* 2002; 22:15-38.	Study design did not meet criteria for RCT, CBA, or ITS
315.	Norris SL, Nichols PJ, Caspersen CJ. Increasing diabetes self-management education in comunity settings. A systematic review. *Am J Prev Med* 2002; 22:39-66.	Study design did not meet criteria for RCT, CBA, or ITS
316.	O'Connor PJ, Pronk NP, IN. Integrating population health concepts, clinical guidelines, and ambulatory medical systems to improve diabetes care. *Journal of Ambulatory.Care Management* 1998; 21:67-73.	Not an evaluation of a QI intervention
317.	Ornstein SM, Garr DR, Jenkins RG, Rust PF, Arnon A. Computer-generated physician and patient reminders. Tools to improve population adherence to selected preventive services. *J Fam Pract* 1991; 32:82-90.	Excluded topic (unrelated to diabetes)/No eligible outcomes
318.	Orton P. Shared care. *Lancet* 1994; 344:1413-5.	Study design did not meet criteria for RCT, CBA, or ITS

319.	Overland J, Mira M, Yue DK. Differential shared care for diabetes: does it provide the optimal partition between primary and specialist care? *Diabet Med* 2001; 18:554-7.	Study design did not meet criteria for RCT, CBA, or ITS
320.	Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ* 1995; 153:1423-31.	Study design did not meet criteria for RCT, CBA, or ITS
321.	Park JY, Daly JM. Evaluation of diabetes management software. *Diabetes Educ* 2003; 29:255-62, 267.	Not an evaluation of a QI intervention No eligible outcomes
322.	Parker MT, Leggett-Frazier N, Vincent PA, Swanson MS. The impact of an educational program on improving diabetes knowledge and changing behaviors of nurses in long-term care facilities. *Diabetes Educ* 1995; 21:541-5.	No eligible outcomes
323.	Perry TL, Mann JI, Lewis-Barned NJ, Duncan AW, Waldron MA, Thompson C. Lifestyle intervention in people with insulin-dependent diabetes mellitus (IDDM). *Eur J Clin Nutr* 1997; 51:757-63.	Patient education or self-management only
324.	Peters A, Rubsamen M, Jacob U, Look D, Scriba PC. Clinical evaluation of decision support system for insulin-dose adjustment in IDDM. *Diabetes Care* 1991; 14:875-80.	Excluded topic (Type 1 diabetes only)
325.	Peters AL. The effect of a diabetes management program on diabetes health care outcomes in health maintenance organizations. *Diabetes 43 suppl 1:84 A 1994.JC CP* 1994; 43:84. (Duplicate/overlap of article #327 from this table)	Overlaps with or duplicates another article that was included
326.	Peters AL, Davidson MB, Ossorio RC. Management of patients with diabetes by nurses with support of subspecialists. *HMO Pract* 1995; 9:8-13.	Study design did not meet criteria for RCT, CBA, or ITS
327.	Peters AL, Davidson MB. Application of a diabetes managed care program. The feasibility of using nurses and a computer system to provide effective care. *Diabetes Care* 1998; 21:1037-43.	Study design did not meet criteria for RCT, CBA, or ITS
328.	Petitti DB, Contreras R, Ziel FH, Dudl J, Domurat ES, Hyatt JA. Evaluation of the effect of performance monitoring and feedback on care process, utilization, and outcome. *Diabetes Care* 2000; 23:192-6.	Study design did not meet criteria for RCT, CBA, or ITS
329.	Petranyi G, Petranyi M, Scobie IN, et al. Quality control of home	Not an evaluation of a QI intervention

	monitoring of blood glucose concentrations. *Br Med J (Clin Res Ed)* 1984; 288:757.	
330.	Philis-Tsimikas A, Walker C. Improved care for diabetes in underserved populations. *J Ambul Care Manage* 2001; 24:39-43.	Study design did not meet criteria for RCT, CBA, or ITS
331.	Pichert JW. Outcomes of a diabetes professional education seminar. *Diabetes Educ* 1984; 9:37-9.	Study design did not meet criteria for RCT, CBA, or ITS No eligible outcomes
332.	Pichert JW, Penha ML. Institutionalization of diabetes care and education programs: a tale of two cities. *Diabetes Educ* 1993; 19:273, 276-7.	Not an evaluation of a QI intervention
333.	Pieber. Evaluation of a structured teaching and treatment programme for type2 diabetes in general practice in a rural area of Austria. *Diabetes Medicine* 1995; 112:349-54.	Patient education or self-management only
334.	Piette JD, Mah CA. The feasibility of automated voice messaging as an adjunct to diabetes outpatient care. *Diabetes Care* 1997; 20:15-21.	Study design did not meet criteria for RCT, CBA, or ITS No eligible outcomes
335.	Piette JD. Perceived access problems among patients with diabetes in two public systems of care. *J Gen Intern Med* 2000; 15:797-804.	No eligible outcomes
336.	Piette JD, Weinberger M, McPhee SJ. The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care: a randomized, controlled trial. *Med Care* 2000; 38:218-30.	No eligible outcomes
337.	Pill R, Stott NC, Rollnick SR, Rees M. A randomized controlled trial of an intervention designed to improve the care given in general practice to Type II diabetic patients: patient outcomes and professional ability to change behaviour. *Fam Pract* 1998; 15:229-35.	Patient education or self-management only
338.	Piwernetz K, Renner R, Mohrlein A, et al. Analysis and processing of data in a hospital-based diabetes management system. *Horm Metab Res Suppl* 1990; 24:109-15.	Not an evaluation of a QI intervention
339.	Porter AM. Organisation of diabetic care [letter]. *British Medical Journal Clinical Research Ed* 1982; 285:1121.	Study design did not meet criteria for RCT, CBA, or ITS

340.	Prasad S, Kamath GG, Jones K, Clearkin LG, Phillips RP. Effectiveness of optometrist screening for diabetic retinopathy using slit-lamp biomicroscopy. *Eye* 2001; 15:595-601.	No eligible outcomes
341.	Pratt, et al. Peer support and nutrition education for older adults with diabetes. *J Nutr Elder* 1987; 6:31.	Patient education or self-management only
342.	Probert CS, Maddison W, Roland JM. Diet, diabetes, and male chauvinism. *BMJ* 1990; 301:1430-1.	No eligible outcomes
343.	Pugh KB, Jenkins AJ, Zheng D, Chinniss S, Hermayer K, Jenkins C. Foot problems and foot care practices in diabetes. A survey of public and private diabetes clinics affiliated with a university hospital. *J S C Med Assoc* 2002; 98:305-10.	Not an evaluation of a QI intervention
344.	Quevedo SF, Blenkiron P, Lynch K. Diabetes case management: experience in the staff and IPA model HMO. *HMO Pract* 1998; 12:44-6.	Study design did not meet criteria for RCT, CBA, or ITS
345.	Quinn DC, Graber AL, Elasy TA, Thomas J, Wolff K, Brown A. Overcoming turf battles: developing a pragmatic, collaborative model to improve glycemic control in patients with diabetes. *Jt Comm J Qual Improv* 2001; 27:255-64.	Study design did not meet criteria for RCT, CBA, or ITS
346.	Rabkin SW, Boyko E, Wilson A, Streja DA. A randomized clinical trial comparing behavior modification and individual counseling in the nutritional therapy of non-insulin-dependent diabetes mellitus: comparison of the effect on blood sugar, body weight, and serum lipids. *Diabetes Care* 1983; 6:50-6.	Patient education or self-management only
347.	Raji A, Gomes H, Beard JO, MacDonald P, Conlin PR. A randomized trial comparing intensive and passive education in patients with diabetes mellitus. *Arch Intern Med* 2002; 162:1301-4.	Patient education or self-management only
348.	Ratner RE. CLIA 1988: impact on diabetes care. *Diabetes Care* 1992; 15:1814-7.	Not an evaluation of a QI intervention
349.	Raz I, Soskolne V, Stein P. Influence of small-group education sessions on glucose homeostasis in NIDDM. *Diabetes Care* 1988; 11:67-71.	Patient education or self-management only
350.	Redhead J, Hussain A, Gedling P, McCulloch AJ. The effectiveness of a primary-care-based diabetes education service. *Diabet Med* 1993;	Study design did not meet criteria for

