

The Cost-Effectiveness of Continuous Glucose Monitoring in Type 1 Diabetes

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OBJECTIVE — Continuous glucose monitoring (CGM) has been found to improve glucose control in type 1 diabetic patients. We estimated the cost-effectiveness of CGM versus standard glucose monitoring in type 1 diabetes.

RESEARCH DESIGN AND METHODS — This societal cost-effectiveness analysis (CEA) was conducted in trial populations in which CGM has produced a significant glycemic benefit (A1C $\geq 7.0\%$ in a cohort of adults aged ≥ 25 years and A1C $< 7.0\%$ in a cohort of all ages). Trial data were integrated into a simulation model of type 1 diabetes complications. The main outcome was the cost per quality-adjusted life-year (QALY) gained.

RESULTS — During the trials, CGM patients experienced an immediate quality-of-life benefit (A1C $\geq 7.0\%$ cohort: 0.70 quality-adjusted life-weeks [QALWs], $P = 0.49$; A1C $< 7.0\%$ cohort: 1.39 QALWs, $P = 0.04$) and improved glucose control. In the long-term, CEA for the A1C $\geq 7.0\%$ cohort, CGM was projected to reduce the lifetime probability of microvascular complications; the average gain in QALYs was 0.60. The incremental cost-effectiveness ratio (ICER) was \$98,679/QALY (95% CI $-60,000$ [fourth quadrant] to $-87,000$ [second quadrant]). For the A1C $< 7.0\%$ cohort, the average gain in QALYs was 1.11. The ICER was \$78,943/QALY (15,000 [first quadrant] to $-291,000$ [second quadrant]). If the benefit of CGM had been limited to the long-term effects of improved glucose control, the ICER would exceed \$700,000/QALY. If test strip use had been two per day with CGM long term the ICER for CGM would improve significantly.

CONCLUSIONS — Long-term projections indicate that CGM is cost-effective among type 1 diabetic patients at the \$100,000/QALY threshold, although considerable uncertainty surrounds these estimates.

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The Diabetes Control and Complication Trial (DCCT) established the clinical benefits of intensive glucose control in type 1 diabetes (1). Despite the availability of insulin pumps and insulin an-

alogues, achieving optimal glucose control, while avoiding hypoglycemia, continues to be a significant challenge for patients.

An important component of glucose control is glucose monitoring. Conventional

self-glucose monitoring permits patients to periodically measure capillary glucose. This leaves patients unaware of postprandial hyperglycemia and asymptomatic nocturnal hypoglycemia (2). Newer continuous glucose monitoring (CGM) technology, which measures glucose levels in subcutaneous tissue, has the potential to overcome these challenges and increase the likelihood that patients with diabetes can achieve and maintain optimal glucose control without symptomatic hypoglycemia. While there are potential advantages of CGM, the technology does have some disadvantages, including discomfort from the probe, ongoing use of conventional monitoring, potential overestimation of the frequency of overnight low glucose levels, and high costs (3).

Recently, parallel multicenter trials comparing CGM with conventional self-glucose monitoring alone were conducted in patients with A1C $\geq 7.0\%$ (A1C $\geq 7.0\%$ cohort) and in patients with A1C $< 7.0\%$ (A1C $< 7.0\%$ cohort) (4). In the A1C $\geq 7.0\%$ cohort, CGM was found to significantly reduce average A1C levels (-0.53 [95% CI -0.71 to -0.35], $P < 0.001$) in adults (aged ≥ 25 years) (5). In the A1C $< 7.0\%$ cohort, CGM helped intervention patients maintain their A1C at 6.5%, while control patients experienced an increase in A1C of 0.3% (6). The purpose of this study is to evaluate the cost-effectiveness of CGM technology compared with standard glucose monitoring in the type 1 diabetic patients from the societal perspective.

RESEARCH DESIGN AND METHODS

The design of the Juvenile Diabetes Research Foundation (JDRF)-CGM trials has been previously described (4–6). In brief, patients with type 1 diabetes were randomized to CGM versus standard glucose monitoring for 6 months. In the A1C $\geq 7.0\%$ study cohort, subjects were stratified into three pre-specified age-groups (8–14, 15–24, and ≥ 25 years). The A1C $< 7.0\%$ cohort was not stratified by age. We conducted cost-utility analyses (CUAs) in the adult (aged ≥ 25 years) A1C $\geq 7.0\%$ cohort and the overall A1C $< 7.0\%$ cohort. For the remainder of this manuscript, the adult

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A1C $\geq 7.0\%$ cohort will be referred to as the A1C $\geq 7.0\%$ cohort.

