Resource Utilization and Costs of Care in the Diabetes Control and Complications Trial

THE DIABETES CONTROL AND COMPLICATIONS TRIAL RESEARCH GROUP

OBJECTIVE — To describe in detail the resources used and costs incurred in the clinical management of patients with insulin-dependent diabetes mellitus (IDDM) in the Diabetes Control and Complications Trial (DCCT).

RESEARCH DESIGN AND METHODS — The resources used for intensive and conventional therapy and to deal with the side effects of therapy were assessed at each of the 29 DCCT clinics and summarized. Unit costs were derived from the DCCT, manufacturers, and Medicare and chosen to reflect what an item would cost to a single-payer national health system. Costs were calculated as the product of resources used and unit costs. The costs of the research component of the DCCT were not included.

RESULTS — In the DCCT, the annual cost of intensive therapy ($4,000 and $5,800/year for multiple daily injections and continuous subcutaneous insulin infusion, respectively) was approximately three times the cost of conventional therapy ($1,700/year). A large portion of the difference in cost was related to the greater frequency of outpatient visits and the greater resources used in self-care.

CONCLUSIONS — DCCT intensive therapy is more expensive than conventional therapy, but it offers the hope of cost savings as a result of averted complications.

The Diabetes Control and Complications Trial (DCCT) demonstrated that intensive therapy delays the onset and slows the progression of microvascular and neurological complications in patients with insulin-dependent diabetes mellitus (IDDM) (1). The DCCT Research Group recommended that most patients with IDDM be treated with closely monitored intensive regimens with the goal of maintaining their glycemic status as close to the normal range as safely possible (1).

To assess the economic impact of implementing DCCT recommendations, an accurate assessment of the costs of intensive therapy relative to conventional care is necessary. The purpose of the current study is to describe in detail the resources used and associated costs of diabetes care in the DCCT. We describe the resources used for the following: initiation of intensive therapy, ongoing intensive therapy with multiple daily injections (MDIs) and with continuous subcutaneous insulin infusion (CSII), and crossover between MDIs and CSII; conventional therapy; and the treatment of weight gain and hypoglycemia. We summarize the unit costs of resources from the perspective of a national health system and calculate the costs of therapy as the product of the resources used and unit costs. We then summarize the costs of therapy, provide an estimate of the variability of resource utilization and cost among clinics, and describe the costs of the major side effects of therapy. Finally, we summarize the total costs of therapy. We do not consider the costs for the research component of the DCCT.

This report provides diabetes care providers, payers, and policy makers with a detailed description of the resources used in the DCCT and the costs of therapy from the perspective of a national health system. The cost of intensive therapy is an important barrier to widespread implementation of the results of the DCCT. The description of resources used provides a point of reference for those who would attempt to translate, modify, and improve the efficiency of intensive therapy (2). The description of costs contained in this report also provides the basis for further economic studies of the cost-effectiveness of intensive therapy in IDDM (DCCT, unpublished observations).

RESEARCH DESIGN AND METHODS

— The objective of this economic analysis was to describe the re-

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CPT, Current Procedural Terminology; CSII, continuous subcutaneous insulin infusion; DCCT, Diabetes Control and Complications Trial; HCFA, Health Care Financing Administration; IDDM, insulin-dependent diabetes mellitus; MDIs, multiple daily injections; SMBG, self-monitoring of blood glucose.

sources used for the clinical management of patients in the DCCT. The resources used and costs associated with the research component of the DCCT, including resources necessary for data collection and for surveillance of complications beyond those recommended for routine clinical practice, were excluded from this economic analysis (2,4). The latter included, for example, the resources used and costs associated with neurobehavioral, psychological, and quality-of-life testing, fundus stereophotography and fluorescein angiography, ^{125}I iothalamate clearance testing, autonomic nervous system testing, and detailed diet history.

For the purpose of this economic analysis, intensive therapy was conceptualized as having five stages: *1*) inpatient initiation of therapy, 2) frequent outpatient supervision immediately after initiation of therapy, 3) changes between MDIs and CSII (and vice versa), 4) ongoing intensive therapy, and 5) treatment of side effects of intensive therapy. Because IDDM had been diagnosed in all patients for at least 1 year and were under treatment, conventional therapy was conceptualized as having only two stages: *1*) ongoing conventional therapy and 2) treatment of the side effects of conventional therapy.

Resources were grouped into four broad categories: inpatient services, outpatient services, case-management services (including telephone calls, letters, team meetings, adherence activities, and other interdisciplinary time used in patient management), and self-care resources (including pumps, syringes, monitoring equipment and supplies, insulin, glucagon, and glucose tablets). Resources measured included labor, fringe benefits, equipment, supplies, medications, tests, procedures, consultations, ambulance services, emergency room services, hospital services, and overhead.

