

# How Our Current Medical Care System Fails People With Diabetes

## Lack of timely, appropriate clinical decisions

**M**any randomized controlled intervention trials have demonstrated that lowering glycemia (1,2), LDL cholesterol (3), and blood pressure (4) will markedly benefit the complications from diabetes. Based on these data, the American Diabetes Association has recommended the following targets for glycemic, lipid, and blood pressure outcome measures, A1C <7.0%, LDL cholesterol <100 mg/dl, and blood pressure <130/80 mmHg, respectively (5).

Most diabetic patients do not meet these recommended goals. Approximately half of the National Health and Nutrition Examination Survey cohort met the glycemic goal (6). In other larger reported populations, 21–43% of patients had A1C levels >9.5%, only 22–46% of diabetic patients met the LDL cholesterol goal, and 29–33% met the blood pressure goal (7). Far fewer, 2–10%, met the combined American Diabetes Association goals for glycemia, lipids, and blood pressure (7).

Many approaches have been tried to improve diabetes care but, with one exception, have been mostly ineffective. These include simply reminding patients about appointments; providing laboratory information on the patient to the physician, even when specific treatment recommendations for the individual patient were included; case management when the case manager could not make independent treatment decisions; education of physicians; and multifaceted quality improvement interventions in the practice setting (7).

The small amount of time a physician has to spend with a patient is an important limiting factor. This was amply illustrated in a study (8) in which eight process measures agreed upon by the physician group and whether the patient was due to receive them were displayed on the physicians' computer screens at the time of the patient visit. The measures due were performed or ordered only one-third of the time. Physicians pinpointed lack of time and other problems that

needed attention as primary obstacles to carrying out the agreed-upon recommendations.

The one approach that has proven to be effective is using specially trained nurses or pharmacists, under appropriate supervision, with authority to make medication changes without consulting the physician as long as the changes fell within approved treatment algorithms. In randomized clinical trials, A1C levels fell threefold more in 1,969 patients followed by nurses and pharmacists compared with 1,573 patients under usual care (7). Several nonglycemic outcome measures also significantly improved with nurse- or pharmacist-directed diabetes care compared with usual care. These included LDL cholesterol, triglycerides, and systolic and diastolic blood pressure (7). These impressive results stand in contrast to case management in which nurses do not have prescriptive authority (7).

Perhaps the best evidence for the importance of the nurse or pharmacist to have authority to make independent clinical decisions comes from a direct comparison of programs in the same institution. A diabetes case management program in which medication changes by nurse practitioners required approval by the primary care physician was initially established and compared with usual care. Baseline A1C levels averaging >9.0% did not change over 18 months in either the control or intervention group (9). Subsequently, in the same medical care setting, a clinical pharmacist was allowed to make independent clinical decisions based on an approved protocol. Baseline A1C levels averaging >10% fell by 0.9% in the control group and 2.1% in the intervention group over 12–24 months (10). The results of these two studies within the same institution treating the same population were supported by a recent metaregression analysis on the effects of quality improvement strategies to improve glycemia in type 2 diabetes (11). Interventions in which case managers could adjust medications without

awaiting physician approval achieved the most robust improvements, whereas other approaches had minimal effect.

The critical factor that underlies the success of specially trained nurses or pharmacists to improve the outcomes of diabetes care is that timely and appropriate clinical decisions are made. The decisions are appropriate because they are based on approved treatment algorithms. However, timeliness of these decisions is also very important. The fact that more time can be spent with the patient, not only in the office dealing specifically with diabetes but also outside of the office via other means of communication, is critical for improved outcomes. For the most part, except for the minority of patients who have polyuria and polydipsia secondary to severe hyperglycemia or those who have diabetes complications, diabetes care is preventive care, i.e., controlling glycemia, lipids, and blood pressure in asymptomatic people. These issues often receive short shrift in the 10 min or so that most patients spend with primary care physicians, who often have other more immediate concerns. Moreover, patients are often seen only every 3 months or so, thus ensuring that glycemia, lipids, and blood pressure could remain out of control for long periods of time. This schedule wastes opportunities to bring these patients under control much more quickly because the maximal responses to changes in medication doses or introduction of new classes of drugs for treating glycemia (except for thiazolidinediones), lipids, and blood pressure all occur within a month.

Most treatment decisions involving control of glycemia, lipids, and blood pressure do not require a face-to-face meeting with a provider. Titration of most oral medications for glycemia can be made based on fasting plasma glucose concentrations measured by a laboratory or by a glucose meter at home, with subsequent dose adjustments based on A1C levels (online appendix of ref. 12, available at [370](http://dx.doi.org/10.2337/dc08-</a></p></div><div data-bbox=)

2046). Insulin dose adjustments are based on the results of home glucose monitoring. Treatment of dyslipidemia is based on measured lipid concentrations. Patients can measure their own blood pressure with home machines. (Glucose meters and blood pressure machines should be compared with office meters and blood pressure machines at periodic office visits.) These results can be made available at appropriate intervals to the primary care physician, who would then respond to the patient via e-mail, phone, or fax. In this manner, timely clinical decisions would be made, the patient would be less inconvenienced, and diabetes outcomes would improve. Of course, in our present medical care system, physicians are not routinely reimbursed for such activities, and therefore these kinds of interactions seldom occur.