CUA data collected during trials

Costs and direct-cost items. The primary costs of interest for this CUA are the costs of CGM technology and training. During the trial, investigative staff reported on time spent with patients during scheduled and nonscheduled encounters. We included staff time devoted to CGM training and diabetes management and excluded research time. The utilization of CGM was routinely collected as days of use per week. The use of standard glucose monitoring was recorded as number of tests per day.

Adult patients and caregivers of children were surveyed at baseline and 6 months regarding health service utilization outside of the trial. Survey data included items for routine office visits, after-hours clinic visits, emergency room visits, 911 calls, and hospitalizations.

Indirect-cost items. Apart from health service utilization, adult patients and caregivers of children were surveyed at baseline and 6 months on the number of hours devoted to diabetes care per day, number of days missed from work or school due to diabetes, and number of days of work underperformance.

Unit costs. The unit costs and their sources are listed in online appendix Table 1 (available at <http://care.diabetesjournals.org/cgi/content/full/dc09-2042/DC1>). The daily cost of CGM technology was calculated based on Food and Drug Administration–recommended frequency of sensor replacement and the expected frequency of receiver and transmitter replacement. The costs of the three devices (DexCom, Medtronic, and Abbott) used during the trial were averaged to arrive at a daily cost of CGM of \$13.85 in year 1 (online appendix Table 2). The costs of CGM equipment reflect full retail prices, with no insurer discounts. This daily cost was multiplied by the reported weekly use of CGM to arrive at an overall cost of CGM technology (e.g., 6 days of use/week = an annual cost of \$4,335).

Measurement of quality-of-life effects

The quality-of-life effects of CGM were expected to manifest themselves in terms of immediate changes in quality of life from using the device as well as from the occurrence of long-term complications of diabetes that might be altered by changes in glycemic control. We collected utilities

from trial patients for both immediate (experienced) quality-of-life effects of CGM and for the quality-of-life effects of potential long-term complications (7).

We collected experienced utility data by using the Health Utility Index (8) and by eliciting time tradeoff (TTO) utilities for overall experience (7). In the TTO method, patients were asked to consider their current state of health in comparison to life in perfect health. Experienced utilities were elicited at baseline, 13 weeks, and 26 weeks. For children aged <18 years, parents served as surrogates in responding to questionnaires. A priori, we planned to use the TTO utilities as the most theoretically grounded measure for the CUA.

For complication utilities, we used the TTO method to elicit utilities for life with blindness, end-stage renal disease (ESRD), lower-extremity amputation, chronic angina, and stroke (7). Parents of children aged <18 years served as surrogates for their children during complication utility elicitation. For the CUA, we used the same set of overall population complication utility weights for both trial arms in long-term projections.

Calculation of the incremental cost-effectiveness ratio

Within-trial analyses. Experienced utilities at baseline, week 13, and week 26 were modeled using a random-effects linear model (9,10). In the regression, we adjusted for treatment arm indicator, time indicators for 13 and 26 weeks, interaction between time and treatment indicators, and a variety of subject-level confounders. Quality-of-life predictions were obtained at weeks 13 and 26 for all subjects (in both control and CGM arms) as if they belonged to either trial arm. This was necessary to account for the difference in baseline quality of life across treatment arms and was accomplished by the method of recycled predictions, where the treatment indicator and its interaction with time were turned on and off subsequently. The total quality-adjusted life weeks (QALWs) were calculated as the area under the quality-of-life time trends under each arm. Total direct and indirect costs over the 6-month period were analyzed separately using generalized linear models with log-link and γ variances. SEs for both costs and effects were obtained simultaneously using 500 bootstrap replicates that were clustered by subjects. Estimates of costs and effects and their empirical distributions were used to cal-

culate the overall incremental cost-effectiveness ratios and their 95% CIs.

