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Implications of STeP for Improved Diabetes Control: A Payer Perspective

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A study published in the February 2011 issue of *Diabetes Care* described significant improvements in glycemic control in patients with poorly controlled, non–insulin-treated type 2 diabetes through utilization of a new structured self-monitoring program (Structured Testing Program [STeP]) over a 12-month period (STeP study).[1] Patients were either part of the structured testing group (STG; n = 256) that used STeP or were part of the active control group (ACG; n = 227). Patients in both groups underwent an initial screening, followed by physician visits at months 1, 3, 6, 9, and 12. All patients received a blood glucose meter and test strips, as well as instructions in their use. In addition, during the 1-, 3-, 6-, 9-, and 12-month visits, all patients underwent laboratory testing and brief physical examinations, and any changes in medications were recorded. Patients in the ACG were advised to follow their physician's regular self-monitoring of blood glucose (SMBG) instructions. Patients in the STG received the additional interventions shown in the **Table**. The ACCU-CHEK 360° View (Roche Diagnostics; Indianapolis, Indiana) utilized in the STG is a validated tool that patients can use to (1) record and plot 7-point SMBG profiles (ie, fasting, preprandial, postprandial, and bedtime) on 3 consecutive days; (2) record meal sizes and energy levels; and (3) comment on their SMBG experiences.[1,2]

Both the STG and ACG had significant reductions in glycosylated hemoglobin (A1C), but the reductions in the STG were significantly greater and more sustainable than those in the ACG in the intent-to-treat analysis (P = .04; **Figure 1**). In addition, the per protocol analysis (Figure 1) revealed greater A1C reductions for the STG patients who adhered to STeP (P = .0025), whereas nonadherent STG patients had 12-month A1C levels that were indistinguishable from those of ACG patients. STG patients were also 3 times more likely to receive a treatment change recommendation at the month 1 visit compared with ACG patients (75.5% vs 28.0%;

ABSTRACT

The goal of this article was to examine the patient care and economic implications of a new structured blood glucose self-monitoring program (Structured Testing Program [STeP]) for managed care organizations (MCOs), as debated by a panel of managed care experts during the course of a roundtable discussion. Although challenges exist to implementing STeP in managed care, the potential benefits of the program appear substantial. Patients receiving the STeP intervention had demonstrated reductions in glycosylated hemoglobin, reduced treatment change inertia (the challenge providers and patients face in altering pharmacotherapy) including insulin initiation, and improved blood glucose testing efficiency. These data, in combination with the large amount of evidence demonstrating the economic costs of treating diabetes and its complications, as well as the long-term cost savings realized through improved glycemic control, suggest that implementation of STeP across MCOs could lead to both improved patient outcomes and significant cost savings.

(Am J Pharm Benefits. 2011;3(5):257-262)

PRACTICAL IMPLICATIONS

Managed care organizations and their members can gain substantial benefits by using the Structured Testing Program (STeP).

- Improved glycemic control achieved through the STeP approach demonstrates that a simple, validated program that prompts greater interaction between physicians and patients can significantly improve the management of diabetes.
- Because STeP offers an intervention that improves glycemic control through better utilization of existing management principles and benefits (ie, testing supplies), implementation in the managed care setting would likely require only minimal investment of time and energy and no real financial investment.

P <.0001), regardless of baseline A1C. The number of office visits during which a treatment change was recommended was significantly greater among STG patients (*P* <.0001; **Figure 2**), and significantly more STG patients were started on intermediate-acting or long-acting insulin than were ACG patients (*P* = .046; **Figure 3**). Finally, despite using a 3-day, 21-point blood glucose profile, STG patients achieved their significantly greater improvements in A1C without an increase in SMBG testing rate compared with the testing rate for ACG patients.

The STeP study researchers concluded that structured self-monitoring through STeP contributed to significant A1C reductions, facilitated timely and appropriate treatment intensification, and improved self-monitoring efficiency by focusing on blood glucose testing quality rather than quantity. The authors also noted the impact of the training received by patients and physicians, as well as the importance of the patient-physician interaction.

The economic costs of diabetes are significant and rising. Recent estimates place the costs associated with diabetes in the United States between $197 billion and $344 billion in 2010, and project the costs to increase to between $264 billion and $473 billion by 2030.[3] Costs associated with diabetes can be correlated directly with blood glucose control,[4] and a 2011 study has suggested that a 1% increase in A1C leads to average cost increases of 6.0% and 4.4% in diabetes-related medical costs for patients with type 1 and type 2 diabetes, respectively.[5] More significantly, a large amount of evidence (eg, the United Kingdom Prospective Diabetes Study) indicates that improved control of A1C reduces the incidence of diabetes-related complications[6-8] as well as the long-term costs associated with diabetes.[4,9-11] Therefore, STeP, as a simple mechanism for improving glycemic control, has the potential for reducing the long-term costs associated with diabetes management.