Let me illustrate with a personal case in point. Dose adjustments in insulin-requiring diabetic patients are particularly challenging. Patients are usually seen about every 3 months, and if they are fortunate the last 2 weeks or so of their glucose values measured at home may be reviewed. Insulin doses are often not stable over 3-month periods, but how can one know when glucose responses over only a small segment of that period are evaluated? This is one reason why A1C levels are higher in diabetic patients taking insulin than in those on oral medications alone. To address this problem, I initiated a pilot project in the second half of the 1990s in which the results of home glucose monitoring were sent via telephone wires to a central server where the individual values were analyzed by an algorithm, plotted on a simple graph, which also depicted the appropriate target range, and faxed to a nurse (13). Based on the patterns on the graph, the nurse could decide in less than a minute what insulin dose changes should be made. These were then phoned to the patients, who had been referred to this pilot project by their endocrinologist. Baseline A1C levels averaging 8.4% in 10 type 1 diabetic and 19 insulin-requiring type 2 diabetic patients fell by 0.7% by 20 weeks. When a start-up company tried to commercialize this product, they were unable to obtain a Current Procedural Terminology code for this activity and soon thereafter went out of business. Thus, insulin-requiring diabetic patients generally continue to be seen every 3 months, and their glycemia remains inadequately controlled.

In the last decade, much easier Web-based communication with patients has become possible. In this issue of *Diabetes Care*, Ralston et al. (14) have described a randomized small trial in which one group received usual care and the other usual care plus Web-based care management for 1 year. The latter group's program consisted of patient access to electronic medical records, secure e-mail access to providers (including a nurse care manager who adjusted hypoglycemic medications and conferred with the primary care provider only as needed), an educational Web site, and an interactive online diary for entering exercise, diet, and medication. After 1 year, unadjusted A1C levels in the intervention group fell from a baseline value of 8.2 to 7.3%, whereas in the control group they increased from 7.9 to 8.1%. The authors stated that they were unable to distinguish which components of Web-based management were most important for the success of the intervention. I strongly suspect it was the nurse care manager making treatment decisions in real time, based on published literature showing the effectiveness of that approach and the ineffectiveness of interventions that did not include that component (7,9–11) as well as the results of several other Web-based interventions described below.

In a study by the Korean Diabetes Association, physicians receiving information (including results of home glucose monitoring) over the Internet from patients utilized the Staged Diabetes Management Guidelines for Korea (15) for management. During the first 3 months, A1C levels fell by 0.6% in the Internet group and rose by 0.3% in a control group receiving usual care (16). Over the subsequent 27 months, mean A1C levels were 0.6% lower in the Internet group than in the control group (17). All differences between the two groups were significant. In a Veterans Affairs study comparing usual care with Web-based nursing care management based on treatment algorithms, A1C levels fell significantly more in the intervention group over a year (0.4% more at 12 months but a greater difference at 3, 6, and 9 months) (18). A comparison of telemedicine case management by nurses following algorithms with usual care in older, medically underserved patients showed a small (0.2%), but significantly greater, drop of A1C levels in the intervention group (19). These nurses, however, had to receive authority to

change management from primary care physicians. Finally, a very intense education and support group program delivered via the Web—which included access to articles and other Web sites concerning diabetes, support group interactions led by a nurse, and self-management feedback from a nurse after the nurse had received home glucose monitored values, meal intake, medication administration, weight, and blood pressure information from the patient—resulted in significant improvements in adjusted A1C (−0.62%), HDL cholesterol (+6.4 mg/dl), total cholesterol (−11.4 mg/dl), weight (−4.5 lbs), systolic blood pressure (−6.8 mmHg), and diastolic blood pressure (−5.2 mmHg) over 6 months, with no significant changes in these parameters in a control group (20).

All of these innovative approaches to deliver diabetes care were supported by either research or institutional funds. Unless payment mechanisms can be established to reimburse providers for the time and effort these effective interactions require, these new promising care models will remain just that—(unkept) promises.

Until a magic medication comes along to stabilize  $\beta$ -cell function or, better yet, to reverse  $\beta$ -cell dysfunction, it will remain difficult to improve diabetes outcomes very much unless the current medical care system can change to facilitate more frequent interactions with knowledgeable providers. This might also include specially trained, appropriately supervised nurses and pharmacists with prescription authority based on approved treatment algorithms. Timely and appropriate clinical decisions for people with diabetes are not being made in most patients under our current medical care system. This leads to increased morbidity and mortality from diabetes complications that could be either considerably delayed or potentially prevented.

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