Lifetime analyses. For the lifetime analyses, we extrapolated the findings from the clinical trials over the projected lifetime of patients. For these lifetime projections, we developed a Monte Carlo–based Markov simulation model that uses framework and data inputs shared by prior cost-effectiveness analyses of treatments in type 1 diabetes (online technical appendix) (11). The model is framed by the simultaneous progression of disease through major categories of complications and their associated Markov states (online appendix Fig. 1) (Microsoft Excel 2000, Microsoft, Seattle, WA; and @Risk 4.0 for Windows, Palisades, Newfield, NY). After assignment of characteristics of hypothetical subjects, the model simulates the natural history of diabetes based on these characteristics.

A detailed description of the model inputs is available in online appendix Table 3. For all microvascular complications, we used the original DCCCT prediction models for intermediate complications that relate A1C with the cumulative probability of developing these intermediate complications (courtesy of Richard Eastman) (12). For the transitions from intermediate to end-stage microvascular complications, we used annual probabilities found in the literature (13–15).

For cardiovascular complications, there were no published prediction models for patients with type 1 diabetes at the time of our analysis. In lieu of such models, we used prediction models for type 2 diabetic patients for ischemic heart disease, myocardial infarction, congestive heart failure, and stroke (16). To calculate cardiovascular risk, we used age- and sex-stratified risk factor data from the study population whenever possible. For blood pressure and cholesterol inputs, we used data for the nondiabetic population from the National Health and Nutrition Examination Surveys. Observational studies have found that type 1 diabetic patients typically have blood pressure and cholesterol levels that are closer to the nondiabetic population than the type 2 diabetic population (17). For mortality related to diabetes complications, we used mortality prediction models developed with type 2 diabetes data (16). To calculate background mortality rates, we used National Vital Statistics Life Tables (18).

For the lifetime analysis, the main outcome of interest was the incremental

Table 1—Baseline characteristics of the study populations

	A1C ≥7.0% cohort		A1C <7.0% cohort	
	Control	CGM	Control	CGM
n	46	52	63	67
Female sex	26 (57)	31 (60)	33 (52)	36 (54)
Age (years)	44.69 ± 12.35	41.23 ± 11.21	31.84 ± 17.63	29.38 ± 16.29
Non-Hispanic white race	42 (91)	52 (100)	61 (97)	64 (96)
Duration of diabetes (years)	21.83 ± 10	23.57 ± 11	18.15 ± 15	16.28 ± 15
Daily insulin dose (units)	45.97 ± 24	43.20 ± 19	42.23 ± 17	39.72 ± 13
Pump users	39 (85)	43 (83)	50 (79)	62 (93)
A1C at baseline (%)	7.61 ± 0.50	7.61 ± 0.49	6.50 ± 0.34	6.39 ± 0.49
Daily home glucose meter reading (times/day)	6.19 ± 1.94	6.89 ± 3.17	6.31 ± 2.72	7.67 ± 3.07

Data are means ± SD or n (%). A1C ≥7.0% cohort is only for those aged ≥25 years. The only statistical difference between control and CGM patients was in the proportion of pump users among the A1C <7.0% cohort (P = 0.03).

cost-effectiveness ratio (ICER) using an intention-to-treat analysis (dollars/QALYs). Unlike the within-trial analyses, the lifetime analysis accounted for lifetime costs and benefits with the assistance of the simulation model. We assumed a lifetime use of the CGM by patients in the CGM trial and no adoption by the control arm.

Projected CGM effects

From the clinical trial, we know that CGM had an impact on glucose levels as well as on immediate, experienced utility. Both effects were incorporated into lifetime simulations. For the impact of CGM on glucose levels, we evaluated CGM's effect as a change in the distribution of A1C levels at 26 weeks and carried this difference in distribution over the remaining lifetime. For the impact of CGM on experienced utility, we evaluated CGM's effect as a change in the distribution of experienced quality of life and carried this difference in distribution over the remaining

lifetime. The assumption that both CGM effects are maintained over time is based on 12-month observational data that has revealed that glycemic control, mean experienced utilities, and utilization of the device were unchanged among CGM patients.

Sensitivity analyses

To assess the relative contributions of immediate quality-of-life and long-term glucose control benefits, we ran analyses in which the only benefit was due to improved glucose control. We also evaluated the impact of variation in the daily cost of CGM on the cost-effectiveness of the technology. CGM use may eventually lead to lower utilization of conventional blood glucose monitors and associated test strip use. To account for this possibility, we conducted a sensitivity analysis around the number of daily test strips used among patients on CGM. We separately evaluated the effect of future costs, including medical costs for unrelated ill-

nesses, nonmedical costs, and future earnings, on the overall cost-effectiveness results (19).