	10:672-5.	RCT, CBA, or ITS
351.	Reiber GE, Smith DG, Boone DA, et al. Design and pilot testing of the DVA/Seattle Footwear System for diabetic patients with foot insensitivity. *J Rehabil Res Dev* 1997; 34:1-8.	Not an evaluation of a QI intervention /No eligible outcomes
352.	Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk Van JT, Assendelft WJ. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care* 2001; 24:1821-33.	Study design did not meet criteria for RCT, CBA, or ITS
353.	Renders CM, Valk GD, Griffin S, Wagner EH, Eijk JT, Assendelft WJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev* 2001:CD001481.	Not an evaluation of a QI intervention
354.	Riddle MC. A strategy for chronic disease. *Lancet* 1980; 2:734-6.	Not an evaluation of a QI intervention
355.	Ridgeway NA, Harvill DR, Harvill LM, Falin TM, Forester GM, Gose OD. Improved control of type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J* 1999; 92:667-72.	Patient education or self-management only
356.	Rimmer JH, Silverman K, Braunschweig C, Quinn L, Liu Y. Feasibility of a health promotion intervention for a group of predominantly African American women with type 2 diabetes. *Diabetes Educ* 2002; 28:571-80.	Study design did not meet criteria for RCT, CBA, or ITS
357.	Rith-Najarian S, Branchaud C, Beaulieu O, Gohdes D, Simonson G, Mazze R. Reducing lower-extremity amputations due to diabetes. Application of the staged diabetes management approach in a primary care setting. *J Fam Pract* 1998; 47:127-32.	Study design did not meet criteria for RCT, CBA, or ITS
358.	Roberts S. Effectiveness of a hospital diabetes specialist nursing service. *Diabet Med* 2002; 19 Suppl 1:9-11.	Study design did not meet criteria for RCT, CBA, or ITS
359.	Robinson TN. Community health behavior change through computer network health promotion: preliminary findings from Stanford Health-Net. *Computer Methods Programs Biomed* 1989; 30:137.	Not an evaluation of a QI intervention /No eligible outcomes
360.	Rodgers J, Walker R. Glycaemic control in type 2 diabetes. *Nurs Times* 2002; 98:56-7.	Not an evaluation of a QI intervention

361.	Rothman R, Malone R, Bryant B, Horlen C, Pignone M, IN. Pharmacist-led, primary care-based disease management improves hemoglobin A1c in high-risk patients with diabetes. *American Journal of Medical Quality* 2003; 18:51-58.	Study design did not meet criteria for RCT, CBA, or ITS
362.	Rotman. A randomized controlled trial of a computer-based physician workstation in an outpatient setting: implementation barriers to outcome evaluation. *J Am Med Inform Assoc* 1996; 3:340.	Excluded topic (unrelated to diabetes)/No eligible outcomes
363.	Rotvold GH, Knarvik U, Johansen MA, Fossen K. Telemedicine screening for diabetic retinopathy: staff and patient satisfaction. *J Telemed Telecare* 2003; 9:109-13.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
364.	Rubin RJ, Dietrich KA, Hawk AD. Clinical and economic impact of implementing a comprehensive diabetes management program in managed care. *J Clin Endocrinol Metab* 1998; 83:2635-42.	Study design did not meet criteria for RCT, CBA, or ITS
365.	Rundall TG, Shortell SM, Wang MC, et al. As good as it gets? Chronic care management in nine leading US physician organisations. *BMJ* 2002; 325:958-61.	Not an evaluation of a QI intervention
366.	Ruoff G, Gray LS. Using a flow sheet to improve performance in treatment of elderly patients with type 2 diabetes. *Fam Med* 1999; 31:331-6.	Study design did not meet criteria for RCT, CBA, or ITS
367.	Rutten G, van Eijk J, de Nobel E, Beek M, van der Velden H. Feasibility and effects of a diabetes type II protocol with blood glucose self-monitoring in general practice. *Fam Pract* 1990; 7:273-8.	Patient education or self-management only
368.	Ryff-de Leche A, Engler H, Nutzi E, Berger M, Berger W. Clinical application of two computerized diabetes management systems: comparison with the log-book method. *Diabetes Res* 1992; 19:97-105.	Excluded topic (Type 1 diabetes only)
369.	Sacerdote AS. Impact of budget cuts on diabetic control in urban adult diabetes clinic. *Diabetes Care* 1988; 11:302-3.	Not an evaluation of a QI intervention
370.	Samaras K, Ashwell S, Mackintosh AM, Fleury AC, Campbell LV, Chisholm DJ. Will older sedentary people with non-insulin-dependent diabetes mellitus start exercising? A health promotion model. *Diabetes Res Clin Pract* 1997; 37:121-8.	Patient education or self-management only
371.	Sanders KM, Satyvavolu A. Improving blood pressure control in diabetes: limitations of a clinical reminder in influencing physician	No eligible outcomes

	behavior. *J Contin Educ Health Prof* 2002; 22:23-32.	
372.	Sarkisian. A systematic review of diabetes self-care interventions for older, African American, or Latino adults. *Diabetes Educ.* 2003; 29:467.	Study design did not meet criteria for RCT, CBA, or ITS
373.	Schachat AP, Lee PP, Wu WC. A quality assurance program for an inpatient department of ophthalmology. 'Indicators and criteria'. *Arch Ophthalmol* 1989; 107:1293-6.	Not an evaluation of a QI intervention
374.	Schneider SH, Khachadurian AK, Amorosa LF, Clemow L, Ruderman NB. Ten-year experience with an exercise-based outpatient life-style modification program in the treatment of diabetes mellitus. *Diabetes Care* 1992; 15:1800-10.	Study design did not meet criteria for RCT, CBA, or ITS
375.	Scholz V, Jorgens V, Berger M, et al. Evaluation of a postgraduate course for diabetes educators. *Diabetes Educ* 1984; 10 SPEC NO:80-4.	Study design did not meet criteria for RCT, CBA, or ITS
376.	Schwartz R, Zaremba M, Ra K. Third-party coverage for diabetes education program. *QRB Qual Rev Bull* 1985; 11:213-7.	Not an evaluation of a QI intervention
377.	Schwedes U, Siebolds M, Mertes G. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. *Diabetes Care* 2002; 25:1928-32.	Patient education or self-management only
378.	Scott, et al. The effectiveness of diabetes education for non-insulin-dependent diabetic persons. *Diabetes Educ* 1984; 10:36.	Patient education or self-management only
379.	Scott M. The NSW Aboriginal Vascular Health Program. *N S W Public Health Bull* 2002; 13:152-4.	Not an evaluation of a QI intervention
380.	Sczupak CA, Conrad WF. Relationship between patient-oriented pharmaceutical services and therapeutic outcomes of ambulatory patients with diabetes mellitus. *American Journal of Hospital Pharmacy* 1977; 34:1238-1242.	Publication prior to 1980
381.	Shandro MT, Pick ME, Gruninger A, Ryan EA, IN. Diabetes care: interventions in the community. *Diabetes Care* 2002; 25:941-942.	Patient education or self-management only
382.	Sharp LK, Lipsky MS. The short-term impact of a continuing medical education program on providers' attitudes toward treating diabetes. *Diabetes Care* 1999; 22:1929-32.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes

383.	Sharp LK, Lipsky MS. Continuing medical education and attitudes of health care providers toward treating diabetes. *J Contin Educ Health Prof* 2002; 22:103-12.	No eligible outcomes
384.	Shultz EK, Bauman A, Hayward M, Rodbard D, Holzman R. Improved diabetic prognosis following telecommunication and graphical processing of diabetic data. *Proc Annu Symp Comput Appl Med Care* 1991:53-7. Duplicate/overlap of article #385 from this table)	Overlaps with or duplicates another article that was included
385.	Shultz EK, Bauman A, Hayward M, Holzman R. Improved care of patients with diabetes through telecommunications. *Ann N Y Acad Sci* 1992; 670:141-5.	Other [§§§]
386.	Sibbald RG, Kensholme A, Carter L, Knowles A, Tyrrell W. Special foot clinics for patients with diabetes. *J Wound Care* 1996; 5:238-43.	Not an evaluation of a QI intervention
387.	Siddall R. Diabetes. Sugar refiner. *Health Serv J* 1999; 109:suppl 3-5.	Not an evaluation of a QI intervention
388.	Sideman K, Padilla B, Huff TA, Stachura ME. Capillary blood glucose monitoring: a comparison of two hospital quality control programs. *Diabetes Educ* 1988; 14:223-6.	Not an evaluation of a QI intervention /Excluded topic (capillary blood glucose testing)
389.	Sidorov J, Gabbay R, Harris R, et al. Disease management for diabetes mellitus: impact on hemoglobin A1c. *Am J Manag Care* 2000; 6:1217-26.	Study design did not meet criteria for RCT, CBA, or ITS
390.	Sidorov J, Shull R, Tomcavage J, Girolami S, Lawton N, Harris R. Does diabetes disease management save money and improve outcomes? A report of simultaneous short-term savings and quality improvement associated with a health maintenance organization-sponsored disease management program among patients fulfilling health employer data and information set criteria. *Diabetes Care* 2002; 25:684-9.	Study design did not meet criteria for RCT, CBA, or ITS
391.	Sifuentes F, Chang L, Nieman LZ, Foxhall LE. Evaluating a diabetes foot care program in a preceptorship for medical students. *Diabetes Educ* 2002; 28:930-2, 935-7.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
392.	Sikka R, Waters J, Moore W, Sutton DR, Herman WH, Aubert RE. Renal assessment practices and the effect of nurse case management of health maintenance organization patients with diabetes. *Diabetes Care* 1999; 22:1-6. (Duplicate/overlap of included	Overlaps with or duplicates another article that was included

	article****)	
393.	Simmons D, Voyle JA. Reaching hard-to-reach, high-risk populations: piloting a health promotion and diabetes disease prevention programme on an urban marae in New Zealand. *Health Promot Internation* 2003; 18:41-50.	Study design did not meet criteria for RCT, CBA, or ITS/Excluded topic (promotion of diabetes prevention program)
394.	Singh BM, Holland MR, Thorn PA. Metabolic control of diabetes in general practice clinics: comparison with a hospital clinic. *Br Med J (Clin Res Ed)* 1984; 289:726-8.	Not an evaluation of a QI intervention
395.	Sinnock P. The use of hospitalization data to evaluate patient education programs. *Diabetes Educ* 1984; 10 SPEC NO:43-5.	Not an evaluation of a QI intervention
396.	Skaer TL, Sclar DA, Markowski DJ, Won JK. Effect of value-added utilities on prescription refill compliance and Medicaid health care expenditures--a study of patients with non-insulin-dependent diabetes mellitus. *J Clin Pharm Ther* 1993; 18:295-9.	Patient education or self-management only
397.	Smith DM, Norton JA, Weinberger M, McDonald CJ, Katz BP. Increasing prescribed office visits. A controlled trial in patients with diabetes mellitus. *Med Care* 1986; 24:189-99. (Duplicate/overlap of article #398 from this table)	Overlaps with or duplicates another article that was included
398.	Smith DM, Weinberger M, Katz BP. A controlled trial to increase office visits and reduce hospitalizations of diabetic patients. *J Gen Intern Med* 1987; 2:232-8.	Patient education or self-management only
399.	Smith SC, Folk JC, Losch ME. Effects of collaborative education on patient satisfaction and knowledge. *Insight* 1992; 17:20-4.	No eligible outcomes
400.	Smith DE, Heckemeyer CM, Kratt PP, Mason DA. Motivational interviewing to improve adherence to a behavioral weight-control program for older obese women with NIDDM. A pilot study. *Diabetes Care* 1997; 20:52-4.	Patient education or self-management only
401.	Smith L, Weinert C. Telecommunication support for rural women with diabetes. *Diabetes Educ* 2000; 26:645-55.	No eligible outcomes
402.	Snoek FJ, Skinner TC. Psychological counselling in problematic diabetes: does it help? *Diabet Med* 2002; 19:265-73.	Study design did not meet criteria for RCT, CBA, or ITS
403.	Solberg LI, Reger LA, Pearson TL, et al. Using continuous quality	Not an evaluation of a QI intervention

	improvement to improve diabetes care in populations: the IDEAL model. Improving care for Diabetics through Empowerment Active collaboration and Leadership. *Jt Comm J Qual Improv* 1997; 23:581-92.	
404.	Sperl-Hillen J, O'Connor PJ, Carlson RR, et al. Improving diabetes care in a large health care system: an enhanced primary care approach. *Jt Comm J Qual Improv* 2000; 26:615-22.	Study design did not meet criteria for RCT, CBA, or ITS
405.	Sperl-Hillen J, Isham GJ. HealthPartners' diabetes care improvement program. *Healthplan* 2002; 43:46-8, 50-1, 53.	Not an evaluation of a QI intervention
406.	Sprafka JM, Crozier M, Whipple D, Bishop D, Kurth D. Response of diabetic patients to a community-based education program. *Diabetes Educ* 1988; 14:148-51.	Study design did not meet criteria for RCT, CBA, or ITS
407.	Stafford J, Helm AM, Beaven DW. The value of short courses: an attempt ot evaluate a four-day teaching programme in Christchurch for diabetes educators. *New Zealand Nursing Journal* 1979; 72:24.	Not an evaluation of a QI intervention
408.	Stange KC, Miller WL, Crabtree BF, O'Connor PJ, Zyzanski SJ. Multimethod research: approaches for integrating qualitative and quantitative methods. *J Gen Intern Med* 1994; 9:278-82.	Not an evaluation of a QI intervention
409.	Starren J, Hripcsak G, Sengupta S, et al. Columbia University's Informatics for Diabetes Education and Telemedicine (IDEATel) project: technical implementation. *J Am Med Inform Assoc* 2002; 9:25-36.	Not an evaluation of a QI intervention
410.	Steel JM, Cramb R, Duncan LJ. How useful are patient-operated blood glucose meters? *Practitioner* 1980; 224:651-3.	Not an evaluation of a QI intervention
411.	Steffens B. Cost-effective management of type 2 diabetes: providing quality care in a cost-constrained environment. *Am J Manag Care* 2000; 6:S697-703; discussion S704-9.	Study design did not meet criteria for RCT, CBA, or ITS
412.	Stegmayer P, Lovrien FC, Smith M, Keller T, Gohdes DM. Designing a diabetes nutrition education program for a Native American community. *Diabetes Educ* 1988; 14:64-6.	Study design did not meet criteria for RCT, CBA, or ITS
413.	Stein GH. The use of a nurse practitioner in the management of patients with diabetes mellitus. *Medical Care* 1974; 12:885-890.	Not an evaluation of a QI intervention

414.	Stoner KL, Lasar NJ, Butcher MK, et al. Improving glycemic control: can techniques used in a managed care setting be successfully adapted to a rural fee-for-service practice? *Am J Med Qual* 2001; 16:93-8.	Study design did not meet criteria for RCT, CBA, or ITS
415.	Stott NC, Rollnick S, Rees MR, Pill RM. Innovation in clinical method: diabetes care and negotiating skills. *Fam Pract* 1995; 12:413-8.	Not an evaluation of a QI intervention
416.	Strock ES, Sandell JL. The ambulatory insulin program: initiating insulin therapy in an outpatient setting. *Diabetes Educ* 1988; 14:338-45.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
417.	Sturmberg JP, Overend D. General practice based diabetes clinics. An integration model. *Aust Fam Physician* 1999; 28:240-5.	Study design did not meet criteria for RCT, CBA, or ITS
418.	Sullivan FM. Whose problem is the diabetic who does not attend a hospital clinic? *Scott Med J* 1988; 33:259-60.	Not an evaluation of a QI intervention
419.	Sullivan FM, Menzies A. The costs and benefits of introducing a nurse-run diabetic review service into general practice. *Practical Diabetes* 1991;8(2):47-50	Study design did not meet criteria for RCT, CBA, or ITS
420.	Surwit RS, van Tilburg MA, Zucker N, et al. Stress management improves long-term glycemic control in type 2 diabetes. *Diabetes Care* 2002; 25:30-4.	Patient education or self-management only
421.	Svac J. Analysis of discharge data in a large hospital in Slovakia. Its application to diabetic patients. *Stud Health Technol Inform* 1994; 14:110-23.	Not an evaluation of a QI intervention
422.	Tai SS, Nazareth I, Donegan C, Haines A. Evaluation of general practice computer templates. Lessons from a pilot randomised controlled trial. *Methods Inf Med* 1999; 38:177-81.	Study design did not meet criteria for RCT, CBA, or ITS/No eligible outcomes
423.	Tape TG, Campbell JR. Computerized medical records and preventive health care: success depends on many factors. *Am J Med* 1993; 94:619-25.	No eligible outcomes
424.	Taplin S, Galvin MS, Payne T, Coole D, Wagner E. Putting population-based care into practice: real option or rhetoric? *J Am Board Fam Pract* 1998; 11:116-26.	Study design did not meet criteria for RCT, CBA, or ITS
425.	Tariq SH, Karcic E, Thomas DR, et al. The use of a no-concentrated-	Not an evaluation of a QI intervention

