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Shinyi Wu, Rand Corporation
Francois Sainfort
Russell Tomar
James L. Tollios
Dennis G. Fryback, et al.

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SHIN-YI WU, MS
FRANCOIS SAINFORT, PHD
RUSSELL H. TOMAR, MD
JAMES L. TOLLAS, MA

DENNIS G. FRYBACK, PHD
RONALD KLEIN, MD, MPH
BARBARA E.K. KLEIN, MD, MPH

OBJECTIVE — To develop a simulation model to assess the impact of type 1 diabetes and its associated complications on health-related quality of life of a population.

RESEARCH DESIGN AND METHODS — The methodology builds upon 1) an existing population model of type 1 diabetes progression, 2) an empirical study designed to measure state- and age-specific health statuses of type 1 diabetes, and 3) existing literature to quantify quality of life of the corresponding health status. Health statuses were measured in a group of type 1 diabetic patients using the Medical Outcomes Study short form 36 (SF-36). A published empirical regression equation was then used to predict corresponding Quality of Well-Being Index (QWB) scores from these assessments. The QWB scores were incorporated into a previously developed type 1 diabetes progression and cost simulation model. Sensitivity analyses on key parameters were performed, and the model was found to be robust.

RESULTS — The augmented model can estimate quality-adjusted life years (QALYs) as well as costs associated with type 1 diabetes on any population of interest over any period of time. The model is used to compare intensive versus conventional treatment strategies using a simplified set of assumptions regarding the relative effects of these alternative treatments. With these assumptions, intensive strategy produces more QALYs than does conventional strategy and is cost-beneficial after 5 years.

CONCLUSIONS — The model enables health planners to perform cost-effectiveness analyses to compare alternative treatment strategies for type 1 diabetes and support subsequent decision making.

Diabetes and its associated complications are major health problems that consume approximately one of every seven health care dollars spend in the U.S. (1,2). Type 1 diabetes is a more dramatic form of the disease, often with an abrupt onset of symptoms requiring prompt medical care (3). Its associated complications include retinopathy, nephropathy, neuropathy, cardiovascular disease, amputation (4). Although only about 5–10% of the estimated 16 million people with diabetes are insulin-dependent (3,5), type 1 diabetes accounts for about 30% of the total costs attributable to diabetes (6).

Type 1 diabetes commonly presents before the age of 30 years, progressing to a series of fairly predictable complications and a shorter expected life span (3). We recently developed and validated a cohort Markov simulation model of type 1 diabetes that simulates the progression of the disease and associated costs for a population (7). The model was found to perform well at estimating costs over time associated with the disease and its complications. However, it did not include information on the impact of type 1 diabetes on health-related quality of life. In this article, we report the results of an empirical study designed to collect and integrate health-related quality-of-life information. Specifically, we administered a generic health status measure—the Medical Outcomes Study short form 36 (SF-36) health survey—on a convenient sample of type 1 diabetic patients. After comparing the results with existing surveys for similar populations, we used a newly derived empirical equation published by Fryback et al. (8) to predict age- and health status-specific Quality of Well-Being Index (QWB) scores from the SF-36 assessments. By incorporating this information into the simulation model of type 1 diabetes progression, we were able to calculate quality-adjusted life years (QALYs) in any study population of interest over any specified period of time. The end result is a simulation model that allows health planners to perform needed cost-effectiveness analyses to compare alternative treatment strategies for type 1 diabetes.

RESEARCH DESIGN AND METHODS

Disease progression model

A Markov cohort simulation model was previously developed using Microsoft Excel 7.0 (7). The model estimates the onset and progression of type 1 diabetes and its complications for a cohort population and computes the associated total direct health care costs of the study population over any prescribed time period. The model assigns an initial population cohort (defined by age-groups) into a set of distinct health states and then simulates the progression of type 1 diabetes by moving individuals among the different health states over time by applying probabilities associated with health-state transitions. At each iteration, the model also estimates the direct health care costs associated with the treatment of individuals with type 1 diabetes. At the
end of the simulation, the total number of people and the corresponding total annual costs for each cycle are summarized across health states and age-groups, and the cumulative discounted costs for the study are calculated. Given the limitations on data available to estimate prevalence, incidence, mortality, health-state transition probabilities, and costs, it was necessary to define groups of health states rather than each possible health state with or without type 1 diabetes. The model currently uses the following six health states, listed in increasing order of severity:

1. Individuals without type 1 diabetes (non-type 1).
2. Type 1 diabetes without chronic microvascular complications (no complication).
3. Type 1 diabetes with diabetic retinopathy only (retinopathy).
4. Type 1 diabetes with diabetic nephropathy alone or neuropathy and retinopathy (nephropathy-plus).
5. Type 1 diabetes with diabetic nephropathy alone, nephropathy and retinopathy, and all three complications (nephropathy-plus).
6. Deceased (expired).

