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Second Interim Report on the Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration: Final Report on Phase I

Final Report

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EXECUTIVE SUMMARY

BACKGROUND

Improving access to care and increasing the quality of care for underserved Medicare beneficiaries with diabetes are important policy objectives of the Medicare program. Diabetes is a leading cause of mortality, morbidity, and health care costs among older Americans (American Diabetes Association 2002a). Some of the serious health complications of the disease are loss of vision, kidney failure, nerve damage, coronary artery disease, cerebrovascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections (American Diabetes Association 2002b). However, appropriate management and regular monitoring of people with diabetes can delay or avert the onset of many of these complications (American Diabetes Association 2002c).

Medicare beneficiaries who have diabetes and who live in medically underserved inner-city or rural areas are likely to have poor access to high-quality diabetes care. These areas, by definition, have an inadequate supply of health care providers, and their geography and lack of affordable transportation, primarily in rural areas, present additional barriers to medical care. The disproportionate impacts of diabetes on minority senior populations, which represent a large share of the population living in underserved areas, compound the effects of these barriers. For example, both African Americans and Hispanics/Latino Americans have much higher rates of diabetes than do white Americans (Harris 2001), and much greater risks of severe complications and death (Karter et al. 2002). Therefore, serving the populations with the greatest need of frequent medical attention to monitor and care for their diabetes is a major goal for the Medicare program.

Telemedicine, the use of telecommunications technology to deliver medical diagnostic, monitoring, and therapeutic services to health care users and providers who are separated geographically, may be a promising means of reducing access barriers for chronically ill Medicare beneficiaries. In particular, home telemedicine allows for regular health monitoring from, and delivery of care to, beneficiaries' homes. Potentially, such improved access to care could prevent the future need for the costly treatment of medical complications. To date, however, little hard evidence exists to demonstrate either the effectiveness or cost-effectiveness of home telemedicine.

To address this knowledge gap, Congress included in the Balanced Budget Act of 1997 a mandate for a demonstration project to use telemedicine networks and services to improve primary care for Medicare beneficiaries with diabetes mellitus. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 subsequently amended this mandate by clarifying that the target population should reside in medically underserved areas and by prohibiting cost sharing for demonstration services.[1]

Key demonstration objectives specified by the original legislation include:

- Improving the access of beneficiaries with diabetes mellitus to care, adherence with appropriate guidelines, and the beneficiaries' quality of life
- Reducing the costs of the care provided to the target population
- Developing a curriculum to train health professionals in the use of telemedicine services
- Developing standards for the application of telemedicine services

[1]See Appendix A for copies of both laws.

- Applying the technologies to beneficiaries with limited English language skills
- Developing cost-effective delivery models of primary care services in both managed care and fee-for-service environments

Congress also mandated an evaluation of the demonstration. The evaluation must include an assessment of telemedicine's impacts on improving access to health care services, reducing Medicare costs, and improving quality of life. The legislation specified that interim and final evaluation reports be submitted to Congress. Although Congress did not specify a schedule for the interim reports, it required that the final report had to be submitted within six months of the demonstration's conclusion.

In February 2000, the Centers for Medicare & Medicaid Services (CMS) awarded a $28 million cooperative agreement to perform the demonstration to a consortium (hereafter identified as *the Consortium*) led by Columbia University College of Physicians and Surgeons and Columbia-Presbyterian Medical Center (hereafter, *Columbia University*). The demonstration is called the Informatics for Diabetes Education and Telemedicine, or *IDEATel*. The law originally required that the demonstration be completed within four years (hereafter, the *first phase* of the demonstration, or *Phase I*). The demonstration began on February 28, 2000. In fall 2003, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress authorized an extension of the demonstration for four more years (referenced as *Phase II*) and added $30 million to the budget for the demonstration and the evaluation.[2] Phase II began on February 28, 2004. The legislation did not modify any other aspect of the original authorization of the

[2]Appendix A also includes a copy of the legislation authorizing the extension of the demonstration.

demonstration. Therefore, the schedule for the delivery of the final report has been delayed by four years; this report is due to Congress in August 2008.

CMS contracted with Mathematica Policy Research, Inc. (MPR) to perform the mandated evaluation independently of the Consortium. The mandated evaluation began 7 months after the award of the demonstration cooperative agreement, and its first phase will last 55 months. MPR also will evaluate the second phase of IDEATel; the evaluation of Phase II began in September 2004 and will last 48 months.