Uncertainty

To express the degree of uncertainty around ICERs, we present 95% CIs, using the percentile method based on bootstrap replicates (20).

RESULTS

A description of the A1C ≥7.0% cohort and the A1C <7.0% cohort is provided in Table 1. The A1C ≥7.0% cohort had a mean baseline A1C level of 7.5%, while the overall secondary cohort had a mean A1C level of 6.3%. Over 80% of patients in both cohorts were insulin pump users.

Within-trial results

During the 6-month period of the trial, CGM improved experienced quality of life and increased costs in both cohorts (Table 2). For the A1C ≥7.0% cohort,

Table 2—Within-trial results

	A1C ≥7.0% cohort			A1C <7.0% cohort		
	Control	CGM	Difference ± SE	Control	CGM	Difference ± SE
QALWs	21.68 ± 0.60	22.38 ± 1.08	0.70 ± 1.03	21.84 ± 0.66	23.23 ± 0.81	1.39 ± 0.69*
Direct costs	\$3,984 ± 242	\$6,375 ± 302	\$2,391 ± 376*	\$3,412 ± 164	\$6,529 ± 277	\$3,117 ± 356*
Indirect costs	\$12,419 ± 3,478	\$15,979 ± 4,100	\$3,560 ± 5,781	\$17,352 ± 4,338	\$25,146 ± 6,238	\$7,794 ± 7,097
Total costs	\$16,403 ± 3,493	\$22,354 ± 4,127	\$5,951 ± 5,847	\$20,764 ± 4,351	\$31,675 ± 6,292	\$10,991 ± 7,163
ICER [\$/QALW (95% CI)]		\$8,501 (not defined)				\$7,849 (−3,397 [fourth quadrant, dominant] to 66,829 [first quadrant])
ICER [\$/QALY (95% CI)]		\$442,052 (not defined)				\$408,148 (−176,644 [fourth quadrant, dominant] to 3,475,108 [first quadrant])

Data are means ± SE, unless otherwise indicated. A1C ≥7.0% cohort is only for those aged ≥25 years. Indirect costs are estimated from reports of subject and parent hours devoted to diabetes care per day, number of days missed from work or school due to diabetes, and number of days of work underperformance. Dominant, intervention improves health at a lower cost compared with control. Not defined, there is so much uncertainty around the ICER that a 95% CI cannot be defined. *P < 0.05.

Table 3—Lifetime cost-effectiveness analysis results

Lifetime probability of:	A1C ≥7.0% cohort		A1C <7.0% cohort	
	Control	CGM	Control	CGM
Blindness	14.56	12.00	16.19	13.96
Neuropathy	34.96	30.56	33.46	30.41
Amputation	10.53	9.13	12.92	11.73
Microalbuminuria	19.30	13.15	12.43	9.46
End-stage renal failure	4.41	2.37	2.4	1.44
Myocardial infarction	11.53	11.24	11.24	11.04
Ischemic heart disease	10.41	10.22	10.82	10.66
Congestive heart failure	2.08	2.04	1.67	1.65
Stroke	1.94	1.92	1.84	1.81
Life expectancy (means)	26.79	26.84	36.54	36.58
Discounted QALYs (means)	13.75	14.35	16.69	17.80
Difference in QALYs	0.60		1.11	
Discounted direct costs (means)	\$159,748	\$217,882	\$200,384	\$285,149
Discounted indirect costs (means)	\$441,322	\$441,955	\$1,911,155	\$1,913,776
Discounted total costs (means)	\$601,070	\$659,837	\$2,111,539	\$2,198,925
Difference in total costs	\$58,767		\$87,386	
ICER [means (95% CI)]	\$98,679 (−60,007 [fourth quadrant, dominant] to −86,582 [second quadrant, dominated])		\$78,943 (14,644 [first quadrant] to −290,780 [second quadrant, dominated])	

Experienced quality-of-life benefit was not statistically significant during the 6-month trial for the A1C ≥7.0% cohort. The A1C ≥7.0% cohort is only for those aged ≥25 years. Dominant, intervention improves health at a lower cost compared with control; Dominated, intervention worsens health at increased cost compared with control.