Data collection and analysis

Much of the data necessary to assess resource utilization was routinely collected as part of the DCCT. A subcommittee of the Research Group drafted a questionnaire to gather the data that were not available from existing sources. The goal of this questionnaire was to measure in detail the time and resources required to provide intensive and conventional therapy in the DCCT. Descriptions of intensive and conventional therapy in the *DCCT Manual of Operations* (5) were used to develop the Clinic Cost Questionnaire. The questionnaire was developed, modified, and field-tested, and nurse-educators from each clinic were trained in its use. Between March and May 1992, the questionnaire was completed by each treatment team member at each of the 29 clinics. Team members estimated the time required for various activities and, when necessary, counted and timed their activities and referred to clinic records to improve the precision of their estimates. At each clinic, the results of the individual questionnaires were reviewed and discussed at a treatment team meeting, and differences were reconciled. A single, fully completed questionnaire representing the consensus of the treatment team was then submitted by each clinic to the coordinating center. The clinic response rate was 100%.

Because data were not distributed normally, results were expressed as medians. Participation rates were calculated because not all groups of providers and patients engaged in all activities at all clinics. Clinic Cost Questionnaire data were weighted according to the number of intensive or conventional therapy patients followed at each clinic so that results could be expressed per DCCT patient. Numbers of visits and calls were rounded to the nearest whole number, and the duration of visits and calls was rounded to the nearest 5 min.

Determination of costs

Unit costs were chosen to reflect what an item would cost in a single-payer national health system. Unit costs for labor and fringe benefits were derived from the DCCT (C. Siebert, personal communication). Unit costs for equipment and supplies were derived from manufacturers' average wholesale prices (P. Rule, personal communication) (6). Costs of equipment were amortized over the expected lifetime of the equipment (3 years for glucose meters, 6 years for insulin pens, and 6 years for insulin pumps). Unit costs for tests, procedures, and consultations were derived from the Health Care Financing Administration (HCFA) and are indexed by Physician's Current Procedural Terminology (CPT) code (D. Wood, personal communication) (7). Costs of ambulance services are indexed by HCFA Common Procedural Coding System code (D. Wood, personal communication) (7). Costs of emergency room and hospital services include the cost of physicians' services and emergency room or hospital services. The costs of physicians' services and emergency room services were derived from Medicare and are indexed by CPT codes (8). The cost of hospital services are based on Medicare Diagnosis Related Groups (9). All costs are expressed in 1994 dollars.

Costs were calculated as the product of the resources used and the unit cost of those resources. Costs associated with time away from normal activities (e.g., time lost from school or work) were not reported.

RESULTS

Resources used for intensive therapy

The *DCCT Manual of Operations* provided the principles of intensive therapy (5). Therapy was implemented by 29 teams of diabetologists, nurses, dietitians, and behavioral scientists at the clinical centers. The specific methods of therapy and the choice of regimens differed among clinics and were not driven by considerations of efficiency or cost. By protocol, all patients randomly assigned to intensive therapy were hospitalized to initiate therapy and chose either MDIs or CSII. Patients were allowed to change from MDIs to CSII, or vice versa, according to personal preference or if intensive treatment goals were not being met. On average, 8% of patients

changed from MDIs to CSII and 8% changed from CSII to MDIs each year. Insulin dosage was adjusted frequently according to changes in diet and activity and the results of self-monitoring of blood glucose (SMBG). Patients in the intensive therapy group visited the clinic each month and were in frequent telephone contact with their treatment team.

Inpatient services. At the time of randomization, 69% of intensive therapy patients elected treatment with MDIs and 31% elected treatment with CSII. Intensive therapy patients were occasionally rehospitalized to adjust therapy. During the final 2 years of the study, 8% of intensive therapy patients were rehospitalized. This included 14% of patients changing from MDIs to CSII who were rehospitalized to teach the elements of CSII. Intensive therapy patients changing from CSII to MDIs were not usually rehospitalized.

Outpatient services. For 4 weeks after initiation of MDI therapy and for 5 weeks after initiation of CSII therapy, patients made more frequent clinic visits (on average, once every 2 weeks) to adjust the intensive regimens and continue the learning process. At each visit, MDI and CSII patients spent 35 and 45 min with the nurse, 25 and 30 min with the dietitian, and 15 and 20 min with the physician, respectively. In addition, during 30% of these visits, patients spent an average of 10 min with the behavioral scientist.

Outpatient follow-up involved 12 visits per year including 1 annual, 1 semiannual, 2 quarterly, and 8 monthly visits. At routine monthly visits (8/year), we emphasized adjustment of the intensive regimens and glycemic control. History and patient-recorded monitoring results were reviewed; adjustments in insulin, diet, and exercise prescriptions were made; new goals were set; and a blood sample was drawn for measurement of HbA_{1c}. At monthly visits the patient typically saw the nurse for 50 min and the physician for 10 min, and at 50% of the visits the patient saw the behavioral scientist for 15 min. At quarterly visits (2/year) and semiannual visits (1/year), a more extensive

Table 1—*Unit costs and sources of estimates for labor, fringe benefits, equipment, supplies, medications, tests, procedures, consultations, treatments, ambulance services, emergency room services, hospital services, and overhead*

