

Outcomes Measurement Design for a Performance Improvement Initiative in Diabetes Care

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ABSTRACT

Background: Despite wide acceptance of diabetes treatment guidelines from the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE), optimal management of patients with type 2 diabetes remains a challenge. Improved patient outcomes, including reduced mortality and associated micro- and macrovascular complications, have been associated with adherence to guideline recommendations. This article describes a performance improvement (PI) initiative designed to improve physician practice behavior and patient outcomes by addressing gaps in process-related diabetes care. PI is an American Medical Association (AMA)-approved, standardized continuing medical education (CME) format in which practitioners, including physicians, nurse practitioners, and physician assistants, can earn up to 20 AMA PRA Category 1 Credits™. In the first stage, participants complete a self-assessment review to identify areas in which patient care can be improved. In the second stage, participants develop and implement a PI plan that addresses these identified areas of care. In the third stage, participants complete a second self-assessment review to determine the impact of their improvement strategies.

Methods: In this diabetes PI initiative, participants will assess their practice by means of performance measures defined by the 2007 AACE and 2008 ADA guidelines within 3 general benchmark areas: (1) lifestyle-modification recommendations (specifically related to discussion on exercise), (2) prevention of microvascular complications (focus on overall foot care), and (3) monitoring of glycemic control (by measuring hemoglobin A_{1c} at recommended intervals and taking action based on the results). After completing a self-assessment and identifying 1 or more areas of improvement, participants will be able to complete educational interventions and to access specific tools that provide guidance on improving adherence to the ADA/AACE guidelines.

Results: The results and analysis of this program will be presented in a subsequent publication. This PI initiative supplements other ongoing quality-improvement initiatives in diabetes in that it uses individual practitioner self-assessment, benchmark-focused CME, and self-developed PI plans to improve process-related diabetes care.

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INTRODUCTION

Diabetes mellitus is a chronic, progressive disease that has reached epidemic proportions in the United States (US). The disease affects 23.6 million people or 8% of the US population [1]. From 2005 to 2007, the total prevalence of diabetes increased by 13.5%, and an additional 29 million Americans are expected to receive diabetes diagnoses by 2050 [2]. With this growing epidemic, the need to improve diabetes care is obvious. Studies have demonstrated that for every percentage point decrease in blood hemoglobin A_{1c} (Hb A_{1c}) values, microvascular complications are reduced by 40% [3]. Yet, implementation of the standards of care for diabetes has been sub-optimal in most clinical settings. A recent report indicated that only 37% of adults with diagnosed diabetes achieved an Hb A_{1c} value of <7%, only 36% had a blood pressure of <130/80 mm Hg, and just 48% had a total cholesterol value of <200 mg/dL [4]. The observation of most concern, however, was that only 7.3% of people with diabetes achieved all 3 treatment goals.

In an effort to improve the quality of life and promote longevity in the US population, including those with diabetes, the US

Department of Health and Human Services has developed a comprehensive set of disease-prevention and health-promotion objectives to be reached by the year 2010 [5]. Healthy People 2010 was designed to identify the most significant preventable health threats and to establish national goals to reduce these threats. With regard to diabetes, the goals include reducing the diabetes death rate from 75 deaths to 45 deaths per 100,000 population, increasing the proportion of adults with diabetes who have Hb A_{1c} levels tested at least once a year from 24% to 50%, and increasing the proportion of adults with diabetes who have annual foot examinations from 55% to 75%.

Unfortunately, primary care physicians, who care for approximately 90% to 95% of adult patients with type 2 diabetes, face significant challenges, along with nurse practitioners and physician assistants, in managing this multifaceted and complex disease [6]. Although treatment goals are well established, guidelines continue to evolve in response to new evidence and advances in therapy [7,8]. With less than 12% of diabetes patients reaching treatment goals for blood glucose, cholesterol, and blood pressure, strategies to improve diabetes care are needed [4].