IMPLICATIONS OF STeP STUDY RESULTS FOR MCOs

The results of the STeP study demonstrate the program's efficacy in reducing A1C levels, most markedly in patients who adhere to the program. It is reasonable to conclude that the program as a whole is responsible for the improvements and may represent an integral part of a change in the way that primary care physicians can help patients manage diabetes. Managed care organizations (MCOs) have generally not promoted standardized approaches to diabetes care beyond starting patients on a single oral agent as an initial pharmacologic intervention and then referring to published treatment guidelines. (The term MCO is being used broadly to include any entity responsible for the administrative, financial, and/or delivery components of healthcare within a managed care environment.) There is no agreed-upon paradigm for MCOs to support "glycemic control" beyond urging physicians to lower their patients' A1C levels, and MCOs have lacked validated tools and programs to assist physicians in conveying to patients how specific changes in treatment directly correlate with better health outcomes.

The patient and physician educational components of STeP broadly enable a standardized approach, which is, in our opinion, one of the program's most valuable characteristics. One aspect of the educational component of STeP that should not be overlooked is that it provides physicians with a *glucose pattern management guideline*. The treatment algorithm in the program allows simple pattern recognition to occur, which assisted physicians in the STG intervention to improve their assessment of glycemic control and promote specific treatment changes. The result is that through use of the ACCU-CHEK 360° View tool, patients' and physicians' appreciation of blood glucose patterns appeared to more readily prompt collaborative decision making on the optimization of lifestyle changes and pharmacologic management.

STeP provides an impetus for this vital collaboration between physicians and patients, and empowers patients to help manage their own care, which may have significant implications for case management and other MCO resource investments. By observing what happens when patients use STeP and monitor their blood glucose levels, it becomes possible to identify those individuals who have the most difficulty with self-management and might most benefit from additional focused interventions through disease or case management. Although simple in design, the program may help segment the patient population and help focus both resources and interventions to improve patient care and control of A1C.

Table. Additional Interventions Received by Structured Testing Group

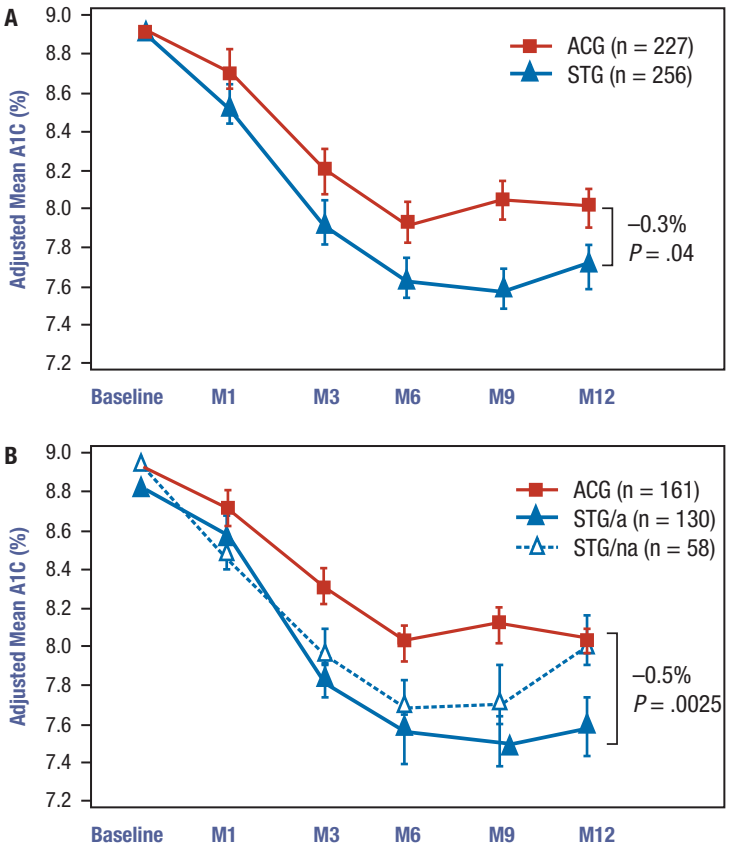
Patients	Physicians	Patients and Physicians
Training on ACCU-CHEK 360° View tool and STeP (DVD)	Training on ACCU-CHEK 360° View tool and STeP	Collaborative review of ACCU-CHEK 360° View tool at each office visit
Reminder to complete ACCU-CHEK 360° View tool 1 week prior to next office visit	Treatment algorithm to identify blood glucose patterns and link potential problem areas to specific medication and/or lifestyle changes	Repeat use and review of ACCU-CHEK 360° View tool at each office visit to evaluate treatment changes

STeP indicates Structured Testing Program.