Category/item	Code	Cost ($)	Source
Labor			
Diabetologist		99,611/year	DCCT, 1994
Behavioral scientist		50,856/year	DCCT, 1994
Nurse educator		44,720/year	DCCT, 1994
Dietitian		32,885/year	DCCT, 1994
Secretary		21,133/year	DCCT, 1994
Fringe benefits		24%	DCCT, 1994
Equipment			
Glucose meters (3-year life)		137.50	Red Book, 1993
Insulin pen (6-year life)		79.80	Red Book 1993
Insulin pump (6-year life)		3,955	MiniMed, 1994
Supplies			
Syringe		0.21	Red Book, 1993
Pen needle		0.10	Red Book, 1993
Pump syringe		2.20	MiniMed, 1994
Pump infusion set		3.73	MiniMed, 1994
Site cover		0.68	MiniMed, 1994
Pump battery		2.88	MiniMed, 1994
Shower pack		0.60	MiniMed, 1994
Alcohol pad		0.02	Red Book, 1993
Lancet		0.06	Red Book, 1993
Glucose test strip		0.68	Red Book, 1993
Meter battery		4.50	Lifescan, 1992
Meter control solution		7.38	Red Book, 1993
Urine dipstick		0.13	Red Book, 1993
6 glucose tablets		1.15	Red Book, 1993
Tube of glucose gel		2.80	Red Book, 1993
Medications			
Insulin, 1,000-U vial		16.34	Red Book, 1993
Insulin, 5 penfills (750 U)		16.32	Red Book, 1993
Glucagon kit		24.51	Red Book, 1993
Tests			
HbA_{1c}	83036	14.22	Medicare, 1992
Plasma glucose	82947	5.92	Medicare, 1992
Serum creatinine	80002	7.11	Medicare, 1992
(1–2) clinical chemistry tests	80002	7.11	Medicare, 1992
Lipid profile	80061	32.46	Medicare, 1992
Urinalysis	81000	4.77	Medicare, 1992
Urine albumin	82042	4.88	Medicare, 1992
Procedures			
Venipuncture	36415	3	Medicare, 1992
Electrocardiogram	93000	26	Medicare, 1992
Consultations			
Ophthalmologist	92012	42	Medicare, 1994
Ambulance services			
Basic life support	A0010	122	Medicare, 1992
Advanced life support	A0220	223	Medicare, 1992
Emergency room services			
Physician services: detailed history and examination	99285	131	Medicare, 1994

Continued on following page

Table 1—*Continued.*

Category/item	Code	Cost ($)	Source
Emergency room charge	99220	121	Medicare, 1994
Hospital services			
Physician services			
Initial critical care services	99291	172	Medicare, 1994
Subsequent critical care	99233	63	Medicare, 1994
Initial hospital care	99254	119	Medicare, 1994
Subsequent hospital care	99262	41	Medicare, 1994
Initial hospital care	99221	60	Medicare, 1994
Subsequent hospital care	99231	31	Medicare, 1994
Discharge day management	99238	54	Medicare, 1994
Hospital services			
Initial critical care services	DRG 295	2,344	Medicare, 1994
Hypoglycemia	DRG 297	1,626	Medicare, 1994
Overhead		41%	Latimer, 1992

history and physical examination were performed. At quarterly and semiannual visits, the patient typically saw the nurse for 45 min, the physician for 25 min, the dietitian for 40 min, and the behavioral scientist for 20 min. At annual visits we performed history and physical examinations; performed surveillance for complications; and reviewed monitoring results, education, and goals. The patient typically saw the nurse for 70 min, the physician for 30 min, the dietitian for 40 min, and the behavioral scientist for 30 min. Urinalysis, quantitative urine albumin, serum creatinine, HbA_{1c}, lipid profile, and retinal examination were performed at the annual visit, and electrocardiograms were performed every 2 years.

During the 1st year of intensive therapy, patients typically had four additional 30-min visits with the dietitian. During subsequent years, 47% of intensive therapy patients required additional dietary counseling to achieve study goals. Each of these patients required three 35-min visits per year with the dietitian.

Patients changing from CSII to MDIs were not seen more frequently, but 30% of those changing from MDIs to CSII had one extra outpatient visit. At the visit, the patient spent 45 min with the nurse and 20 min with the physician. Also, 70% spent 30 min with the dietitian, and 30% spent 20 min with the behavioral scientist.

Other outpatient services related to intensive therapy. For 4 weeks after initiation of MDI therapy and for 5 weeks after initiation of CSII therapy, telephone calls were frequent. The intensive therapy patient received an average of three 15-min calls per week from the nurse. In addition, on average the patient called the nurse once a week outside of normal business hours. Each call lasted 10 min.

Each year, each intensive therapy patient routinely received 30 20-min calls from the nurse and 1 10-min call from the physician. A physician or a nurse was also available to take calls outside of normal business hours. Typically, there were two such calls per patient per year. Of these calls, 75% were taken by the nurse with each call lasting 15 min, and 25% were taken by the physician with each call lasting 10 min. Telephone calls were also made as a part of dietary counseling to achieve study goals. Each patient requiring additional dietary counseling to achieve study goals received two 10-min calls per year from the dietitian.