Retinopathy is defined as any sign of retinopathy on examination; neuropathy as loss of sensation in the hands or feet; and nephropathy as urinary protein \( \geq 300 \text{ mg/dl} \). More information on these health states can be found in our previous work (7).

Although the model currently keeps track of yearly and total costs associated with each of the health states for the entire population, it currently does not allow the user to perform cost-effectiveness analysis because it does not incorporate a measure of overall population quality of life. Although health-related quality of life (HRQOL) is a difficult concept and its measurement is controversial (9), one approach consists of measuring utilities associated with health states, leading to the calculation of quality-adjusted life years (QALYs)—a numbering system that represents the relative value or desirability of different health states to patients (10–12). A QALY is calculated by weighting the number of years living in a certain clinical condition by the utility score (between 0 and 1) associated with that condition (13). That is, if a type 1 diabetic patient is expected to live in three health states and then die, let \( a, b, \) and \( c \) represent numbers of years living in each health state, and let \( x, y, \) and \( z \) represent the utilities of living in each corresponding health state. Thus, the patient lives for \( a \) years with \( x \) utility in health state 1, \( b \) years with \( y \) utility in health state 2, and \( c \) years with \( z \) utility in health state 3, and then dies. Then, the total QALYs for this patient over \( a + b + c \) years are given by:

\[
\text{QALYs} = a \times x + b \times y + c \times z.
\]

Thus, QALYs can be calculated for one person over a period of time and can also be aggregated across individuals for a population. The current simulation model keeps track of the number of years spent in each health state by each individual in the population of interest. Estimates of the HRQOL corresponding to each health state defined in the model are needed for the model to perform the necessary calculations.

**HRQOL measures**

The QWB is the most widely applied preference-based measure for overall health that may be used for QALY computation (14). QWB scores range on a continuum of health from 0 (death) to 1 (asymptomatic optimum function). However, state-specific QWB scores of type 1 diabetes are not available in the literature, and obtaining new QWB scores for a given state requires extensive resources for data collection (such as personal interview) and a significant amount of time to administer (15). Fortunately, as part of the Beaver Dam Health Outcomes Study (BDHOS), Fryback et al. (8) have derived an empirical equation that allows analysts to translate data from a simple generic health status assessment instrument, the SF-36, into predicted QWB scores. The SF-36 instrument consists of 36 questions that together produce measures of eight health domains profiling HRQOL experienced by a person (16):

1. Physical function (PF);
2. Role function as limited by physical problems (RP);
3. Bodily pain (BP);
4. General health perceptions (GH);
5. Vitality (VT);
6. Social function (SF);
7. Role function as limited by emotional problems (RE); and
8. Mental health (MH).

Using scores on these domains, predicted QWB scores from Fryback et al.'s regression equation are then calculated as follows:

\[
\text{QWB} = 0.59196 + 0.0012588 \times PF - 0.0011709 \times \text{XMH} - 0.0014256 \times \text{BP} + 0.00000705 \times \text{GH} \times \text{BP} + 0.0000140 \times \text{PF} \times \text{BP} + 0.000001931 \times \text{MH} \times \text{BP}.
\]

Although this equation only accounts for 57% of the variation according to Fryback et al. (8), most of the residual variance unaccounted for by the equation is due to limitations of measurement error in the two instruments, SF-36 and QWB, and not a lack in the underlying predictable relationship of the QWB and SF-36 variables. In other words, this equation should be justifiable for our purpose of predicting QWB scores from SF-36 data.

Thus, in this study, instead of collecting QWB data directly from patients with various states of type 1 diabetes, we collected SF-36 data on such patients and then applied the regression equation to derive the necessary QWB scores.