	sweets diet in the management of type 2 diabetes in nursing homes. *J Am Diet Assoc* 2001; 101:1463-6.	
426.	Tasker PR. Diabetes care: whose responsibility? *Br Med J (Clin Res Ed)* 1985; 290:1632.	Not an evaluation of a QI intervention
427.	Tattersall R, Gale E. Patient self-monitoring of blood glucose and refinements of conventional insulin treatment. *Am J Med* 1981; 70:177-82.	Not an evaluation of a QI intervention
428.	Taylor R. Practical community screening for diabetic retinopathy using the mobile retinal camera: report of a 12 centre study. British Diabetic Association Mobile Retinal Screening Group. *Diabet Med* 1996; 13:946-52.	Study design did not meet criteria for RCT, CBA, or ITS
429.	Testa MA, Simonson DC. Health economic benefits and quality of life during improved glycemic control in patients with type 2 diabetes mellitus: a randomized, controlled, double-blind trial. *JAMA* 1998; 280:1490-6.	Not an evaluation of a QI intervention
430.	Teza SL, DeVito AV, 2nd, Hiss RG. Resource manual to help your program meet the national standards. *Diabetes Educ* 1987; 13 Suppl:210-28.	Not an evaluation of a QI intervention
431.	Thackeray R, Neiger BL. Using social marketing to develop diabetes self-management education interventions. *Diabetes Educ* 2002; 28:536-40, 542-4.	Not an evaluation of a QI intervention
432.	Thompson. A team approach to diabetic foot care: the Manchester experience. *Foot* 1991; 1:75-82.	Other ^^^^
433.	Thorn PA, Watkins PJ. Organisation of diabetic care. *Br Med J (Clin Res Ed)* 1982; 285:787-9.	Not an evaluation of a QI intervention
434.	Tildesley HD, Mair K, Sharpe J, Piaseczny M. Diabetes teaching--outcome analysis. *Patient Educ Couns* 1996; 29:59-65.	Study design did not meet criteria for RCT, CBA, or ITS
435.	Tobe SW, McFarlane PA, Naimark DM. Microalbuminuria in diabetes mellitus. *CMAJ* 2002; 167:499-503.	Study design did not meet criteria for RCT, CBA, or ITS
436.	Trento M, al. e. Therapeutic group education in the follow-up of patients with non-insulin treated, non-insulin dependent diabetes mellitus. *Diabetes Metab Clin Exp* 1998; 11:212-216.	Patient education or self-management only

437.	Trento M, Passera P, Tomalino M, et al. Group visits improve metabolic control in type 2 diabetes: a 2-year follow-up. *Diabetes Care* 2001; 24:995-1000.	Patient education or self-management only
438.	Trento M, Passera P, Bajardi M, et al. Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia* 2002; 45:1231-9.	Patient education or self-management only
439.	Tsang MW, Mok M, Kam G, et al. Improvement in diabetes control with a monitoring system based on a hand-held, touch-screen electronic diary. *J Telemed Telecare* 2001; 7:47-50.	Patient education or self-management only
440.	Tu KS, McDaniel G, Gay JT. Diabetes self-care knowledge, behaviors, and metabolic control of older adults--the effect of a posteducational follow-up program. *Diabetes Educator.* 1993; 19:25-30.	Patient education or self-management only
441.	Turner RC, Peden JG, Jr., O'Brien K. Patient-carried card prompts vs computer-generated prompts to remind private practice physicians to perform health maintenance measures. *Arch Intern Med* 1994; 154:1957-60.	No eligible outcomes
442.	Turnin MC, Beddok RH, Clottes JP, et al. Telematic expert system Diabeto. New tool for diet self-monitoring for diabetic patients. *Diabetes Care* 1992; 15:204-12.	Study design did not meet criteria for RCT, CBA, or ITS
443.	Tyrrell W. Orthotic intervention in patients with diabetic foot ulceration. *J Wound Care* 1999; 8:530-2.	Not an evaluation of a QI intervention
444.	Uusitupa, et al. The maintenance of improved metabolic control after intensified diet therapy in recent type 2 diabetes. *Diabetes Res Clinic Pract* 1993; 19:227.	Patient education or self-management only
445.	Uusitupa MI. Early lifestyle intervention in patients with non-insulin-dependent diabetes mellitus and impaired glucose tolerance. *Ann Med* 1996; 28:445-9. (Duplicate/overlap of article #444 from this table)	Overlaps with or duplicates another article that was included
446.	Valk GD, Kriegsman DM, Assendelft WJ. Patient education for preventing diabetic foot ulceration. A systematic review. *Endocrinol Metab Clin North Am* 2002; 31:633-58.	Study design did not meet criteria for RCT, CBA, or ITS
447.	Varroud-Vial M, Charpentier G, Vaur L, et al. Effects of clinical audit on the quality of care in patients with type 2 diabetes: results of the	Not an evaluation of a QI intervention

	DIABEST pilot study. *Diabetes Metab* 2001; 27:666-74.	
448.	Vijan S, Stevens DL, Herman WH, Funnell MM, Standiford CJ. Screening, prevention, counseling, and treatment for the complications of type II diabetes mellitus. Putting evidence into practice. *J Gen Intern Med* 1997; 12:567-80.	Not an evaluation of a QI intervention
449.	Vinicor F, Cohen SJ, Mazzuca SA, et al. DIABEDS: a randomized trial of the effects of physician and/or patient education on diabetes patient outcomes. *Journal of Chronic Diseases* 1987; 40:345-356. (Duplicate/overlap of included article^^)	Overlaps with or duplicates another article that was included
450.	Vrijhoef HJ, Diederiks JP, Spreeuwenberg C, Wolffenbuttel BH. Substitution model with central role for nurse specialist is justified in the care for stable type 2 diabetic outpatients. *J Adv Nurs* 2001; 36:546-55.	No eligible outcomes
451.	Vrijhoef HJ, Spreeuwenberg C, Eijkelberg IM, Wolffenbuttel BH, van Merode GG. Adoption of disease management model for diabetes in region of Maastricht. *BMJ* 2001; 323:983-5.	Not an evaluation of a QI intervention
452.	Vrijhoef HJ, Diederiks JP, Spreeuwenberg C, Wolffenbuttel BH, van Wilderen LJ, IN. The nurse specialist as main care-provider for patients with type 2 diabetes in a primary care setting: effects on patient outcomes. *International Journal of Nursing Studies* 2002; 39:441-451.	Study design did not meet criteria for RCT, CBA, or ITS No eligible outcomes
453.	Watkins GB, Sutcliffe T, Pyke DA, Watkins PJ. Computerisation of diabetic clinic records. *Br Med J* 1980; 281:1402-3.	Not an evaluation of a QI intervention
454.	Watts GF, Macleod AF, Benn JJ, et al. Comparison of the real-time use of glycosylated haemoglobin and plasma fructosamine in the diabetic clinic. *Diabet Med* 1991; 8:573-9.	Not an evaluation of a QI intervention
455.	Weinberger M, Ault KA, Vinicor F. Prospective reimbursement and diabetes mellitus. Impact upon glycemic control and utilization of health services. *Med Care* 1988; 26:77-83.	Study design did not meet criteria for RCT, CBA, or ITS No eligible outcomes
456.	Weinberger M, Oddone EZ, Henderson WG. Does increased access to primary care reduce hospital readmissions? Veterans Affairs Cooperative Study Group on Primary Care and Hospital Readmission. *N Engl J Med* 1996; 334:1441-7.	No eligible outcomes