In recent years, healthcare organizations have implemented strategies to improve diabetes care. Because achieving glycemic control, treating hypertension, and controlling blood lipid levels are the cornerstones of preventing diabetes-related complications, successful programs have reported improvements in these process measurements [7]. In a study to improve physician adherence to diabetes guidelines, significant improvements were observed in patient blood pressure, foot examinations, and Hb A_{1c} measurements 1 year after the implementation of various interventions [9]. In another study of 57 general practitioners, patients' Hb A_{1c} levels decreased by 0.31% after physicians were educated in a diabetes-management program; Hb A_{1c} levels increased by 0.56% in the control group ($P = .001$) [10]. We describe a performance improvement (PI) continuing medical education (CME) initiative designed to identify and address healthcare practitioner barriers and to improve adherence to guidelines, with the ultimate goal of improving patient outcomes. The results, along with an analysis of this PI initiative, will be described in a subsequent publication.

Why Diabetes PI?

Convened by the American Medical Association (AMA), the Physician Consortium for Performance Improvement

seeks to enhance the quality and value of patient care through the implementation of evidence-based performance measures [11]. Supported by national societies, including the American Association of Clinical Endocrinologists (AACE), the American Academy of Family Physicians, and the American College of Physicians, as well as numerous state medical societies, federal agencies, and the Alliance for Continuing Medical Education, PI activities seek to personalize physician education with improvements that are specific to individual clinical practices. PI activities are described by the AMA as “structured, long-term processes by which a physician or group of physicians can learn about specific performance measures, retrospectively assess their practice, apply these measures prospectively over a useful interval, and reevaluate their performance.” In contrast to traditional lectures and conferences, physician self-assessment of their practice-based data and self-directed efforts for continuous professional development are more closely aligned with behavior and systems change.

In addition, the American Board of Medical Specialties' Maintenance of Certification has placed an emphasis on programs and systems that are designed to help physicians evaluate, learn, and incorporate specific improvements into their clinical and hospital practices [12]. The