**SF-36 assessment**

We conducted a health status assessment on a sample of 143 type 1 diabetic patients who had been continually cared for by a local health maintenance organization (HMO) (University Health Care, Madison, WI) for at least 2 years. A standard SF-36 health survey was mailed to the 143 patients in July 1996. A follow-up survey was mailed to nonrespondents 6 weeks later. The patients’ age, sex, and disease status were directly obtained from the local HMO medical records. This allowed us to categorize the patients into several groups according to their current health states (i.e., no complication, retinopathy, neuropathy-plus, and nephropathy-plus) and their age to estimate the HRQOL for each possible age-specific health state. After the first mailing, 79 responses were received, and another 20 from the second mailing were received, for a total of 99 responses. Of these, 10 were excluded from the analysis because of 4 misdiagnoses, 1 too young to participate, 2 incomplete surveys, 2 deaths, and 1 wrong address. Among the 89 respondents, 58% were female, with an age range of 14–87 years and an average of 52.9 years. There were no significant differences in demographics between respondents and nonrespondents.

We divided the type 1 diabetic patients into several groups according to their age and health state to obtain age-group– and health-state–specific utility for the QALY calculation. While the simulation model defines four type 1 diabetes health states and
defines age in 5-year intervals, the sample size in this study was too small to reliably estimate HRQOL for each possible combination of health state and age-group. For example, among the 89 valid respondents, only 12 were in the health state of neuropathy-plus and only 8 were neuropathy-plus. Thus, we combined these 20 patients into one category labeled "other" to estimate the HRQOL corresponding to the two health states combined (i.e., neuropathy-plus and neuropathy-plus). We grouped the SF-36 data into three age-groups and three type 1 diabetic states. Table 1 shows the sample distribution in terms of age and health states.

### RESULTS

The summary statistics for the eight SF-36 dimensions are shown in Table 2. Averaged patient scores on the eight SF-36 dimensions ranged from 51 (vitality) to 75 (social functioning) on a 0 to 100 scale, where 100 is the best possible rating. The two role-functioning dimensions, limited by physical problems and limited by emotional problems, have the highest standard deviations (39.70 and 41.19); mental health has the lowest standard deviation (17.44). As shown in Table 2, seven dimensions the Cronbach's α statistics display high internal consistency, with a Cronbach's α ranging from 0.83 to 0.94. Only one dimension—social functioning—shows a lower but acceptable internal consistency of 0.66.

These results compare well with other existing studies of SF-36 scores reported for diabetic patients (18–20). Nerenz et al. (18) surveyed 268 type 1 diabetic patients and 204 type 2 diabetic patients; Johnson et al. (19) conducted the assessment on 54 diabetic Pima Indians, including both type 1 and type 2 patients; and Weinberger et al. (20) studied 275 type 2 diabetic patients. Overall, the mean scores we found for all eight domains were similar to the mean scores found in these three studies. The standard deviations of the eight health domains in our study were also found to be similar to Johnson et al. (19) and Weinberger et al. (20). This comparison shows the robustness and validity of the SF-36 in measuring the HRQOL of diabetic patients.

Applying Fryback et al.'s equation, we obtained the predicted QWB score for each of the 89 type 1 diabetic patients who participated in the SF-36 health survey. The predicted QWB scores ranged from 0.50 to 0.84. The scores were then clustered into the three age-groups and the three health states corresponding to the nine subgroups described above. Because patients' age was significantly correlated with the predicted QWB scores (at α = 0.01 level, using Pearson's correlation test), the three age-groups were also found to be significantly correlated with the predicted QWB scores, at α = 0.01 level.

The average QWB scores as well as standard deviations for the nine subgroups are listed in Table 3. These are the final age- and health-state-specific utility estimates for type 1 diabetic patients used in the simulation model for performing QALY calculation. The QWB scores of subjects without type 1 diabetes are also provided in the table. These scores are for the general population as reported by Kaplan et al. (21) for the group <45 years of age, and from Fryback et al. (15) for the other two age-groups. About 0.6% of the general population has type 1 diabetes (3). We used these scores from the general population to represent the health utilities of individuals without type 1 diabetes.