457.	Werdier D, Jesdinsky HJ, Helmich P. A randomized, controlled study on the effect of diabetes counseling in the offices of 12 general practitioners. *Rev Epidemiol Sante Publique* 1984; 32:225-9.	Patient education or self-management only
458.	White N, Carnahan J, Nugent CA, Iwaoka T, Dodson MA. Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care* 1986; 9:490-6.	Patient education or self-management only
459.	White B. 13 months of quality improvement: did it work? *Fam Pract Manag* 2001; 8:55-7.	Study design did not meet criteria for RCT, CBA, or ITS
460.	Williams D, Munroe C, Hospedales CJ, Greenwood RH. A Three-Year Evaluation of the Quality of Diabetes Care in the Norwich Community Care Scheme. *Diab Medicine* 1990; 7:74.	Study design did not meet criteria for RCT, CBA, or ITS
461.	Wilson W, Pratt C. The impact of diabetes education and peer support upon weight and glycemic control of elderly persons with noninsulin dependent diabetes mellitus (NIDDM). *Am J Public Health* 1987; 77:634-5.	Patient education or self-management only
462.	Wing RR, Epstein LH, Nowalk MP, Scott N, Koeske R, Hagg S. Does self-monitoring of blood glucose levels improve dietary compliance for obese patients with type II diabetes? *Am J Med* 1986; 81:830-6.	Patient education or self-management only
463.	Wing. Self-regulation in the treatment of type II diabetes. *Behav Ther* 1988; 19:11. (Duplicate/overlap of article #462 from this table)	Overlaps with or duplicates another article that was included
464.	Wing RR, Anglin K. Effectiveness of a behavioral weight control program for blacks and whites with NIDDM. *Diabetes Care* 1996; 19:409-13.	No eligible outcomes
465.	Wise PH, Dowlatshahi DC, Farrant S, Fromson S, Meadows KA. Effect of computer-based learning on diabetes knowledge and control. *Diabetes Care* 1986; 9:504-8.	Patient education or self-management only
466.	Woodcock AJ, Kinmonth AL, Campbell MJ, Griffin SJ, Spiegal NM. Diabetes care from diagnosis: effects of training in patient-centred care on beliefs, attitudes and behaviour of primary care professionals. *Patient Educ Couns* 1999; 37:65-79.	No eligible outcomes
467.	Wooldridge J, Moreno L. Evaluation of the costs to Medicare of covering therapeutic shoes for diabetic patients. *Diabetes Care* 1994;	No eligible outcomes

	17:541-547.	
468.	Worth. Shared care for diabetes in Chester: preliminary experience with a 'clinic-wide' scheme. *Practical Diabetes* 1990; 7:266.	Study design did not meet criteria for RCT, CBA, or ITS
469.	Wylie-Rosett J, Engel S, D'Eramo G, et al. Delivery of diabetes care to low--income patients: assessment of a federally funded program. *Diabetes Educ* 1989; 15:366-9.	Not an evaluation of a QI intervention
470.	Wylie-Rosett J, Villeneuve M, IN. Overcoming resistance to change in a long-term care facility: analysis of the team approach and consensus process. *Diabetes Educator.* 1989; 15:122-123.	Not an evaluation of a QI intervention
471.	Young-Hyman D. Provider impact in diabetes education. What we know, what we would like to know, paradigms for asking. *Diabetes Educ* 1999; 25:34-42.	Not an evaluation of a QI intervention

* Combination of reasons: 1) follow-up < 80%; patients were allowed to change treatment assignment, but there was no ITT; main outcome was HbA1c, but all 4 values (control pre/post, Intervention pre/post) were equal AND the common value of 5.3 is too low, possibly b/c study was conducted before assay standardization. Lastly, borderline QI vs. equivalency study

^ Insufficient information; contacted first author - still not available as journal publication or completed manuscript

† **Branger, P.J., van't Hooft, A., van der Wouden, J.C., Moorman, P.W., van Bemmel, J.H.** Shared care for diabetes: supporting communication between primary and secondary care. *Int J Med Inf.* 1999;53(2-3):133-42.

§ **Franz, M.J., Monk, A., Barry, B., et al.** Effectiveness of medical nutrition therapy provided by dietitians in the management of non-insulin-dependent diabetes mellitus: a randomized, controlled clinical trial. *Journal of the American Dietetic Association.* 1995;95(9):1009-1017.

** **Gaede, P., Vedel, P., Larsen, N., Jensen, G.V., Parving, H.H., Pedersen, O.** Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *N Engl J Med.* 2003;348(5):383-93.

^^ **Weinberger, M., Kirkman, M.S., Samsa, G.P., et al.** A nurse-coordinated intervention for primary care patients with non-insulin-dependent diabetes mellitus: impact on glycemic control and health-related quality of life. *J Gen Intern Med.* 1995;10(2):59-66.

†† Specified patients only as “insulin dependent diabetics,” but average age and duration of disease suggested that patients were all Type I diabetics.

§§ **Lobach, D.F., Hammond, W.E.** Computerized decision support based on a clinical practice guideline improves compliance with care standards. *Am J Med*. 1997;102(1):89-98.

*** Article compares usual care versus provider education only, usual care versus patient and provider education, and usual care versus patient education only. Exclusion is of usual care versus patient education only comparison.

^^^ Design makes results unusable, study too old to contact authors for more information.

††† Insufficient patient population size information.

§§§ Cross-over trial with insufficient wash out period and insufficient information to split into two.

**** **Aubert, R.E., Herman, W.H., Waters, J., et al.** Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. A randomized, controlled trial. *Ann Intern Med*. 1998;129(8):605-12.

^^^^ Unable to obtain article.

Appendix H. Additional tables for diabetes results and analysis

Tables H1-H3. Re-analysis of adherence in terms of maximum rather than median effect reported by each study

In the main analysis, we pooled the various adherence outcomes reported by the included studies into a general provider adherence outcome. For each study, this measure was based on the adherence outcome exhibiting the median effect.

In Appendix Tables H1-H3, we show the results obtained if, instead of taking the outcome with median effect, one selects the outcome with maximum effect (i.e., the outcome for which the intervention group showed the greatest increase in adherence above any increases in the control group).

The purpose of the comparison is not the different magnitudes size between the maximum and median adherence (as these are expected to differ in this regard) but rather, the degree to which the patterns across QI types, strata of sample size and trial design are the same. In other words, it is unlikely that the relationships discussed in the main analysis simply reflect the definition of the generalized adherence outcome in terms of the median effect associated with each study. The same general relationships emerge on analyzing the studies in terms of the maximum impact on adherence achieved by each study.

Tables H4a-c. Alternate classification scheme for numbers of QI strategies per intervention

The main analysis showed a benefit for intervention with at least 2 QI strategies compared to single-faceted ones. Since this finding relates to one of our *a priori* hypotheses (that multi-faceted interventions achieve greater impact than single faceted ones), we further explored this question by reclassifying each intervention using a scheme similar to that used by other authors, in which major subtypes are regarded as their own category. Specifically, we replaced the broad category of provider education with separate categories for workshops or meeting, educational outreach or academic detailing, and distribution of educational materials. Similarly, we promoted disease management, team or personnel changes, and changes to the existing medical record system to their own categories, rather than pooling them within the broad category of organizational change.