Five letters were written for each intensive therapy patient each year. These letters were written to referring physicians, insurance companies, licensing agencies, and others. Each letter required 15 min of a nurse's time and 10 min of a secretary's time. Clinics also prepared newsletters and cards. Nurses spent 6 h, dietitians spent 2 h, and secretaries spent 18 h per year related to these activities. About 60% of the physicians and 45% of the behavioral scientists aided with these activities, spending on average 2 h per year.

Each week, clinics held a treatment team meeting to discuss issues related to patient management. The meetings lasted 70 min, and 45 min were devoted to intensive therapy patients. The meetings were usually attended by two nurse educators, two physicians, a dieti-

Table 2—*Cost of initiation of intensive therapy in the DCCT by type of intensive therapy*

		Cost (%)		
		MDIs		CSII
Inpatient initiation of therapy				
Hospital services (DRG 295)		2,344		2,344
Physician services		176		176
Total		2,520		2,520
Intensive posthospital follow-up				
Outpatient visits	3 visits @ $32	96	3 visits @ $41	123
Management calls	12 @ $16	192	15 @ $16	240
After hours calls	4 @ $4	16	5 @ $4	20
Total		304		383
Grand total		$2,824		$2,903

Cost does not include the cost of a CSII pump.

Table 3—*Cost of crossover from CSII to MDIs and from MDIs to CSII*

		Cost ($)		
		CSII to MDIs		MDIs to CSII
Inpatient initiation of therapy				
Hospital services		0	14% × $2,344 (DRG 295)*	328
Physician services		0		20
Total		0		348
Intensive follow-up				
Outpatient visits	$0	0	30% 1 visit @ $50†	15
Management calls	5 @ $7	33	12 @ $7	80
After-hours calls	3 @ $3	8	5 @ $7	33
Total		41		128
Grand total		41		476

Cost does not include the cost of a CSII pump and may not exactly equal product of event rate and unit cost because of rounding. *Percentage of patients changing from MDIs to CSII who were hospitalized for reeducation. †Percentage of patients changing from MDIs to CSII who had an extra outpatient visit.

tian, and a behavioral scientist. A secretary attended 70% of the meetings.

In a typical year, three group meetings were scheduled for intensive therapy patients to promote adherence. Each meeting lasted 3 h. The nurses, physicians, dietitians, behavioral scientists, and secretaries all participated in the planning, spending 6, 1, 4, 1, and 4 h, respectively, on a typical meeting. Clinics spent ~$20 per patient per meeting. The staff members attending most often were two nurses, two physicians, one dietitian, one behavioral scientist, and one secretary.

During the first 2 weeks after changing from CSII to MDIs, patients received an average of five 15-min calls from the nurse. Of the patients, 60% made three 10-min calls to the nurse outside of normal business hours. During the first 4 weeks after changing from MDIs to CSII, patients received 12 15-min calls from the nurse and made 5 15-min calls to the nurse outside of normal business hours.

Self-care supplies. MDI patients were treated with a median of three injections per day. Most patients used two types of human insulin. The median insulin dose was 56 U/day. Patients were instructed to discard insulin vials 1 month after they were opened. For 60% of MDI patients, insulin pens were prescribed as a convenience device, and 35% of all insulin doses were administered by pen. Patients changed pen needles every three doses.

For patients using CSII, the median insulin dose was 51 U/day. Patients changed syringes and catheters on average every other day. Most patients cleaned their infusion sites with alcohol alone, and 60% used a site cover other than the one provided with the catheter. CSII patients used two shower packs per month.

On average, intensive therapy patients performed SMBG four times per day. All used meters for SMBG. Patients also monitored urine ketones on average eight times per year. For the treatment of hypoglycemia, intensive therapy patients received 39 six-tablet boxes of glucose tablets, two tubes of glucose gel, and one glucagon kit per year.

Resources used for conventional therapy

Conventional therapy consisted of one or two injections of insulin per day and daily self-monitoring of urine or blood glucose. Patients in the conventional therapy group visited the clinic every 3 months.

Inpatient services. Patients assigned to conventional therapy were not hospitalized after randomization, but the protocol required that women assigned to conventional therapy change to intensive therapy while attempting to become pregnant and during pregnancy. Each year, 4.8% of women in the conventional therapy group began intensive therapy for reasons related to pregnancy, and 80% were admitted to the hospital to initiate therapy.

Outpatient services. Although some patients randomly assigned to conventional therapy required substantial education related to diabetes self-management and diet, we did not measure or include the increased use of outpatient services associated with initiation of conventional therapy in the DCCT.