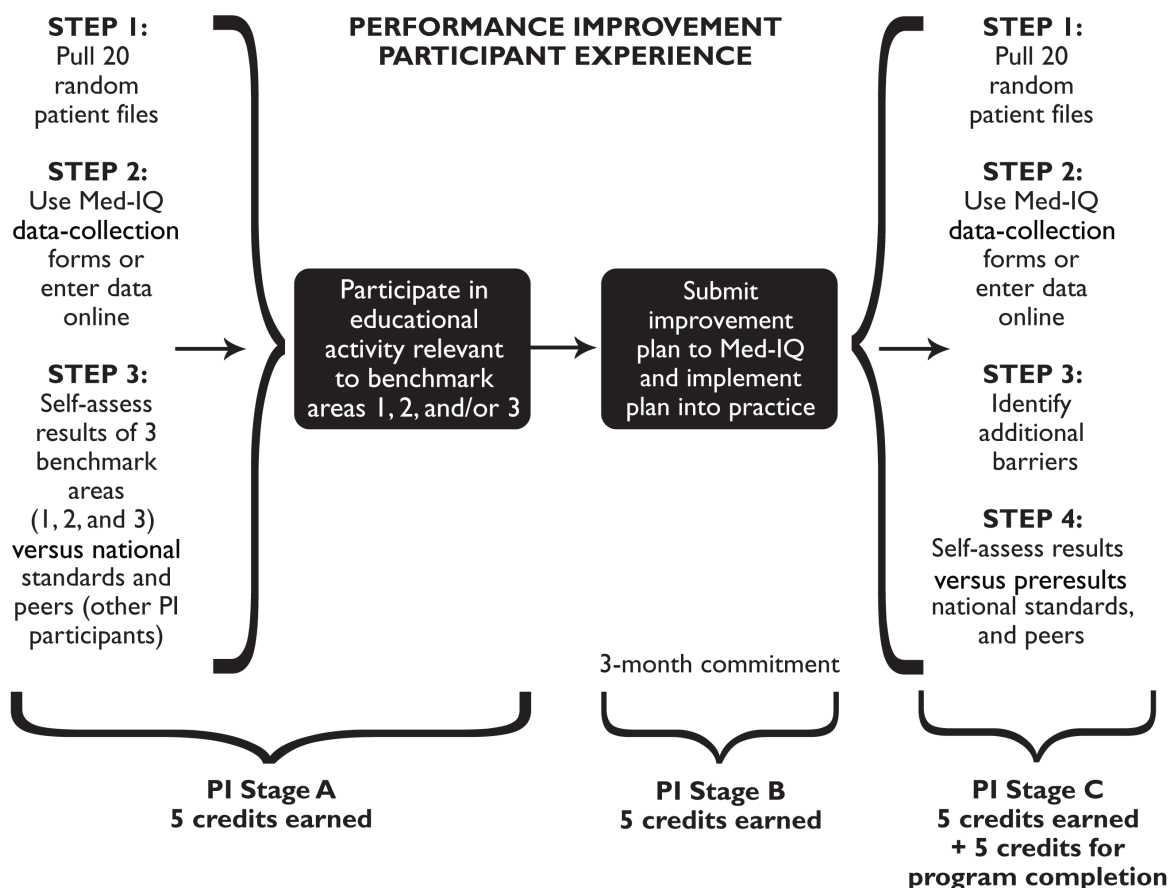


Figure 1. Performance Improvement (PI) process.

American Diabetes Association (ADA) recommends that physicians undertake quality-improvement programs that combine continuous cycles of analysis and intervention with provider performance data as a method to improve diabetes care [13]. In response to these recommendations, Med-IQ, an accredited medical education company, in conjunction with the Endocrine Society and expert faculty, developed a multi-platform, CME-certified PI initiative in diabetes care that incorporates measurable performance standards consistent with the AMA definition of PI.

STUDY DESIGN AND PROCEDURES

The PI Process

PI is the AMA-approved, nationally standardized CME format in which physicians, nurse practitioners, and physician assistants can earn up to 20 *AMA PRA Category 1 Credits*TM by completing 2 phases of self-assessment along with developing and implementing a PI plan to address self-identified areas in which patient care can be improved. Participants complete 3 stages, each associated with 5 CME credits (Figure 1). On completion of the initiative, an additional 5 credits are awarded.

Stage A: Learning from Current Practice Performance Assessment

Participants self-assess their current practice by means of predetermined practice performance measures (ie, benchmarks) identified through retrospective chart reviews with a standardized data-collection form. In an effort to identify one or more potential areas of improvement for this PI initiative, participants are required to conduct 20 chart reviews of patients who have had diabetes diagnosed for at least 1 year. Benchmarks include exercise, foot care, and blood pressure, Hb A_{1c}, and total cholesterol measurements. Participants are asked to evaluate their performance in these areas with regard to whether or not they established an exercise plan with the patient; performed foot examinations; carried out blood

pressure, Hb A_{1c}, and total cholesterol measurements; adequately documented these results in the patient chart; and taken any further actions if the patient was not at goal. Participants are actively involved in data collection and analysis. After completing all 20 chart reviews, participants receive a graphical representation of how their practice performance compares with data submitted by their peers (ie, other participants in the PI initiative) and with national standards based on ADA and/or AACE guideline recommendations. Using these results, participants identify 1 or more benchmark areas for improvement. To continue in the initiative beyond stage A, participants must select at least 1 area for improvement.

Stage B: Learning from the Application of PI to Patient Care

After completing their self-assessment, participants are directed to educational interventions and practical tools that provide benchmark-focused education. Using this education along with the self-assessment of their current practice, participants then develop an improvement plan for each of the benchmark areas they selected for improvement in stage A. Med-IQ clinical staff provide guidance on the practical aspects of each improvement plan and additional tips and strategies for participants to consider in their improvement plans. Participants then implement their improvement plan for a minimum of 3 months. After the 3-month implementation period, participants attest to having implemented their plan by completing a brief form indicating how their diabetes practice changed.

Stage C: Learning from the Evaluation of the PI Effort

Participants reevaluate and reflect on performance in practice (stage B) by comparing their stage A assessment with a second chart review. The second chart review consists of 20 additional patient charts. Patient visits, from which data are collected at this stage, must have occurred after the submission of the improvement plan.