This study is the first to present the QWB scores of type 1 diabetic patients according to their age-group and health state. As shown in Table 3, patients' ages were inversely correlated to their predicted QWB scores. Patients in the health state "other" had more severe complications. As expected, the average predicted QWB scores for these patients were lower than patients in the same age-groups but having less severe health states (general population, type 1 without complications, and type 1 with complications). General-population individuals had the highest QWB scores, which reflects a better health-related quality of life overall. It should be noted that this study found an inverted U-shaped distribution of QWB scores as a function of severity of health states, with patients with no complication having a lower QWB score than patients with complications. Although this might appear surprising at first, it is consistent with Nerenz et al.'s (18) results. They reported the same observation and suggested that further study was needed to explore the underlying reasons, if such observation could be replicated. Thus, we conclude that the estimated QWB scores obtained from this study are reliable and valid and can be included and used in the simulation model. The following section illustrates additional data that augments the capabilities of the simulation model.

### Application of the simulation model

The Markov cohort simulation model was applied to the 1992 Wisconsin population over a period of 10 years. At the start of the simulation (year 0), the 1992 Wisconsin population consists of 4,993,997 individu-

### Table 1—Sample health state and age distribution

<table>
<thead>
<tr>
<th></th>
<th>Age &lt;45 years</th>
<th>Age 45-64 years</th>
<th>Age ≥65 years</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No complication</td>
<td>6 (6.7)</td>
<td>10 (11.2)</td>
<td>8 (9.0)</td>
<td>24 (27.0)</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>17 (19.1)</td>
<td>19 (21.3)</td>
<td>9 (10.1)</td>
<td>45 (50.1)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (5.6)</td>
<td>8 (9.0)</td>
<td>7 (7.9)</td>
<td>20 (22.5)</td>
</tr>
<tr>
<td>Total</td>
<td>28 (31.3)</td>
<td>37 (41.6)</td>
<td>24 (27.0)</td>
<td>89 (100)</td>
</tr>
</tbody>
</table>

Data are n (%). No complication, type 1 diabetic individuals without complications; retinopathy, type 1 diabetic individuals with diabetic retinopathy only; other, type 1 diabetic individuals with diabetic neuropathy or nephropathy alone or with any other complication.

### Table 2—SF-36 descriptive statistics and reliability coefficients

<table>
<thead>
<tr>
<th>Scale</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean ± SD</th>
<th>Cronbach's α</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical function</td>
<td>0</td>
<td>100</td>
<td>71.35 ± 30.44</td>
<td>0.94</td>
</tr>
<tr>
<td>Role function (physical)</td>
<td>0</td>
<td>100</td>
<td>64.04 ± 39.70</td>
<td>0.86</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>0</td>
<td>100</td>
<td>65.85 ± 24.69</td>
<td>0.88</td>
</tr>
<tr>
<td>General health</td>
<td>0</td>
<td>100</td>
<td>52.34 ± 25.09</td>
<td>0.88</td>
</tr>
<tr>
<td>Vitality</td>
<td>0</td>
<td>100</td>
<td>50.73 ± 22.97</td>
<td>0.91</td>
</tr>
<tr>
<td>Social function</td>
<td>12.5</td>
<td>100</td>
<td>74.86 ± 27.41</td>
<td>0.66</td>
</tr>
<tr>
<td>Role function (emotional)</td>
<td>0</td>
<td>100</td>
<td>73.41 ± 41.19</td>
<td>0.92</td>
</tr>
<tr>
<td>Mental health</td>
<td>8</td>
<td>100</td>
<td>73.28 ± 7.44</td>
<td>0.83</td>
</tr>
</tbody>
</table>
Impact of diabetes on quality of life

Table 3—Age- and health-specific QWB scores

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>General population</th>
<th>No complication</th>
<th>Retinopathy</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;45</td>
<td>0.82</td>
<td>0.73 ± 0.07</td>
<td>0.76 ± 0.05</td>
<td>0.70 ± 0.08</td>
</tr>
<tr>
<td>45–64</td>
<td>0.75</td>
<td>0.68 ± 0.09</td>
<td>0.72 ± 0.09</td>
<td>0.66 ± 0.07</td>
</tr>
<tr>
<td>≥65</td>
<td>0.70</td>
<td>0.64 ± 0.08</td>
<td>0.62 ± 0.07</td>
<td>0.55 ± 0.05</td>
</tr>
</tbody>
</table>