All conventional therapy patients were seen at 3-month intervals. We obtained a medical history, focusing on symptoms of hyper- and hypoglycemia, performed a physical examination, with particular emphasis on growth in adolescents and children, and reviewed patient-recorded home urine and/or blood tests. Each patient was provided with an individualized education program that covered a complete cycle of subject matter every 2 years. At quarterly visits (2/year), the patient typically saw the nurse for 40 min and the physician for 20 min. At 50% of quarterly visits, the patient also saw the behavioral scientist for 10 min. The semiannual visit (1/year) differed from the quarterly visits only in that the patient also saw the dietitian for 30 min. At the annual visit, the patient saw the nurse for 55 min, the physician for 25 min, the dietitian for 30 min, and the behavioral scientist for 30 min. HbA_{1c} was measured every 3 months. Otherwise, laboratory evaluation was the same as for patients receiving intensive therapy.

If an adolescent patient failed to grow normally, or if any conventional therapy patient experienced symptoms of hyperglycemia, developed persistent ketonuria, or experienced serious hypogly-

Table 4—*Annual cost of MDI therapy*

	Events/year	Cost/event ($)	Annual cost ($)
Inpatient services			
Hospitalization to adjust dose	0.04	3,035	127
Total (%)			127 (3%)
Outpatient services			
Monthly visit	8	72	578
Quarterly visit	2	121	242
Semiannual visit	1	121	121
Annual visit	1	280	280
Dietary counseling	0.47	46	22
Total (%)			1,243 (31%)
Case management services			
Telephone calls	32	8	252
Letters	5	9	49
Treatment team conferences		183	183
Other time (hours)	12	5	61
Crossover from CSII	0.08	41	3
Total (%)			548 (14%)
Self-care			
Insulin (1000 U)	24	16.34	392
Syringe	1,095	0.21	230
Alcohol preparation	1,095	0.02	22
Glucose meter (3-year life)	0.33	137.50	46
Battery for meter	6	4.50	27
Control solution	1	7.38	7
Glucose test strip	1,460	0.68	993
Lancet	1,460	0.06	88
Urine test strip	8	0.13	1
Box of 6 glucose tablets	39	1.15	45
Tube of glucose gel	2	2.80	6
Glucagon kit	1.2	24.41	29
Total (%)			1,886 (47%)
Treatment of side effects of therapy			
Weight management	0.32	137	44
Hypoglycemia	0.62	268	166
Total (%)			210 (5%)
Grand total			4,014/year

Cost may not exactly equal product of event rate and unit cost because of rounding.

cemia, or if the HbA_{1c} level exceeded 2 SD above the mean value prevailing in IDDM populations (i.e., >13.11%), a modification in the conventional therapy regimen was required. On average, 4.5% of conventional therapy patients required such a modification each year. When this occurred, the patient typically made two additional outpatient visits and had one additional HbA_{1c} measurement performed. At each visit, the patient saw the nurse for 30 min and the physician for 20 min. At 65% of such visits the patient saw the dietitian for 30 min, and at 55% the patient saw the behavioral scientist for 30 min.

Each year, 8% of conventional therapy patients required additional dietary counseling to achieve study goals. Such patients usually had two additional visits with the dietitian, each visit lasting 45 min.

Other outpatient services related to conventional therapy. Each year, conventional therapy patients routinely received three 15-min telephone calls from the nurse and one 10-min call from the physician; 40% received one 10-min call from the dietitian and one 15-min call from the behavioral scientist. A physician or a nurse was also available to take calls outside of normal business hours. On average, each patient called once every 2 years. Of these calls, 75% were taken by the nurse with each call typically lasting 15 min, and 25% were taken by the physician with each call lasting 10 min. Telephone calls were also made to modify the conventional therapy program and as a part of dietary counseling to achieve study goals. Conventional therapy patients who required modification of their treatment program (4.5% of all conventional therapy patients per year) received four additional 15-min calls from the nurse, 40% received a 10-min call from the physician, 40% received a 10-min call from the dietitian, and 30% received a 15-min call from the behavioral scientist. Each patient who received additional dietary counseling to achieve study goals received one additional 15-min call from the dietitian.

Two letters were written for each conventional therapy patient each year, and patients also received newsletters and cards. Resources used to prepare letters, newsletters, and cards were the same as for intensive therapy patients.

At the weekly treatment team meeting, 10 min was devoted to conventional therapy patients. In a typical year, two 3-h group meetings were scheduled for conventional therapy patients to promote adherence. Resources used to prepare for group meetings and staff members attending group meetings were the same as for intensive therapy patients.

Self-care supplies. On average, conventional therapy patients took two injections per day. Most patients used two types of insulin, and 46% used human insulin. The median insulin dose was 49 U/day. Patients were instructed to discard insulin vials 1 month after they were opened. Insulin pens were not generally used by conventional therapy patients.