Table 1. Criteria for Inclusion of Performance Measures*

Performance Measures Met the Following Criteria:

Criteria relevant and important to diabetes patient care:

- Support by evidence-based literature and/or included in the ADA 2008 and AACE 2007 guidelines for clinical practice for the management of diabetes mellitus
- Process-related measures that participants are able to employ to improve patient outcomes
- Applicable to a large number of patients with diabetes mellitus

Associated with improved patient outcomes in clinical trials or supported by strong professional consensus as a required measure for high-quality care

Amenable to improvement

Feasible to assess through review of medical charts

*ADA indicates American Diabetes Association; AACE, American Association of Clinical Endocrinologists.

Again, participants receive a graphical representation of how their practice performance at stage C compares with their own results from stage A, results from their peers, and national standards. Participants then complete a final evaluation form in which they may summarize any practice, process, and/or outcome change(s) that resulted from implementing their PI plan.

Selection of Quality-Improvement Measures

A 10-member expert panel consisting of endocrinologists, primary care physicians, certified diabetes educators, and practice-management experts was convened by Med-IQ and the Endocrine Society to develop the measures for participant self-assessment. The development process also included data collected from: (1) in-practice research of primary care practices, in which observations of individual practitioners, office staff, and patient flow were used to identify front-line primary care practice needs with respect to diabetes care; (2) a comprehensive survey sent to primary care physicians; (3) ADA and AACE treatment guidelines; (4) a review of current evidence-based literature; and (5) outcomes and evaluation data from current and past Med-IQ educational activities on diabetes. The criteria considered for inclusion of the performance measures are listed in Table 1.

Analysis of the data identified 3 readily apparent general benchmark areas: (1) lifestyle-modification recommendations (specifically related to discussion on exercise), (2) prevention of microvascular complications (focus on overall foot care), and (3) monitoring of glycemic control (by measuring Hb A_{1c} at recommended intervals and taking action based on the results). Several specific measures are included in each of the general benchmark areas (Table 2).

Fundamental to the management of diabetes, Hb A_{1c} measurement has strong predictive value for diabetes-related complications. In a study by the UK Prospective Diabetes Study Group, each 1% reduction in mean Hb A_{1c} concentration was associated with a reduction in risk

for myocardial infarction, microvascular complications, and death [3]. In addition, regular exercise can improve blood glucose control, as well as reduce cardiovascular disease risk, lead to weight loss, and improve overall well-being. Even without significant changes in the body mass index, exercise has been shown to lower Hb A_{1c} by a mean of 0.66% in patients with diabetes mellitus [14]. Amputation and foot ulceration, in addition to peripheral artery disease and diabetic neuropathy, are also major causes of disability and morbidity for patients with diabetes mellitus. Reducing the risk of adverse outcomes requires early recognition and management of these comorbidities to achieve healthy patient outcomes.

The 3 benchmark areas of exercise, foot care, and Hb A_{1c} values and their associated specific performance measures were chosen because they met the criteria listed in Table 1. These performance measures were also included in the ADA Standards of Medical Care in Diabetes—2008 and in the AACE Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus [7,8].

Data Analysis

To assess the overall impact of the PI initiative, analyses will compare charts reviewed in stage A (preintervention) with charts reviewed in stage C (postintervention). A goal of 30 participants, each submitting 20 charts for a total of 600 charts for both stage A and stage C, is anticipated. Such a large sample size allows detection of even very small changes in rates of charting specific behaviors and in the overall quality of care provided. Analyses will compare each item on the chart review to assess changes in specific behaviors. These analyses will indicate relative strengths and areas for improvement in the program content and emphasis. Most items are categorical or nominal in nature (eg, foot examination charted or not), and these results will be analyzed with chi-square tests for independence. Continuous measures (eg, Hb A_{1c}) will be assessed with independent group Student *t* tests to compare means, but these measures will also be