In an environment in which there is a significant amount of turnover in health insurance as a result of economic considerations, STeP should become one significant constant in patient care that does not depend on plan benefits or changes between plans because the consistency afforded by the program will lead to better outcomes. The program should not be limited to physicians; rather, the opportunities created by this program suggest the importance of further integration across healthcare providers in MCOs and medical groups. To fully realize the potential benefits of STeP for patient care, endocrinologists can be engaged to work with the primary care providers and physician extenders who use and understand the program in order to identify patients who need more complex educational and case management interventions, as well as those who need the benefit of endocrinologist consultation. Furthermore, its simplicity makes it well suited for introduction into pharmacies to be used to support medication therapy management programs.

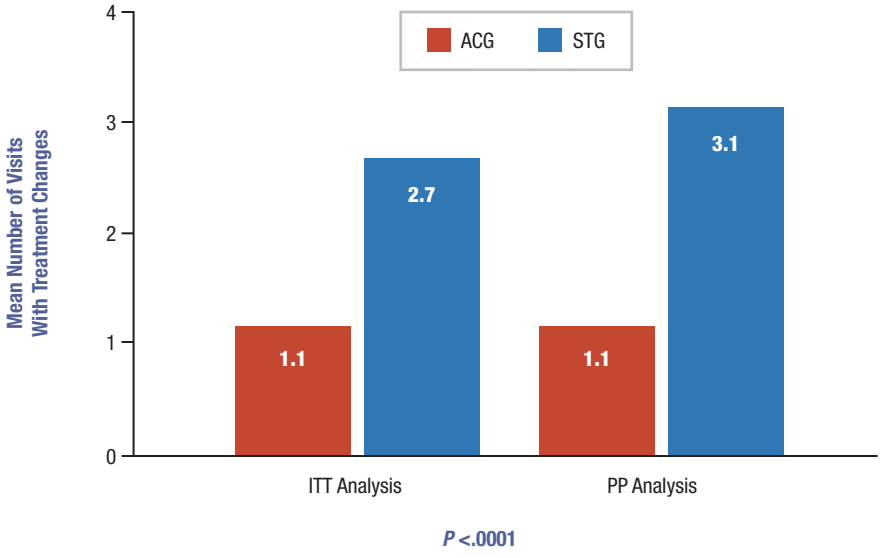
Treatment adjustments in diabetes have always been an issue for both physicians and patients, and it is frequently difficult to convince patients of the necessity of changing their medications, especially when that change involves the prescription of an additional oral agent or the initiation of insulin. Over time, more oral agents have been developed to control hyperglycemia, and patient care now often includes a transitional step of oral therapies plus insulin. In addition, with the advent of the National Committee for Quality Assurance and Healthcare Effectiveness Data and Information Set (HEDIS) measures for the evaluation of diabetes care, MCOs now focus intently upon the clinical outcomes achieved by this population. Indeed, MCOs have embraced the notion that because diabetes is a strong comorbid contributor to other disease states, it is one of the most costly disorders to treat. MCOs have urged their providers to reduce A1C levels using all available therapeutic means. Here again, STeP may provide an opportunity for improving patient care. The ability of physicians

Figure 1. Mean Changes in A1C (Intent-to-Treat Analysis and Per Protocol Analysis) Over 12 Months[a,b]



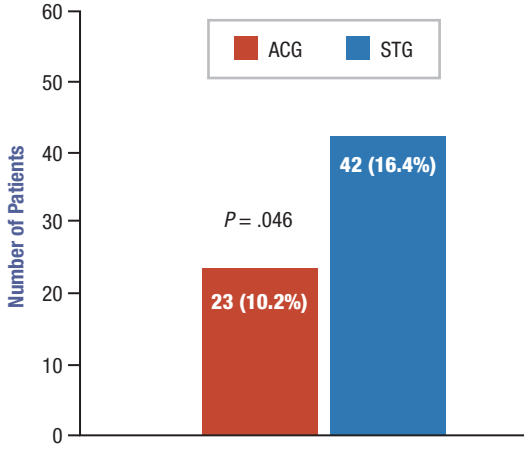
A1C indicates glycosylated hemoglobin; ACG, active control group; M, month; STeP, Structured Testing Program; STG, structured testing group; STG/a, structured testing group patients who adhered to STeP; STG/na, structured testing group patients who did not adhere to STeP.
[a]**Panel A:** In the intent-to-treat analysis, STG patients had a significantly greater reduction in the 12-month A1C compared with ACG patients. **Panel B:** In the per protocol analysis, STG/a patients had a significantly greater reduction in the 12-month A1C compared with ACG patients and STG/na patients. No difference was observed between ACG patients and STG/na patients.
[b]Reprinted with permission from reference 1.