Table H1a. Association between maximum improvements in provider adherence† and type of quality improvement strategy stratified by study sample size (median adherence included for comparison)

	Median Improvement in clinician adherence [inter-quartile range] N=Number of trials	Maximum Improvement in provider adherence [inter-quartile range] N=Number of trials				
	All Trials	All Trials	Trials with sample size in lowest quartile	Trials with sample size in lower 2 quartiles	Trials with sample size in upper 2 quartiles	Trials with sample size in highest quartile
All QI types	4.8 [3.8, 15.0] N=17	11.6 [7.0, 23.7] N=17	21.8 [21.4,30.9] N=3	25.9 [21.2,37.5] N=6	11.0 [6.5,13.5] N=11	10.8 [6.5,12.6] N=8
Provider Education	5.6 [4.15, 17.2] N=11	21.8 [11.3,28.5] N=11	21.8 [21.4,30.9] N=3	30.0 [21.8,40.0] N=5	11.3 [11.0,2.07] N=6	11.3 [10.9,14.6] N=4
Provider Reminders	3.4 [2.2, 3.6] N=3	11.0 [10.8,13.2] N=3	- - - - N=0	- - - - N=0	11.0 [10.8,13.2] N=3	13.0 [10.5,15.4] N=2
Facilitated relay	4.85 - - - - N=1	4.85 - - - - N=1	- - - - N=0	4.85 - - - - N=1	- - - - N=0	- - - - N=0
Patient Education	4.9 [4.7, 5.4] N=3	6.0 [5.4,23.0] N=3	40.0 - - - - N=1	22.4 [4.9,40.0] N=2	6.0 - - - - N=1	- - - - N=0
Self-management	6.0 - - - - N=1	6.0 - - - - N=1	- - - - N=0	- - - - N=0	6.0 - - - - N=1	- - - - N=0
Patient reminders	2.8 [1.0,4.5] N=2	9.0 [7.0,11.0] N=2	N=0	N=0	9.0 [7.0,11.0] N=2	7.0 - - - - N=1

Table H1a. Association between maximum improvements in provider adherence† and type of quality improvement strategy stratified by study sample size (median adherence included for comparison) (continued)

Audit & feedback	5.6 [3.4, 16.4] N=9	15.4 [11.0,23.7] N=9	21.8 - - - - N=1	31.8 [21.8,41.7] N=2	11.6 [11.0,19.6] N=7	11.6 [11.0,15.4] N=5
Organizational Change	4.7 [4.1, 5.7] N=6	6.5 [5.3,10.0] N=6	4.9 - - - - N=1	17.4 [4.9,30.0] N=2	6.5 [5.8,8.0] N=4	6.0 [5.0,7.0] N=2

† For each study, the general provider adherence outcome captured the adherence outcome with the median effect size reported by that study. In this set of appendix tables, we show the results obtained if, instead of taking the outcome with median effect, one selects the outcome with maximum effect (i.e., the outcome for which the intervention group showed the greatest increase in adherence above any increases in the control group).

* When N=2, square brackets show the actual results of each study rather than interpolated 25th and 75th percentiles.

Table H1b. Associations between improvements in glycemic control and provider adherence stratified by trial design (median adherence included for comparison)

	Median Improvement in provider adherence [inter-quartile range*] N=Number of trials			Maximum Improvement in provider adherence [inter-quartile range*] N=Number of trials		
	All Trials	**RCT**	**Non-RCT†**	**All Trials**	**RCT**	**Non-RCT†**
All QI types	4.9 [3.8, 15.0] N=17	4.5 [3.5, 5.4] N=14	18.0 [17.2, 21.0] N=3	11.6 [7.0,23.7] N=17	11.0 [6.3,19.6] N=14	30.0 [28.5,35.9] N=3
Provider Education	5.6 [4.2, 17.2] N=11	4.8 [3.1,8.0] N=8	18.0 [17.2, 21.0] N=3	21.8 [11.3,28.5] N=11	16.3 [11.0,22.3] N=8	30.0 [28.5,35.9] N=3
Provider Reminders	3.4 [2.2, 3.6] N=3	3.4 [2.2, 3.6] N=3	- - - - N=0	11.0 [10.8,13.2] N=3	11.0 [10.8,13.2] N=3	- - - - N=0
Facilitated relay	4.9 - - - - N=1	4.9 - - - - N=1	- - - - N=0	4.85 - - - - N=1	4.85 - - - - N=1	- - - - N=0
Patient Education	4.9 [4.7, 5.4] N=3	4.9 [4.7, 5.4] N=3	- - - - N=0	6.0 [5.4,23.0] N=3	6.0 [5.4,23.0] N=3	- - - - N=0
Self-management	6.0 - - - - N=1	6.0 - - - - N=1	- - - - N=0	6.0 - - - - N=1	6.0 - - - - N=1	- - - - N=0
Patient reminders	2.8 [1.0,4.5] N=2	2.8 [1.0, 4.5] N=2	- - - - N=0	9.0 [7.0,11.0] N=2	9.0 [7.0,11.0] N=2	- - - - N=0
Audit & feedback	5.6 [3.4, 16.4] N=9	5.0 [3.2, 10.3] N=7	20.2 [16.4,23.9] N=2*	15.4 [11.0,23.7] N=9	11.6 [11.0,18.6] N=7	34.3 [26.9,41.7] N=2*
Organizational Change	4.7 [4.1, 5.7] N=6	4.5 [4.0, 4.9] N=5	18.0 - - - - N=1	6.5 [5.3,10.0] N=6	6.0 [5.0,7.0] N=5	30.0 - - - - N=1

* When N=2, square brackets show the actual results of each study rather than interpolated inter-quartile range.

† Non-RCT included 16 controlled before-after studies and 1 quasi-randomized trial.

Table H1c. Impacts on glycemic control and provider adherence stratified by trial design and sample size (median adherence included for comparison)

		All sizes	Trials with sample size in lowest quartile	Trials with sample size in lower 2 quartiles	Trials with sample size in upper 2 quartiles	Trials with sample size in highest quartile
Median Improvement in provider adherence (%) [inter-quartile range†] N=Number of trials	**All trial designs**	4.8 [3.8, 15.0] N=17	4.5 [2.8, 11.4] N=3	10.6 [4.6, 17.6] N=6	4.5 [3.6, 5.8] N=11	4.2 [3.7, 5.2] N=8
	RCTs	4.5 [3.5,5.5] N=14	4.5 [2.8,11.4] N=3	4.7 [3.6,8.2] N=4	4.3 [3.5,5.5] N=10	4.3 [3.7,5.2] N=8
	Non-RCTs	18.0 [17.2,21.0] N=3	N=0	17.2 [16.4,18.0] N=2	23.9 - - - - N=1	N=0
Maximum Improvement in provider adherence (%) [inter-quartile range†] N=Number of trials	**All trial designs**	11.6 [7.0, 23.7] N=17	21.8 [21.4,30.9] N=3	25.9 [21.2,37.5] N=6	11.0 [6.5,13.5] N=11	10.8 [6.5,12.6] N=8
	RCTs	11.0 [6.3,19.6] N=14	21.8 [21.4,30.9] N=3	21.4 [17.0,26.4] N=4	10.8 [6.3,11.5] N=10	10.8 [6.5,12.6] N=8
	Non-RCTs	30.0 [28.5,35.9] N=3	N=0	35.9 [30.0,41.7] N=2	26.9 - - - - N=1	N=0

Table H2a. Association between improvement in provider adherence and number of QI strategies stratified by study sample size (median adherence included for comparison)

Number of QI Strategies	Median Improvement in Provider Adherence (%) [inter-quartile range] N=Number of trials	Maximum Improvement in Provider Adherence (%) [inter-quartile range] N=Number of trials				
	All Trials	All Trials	Trials with sample size in lowest quartile	Trials with sample size in lower 2 quartiles	Trials with sample size in upper 2 quartiles	Trials with sample size in highest quartile
Any number (for comparison purposes)	4.8 [3.8, 15.0] N=17	11.6 [7.0, 23.7] N=17	21.8 [21.4,30.9] N=3	25.9 [21.2,37.5] N=6	11.0 [6.5,13.5] N=11	10.8 [6.5,12.6] N=8
1 strategy only	3.0 [2.0,3.5] N=3	5.0 [4.5,13.0] N=3	21.0 ---- N=1	21.0 ---- N=1	4.5 [4.0,5.0] N=2	4.5 [4.0,5.0] N=2
≥ 2 strategies	5.3 [4.5,16.1] N=14	13.5 [10.6,26.1] N=14	30.9 [21.8,40.0] N=2	30.0 [21.8,40.0] N=5	11.0 [10.5,15.4] N=9	11.3 [10.6,14.5] N=6
≥ 3 strategies	4.9 [2.9,5.4] N=3	6.0 [5.4,8.5] N=3	N=0	4.9 ---- N=1	8.5 [6.0,11.0] N=2	N=0
≥ 4 strategies	1.0 ---- N=1	11.0 ---- N=1	N=0	N=0	11.0 ---- N=1	N=0
5 strategies *	1.0 ---- N=1	11.0 ---- N=1	N=0	N=0	11.0 ---- N=1	N=0

* No study involved an intervention with more than 5 QI types.