Table 2. Summary of Benchmark Areas for Participant Self-Assessment*

Performance Improvement Measures in Diabetes Care		
1. Exercise	2. Foot Care	3. Hb A _{1c} *
<ul style="list-style-type: none"> Establishment and discussion of patient exercise plan Documentation of the exercise plan Progress made by the patient 	<ul style="list-style-type: none"> Performance and documentation of foot exams Performance and documentation of: visual inspection, use of 10-g monofilament, use of 128-Hz tuning fork, and palpation of dorsalis pedis and posterior tibial pulses Discussion of foot exam results with the patient 	<ul style="list-style-type: none"> Documentation of most recent Hb A_{1c} value Discussion of test results with the patient Actions take if Hb A_{1c} value was ≥7%

*Hb A_{1c} indicates hemoglobin A_{1c}.

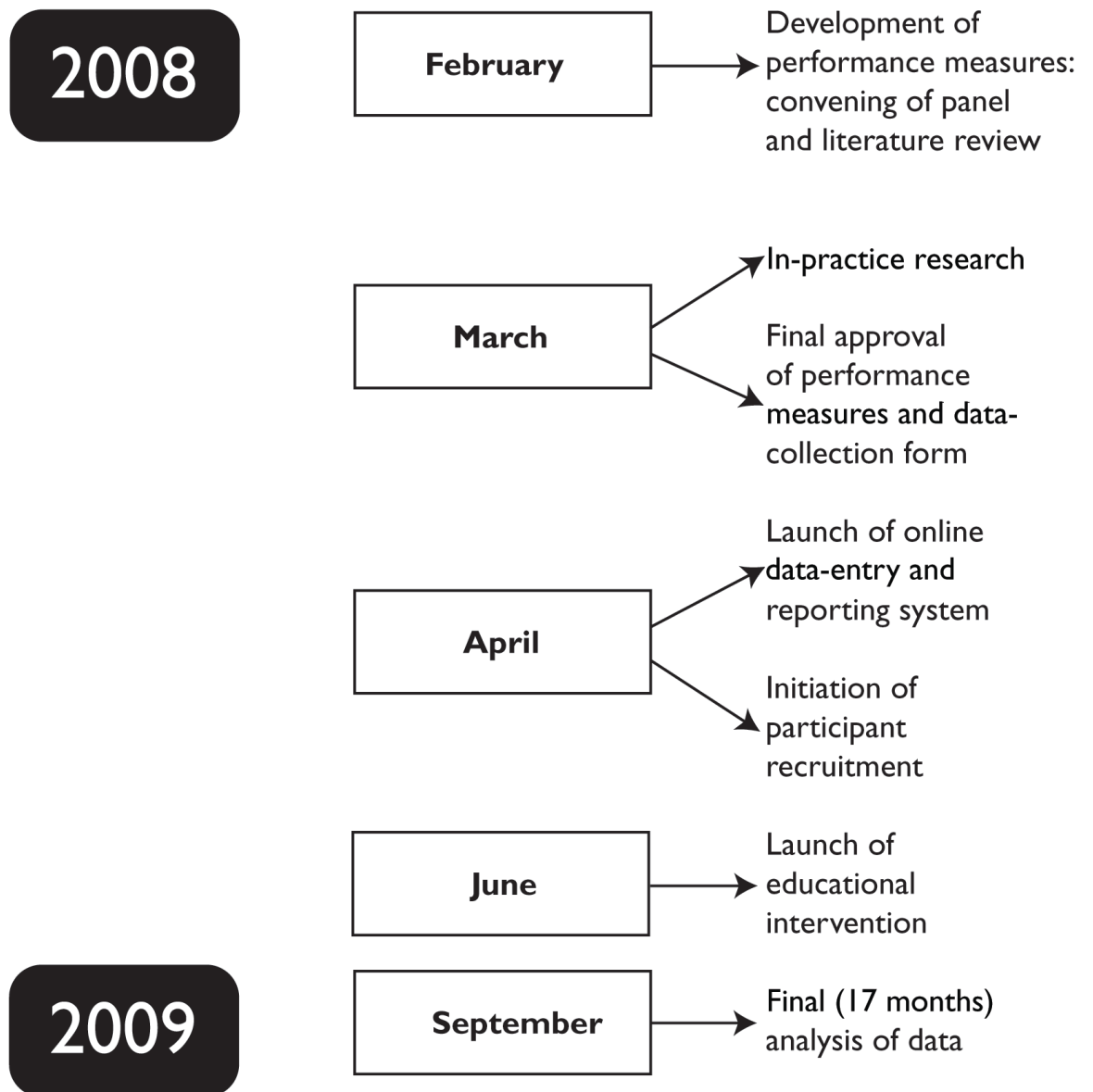


Figure 2. Program timeline.

categorized into “optimal” and “suboptimal” levels and assessed with chi-square tests. We will construct a summary index across the 5 benchmark items (exercise, foot examination, Hb A_{1c}, total cholesterol, blood pressure) for each chart that will reflect the percentage of these 5 behaviors charted. This measure represents a broad indication of the overall quality of care recorded in the chart. Independent group Student *t* tests will compare means from stage A with those from stage C to assess the improvement in the overall quality of care provided.

Patient Confidentiality, Participant Confidentiality, and Exemption from Consent

No identifying personal medical information of patients is submitted as part of this PI initiative. Compliance

with Health Insurance Portability and Accountability Act requirements is ensured by the submission of only deidentified data. Likewise, data regarding PI participants will only be reported anonymously and in aggregate. No data regarding individual participant performance will be shared publicly.

Approval by institutional review board is not required for this PI initiative. For research involving the collection or study of existing data, documents, and records, the Department of Health and Human Services states that such research is exempt from review by an institutional review board “if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly, or through identifiers linked to the subjects” [15].