Data are means ± SD. General population QWB scores are estimated from Kaplan et al. (21) for <45 years of age and from Fryback et al. (15) for other age-groups. No complication, type 1 diabetic individuals without complications; retinopathy, type 1 diabetic individuals with diabetic retinopathy only; other, type 1 diabetic individuals with diabetic neuropathy or nephropathy alone or with any other complication.

als. The model initially estimates that of those, 10,219 have type 1 diabetes without complication; 11,579 have type 1 diabetes with retinopathy alone; 4,060 have type 1 diabetes with neuropathy alone or neuropathy and retinopathy; and 2,940 have nephropathy alone or with any other complication. All other individuals (4,965,199) are free of type 1 diabetes. Each subsequent year, the model keeps some individuals in the same health states and moves others to more severe states (including death). By applying the age-specific QWB scores estimated above to the corresponding states, we can estimate the total number of QALYs accumulated every year (and over time) by the entire population. For example, Fig. 1 shows what happens in terms of quality of life to the 10,219 type 1 diabetic individuals without complication at the beginning of the simulation. In the 1st year, these individuals are all in the same state and combined for a total of 6,841 QALYs (at year 0 in Fig. 1) compared with 10,219 unadjusted life years.

In the following year (year 1), 747 die, 1,366 move to the retinopathy health state, 270 move to the neuropathy state, 112 move to the nephropathy state, and 7,724 remain in the no-complication state. Accounting for the different age-specific QWB scores, these individuals in year 1 combine for 6,359 QALYs compared to 9,472 unadjusted life years. Figure 1 shows the total QALYs for each year as well as the QALYs from different states. After 10 years, almost all type 1 diabetic individuals starting without complication have developed complications or died. Only 747 individuals are alive and have not developed any complication after 10 years.

The QWB scores used to calculate the QALYs were predicted from the SF-36 data collected on a relatively small sample. Therefore, we performed sensitivity analyses to determine the effects of changes in these baseline QWB estimates. Total QALYs for the Wisconsin population over 10 years were relatively insensitive to changes in QWB scores of each type 1 diabetic health state from 70 to 120% of its baseline estimate. One-way sensitivity analyses (varying each estimate one at a time) showed that the predicted QWB scores of retinopathy had the greatest impact on QALYs overall and that nephropathy-plus had the least impact. Thus, estimates obtained in this study are considered fairly robust and can be used to study cost-effectiveness of alternative treatment strategies.

As an example, we applied the model to study the cost-effectiveness of intensive treatment strategy for type 1 diabetes compared with conventional treatment strategy. The Diabetes Control and Complications Trial (DCCT) research group has reported the results of the DCCT regarding type 1 diabetes treatment (22,23). By sustained lowering of blood sugar, the intensive therapy reduced the risk of development of retinopathy by 76% for those patients without complications and slowed the progression of retinopathy by 54% for those patients who already had this complication. This treatment regimen also reduced the risk of nerve disease (neuropathy) by 60% and kidney disease (nephropathy) by 50% for both cohorts of patients who either had no complications or retinopathy only (24).

Health-state transition probabilities were altered to reflect the impact of intensive treatment in the simulation model. Table 4 shows both costs and transition probabilities of the two treatment strategies. For simplicity, we assumed that intensive treatment can be provided to all patients and that all respond to it in the same manner. In this application, the annual costs of the intensive therapy are assumed to be $1,500 more per capita than the conventional therapy according to estimates from a local HMO, University Health Care, Inc. Although estimating the true difference in costs from charges from an HMO is limited, it is nevertheless relevant if the cost-effectiveness study is carried out from the perspective of such an HMO. In terms of HRQOL, for the same health states, both Parkerson et al. (24) and the DCCT Research Group (25) found no difference between intensive and conventional treatment. Therefore, the QWB scores estimates

![Figure 1—Year-by-year QALYs over time by health state for 10,219 type 1 diabetic patients starting at year 0 without complications.](image)
Table 4—Costs and transition probabilities associated with conventional and intensive treatments