PURPOSE OF THIS REPORT

This interim report is the second one to Congress about the mandated evaluation. It updates the first report, submitted to Congress in spring 2003, and draws overall conclusions about the impacts of the demonstration during its first four years (Phase I). The first interim report examined the original design of the demonstration, the evolution of the demonstration, and the challenges that the Consortium encountered during the first 21 months of the demonstration's implementation (February 2000 through November 2001) (U.S. Department of Health and Human Services 2003).

The current report addresses the three major issues laid out in the legislation that mandated the demonstration: (1) whether the demonstration was implemented as Congress intended; (2) whether participants used the technology through which the intervention was delivered; and (3) whether the demonstration had impacts on enrollees' access to care, behavioral and physiologic outcomes, health services use, Medicare costs, quality of life, and satisfaction with care. The report's findings are based on data collected by MPR during telephone discussions in fall 2002 and fall 2003 with the Consortium leadership and with Consortium staff who were involved with various aspects of the demonstration. This report also relies on patient data and medical records

data that the Consortium collected through July 31, 2003, on beneficiaries who remained enrolled in the demonstration, as well as on Medicare enrollment and claims data for the period 1999 through 2003 on all demonstration enrollees. The report also synthesizes findings from MPR's previous report and presents conclusions about the first phase of the demonstration.

DEMONSTRATION OVERVIEW

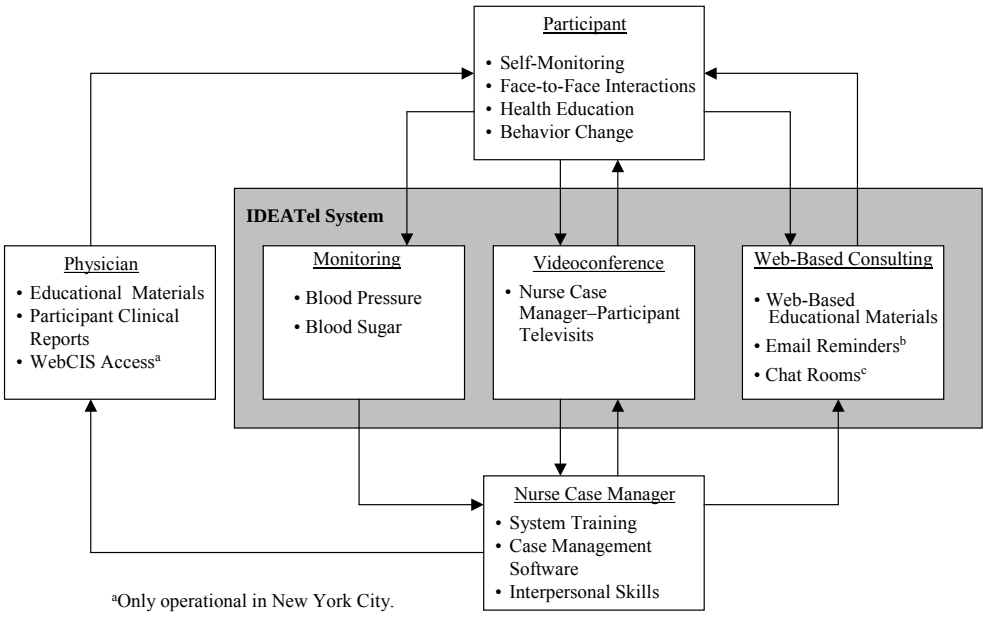
The Consortium consists of two large academic medical centers (Columbia-Presbyterian Medical Center and the State University of New York Upstate Medical University), several smaller regional hospitals in New York State, a telecommunications provider, and several vendors. The demonstration targets Medicare beneficiaries with diabetes mellitus who live in federally designated, medically underserved areas or primary care health professional shortage areas in New York City or upstate New York (hereafter identified as the *upstate site*). Many of the beneficiaries in the target areas have low incomes, and those in the New York City site are predominantly of Hispanic/Latino ancestry, and with limited English skills. High-quality, timely diabetes care typically is not available for this population.