Recruitment and Criteria for Participation

Starting in April 2008, primary care physicians were invited to enroll in the PI initiative. Because of participant interest, the PI initiative was opened to nurse practitioners and physician assistants 6 months after the initial launch of the program. Invitations to enroll continued on an ongoing basis for 1 year through a series of electronic mailings, paper-based invitations, and faxed flyers. Invitation materials detailed the PI process and the resources available to help participants through the 3 stages of PI. The initiative was targeted to US-based primary healthcare providers but was also available to providers practicing outside the US.

Program Components and Timeline

This PI program was designed to provide minimal barriers to healthcare provider participation. Data can be submitted in 3 formats, depending on participant preference: mail, fax, or online. The online system uses a convenient and intuitive interface to simplify data entry. The initiative is self-paced, allowing participants to submit data in a time frame convenient for them. The summary report of an individual participant's performance is generated rapidly—either automatically if the data are submitted online by the participant or within 2 business days after the data are received via other formats.

Much of the data entered are dichotomous or categorical; the investigators will analyze open-ended results but will not use them for the individual's self-assessment. As recommended by the AMA, requirements for data submission are intentionally kept to a minimum in an effort to increase healthcare provider participation.

PI programs are a relatively new form of CME. Therefore, to help participants navigate through the PI process and to make participation as convenient as possible, professional Med-IQ experts are available to explain the service and program, provide reminders, and share tips to encourage progression through the 3 stages of PI. These Med-IQ experts are available to help via telephone, fax, and e-mail.

The timeline for the initiative is shown in Figure 2. Milestones include final approval of the performance measures, launch of the online system, launch of the educational interventions, and scheduled analysis time points.