Figure 2. Recommended Treatment Changes During Study Period[a,b]



ACG indicates active control group; ITT, intent to treat; PP, per protocol; STG, structured testing group.
[a]In both the ITT and PP analyses, STG patients received significantly more treatment change recommendations during the 12-month study period than did ACG patients.
[b]Adapted from data in reference 1.

Figure 3. Insulin Initiation During Study Period[a,b]



ACG indicates active control group; STG, structured testing group.
[a]Over the duration of the study, significantly more STG patients were started on insulin treatment compared with ACG patients.
[b]Adapted from reference 1.

and patients to review a simple graph and make mutually agreed-upon treatment changes to control A1C will help both parties advance through the pharmacotherapeutic treatment continuum. A significant portion of the diabetic population benefits from receiving insulin earlier in their clinical course in order to control their A1C levels. Based on results of the STeP study, it is possible for both physicians and patients to overcome "treatment inertia" to accomplish lifestyle and pharmacologic management adjustments.

The decreased number of blood glucose tests for STG patients appears to be noteworthy because it suggests that SMBG testing is more efficient with STeP. The program may promote adherence because patients may be able to test less but still experience an improved outcome. The data indicate that increased testing is not required; rather, periodically concentrating the testing appears to be effective as a diabetes management tool. The STeP study authors noted that these results suggest the focus of SMBG testing should shift from *quantity* to *quality*.[1] STeP leads to more effective and efficient use of resources already covered by health insurance benefits (eg, testing strips, supplies), as well as contributing to the behavioral motivation necessary to adhere to an optimized treatment regimen.

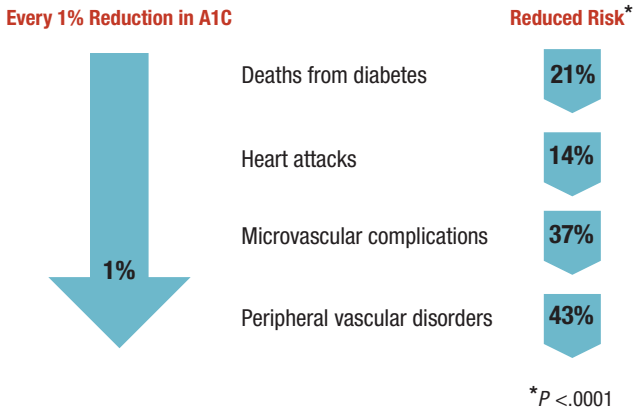
POTENTIAL COST IMPLICATIONS OF STeP STUDY RESULTS FOR MCOs

Across the spectrum of MCOs, a segment of the membership actively seeks out physician-driven and pharmacist-driven tools to help manage chronic disease within benefit constraints such as copayments and coinsurance, first dollar coverage limitations, and gap coverage. However, an elegant, comprehensive program such as STeP, which a physician or pharmacist can readily use at the point of care, can have a significant pharmacoeconomic

impact when considering costs related to drug utilization and overall outcomes.

Most often, aggressive treatment of diabetes focuses on the addition of new medications to those a patient is already receiving, and many MCOs have made conscious decisions to place diabetes drugs on lower pharmacy co-payment tiers in order to provide patients with as many affordable options as possible to control their disease. It is well known that lowering A1C reduces the risk of various complications (**Figure 4**), and there is widespread agreement that improved control of A1C is associated with reductions in long-term healthcare costs.[4,9-11] The majority of MCOs have adopted a nearly "open checkbook" approach to the pharmacologic management of diabetes, but STeP offers an intervention that reduces A1C through better utilization of existing management principles. This program shows us how to more effectively use an existing benefit (test strips, supplies) for added value.

Figure 4. Decreased Risk of Complications With Lower A1C[a,b]



A1C indicates glycosylated hemoglobin.
[a]Data from the United Kingdom Prospective Diabetes Study demonstrated that reductions in A1C were associated with significantly reduced risks of diabetes-related complications and comorbidities.
[b]Adapted from reference 8.

