



Effect of Diabetes-Trained Nurse Practitioners on Glycemic Outcomes: Their Suggested Use in Busy Primary Care Practices

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A Federally Qualified Health Center received ongoing external support for half-time salaries for two nurse practitioners to treat people with poorly controlled diabetes (A1C >9.0%) in the clinic's diabetes program using approved detailed treatment protocols. Patients were treated for 1 year and graduated from this program if their A1C fell to <7.5%. Ninety-one percent graduated, and treatment was deemed to have failed in 9% who did not achieve an A1C <7.5% by the end of the year of treatment. The suggestion is made to assign a specially trained diabetes nurse or physician assistant to serve many primary care providers at important clinical junctures to improve diabetes outcomes throughout busy primary care practices.

Only half of people with diabetes achieve the American Diabetes Association (ADA) general A1C goal of <7.0% (1,2). Twenty-eight percent of people with diabetes have A1C levels >8.0%, and 16% have levels >9.0% (2). Risk factors for the latter are a long duration of diabetes, infrequent office visits, and insulin therapy (3). Only one-fourth of patients with A1C levels >9.0% are able to lower levels to <8.0% in 1 year (3). Ninety percent of people with diabetes receive their diabetes care from primary care provider (PCPs) (4), who are particularly challenged in using insulin. This fact is evidenced by 1) the 3–7 years it takes to start insulin once people with type 2 diabetes (A1C >8%) have failed maximal doses of two or three noninsulin drugs (5,6), 2) an average A1C range of 8.9–9.8% with a mean of 9.3% when insulin is started (5–9), 3) a mean A1C level of 9.7% when insulin is intensified in patients for whom basal insulin alone does not adequately control glucose levels (6,9), 4) insulin intensification occurring in only 25–30% of patients while its discontinuation occurs in a similar number (9–16), and

5) an average A1C range of 7.9–9.3% with a mean of 8.5% in patients receiving insulin (7,17,18).

For nearly 40 years, the author has taught detailed treatment protocols to >40 registered nurses (RNs), nurse practitioners (NPs), physician assistants (PAs), and clinical pharmacists, who used them to treat mostly minority, under-resourced patients followed in Federally Qualified Health Centers (FQHCs). Outcomes have been significantly better compared with usual diabetes care at these clinics (19–25). One diabetes program carried out by a specially trained RN working under approved treatment protocols at a Los Angeles County, CA, clinic decreased urgent care and emergency department visits by 51% and hospitalizations by 83% (26).

This article describes the glycemic outcomes over a 6-year period from NPs following these treatment protocols in an FQHC and suggests how specially trained nurses and PAs can be incorporated into busy primary care practices to facilitate improved diabetes care.

Research Design and Methods

The Venice Family Clinic (VFC), an FQHC, has received ongoing grant support for the past 6 years for an NP salary to improve diabetes care. The clinic hired two full-time NPs, assigned them to spend 50% of their time (grant supported) seeing patients with diabetes, and paid the other half of their full-time salaries from clinic funds to see patients in primary care. The author trained both NPs in his diabetes program at the Martin Luther King, Jr., Outpatient Center in Los Angeles County. The NPs were referred patients whose A1C levels were >9.0%. The patients were treated following the previously mentioned

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protocols for up to 1 year with three possible outcomes: 1) achieving an A1C $\leq 7.5\%$, at which time they were considered graduates of the program and referred back to their PCPs; 2) maintaining A1C levels $>7.5\%$ at year's end, at which time their program treatment was considered to have failed and they were referred back to their PCPs; or 3) being discharged from the program because of loss of follow-up or noncompliance with treatment recommendations. Loss of follow-up occurred if patients missed 2 months of appointments despite multiple attempts to contact them. This occurrence was not uncommon because these Latinx patients often went to Mexico for long periods, especially during the Christmas and New Year's holidays. Noncompliance was defined after the NPs made at least three or four attempts to convince patients to follow their recommendations.

The general principle of the glycemia protocol used by the NPs is to determine as quickly as possible whether an introduced class of drugs will achieve target levels or whether the addition of a drug from another class will be needed. Of the 11 classes of noninsulin drugs that have been approved for the treatment of type 2 diabetes, only two need titration: metformin because of its potential for gastrointestinal side effects and sulfonylureas (SUs) because of their potential for hypoglycemia. The maximal effect of both of these drugs when they are started or when their doses increase occurs within 2–3 weeks. Thus, the first protocol target is a fasting plasma glucose (FPG) concentration <130 mg/dL measured after that time interval. The dose of the first drug (usually metformin) is increased until the FPG target is achieved. If it is not achieved after a maximal dose is reached, a drug from another class is added. If the second drug is an SU, the dose is similarly increased until the FPG target is reached. Whenever the FPG target is achieved, an A1C level measured 3 months later determines whether the current drug regimen and doses are sufficient.

Because metformin does not cause hypoglycemia, appropriate patients can self-titrate its doses every 2 weeks until the maximal dose of 2,000 mg is reached in 6 weeks. An FPG test 2 weeks later (8 weeks after initiating metformin) determines whether the FPG target has been achieved. Self-titration of metformin has two advantages. It avoids not only laboratory or office visits for two FPG tests, but also a situation in which the FPG target is reached with a submaximal dose of metformin but the A1C test 3 months later is not at target and the metformin dose must be increased further. This situation would increase the amount of time a patient's glycemia remains out of control.