CGM patients had a higher quality of life than control patients (means ± SE) (0.70 ± 1.03 QALWs, *P* = 0.49) that was not statistically significant. They also incurred higher direct medical (\$2,391 ± \$376) and total costs (\$5,951 ± \$5,847). The societal ICER for the within-trial period was \$8,501/QALW or \$442,052/QALY. There was considerable uncertainty around the ICER, such that 95% CIs could not be defined.

For the A1C <7.0% cohort, CGM patients had a significantly higher quality of life during the trial (1.39 ± 0.69 QALWs, *P* = 0.04) compared with control patients. CGM patients also incurred higher direct medical costs (\$3,117 ± \$356) and total costs (\$10,991 ± \$7,113). The societal ICER was \$7,849/QALW or \$408,148/QALY. CIs for the societal ICER ranged from dominant to \$213,000/QALY.

Long-term results

Base case analyses. In the lifetime analysis for both cohorts, CGM reduced the expected lifetime incidence of intermediate and end-stage complications of type 1 diabetes while also increasing costs.

In the A1C ≥7.0% cohort, the model predicted that the use of CGM would lead to reductions in lifetime risk of blindness (14.56→12.00%), amputation

(10.53→9.13%), and end-stage renal disease (4.41→2.37%). Life expectancy for both intervention and control cohorts was ~27 years. The average improvement in quality of life was 0.60 QALYs. The ICER for the base case was \$98,679/QALY. The CIs for this ICER spanned the southeast and northwest quadrants of the cost-effectiveness plane (95% CI −60,007 [fourth quadrant, dominant] to −86,582 [second quadrant, dominated]). The CIs reflect a large degree of uncertainty about the ICER point estimate.

For the A1C <7.0% cohort, the model also predicted that CGM use would lead to reductions in blindness (16.19→13.96%), amputation (12.92→11.73%), and end-stage renal disease (2.40→1.44%). Life expectancy for both intervention and control cohorts was ~37 years. The average improvement in quality of life was 1.11 QALYs. The ICER for the base case was \$78,943/QALY. The CIs for this ICER spanned the northeast and northwest quadrants of the cost-effectiveness plane (95% CI 14,644 [first quadrant] to −290,780 [second quadrant, dominated]). The CIs for this cohort were narrower than for the A1C ≥7.0% cohort but still reflect considerable uncertainty around the ICER.

Sensitivity analysis

If the benefit of CGM was limited to glucose lowering and subsequent complication prevention, CGM would not be cost-effective by most conventional thresholds. In the A1C ≥7.0% cohort, the average gain in QALYs would be 0.08 and the ICER would be \$701,397/QALY. In the A1C <7.0% cohort, the average gain in QALYs would be 0.07 and the ICER would be \$1,185,384/QALY. The benefits from improved glycemic control are relatively small due to the fact that complications are predicted to develop late in life, and the benefits of complication reduction are therefore heavily discounted.

We also performed sensitivity analyses on the average daily cost of CGM holding utilization of the device constant (online appendix Fig. 2). If the daily costs of CGM were reduced from \$13.85/day (\$4,335/year) to \$9.89/day (\$3,096/year) or below, the ICER would be below \$70,000/QALY for both study populations. In the test strip sensitivity analysis, if test strip use among CGM patients was two test strips per day as recommended for calibration, CGM would be cost saving compared with standard glucose monitoring. When accounting for future costs, the ICERs for the two populations did not qualitatively change from the base case.

CONCLUSIONS— Real-time continuous glucose monitors have been found to improve glycemic control in type 1 diabetes in recent trials. In study populations where CGM improved glycemic control, our within-trial analysis revealed that CGM improved experienced quality of life (significant for the A1C <7.0% cohort and nonsignificant for the A1C \geq 7.0% cohort) and increased costs. Based on ICER point estimates, CGM was not cost-effective by conventional metrics during the first 6 months of use of the device, although there was considerable uncertainty around these results.

When extrapolating benefits in experienced quality of life and glycemic control over a lifetime, the ICER point estimates from our analyses suggest that CGM is a cost-effective technology, based on the ICERs of commonly accepted diabetes therapies (21). Recent studies suggest that the acceptable ICER threshold is between \$109,000 and \$297,000/QALY, above the commonly discussed \$50,000/QALY threshold (22). While the ICER point estimates suggest that CGM is a good value relative to the \$109,000 threshold, the CIs were wide, reflecting considerable uncertainty. For example, for the A1C \geq 7.0% cohort, the CIs include the possibility that CGM is dominant (i.e., beneficial and cost saving) but also include the possibility that CGM is dominated (i.e., harmful and cost increasing). Most of the incremental cost of CGM is due to adding the CGM system (\$4,335 in year 1), while maintaining confirmatory blood glucose testing. If CGM were to lead to less confirmatory testing, the ICER for CGM would improve dramatically.