Table 5—*Annual cost of CSII therapy*

Service	Events/year	Cost/event ($)	Annual cost ($)
Inpatient services			
Hospitalization to adjust dose	0.04	3,035	127
Crossover from MDIs	0.08	348	28
Total (%)			155 (3%)
Outpatient services			
Monthly visit	8	72	578
Quarterly visit	2	121	242
Semiannual visit	1	121	121
Annual visit	1	280	280
Dietary counseling to meet study goals	0.47	46	22
Crossover from MDIs	0.08	15	1
Total (%)			1,244 (21%)
Case management services			
Telephone calls	32	8	252
Letters	5	9	49
Treatment team conference		183	183
Other time (hours)	12	5	61
Crossover from MDIs	0.08	113	9
Total (%)			554 (9%)
Self-care			
Insulin (buffered, 1,000 U)	24	16.34	392
Insulin infusion pump	0.17	3,955	659
Pump battery	36	2.88	104
Pump syringe	183	2.20	402
Infusion set	183	3.73	683
Alcohol preparation	183	0.02	4
Site cover	183	0.68	124
Shower pack	24	0.60	14
Glucose meter (3-year life)	0.33	137.50	46
Battery for meter	6	4.50	27
Control solution	1	7.38	
Glucose test strip	1,460	0.68	993
Lancet	1,460	0.06	88
Urine test strip	8	0.13	1
Box of 6 glucose tablets	40	1.15	46
Tube of glucose gel	2	2.80	6
Glucagon kit	1	24.51	25
Total (%)			3,621 (63%)
Treatment of side effects of therapy			
Weight management	0.32	137	44
Hypoglycemia	0.62	268	166
Total (%)			210 (4%)
Grand total			$ 5,784/year

Cost may not exactly equal product of event rate and unit cost because of rounding.

Of conventional therapy patients, 73% routinely performed SMBG and, at the end of the study, 75% of those performing SMBG used meters. Patients usually monitored once per day. Urine glucose monitoring was performed routinely by 27% of conventional therapy patients. Such patients monitored three times per day. Conventional therapy patients monitored urine ketones on average once per week. For the treatment of hypoglycemia, patients received 10 six-tablet boxes of glucose tablets, one tube of glucose gel, and one glucagon kit per year.

Resources used for the treatment of side effects of therapy

We next describe the resources used for the treatment of the major side effects of therapy (weight gain and hypoglycemia). Although rates of hypoglycemia differed between treatment groups, there was no difference in the management. Management of weight gain did differ between treatment groups, so we present management strategies separately for the intensive and conventional treatment groups.

Weight gain. Each year, 32% of intensive therapy patients required additional counseling for weight management. These patients typically saw the dietitian four times per year for 35 min per visit. Each year, 65% of these patients had four 20-min visits with the nurse, 30% had four 10-min visits with the physician, and 40% had four 30-min visits with the behavioral scientist. Each year, each of these patients typically received four 15-min calls from the dietitian and one 10-min call from the nurse.

Each year, 15% of conventional therapy patients required additional counseling for weight management. These patients typically made two additional visits per year. At each visit, the patient saw the dietitian for 30 min and the nurse for 15 min; 35% of these patients saw the physician for 10 min, and 25% saw the behavioral scientist for 15 min. Conventional therapy patients requiring additional dietary counseling typically received two 15-min calls from the dietitian, and 50% received three 10-min calls from the nurse each year.

Hypoglycemia. Severe hypoglycemia was approximately three times as frequent with intensive therapy as with conventional therapy (1). Of all episodes of hypoglycemia with coma or seizure, 24% were evaluated in an emergency room. For ~70% of such events, the patients were transported to the emergency room by basic life support ambulance, and for 30% the patients were transported by ad-

Table 6—*Annual cost of conventional therapy*

Service	Events/year	Cost/event ($)	Annual cost ($)
Inpatient services			
Pregnancy-related hospitalization	0.023	2,520	58
Total (%)			58 (4%)
Outpatient services			
Quarterly visit	2	81	162
Semiannual visit	1	98	98
Annual visit	1	250	250
Dietary counseling to meet study goals	0.08	34	3
Total (%)			513 (31%)
Case management services			
Telephone calls	4	7	30
Letters	2	9	18
Treatment team conference		60	60
Other time (hours)	4	2	8
Total (%)			116 (7%)
Self-care			
Insulin (1,000 U)	24	16.34	392
Syringe	730	0.21	153
Alcohol preparation	730	0.02	15
Glucose meter (3-year life)	0.33	137.50	46
Battery for meter	6	4.50	27
Control solution	1	7.38	7
Glucose test strip	267	0.68	181
Lancet	267	0.06	16
Urine test strip	296	0.13	38
Box of six glucose tablets	10	1.15	11
Tube of glucose gel	0.4	2.80	1
Glucagon kit	0.9	24.51	22
Total (%)			909 (54%)
Treatment of side effects of therapy			
Weight management	0.15	60	9
Hypoglycemia	0.19	268	51
Treatment modification	0.04	221	10
Total (%)			70 (4%)
Grand total			1,666/year

Cost may not exactly equal product of event rate and unit cost because of rounding.

vanced life support ambulance. For 5% of all episodes with coma or seizure, the patients were hospitalized. For 29% of those episodes, the patients who were hospitalized experienced catastrophic hypoglycemia and received critical care services. For the remaining 71% of the episodes, the patients received routine inpatient services.

If a patient experienced severe hypoglycemia with coma or seizure, one extra DCCT outpatient visit was usually scheduled per episode. The patient saw the nurse for 30 min and the physician for 15 min; 75% saw the dietitian for 25 min, and 60% saw the behavioral scientist for 20 min. In addition, the nurse made two extra 20-min calls related to each severe hypoglycemic event. Of these patients, 65% received one 10-min call from the physician, and 55% received one 10-min call from the dietitian.