Table H2b. Associations between number of quality improvement strategies and improvements in glycemic control and provider adherence stratified by trial design

	Median Reduction in HbA_{1c} [inter-quartile range*] N=Number of trials			Maximum Improvement in provider adherence [inter-quartile range*] N=Number of trials		
	All Trials	**RCT**	**Non-RCT†**	**All Trials**	**RCT**	**Non-RCT†**
Any number (for comparison purposes)	4.9 [3.8, 15.0] N=17	4.5 [3.5, 5.4] N=14	18.0 [17.2, 21.0] N=3	11.6 [7.0,23.7] N=17	11.0 [6.3,19.6] N=14	30.0 [28.5,35.9] N=3
Single strategy only	3.0 [2.0,3.5] N=3	3.0 [2.0,3.5] N=3	N=0	5.0 [4.5,13.0] N=3	5.0 [4.5,13.0] N=3	N=0
≥ 2 strategies	5.3 [4.5,16.1] N=14	4.9 [4.2,5.8] N=11	18.0 [17.2,21.0] N=3	13.5 [10.6,26.1] N=14	11.0 [8.8,18.6] N=11	30.0 [28.5,35.9] N=3
≥ 3 strategies	4.9 [2.9, 5.4] N=3	4.9 [2.9, 5.4] N=3	N=0	6.0 [5.4,8.5] N=3	6.0 [5.4,8.5] N=3	N=0
≥ 4 strategies	1.0 ---- N=1	1.0 ---- N=1	N=0	11.0 ---- N=1	11.0 ---- N=1	N=0
5 strategies*	1.0 ---- N=1	1.0 ---- N=1	N=0	11.0 ---- N=1	11.0 ---- N=1	N=0

* No study involved an intervention with more than 5 QI types.

Table H3a. Median and maximum improvements in provider adherence associated with specific substrategies of organizational change stratified by study design

	Median Reduction in HbA_{1c} [inter-quartile range *] N=Number of trials			Maximum Improvement in provider adherence [inter-quartile range] N=Number of trials		
Type of organizational change	**All Trials**	**RCT**	**Non-RCT**	**All Trials**	**RCT**	**Non-RCT**
All QI types	4.85 [3.8,15.03] N=17	4.5 [3.5,5.45] N=14	18.0 [17.2,20.95] N=3	11.6 [7.0,23.7] N=17	11.0 [6.3,19.6] N=14	30.0 [28.5,35.9] N=3
Any type of organizational change	4.7 [4.1,5.7] N=6	4.5 [4.0,4.9] N=5	18.0 ---- N=1	6.5 [5.3,10.0] N=6	6.0 [5.0,7.0] N=5	30.0 ---- N=1
No organizational change	5.0 [3.6,15.7] N=11	4.5 [3.4,5.6] N=9	20.2 [16.4,23.9] N=2	21.0 [11.3,25.3] N=11	15.4 [11.0,21.8] N=9	34.3 [26.9,41.7] N=2
Disease/case management	4.9 ---- N=1	4.9 ---- N=1	N=0	4.9 ---- N=1	4.9 ---- N=1	N=0
No disease/case management	4.8 [3.7,15.4] N=16	4.5 [3.4,5.6] N=13	18.0 [17.2,21.0] N=3	13.5 [9.6,24.5] N=16	11.0 [7.0,21.0] N=13	30.0 [28.5,35.9] N=3
No disease/case management (some other organizational change present)	4.5 [4.0,6.0] N=5	4.3 [3.3,4.9] N=4	18.0 ---- N=1	7.0 [6.0,11.0] N=5	6.5 [5.8,8.0] N=4	30.0 ---- N=1

*No study involved an intervention with more than 5 QI types.

Table H3a. Median and maximum improvements in provider adherence associated with specific substrategies of organizational change stratified by study design (continued)

Team/staffing changes	12.0 [6.0,18.0] N=2	6.0 ---- N=1	18.0 ---- N=1	18.0 [6.0,30.0] N=2	6.0 ---- N=1	30.0 ---- N=1
No team/staffing changes	4.5 [3.6,10.3] N=15	4.5 [3.4,5.0] N=13	20.2 [16.4,23.9] N=2	11.6 [8.8,22.8] N=15	11.0 [7.0,21.0] N=13	34.3 [26.9,41.7] N=2
No team/staffing changes (some other organizational change present)	4.3 [3.3,4.6] N=4	4.3 [3.3,4.6] N=4	N=0	6.0 [5.0,8.0] N=4	6.0 [5.0,8.0] N=4	N=0
Medical record changes	1.0 ---- N=1	1.0 ---- N=1	N=0	11.0 ---- N=1	11.0 ---- N=1	N=0
No medical record changes	4.9 [4.0,15.4] N=16	4.5 [3.8,5.6] N=13	18.0 [17.2,21.0] N=3	13.5 [16.8,24.5] N=16	11.0 [6.0,21.0] N=13	30.0 [28.5,35.9] N=3
No medical record changes (some other organizational change present)	4.9 [4.5,6.0] N=5	4.7 [4.4,5.1] N=4	18.0 ---- N=1	6.0 [5.0,7.0] N=5	5.5 [5.0,6.3] N=4	30.0 ---- N=1

Table H3b. Median and maximum improvements in provider adherence associated with various roles for clinical information systems

	Median Reduction in HbA_{1c} [inter-quartile range *] N=Number of trials			Maximum Improvement in provider adherence [inter-quartile range] N=Number of trials		
Type of clinical information system (CIS)	**All Trials**	**RCT**	**Non-RCT**	**All Trials**	**RCT**	**Non-RCT**
All Trials	0.48 [0.20, 1.38] N=38	0.39 [0.1,0.73] N=28	1.4 [1.1,1.78] N=10	11.6 [7.0,23.7] N=17	11.0 [6.3,19.6] N=14	30.0 [28.5,35.9] N=3
Any CIS	0.9 [0.3,1.42] N=20	0.4 [0.1,0.8] N=12	1.4 [1.33,1.92] N=8	7.0 [6.0,10.5] N=5	7.0 [6.0,10.5] N=5	---- N=0
No CIS	0.35 [0.2,0.59] N=18	0.3 [0.15,0.65] N=16	0.53 [0.5,0.56] N=2	21.4 [11.0,27.7] N=12	11.6 [11.0,21.8] N=9	30.0 [28.5,35.9] N=3
Identification of eligible participants	0.35 [0.1,0.96] N=6	0.1 [0.1,0.6] N=5	1.4 ---- N=1	6.0 [5.5,6.5] N=3	6.0 [5.5,6.5] N=3	---- N=0
No identification of eligible participants	0.48 [0.21,1.4] N=32	0.4 [0.2,0.76] N=23	1.4 [0.56,1.9] N=9	18.2 [11.0,26.1] N=14	11.6 [10.8,21.4] N=11	30.0 [28.5,35.9] N=3
No identification of eligible participants (some other role for CIS present)	1.25 [0.401.49] N=14	0.41 [0.39,1.09] N=7	1.40 [1.25,1.95] N=7	13.0 [10.5,15.4] N=2	13.0 [10.5,15.4] N=2	---- N=0

***** When N=2, square brackets show the actual results of each study rather than interpolated inter-quartile range.

Table H3b. Median and maximum improvements in provider adherence associated with various roles for clinical information systems (continued)