<table>
<thead>
<tr>
<th>Costs (dollars)</th>
<th>No complications</th>
<th>Retinopathy</th>
<th>Neuropathy-plus</th>
<th>Nephropathy-plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>8,251</td>
<td>7,178</td>
<td>20,372</td>
<td>30,064</td>
</tr>
<tr>
<td>Intensive</td>
<td>9,751</td>
<td>8,678</td>
<td>21,872</td>
<td>31,564</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transition probabilities (per year)</th>
<th>No complications</th>
<th>Retinopathy</th>
<th>Neuropathy-plus</th>
<th>Nephropathy-plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No complications</td>
<td>0.8155</td>
<td>0.1442</td>
<td>0.0285</td>
<td>0.0118</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>0.0000</td>
<td>0.9105</td>
<td>0.0469</td>
<td>0.0426</td>
</tr>
<tr>
<td>Neuropathy-plus</td>
<td>0.0000</td>
<td>0.0000</td>
<td>0.9030</td>
<td>0.0970</td>
</tr>
<tr>
<td>Nephropathy-plus</td>
<td>0.0000</td>
<td>0.0000</td>
<td>0.0000</td>
<td>1.0000</td>
</tr>
<tr>
<td>Intensive treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No complications</td>
<td>0.9438</td>
<td>0.0362</td>
<td>0.0127</td>
<td>0.0073</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>0.0000</td>
<td>0.9534</td>
<td>0.0249</td>
<td>0.0217</td>
</tr>
<tr>
<td>Neuropathy-plus</td>
<td>0.0000</td>
<td>0.0000</td>
<td>0.9030</td>
<td>0.0970</td>
</tr>
<tr>
<td>Nephropathy-plus</td>
<td>0.0000</td>
<td>0.0000</td>
<td>0.0000</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

No complications, type 1 diabetic individuals without complications; retinopathy, type 1 diabetic individuals with diabetic retinopathy only; neuropathy-plus, type 1 diabetic individuals with diabetic neuropathy alone or neuropathy and retinopathy; nephropathy-plus, type 1 diabetic individuals with diabetic nephropathy alone or with any other complication.

for the different health states are independent of the therapies.

Using these additional data, we ran a 10-year simulation with a study cohort consisting of the Wisconsin 1992 population. The simulation results are shown in Figs. 2 and 3. Figure 2 shows yearly total QALYs for the individuals with type 1 diabetes under both treatment strategies. As shown in Fig. 2, intensive therapy leads to more QALYs than does the conventional therapy because of its delayed onset of complications. However, intensive strategy is more expensive. Figure 3 shows the total yearly costs associated with type 1 diabetes under both strategies. As shown in Fig. 3, intensive therapy is more expensive in treating type 1 diabetic patients than is conventional therapy in the first 5 years, but it becomes less expensive in the 6th year because of the delayed complication development. In Figs. 2 and 3, both costs and QALYs are discounted at a 3% discount rate.

This example illustrates that the Markov model can simulate progression, costs, and impact on quality of life of type 1 diabetes and can help decision-makers perform cost-effectiveness analyses to compare the alternative treatment regimens.

**CONCLUSIONS** — In this study, we proposed an approach to compute QALYs of type 1 diabetes for a cohort population from the SF-36 data to augment a Markov simulation model that we developed earlier (7). An HRQOL assessment was conducted on a group of 143 patients with type 1 diabetes using the SF-36 to obtain type 1 diabetic patients' health profiles. We applied the empirical equation explored by Fryback et al. (8) to derive predicted QWB scores for health states describing the various complications of type 1 diabetes. An illustration was given in the context of comparing two alternative treatment strategies for type 1 diabetic patients. Although the model performs well and is deemed useful, several methodological issues should be discussed.