Unit costs

Table 1 summarizes the unit costs of labor, fringe benefits, equipment, supplies, medications, tests, procedures, consultations, ambulance services, emergency room services, hospital services, overhead (10), and the sources of the estimates.

Costs of therapy calculated from resources used and unit costs

Costs of initiation of intensive therapy. Table 2 summarizes the costs of initiation of intensive therapy at the time of randomization. These costs are the sum of two sequential stages: inpatient initiation and intensive posthospital follow-up. Self-management costs, including the cost of insulin infusion pumps, are not included but are considered as part of the cost of annual therapy.

The cost of initiation of CSII ($2,903) was essentially no different than the cost of initiation of MDIs ($2,824). Inpatient services accounted for >85% of the cost of initiation of both CSII and MDIs.

Costs of ongoing intensive and conventional therapy. Table 3 shows the costs of crossing over from CSII to MDIs and from MDIs to CSII, Tables 4 and 5 summarize the annual costs of intensive therapy using MDIs and CSII, and Table 6 shows the annual costs of conventional therapy.

Although the cost of changing from CSII to MDIs was negligible, the cost of changing from MDIs to CSII was $476. (The cost of the insulin infusion pump was not included in this cost but was considered as part of the cost of annual therapy.) Of the cost of changing from MDI to CSII, 73% was attributable to the cost of rehospitalization.

The annual cost of intensive therapy with CSII ($5,784/year) was 44% greater than that of MDIs ($4,014/year). The difference in cost was $1,770 per year. Essentially all of the difference in cost was attributable to the greater cost of the pump and pump supplies.

Intensive therapy with MDIs ($4,014/year) was ~$2,300 more expensive than conventional therapy ($1,666/year), or ~2.4 times as expensive as conventional therapy. Three-quarters of the difference in cost was accounted for by

Table 7—*Staff utilization and costs of labor by treatment group and clinic*

Intensive therapy					Conventional therapy				
Physician	Nurse	Behaviorist	Dietitian	Cost ($)	Physician	Nurse	Behaviorist	Dietitian	Cost ($)
40	210	30	183	208	20	100	0	60	84
120	310	0	120	296	40	150	0	60	126
70	400	10	150	301	70	160	0	60	160
44	465	60	90	310	20	200	45	90	161
205	310	75	80	405	85	130	30	60	177
125	280	195	180	405	45	90	0	60	104
205	350	45	90	411	90	135	30	60	184
125	600	10	90	425	40	85	10	60	102
240	240	65	312	479	120	180	80	60	259
10	795	210	85	497	10	165	0	60	103
165	610	70	184	520	135	195	40	60	260
280	340	155	45	521	120	135	39	30	208
220	450	155	100	529	120	105	50	90	220
90	720	190	120	544	70	300	44	120	264
90	720	190	120	544	70	300	44	120	264
255	530	85	60	550	115	180	55	30	231
252	475	45	208	551	102	180	45	90	233
240	450	160	200	584	166	160	45	60	276
90	600	375	120	584	65	180	65	60	197
210	480	105	400	605	88	310	70	70	283
200	630	60	360	626	120	210	60	120	282
280	560	210	30	642	60	225	75	30	207
420	484	86	120	669	120	180	75	120	278
255	720	120	184	693	120	240	120	60	306
355	630	320	280	865	150	270	12	40	288
385	555	180	450	866	111	120	40	40	196
360	555	0	900	897	90	180	25	150	231
240	720	360	540	916	80	240	0	60	205
360	750	360	224	945	135	300	60	80	323

Clinics are listed in order of increasing cost of intensive therapy. Staff utilization is given in minutes/year and cost in $/year.

the greater use of outpatient services (difference: $730/year) and self-care (difference: $977/year) by MDI patients. Monthly clinic visits accounted for 79% of the difference in the cost of outpatient services between MDIs and conventional therapy, and the increased frequency of SMBG (1,460 vs. 267 tests per patient per year) accounted for 83% of the difference in the cost of self-care.

To describe the variability of outpatient resource utilization among clinics, we report the use of staff time and calculate the direct costs of labor for each of the 29 clinics (Table 7). We chose to present detailed resource utilization and cost data for this component of therapy because it accounted for a large proportion of the difference in cost between intensive and conventional therapy and was quite variable. In almost all clinics, the nurse-educator was the primary provider of care. For intensive therapy, the median aggregate cost of labor for monthly, quarterly, semiannual, and annual visits was $544 per year, the minimum cost was $208 per year, and the maximum cost was $945 per year. For conventional therapy, the median cost of outpatient services was $220 per year, the minimum cost was $84 per year, and the maximum cost was $323 per year. In both treatment groups, the costs of labor tended to increase with the amount of physician time used. In neither group was there a significant correlation between the direct cost of labor and the median HbA_{1c} levels achieved (data not shown).