Reminder system	0.71 [0.39,1.69] N=11	0.4 [0.24,0.56] N=7	1.95 [1.7,2.19] N=4	10.5 [8.8,13.0] N=3	10.5 [8.8,13.0] N=3	---- N=0
No reminder system	0.47 [0.15,1.19] N=27	0.3 [0.1,0.8] N=21	0.98 [0.52,1.4] N=6	16.3 [7.3,26.1] N=14	11.0 [5.5,21.4] N=11	30.0 [28.5,35.9] N=3
No reminder system (some other role for CIS present)	1.08 [0.10,1.40] N=9	0.60 [0.10,1.08] N=5	1.40 [1.08,1.40] N=4	5.5 [5.0,6.0] N=2	5.5 [5.0,6.0] N=2	---- N=0
Computerized decision support system (CDSS)	1.1 [0.37,1.99] N=5	0.24 [0.1,0.37] N=2	1.99 [1.55,2.4] N=3	13.0 [10.5,15.4] N=2	13.0 [10.5,15.4] N=2	---- N=0
No CDSS	0.47 [0.2,1.30] N=33	0.4 [0.12,0.78] N=26	1.4 [0.53,1.4] N=7	11.6 [6.5,25.3] N=15	11.0 [5.8,21.2] N=12	30.0 [28.5,35.9] N=3
No CDSS (some other role for CIS present)	0.71 [0.25,1.40] N=15	0.51 [0.17,0.99] N=10	1.40 [1.40,1.40] N=5	6.0 [5.5,6.5] N=3	6.0 [5.5,6.5] N=3	---- N=0
Audit system	1.4 [0.75,1.45] N=3	0.8 [0.1,1.5] N=2	1.4 ---- N=1	15.4 ---- N=1	15.4 ---- N=1	---- N=0
No Audit system	0.47 [0.2,1.2] N=35	0.39 [0.12,0.68] N=26	1.4 [0.56,1.9] N=9	11.3 [6.8,24.5] N=16	11.0 [6.0,21.0] N=13	30.0 [28.5,35.9] N=3

Table H3b. Median and maximum improvements in provider adherence associated with various roles for clinical information systems (continued)

No Audit system (some other role for CIS present)	0.71 [0.37,1.40] N=17	0.40 [0.17,0.68] N=10	1.40 [1.25,1.95] N=7	6.5 [5.8,7.9] N=4	6.5 [5.8,7.9] N=4	---- N=0

Table H4a. Association between improvement in glycemic control and number of quality improvement strategies stratified by study sample size, but with number of QI strategies including important substrategies

	Median Reduction in HbA_{1c} [inter-quartile range] N=Number of trials				
Number of QI Strategies *	**All Trials**	**Trials with sample size in lowest quartile**	**Trials with sample size in lower 2 quartiles**	**Trials with sample size in upper 2 quartiles**	**Trials with sample size in highest quartile**
Any number of strategies	0.48 [0.20, 1.38] N=38	1.35 [0.60,1.48] N=10	0.80 [0.41, 1.44] N=19	0.21 [0.10, 0.60] N=19	0.10 [0.10, 0.33] N=10
1 strategy only	0.00 [0.0,0.10] N=5	-0.20 ^ - - - - N=1	0.15 [0.10,0.20] N=2 †	0.00 [0.00,0.11] N=3	0.00 [0.00,0.00] N=2
≥ 2 strategies	0.60 [0.30, 1.40] N= 33	1.40 [0.71,1.50] N=9	1.08 [0.47, 1.47] N=17	0.34 [0.10, 0.73] N=16	0.15 [0.10, 0.40] N=8
≥ 3 strategies	0.66 [0.33, 1. 40] N=22	1.35 [1.15, 1.40] N=4	1.19 [0.53, 1.40] N=10	0.55 [0.20, 1.18] N=12	0.35 [0.17, 0.53] N=4
≥ 4 strategies	0.6 [0.41,1.1] N=13	0.71 - - - - N=1	0.59 [0.43,0.99] N=6	0.6 [0.4, 1.5] N=7	0.50 [0.35,0.55] N=3
≥ 5 strategies	0.71 [0.53,1.29] N=7	0.71 - - - - N=1	0.71 [0.59,1.09] N=3	0.85 [0.50,1.53] N=4	0.40 [0.20,0.60] N=2
6 strategies*	1.09 [0.71,1.47] N=2	0.71 - - -- N=1	1.09 [0.71,1.47] N=2	N=0	N=0

***** Under this alternate classification of the QI strategies, Five studies were still single-faceted, [1-5] but the median number of strategies increased from two to three and the maximum number of strategies increased from five to six (seen in two comparisons [6, 7]).

^ All changes were standardized to reflect reductions. Thus, the negative sign here indicates an *increase* in serum HbA_{1c}.

† When N=2, the numbers in square brackets reflect the results for each of the two studies rather than the inter-quartile range.

Table H4b. Association between improvement in provider adherence and number of quality improvement strategies stratified by study sample size, but with number of QI strategies including important subtypes*

Number of QI Strategies	Median Improvement in Provider Adherence (%) [inter-quartile range] N=Number of trials				
	All Trials	Trials with sample size in lowest quartile	Trials with sample size in lower 2 quartiles	Trials with sample size in upper 2 quartiles	Trials with sample size in highest quartile
Any number (for comparison purposes)	4.9 [3.8, 15.0] N=17	5.2 [4.4, 8.8] N=4	5.2 [4.1, 15.8] N=8	4.5 [3.8, 6.0] N=9	4.5 [4.0, 5.0] N=5
1 strategy only	3.0 [3.0,4.0] N=2 ^	3.0 ---- N=1	3.0 ---- N=1	4.0 ---- N=1	4.0 ---- N=1
≥ 2 strategies	5.0 [4.2,15.7] N=15	5.6 [5.2,12.0] N=3	5.6 [4.7,16.7] N=7	4.8 [3.7,8.6] N=8	4.8 [4.2,8.3] N=4
≥ 3 strategies	5.6 [4.7,16.5] N=11	5.6 [5.2,12.0] N=3	5.6 [4.7,16.7] N=7	5.5 [4.0,9.0] N=4	11.5 [5.0,18.0] N=2
≥ 4 strategies	4.5 [2.8,11.3] N=3	---- N=0	4.5 ---- N=1	9.5 [1.0,18.0] N=2	18.0 ---- N=1
≥ 5 strategies	1.0 ---- N=1	---- N=0	---- N=0	1.0 ---- N=1	---- N=0
6 strategies	---- N=0	---- N=0	---- N=0	---- N=0	---- N=0

* Analogous to Table 5b, but with major substrategies within provider education and organizational change counted as separate strategies. Specifically, the broad category of provider education has been replaced by three categories (workshops or meetings, distribution of educational materials, and educational outreach) and organizational change has been replaced by three strategies (disease or case management, changes to team structure or personnel, changes to medical records system, and "other organizational change").

^ When N=2, the numbers in square brackets reflect the results for each of the two studies rather than the inter-quartile range.

Table H4c. Associations between number of QI strategies and improvements in glycemic control and provider adherence stratified by trial design, but with number of QI strategies including important subtypes

	Median Reduction in HbA_{1c} [inter-quartile range*] N=Number of trials			Median Improvement in provider adherence [inter-quartile range*] N=Number of trials		
	All Trials	**RCT**	**Non-RCT†**	**All Trials**	**RCT**	**Non-RCT†**
Any number (for comparison purposes)	0.48 [0.20, 1.38] N=38	0.39 [0.10, 0.73] N=28	1.4 [0.70, 1.78] N=10	4.9 [3.8, 15.0] N=17	4.5 [3.5, 5.4] N=14	18.0 [17.2, 21.0] N=3
1 strategy only	0.00 [0.0,-0.1] N=5	0.00 [0.0,-0.1] N=5	---- N=0	3.0 [3.0,4.0] N=2	3.0 [3.0,4.0] N=2	---- N=0
≥ 2 strategies	0.60 [0.30, 1.40] N= 33	0.41 [0.25,0.94] N=23	1.4 [0.7,1.78] N=10	5.0 [4.2,15.7] N=15	4.7 [3.7,5.7] N=12	18.0 [17.2,21.0] N=3
≥ 3 strategies	0.66 [0.33, 1. 40] N=22	0.44 [0.22,0.68] N=14	1.4 [1.33,1.92] N=8	5.6 [4.7,16.5] N=11	5.0 [4.5,6.0] N=9	21.0 [18.0,23.9] N=2
≥ 4 strategies	0.6 [0.41,1.1] N=13	0.47 [0.3,0.71] N=9	1.5 [0.95,2.13] N=4	4.5 [2.8,11.3] N=3	2.8 [1.0,4.5] N=2	18.0 ---- N=1
≥ 5 strategies	0.71 [0.53,1.29] N=7	0.6 [0.47,0.71] N=5	1.95 [1.1,2.8] N=2	1.0 ---- N=1	1.0 ---- N=1	---- N=0
6 strategies	1.09 [0.71,1.47] N=2	1.09 [0.71,1.47] N=2	---- N=0	---- N=0	---- N=0	---- N=0

Appendix H References

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