POTENTIAL LIMITATIONS

A PI CME activity has limitations related to global scope and assessment as well as to procedural concerns. This PI study was designed as a method to improve patient care through process improvement. Although health outcomes may be an ideal measure, external factors that may influence patient and healthcare outcomes, such as the ability of the patient to carry out exercise routines or to arrange travel to multiple appointments, cannot

be controlled and may introduce bias. In addition, process measures are able to provide participant feedback in areas of excellence along with recognizing areas in need of improvement. Most importantly, improving guideline-based process measures can produce improved clinical outcomes and is, therefore, an important method of assessing quality of care. In the TRANSLATE trial, diabetes process measures were recorded from 238 healthcare providers who received 69,965 visits from 8405 adults patients with diabetes mellitus [16]. Significant increases in foot examinations, Hb A_{1c} testing, blood pressure monitoring, low-density lipoprotein testing, and annual eye examinations were found after a multicomponent performance intervention ($P < .001$). Intervention practices also demonstrated significant declines in mean Hb A_{1c} values to 7.26% ($P < .02$) and showed that recommended Hb A_{1c} values were more often attained in a mean of 49% of patients, compared with a mean of 43.8% for control patients ($P < .001$). As demonstrated by this trial and others, assessing improvements of evidence-based care processes is valid [10,17,18].

This PI initiative was established specifically to evaluate the individual participant through self-assessment of competencies and practice patterns in order to identify gaps in care. Identified gaps may be due in part to healthcare provider behaviors. Gaps may also be attributable to system barriers, however, and such causes cannot be addressed through this assessment. Despite this shortcoming, the PI program allows participants to compare their own data directly with those of their peers, as well as with national standards. Consequently, participants may feel more accountable for processes of care when the data reflect their own performance [19]. This method allows for direct applicability and rapid implementation of a specific implementation plan without cost to the participant or the institution.

The selection of medical records may introduce bias in this study because selection is left to the discretion of the participant. Inclusion criteria were developed by the authors, but no attempts are made to ensure random chart selection, nor are any attempts made to ensure a representative sampling of patient types and medical complications. Data extraction and collation are performed without audit verification. Additionally, limitations related to data collection may influence chart selection; such limitations include the availability or lack of electronic healthcare record systems or the familiarity of the participant with data extraction from those systems.

The absence of documentation is a possible limitation to interpreting results from this study. If the chart does not clearly document findings from an examination, it is possible that either no examination was performed or there was neglect in recording the examination results. Although healthcare provider charting is improving, it is still not 100% accurate. If a participant's charting bias remains unchanged during the

study, then comparisons of pre- and postintervention results will reflect real change in patient care; however, if PI causes a participant to improve his or her charting, part of any improvement observed from the preintervention phase to the postintervention phase could be due to improved documentation rather than to a true improvement in patient care.

Finally, a significant factor in the design of this PI initiative requires the participation of busy healthcare professionals. Furthermore, participants are asked to evaluate their current practice and implement their self-assessed improvement plan within a limited time. Given the volume of patients that healthcare providers see each day, some participants may feel they will not have the extra time required to complete these study components. Because of these constraints, we may not find a representative sample of healthcare providers willing to participate.

GOALS AND CONCLUSIONS

The hope of this educational intervention is to improve the care of patients with diabetes by achieving optimal rates of process-oriented performance measures, as defined by the 2007 AACE and 2008 ADA guidelines for the management of diabetes mellitus. Specific to the PI program, anticipated PIs include:

- Creation and implementation of patient-tailored exercise plans;
- Annual comprehensive foot examinations along with visual inspections during each visit;
- Adherence to guideline-recommended Hb A_{1c} goals and more time adjustment of antiglycemic therapies for patients who are not at goal;
- Better overall documentation of these benchmarks.

The PI initiative supplements other ongoing quality-improvement initiatives in diabetes care, such as the following: the Agency for Healthcare Research and Quality program, Improving the Quality of Diabetes Care; the California Diabetes Performance Improvement Plan; and the Diabetes Quality Improvement Project, whose members include the ADA, the Foundation for Accountability, the Health Care Financing Administration, the National Committee for Quality Assurance, the American Academy of Family Physicians, the American College of Physicians, and the Veterans Administration [20-22]. This program is focused on using individual practitioner self-assessment and personalized PI plans along with directed CME to improve process-related care of patients with diabetes. Owing to the continued interest in this diabetes PI initiative, the program has been extended for a second year, and the latest version can be accessed at <http://www.pi-iq.com/diabetes>. Readers and participants should note that because of participant feedback and program evaluations, some procedures have been modified since the publication of this document.

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