CHALLENGES AND OPPORTUNITIES IN IMPLEMENTING STeP IN MCOs

Implementation of STeP within an integrated health delivery system in which all stakeholders share in aligned incentives would support the common goals of improved clinical and financial performance, but other delivery systems will also benefit from STeP. One can envision the implementation of STeP in areas in which MCOs already have experience in managing multidisciplinary cooperation to reach an end point, such as pay-for-performance and risk-sharing relationships. STeP is a simple program that can be used by practitioners at many levels, including physicians, pharmacists, health educators, and nurse practitioners, all of whom seem destined to become more involved in diabetes management as a consequence of the impending changes proposed for the US healthcare delivery system. In addition, these provider organizations are expected to have endocrinologists available to help manage their most complex patients, guide the primary care physicians and physician extenders, support primary care interventions, and even engage in case management and disease management programs.

Accountable care organizations, particularly those being developed by large, experienced medical groups, could also successfully deploy STeP. In this case, the program presents the opportunity for medical groups to better manage patients with diabetes, improve their HEDIS scores, and enhance their collective financial performance. Implementation of STeP would also yield significant benefits for patient-centered medical home programs, which are often focused on the management of chronic diseases such as diabetes. Recent evidence indicates that patient-centered medical homes have had success in improving patient outcomes and decreasing costs associated with diabetes,[12] and this setting seems ideal for implementing STeP.

The most significant barrier to implementing STeP in managed care may be at the physician level. Although MCOs have experience offering quality incentives, there is no guarantee of physician buy-in. Physicians may not be willing to participate in the baseline program training for a myriad of reasons, such as perceived time or administrative burdens. However, as compensation models move toward an outcomes and performance basis and away from production-based systems, it seems likely that physicians will become more receptive to mastering new approaches that can help reach targets such as A1C reductions. Decisions about program implementation by MCOs may occur at a higher, leadership level rather than at the provider level. This is not to suggest that individual physicians or small group practices could not successfully implement STeP. In fact, the program's simplicity makes it adoptable across a broad range of healthcare providers, and there are likely many potential innovative ways in which smaller practices and even local health departments can utilize this practical clinical approach.

Having agreed that STeP offers a viable approach to improved clinical and financial outcomes in diabetes management, the roundtable considered *how* one should implement STeP. In order to operationalize this program, it is vital to engage all of the stakeholders within the

continuum of care—the pharmacies, the diabetes educators, the physicians, and the patients. Implementation requires a minimal investment of time and energy, with no real financial investment required. Securing support from provider organizational stakeholders promotes effective utilization and implementation. Participation in the one-time provider training session then follows. For MCOs, providing member access to the necessary tools and supplies, and ultimately perhaps supporting a change in the incentive arrangements within the delivery system, will help ensure that patients are receiving the best chance at optimal diabetes outcomes. In this way, those involved in the management of diabetes—those who will be using STeP—can begin to develop their own multidisciplinary approach to implementing the program.

The stakeholders in MCOs and medical groups know that diabetes and poorly controlled A1C have significant ramifications for long-term patient care and costs. Whether they are willing to embrace STeP with its demonstrated success in reducing A1C and prompting increased treatment change recommendations will be a local conversation that will be replicated nationally. Consideration of the known costs associated with poorly controlled A1C should provide the impetus for MCOs to study STeP and consider its implementation.

Acknowledgments

The authors would like to thank John M. Goldenring, MD, MPH, JD, for his contributions to the conceptualization and writing of this article. The authors would also like to thank Jonathan Sokolowski, PhD, of Access Medical, LLC, for editorial assistance in preparing the manuscript.

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Funding Source: Access Medical, LLC, received funding from Roche Diagnostics for editorial assistance with this manuscript.

Author Disclosures: Dr LoNigro reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article. Dr Sredzinski reports receiving paid consultancies and honoraria from Roche Diabetes Advisory Boards.

The views presented herein are those of the authors and are not to be construed as the views or policies of CeltiCare Health Plan of Massachusetts, Inc, or ScriptSave, and these organizations are listed for the sole purpose of identifying author affiliations.

Authorship Information: Concept and design (MS); acquisition of data (MS); analysis and interpretation of data (RL, MS); drafting of the manuscript (RL, MS); critical revision of the manuscript for important intellectual content (RL, MS); statistical analysis (MS); provision of study materials or patients (MS); obtaining funding (MS); administrative, technical, or logistic support (MS); and supervision (MS).

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