This was the standard treatment protocol taught to the VFC NPs at the Martin Luther King, Jr., Outpatient Center. However, because of a legal settlement, a pharmaceutical company was required to provide free drugs to FQHCs. A combination of metformin plus a dipeptidyl dipeptidase 4 (DPP-4) inhibitor was available without cost to the pharmacy and was used as the initial drug instead of metformin alone. Because the major mechanism of action of both DPP-4 inhibitors and SUs is to increase insulin secretion, they are not used together in the glycemic protocol. The combination drug was quickly titrated as described above for metformin alone.

With the exception of metformin and SUs, maximal doses of all other noninsulin drugs are initiated, and the A1C level 3 months later determines whether another class of drugs should be added. Sodium–glucose cotransporter 2 inhibitors became available for some patients at the VFC in year 3, and glucagon-like peptide-1 receptor agonists became available in year 5. The latter are started at a lower dose but increased to the maximal dose after 1 month if gastrointestinal symptoms allow. Both are added before insulin is started.

When achievement of target glycemia is not met using the above medication strategies, insulin is initiated. The NPs used an effective, straightforward, quantitative approach to adjusting insulin doses (27). Depending on when it is injected, each component of the insulin regimen has a maximal effect in a specific period of the 24-h cycle (e.g., overnight or in the morning, afternoon, or evening). The glucose pattern in that period determines whether the dose of that component of the insulin regimen requires adjusting.

Caring for the patient population in this FQHC can be challenging. The population is 56% Latinx, 27% Caucasian, 10% African American, 4% Asian, and 3% other; 75% live below the federal poverty level; 38% speak Spanish as their primary language; and 16% are homeless. Because patient data in this observational, retrospective study were de-identified, informed consent was not required.

Results

The glycemic results of the 6 years of this diabetes program are summarized in Table 1. The baseline A1C was $10.8 \pm 1.5\%$. Fewer than 5% of the patients had type 1 diabetes. The fluctuating number of patients followed each year reflects the birth of two children to each of the two NPs, with a subsequent 6-month postpartum medical leave during the 6-year period.

In the first several years, the breakdown between patients on noninsulin drugs alone and those taking insulin at the

TABLE 1 Glycemic Outcomes

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total treated during year, <i>n</i> *	200	247	310	189	256	294
Status at end of year, <i>n</i>						
Still being followed	135	119	130	108	111	116
Graduates†	35	53	110	53	94	106
Treatment failures‡	—	19	13	1	0	9
Discharges§	32	56	57	27	51	63
Participants graduated, %	—	74	89	98	100	85
Participants discharged, %¶	16	43	18	14	20	21

*Patients carried over from previous year plus those newly enrolled. †Achieved an A1C $\leq 7.5\%$. ‡Treatment failed to yield an A1C $< 7.5\%$ after 1 year. §Patients who were noncompliant or lost to follow-up. ||Of those who completed 1 year of treatment. (None could have completed 1 year of treatment in year 1 except the first enrolled patient.) ¶Of those who received treatment during the year.

end of the year of treatment was approximately 25%/75%, whereas in the last several years, with the availability of more recent classes of noninsulin drugs, it was approximately 50%/50%. The availability of the new classes of diabetes drugs spared the need to switch to insulin for many patients. A remarkable finding was the very high percentage of graduates (~90%) and the low number of treatment failures among those who persisted with treatment during the entire year they were enrolled in the program, especially during the last 3 years, when new drug classes reduced the need for insulin.

Discussion

The results summarized in Table 1 certainly attest to the effectiveness of the glycemic protocol used by the NPs. The NPs also used blood pressure and lipid protocols to treat their patients. Only 2–13% of people with diabetes have been found to meet all three ADA targets for A1C, blood pressure, and LDL cholesterol (25). In contrast, a diabetes-trained RN following these three protocols in a county clinic serving a population similar to the one in this diabetes program achieved all three ADA targets in 47% of her patients (25).

Apart from appropriate pharmacological therapy, another important reason for the success of this diabetes program is that, given more time to focus exclusively on diabetes, the NPs are better able to engage patients in their own diabetes care. Patients feel more invested in their health and build partnerships with their NP to achieve better longer-term diabetes outcomes.

A further reason for the poorer outcomes under usual diabetes care is the relatively infrequent interactions between PCPs and their patients (3). Patients, especially

those from under-resourced populations, are typically seen every 3–6 months in busy primary care practices. This schedule can lead to problems with medication adherence, missed laboratory tests, missed visits, and—importantly—long intervals in which intensification of therapy should be occurring. Diabetes-trained nurses (NPs or RNs working either under the supervision of PCPs or under approved protocols) can address these issues. This strategy would leverage their effect on improving diabetes outcomes throughout the practice compared with providing ongoing diabetes care to only the individual patients they are assigned for primary care. Some examples in which these nurses could have a positive impact include ensuring that FPG tests are done when metformin and SUs are being titrated and that doses are increased if warranted; handling midlevel visits for blood pressure measurements and appropriate medication changes if necessary; periodically reviewing electronic health records to ensure ongoing care and necessary LDL cholesterol and A1C testing to monitor compliance with medications; and obtaining and reviewing glucose meter readings (from patients at home or during visits) for possible adjustment of insulin doses under protocol or direct supervision from PCPs. Frequent ongoing interactions with specially trained nurses or PAs concerning their diabetes issues should also allow patients to build relationships and partnerships that would benefit longer-term diabetes outcomes.

In conclusion, nurses or PAs who are specially trained in diabetes care could serve a number of PCPs by focusing on their patients with diabetes at the important clinical junctures described above, which could in turn improve diabetes outcomes throughout a busy practice.

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DUALITY OF INTEREST

No potential conflicts of interest related to this article were reported.

GUARANTOR STATEMENT

The author volunteers at the VFC, developed the treatment algorithms, trained the NPs, wrote the article, and, as the sole author, takes responsibility for its content.

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