Costs of the side effects of treatment. Table 8 summarizes the costs of the side effects of therapy. Major weight gain was more frequent with intensive therapy (2.1-fold increased risk compared with conventional therapy), and more patients in the intensive therapy group required counseling for weight management than did patients in the conventional therapy group (32 vs. 15% per year). The resources used for weight management counseling were greater for the intensive therapy patients than for the conventional

Table 8—*Costs of side-effects of treatment in the DCCT*

	Weight management	
	Intensive therapy	Conventional therapy
Outpatient cost ($)	113	44
Case management cost ($)	24	16
Total cost per year ($)	137	60

	Severe hypoglycemia		
Service	% receiving	Unit cost ($)	Cost ($)
Ambulance	29	152	44
Physicians' services (outpatient)	24	131	31
Emergency room	24	121	29
Inpatient	5	1,626	84
Physicians' services (inpatient)	5	245	13
Outpatient	100	41	41
Case management	100	26	26
Total cost per episode			268

	Intensified management for conventional therapy
Outpatient, cost ($)	196
Laboratory cost ($)	26
Total cost per episode ($)	221

Cost may not exactly equal product of event rate and unit cost because of rounding.

therapy patients, and the costs were higher ($137 vs. $60 per patient per year). The average cost of a single episode of severe hypoglycemia was constant across study groups ($268), but the rate of severe hypoglycemia was greater in the intensive therapy group than in the conventional therapy group (62 vs. 19 episodes per 100 patient years). Each year 4.5% of conventional therapy patients required modification of their treatment program to achieve study goals. The cost of such a modification was $221 per patient per year. Taken together, the costs of the side effects of therapy (e.g., weight gain and hypoglycemia) contributed only ~5% to annual costs of therapy regardless of intensive treatment group or type of intensive treatment (Tables 4–6).

CONCLUSIONS — In the DCCT, the annual cost of intensive therapy with MDIs (~$4,000/year) was $2,300, or 2.4 times greater than the cost of conventional therapy (~$1,700/year). A large proportion of the difference in cost between intensive therapy with MDIs and conventional therapy was related to the differences in frequency of outpatient visits (12 vs. 4 per year) and in the frequency of SMBG (1,460 vs. 267 per patient per year). The annual cost of intensive therapy with CSII (~$5,800/year) was ~$1,800, or 1.4 times greater than the cost of intensive therapy with MDIs. The higher cost of CSII compared with MDIs was entirely related to the cost of the pump and pump-related supplies. The cost of the side effects of intensive therapy ($210/year) was three times the cost of the side effects of conventional therapy ($70/year), but these costs accounted for only ~5% of the total costs of therapy in both groups.

These analyses describe the costs of providing intensive therapy according to the DCCT protocol. The overriding goal of intensive therapy was to achieve blood glucose levels as close to the nondiabetic range as possible. Accordingly, if an intervention was believed to have a salutary effect on glycemic control, it was incorporated into the protocol for intensive therapy. In the DCCT, the cost of initiation of intensive therapy was ~$2,900. More than 85% of this cost was associated with hospitalization to initiate intensive therapy, which may not be necessary in the nonresearch setting. One of the major reasons that intensive therapy patients were hospitalized to initiate therapy was the desire to establish a difference in glycemia between the two treatment groups as quickly as possible. Similar time constraints are not applicable in the nonpregnant, nonresearch IDDM population.

The goal of conventional therapy was to mimic care provided in academic medical centers. As a result, DCCT conventional therapy probably consumed more resources and was more expensive than conventional therapy for IDDM in other settings. A recent study has shown that conventional therapy in the DCCT was more intensive than standard community care for IDDM (11). Finally, it must be recognized that costs were calculated from the perspective of a national health system. These costs are very different from charges and may not be appropriate to set reimbursement levels.

The wide range in personnel costs associated with both intensive and conventional therapy and the lack of correlation between resources used and HbA_{1c} achieved suggest that levels of glycemic control similar to those achieved in the intensive therapy group could be obtained at reduced costs. An informal survey of 70 individuals in centers of excellence for diabetes care in the U.S. and Canada indicated that in comparison with the DCCT, fewer patients were admitted to the hospital for initiation of intensive therapy, fewer patients used CSII in intensive therapy, less staff time was

used in the outpatient management of intensive therapy patients, and monthly outpatient visits were not always needed once a stable regimen was established (DCCT, unpublished observations). The potential impact of these changes on outcomes is uncertain because they were not tested in the DCCT. They might reduce the effectiveness of therapy as measured by HbA_{1c} level or result in an increase in the side effects of therapy. Further studies are needed to assess prospectively resources, costs, and outcomes, and to maximize the efficiency of alternative models of intensive therapy.

The DCCT demonstrated the power of preventive medicine in patients with IDDM. This analysis demonstrates that such a prevention strategy is associated with a substantial increment in cost. However, the relative costs of intensive and conventional therapy may be different in settings where controlling costs is a priority. The costs of such a prevention strategy must be balanced against the cost savings related to averted complications (DCCT, unpublished observations).

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