![Figure 2—Annual QALYs of patients with type 1 diabetes among the study cohort of Wisconsin population in 1992.](image-url)
Impact of diabetes on quality of life

![Graph showing annual costs at 3% discount rate](image)

**Figure 3**—Annual costs of patients with type 1 diabetes among the study cohort of Wisconsin population in 1992.

One methodological issue involved in assessment of HRQOL is whether generic or disease-specific instruments have greater relative merit (24). Jacobson et al. (26) examined the effects of type 1 and type 2 diabetes on patient perceptions of their quality of life and compared the psychometric properties of a generic (SF-36) versus a diabetes-specific quality of life measure (Diabetes Quality of Life Measure [DQOL]). They concluded that the two measures examine quality of life from different but complementary perspectives. The DQOL seems more sensitive to lifestyle issues and contains special questions oriented toward younger patients, whereas the SF-36 provides more information about functional health status. Another study was conducted by Parkerson et al. (24) on 170 adult type 1 diabetic patients to compare the DQOL and two generic instruments, the Duke Health Profile and the General Health Perceptions Questionnaire. They found that the generic measures provided as much or more information about HRQOL as the disease-specific instrument. Thus, using a generic measure to capture HRQOL in this context seems appropriate. Although specificity may be lost, it offers greater potential for comparing results across diseases and conditions.

Although SF-36 data collected in this study was reliable and valid, applying Fryback et al.'s (8) regression equation to derive predicted QWB might be a concern because the equation was based on general population data and not disease-specific population data. In particular, since type 1 diabetic patients report generally lower values on the SF-36 dimensions, if the relationship between SF-36 scores and QWB scores is dependent on overall health status, the equation used in this model may not be appropriate. However, when averaged, the QWB scores in this study show similar results to those of the Beaver Dam Health Outcomes Study (15). The Beaver Dam study surveyed the HRQOL in a cohort of community population of ≥45 years of age. Thirty-eight people with type 1 diabetes and complications were interviewed to measure their QWB scores. These individuals' QWB scores ranged from 0.484 to 0.856, with an average of 0.646. Their ages ranged from 48 to 82 years, with an average of 68.4 years. Our study derived QWB scores with an average of 0.663, ranging from 0.5 to 0.82 for patients ≥45 years of age, with an average of 60.6 years. Because age was found to be significantly confused with predicted QWB scores, it is justifiable to see a slightly higher average QWB score for a younger population in this study than in the Beaver Dam Study, which had an older population overall. The standard deviation for QWB scores in the Beaver Dam Study was 0.111, as opposed to 0.092 in the current study. Thus, these results show that the regression equation performed well in comparison with the actual QWB scores for type 1 diabetes patients.

Regarding the simulation undertaken to study the cost-effectiveness of intensive versus conventional therapies, it should be reemphasized that the results obtained are based on a simplified set of assumptions regarding the relative impact of intensive therapy on disease progression. In particular, following the DCCT research group, we made the assumption that the utilities of the same health states will be independent of the therapies. We ran sensitivity analyses and found that the intensive therapies lead to additional QALYs unless utilities of health states for intensively treated patients were 5% lower than corresponding utilities of health states for conventionally treated patients. We feel that a decrease of 5% is very unlikely, because it would imply that individuals with no complications but intensive treatment experience the same quality of life as individuals with neuropathy or nephropathy with conventional treatment. In addition, we assume 1) a simple increase in cost of $1,500 resulting from intensive therapy and 2) intensive treatment applied to all diabetic patients age 10–59 years. In spite of these simplified assumptions, most of the results obtained are consistent with results reported by the DCCT research group (25). Regarding the relative impact of intensive versus conventional therapy on progression of disease, our simulation model leads to results very similar to the DCCT study: delay of complications, especially in intermediate stages of the disease; increase in survival; and gain in quality of life. This was expected because we based our changes in transition probabilities for intensive therapy on DCCT data. However, in terms of the economic analysis, results are different. Whereas the DCCT group reports a cost per QALY gained of $19,987 (27), our results show a cumulative cost saving after 6–7 years. This is because 1) we used a different population; 2) although differences between overall annual costs of intensive versus conventional strategies are similar, different cost structures for complications are used; and 3) we used a 10-year time frame as opposed to a lifetime study period. Thus, although additional studies are necessary to better estimate the cost-effectiveness of intensive therapy, this particular study reinforces the findings of the DCCT research.
group, i.e., that "health policy should foster the use of intensive therapy for persons with diabetes mellitus" (27, p. 694).

In conclusion, we believe that the model presented in this study can reliably estimate QALYs as well as costs associated with type 1 diabetes on any population of interest over any period of time. Hence, it provides health planners with a useful tool to perform cost-effectiveness analyses to compare alternative treatment strategies for type 1 diabetes and support subsequent decision making.

References