One important insight from our analysis is that the overall quality-of-life effect of CGM arises from its ability to both improve the immediate quality of life of diabetic patients as well as reduce future complications through enhanced glycemic management. The immediate quality-of-life effect of CGM was responsible for the majority of projected lifetime benefits of the technology. For many patients, CGM provides some of the first insights into their dynamic patterns of glucose control. The provision of greater glucose control data may have improved the quality of life of patients by facilitating decisions related to food intake and insulin regimens as well as by reducing the risks and fears of hypoglycemia. These improvements occurred during the 6-month trial despite the fact that a large proportion of patients enrolled in these trials had

very high baseline quality of life (online appendix Fig. 3).

The analysis of quality-of-life data also suggests that the quality-of-life effect of the CGM differed between the A1C \geq 7.0% and A1C <7.0% cohorts. In comparison to the adult patients with suboptimal glucose control, patients who were already at optimal glucose control levels achieved a significant immediate quality-of-life benefit from CGM. This difference could have been due to a lack of statistical power for the adult A1C \geq 7.0% cohort but may also have been due to a relatively larger improvement in quality of life for the A1C <7.0% cohort. The exact reasons for the larger improvement in quality of life for the A1C <7.0% cohort are not entirely known. Quality of life of CGM subjects may have improved due to a reduction in time spent with biochemical hypoglycemia (median 54 vs. 91 min/day), although this difference was not statistically significant (6). The difference in experiences for these two trial cohorts suggests that the effect of CGM may differ across diabetic subpopulations, varying by diabetes type, baseline glucose control, and current therapy.

Our study has a number of important limitations. Criticism could still be leveled against our model choices. The DCCT models of microvascular complications may not reflect the modern natural history of type 1 diabetes (23). For cardiovascular complications, we relied on type 2 diabetes cardiovascular models due to a lack of type 1 diabetes cardiovascular models (24). Despite this limitation, we found that the cardiovascular event rate predicted by our model for the DCCT population was very similar to CVD rates observed in the 20-year follow-up of DCCT/Epidemiology of Diabetes Interventions and Complications Study (25). Our model also does not account for the potential impact of long-term reductions in hypoglycemia that may be produced by CGM. And finally, as mentioned earlier, the patients in our cohorts had high baseline utilities, measured by the TTO method, which effectively placed a ceiling on the magnitude of potential quality-of-life benefit that could be brought about by CGM.

Despite these limitations, this study provides some of the first formal estimates of the cost-effectiveness of CGM technology. These estimates will require future revision as the prices and functionality of this technology evolves over time. The limitations of the current study highlight

important areas of future research for the economic evaluation of chronic disease self-management technologies. The value of such technologies depends in part on their ability to improve the immediate quality of life of patients. Commonly accepted approaches to quantifying quality-of-life effects are designed to measure changes in traditional symptoms, such as pain and daily functions such as walking. These approaches may not accurately reflect the subtle, but important, effects new devices have on addressing transient symptoms, reducing anxiety and providing greater convenience for disease management. This study also raises fundamental questions about the approach to assessing the economic value of a technology that may be highly valuable to patients willing to use the technology but not to others.

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L.L. has received consulting fees from Lifescan, consulting fees and a speaker honorarium from Abbott Diabetes Care, consulting fees and research funding from Medtronic MiniMed, and consulting and speaker fees from Roche. W.T. has received consulting fees from Abbott Diabetes Care and Lifescan and consulting fees, a speaker honorarium, and research funding from Medtronic MiniMed. S.M. has received research support, a speaker honorarium, and travel reimbursement from Medtronic MiniMed and a speaker honorarium from Animas Corp/Lifescan. No other potential conflicts of interest relevant to this article were reported.

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but did not play a role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation or approval of the manuscript. DexCom (San Diego, CA), Medtronic MiniMed (Northridge, CA), Abbott Diabetes Care (Alameda, CA), LifeScan, and Abbott Diabetes Care had no involvement in the design, conduct, or analysis of the trial or the preparation of this manuscript.

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