The demonstration had clinical goals as well as behavioral goals for participants and their physicians. The three primary clinical goals were (1) control of blood sugar; (2) reduction or control of such risk factors as smoking, obesity, physical inactivity, high blood pressure, and abnormal lipid levels; and (3) regular provision of preventive care. To accomplish these goals, the demonstration sought to increase the frequency with which participants monitored their blood pressure and blood sugar, improve participants' adherence to medication regimens, increase the rate at which participants kept medical appointments, promote smoking cessation and weight loss, improve participants' diets, and increase the amount and frequency of participants' exercise. The demonstration's goals for physicians were to improve the quality of care the

physicians provide by ensuring that the care was as consistent as possible with the recommendations of clinical practice guidelines. To implement its multi-pronged approach, the Consortium developed an intervention that provided remote monitoring, videoconferencing, and Web-based consulting, as well as a curriculum for physicians (Figure 1).

FIGURE 1

THE IDEATel SYSTEM INTERVENTION



[a]Only operational in New York City.

[b]Email reminders were not systematically implemented in the upstate site.

[c]Chat rooms were not implemented in either site.

Source: Synthesis from Columbia University (1998) and other demonstration materials.

WebCIS = Clinical Information System, Columbia-Presbyterian Medical Center, New York.

Between December 2000 and October 2002, the demonstration randomly assigned 1,665 eligible Medicare beneficiaries (775 in New York City and 890 in the upstate site) equally to a treatment or control group (Table 1). Enrollees randomized to the treatment group received a home

TABLE 1

DISTRIBUTION OF IDEATel ENROLLEES, BY SITE AND EVALUATION GROUP

Site	Evaluation Group		Total
	Treatment	Control	
Full Sample			
New York City	397	378	775
Upstate New York	447	443	890
Total	844	821	1,665
Survey Sample[a]			
New York City	338	349	687
Upstate New York	338	339	677
Total	676	688	1,364

Source: IDEATel tracking status file and IDEATel Year 1 in-person interview (Columbia University 2003c and 2003d.)

[a]As of July 31, 2003.

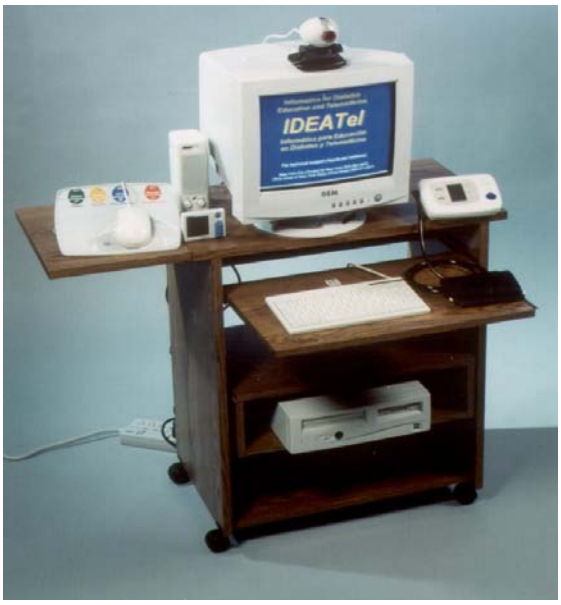
telemedicine unit (HTU) and diabetes care management provided by a nurse case manager.[3] The HTU consisted of a personal computer with audio/video communication capabilities and devices for measuring blood sugar and blood pressure (Figure 2). The participants used the HTUs to:

- ***Monitor*** their blood pressure and blood sugar and ***transmit*** these measurements to their nurse case managers
- ***Communicate*** via audio/video conferencing with their nurse case managers (televisits)
- ***Access web-based features*** of the intervention, such as educational materials and chat rooms, that were accessible only to participants

[3]An enrollee is an eligible Medicare beneficiary enrolled in the demonstration. A participant is an enrollee in the treatment group, regardless of whether he or she received the intervention and used the services offered.

FIGURE 2

IDEATel's HOME TELEMEDICINE UNIT



Source: Starren et al. (2003).

Control group members received their usual care from their primary care physicians. They did not have HTUs, nor did they have any contact with the nurse case managers.

FINDINGS FROM THE DEMONSTRATION'S FIRST PHASE

The Consortium effectively implemented IDEATel, despite early hardware and software problems.

The Consortium successfully implemented the first phase of the IDEATel demonstration. It confirmed that the numerous challenges that arose at each stage of the implementation of the demonstration's first phase could be overcome with sufficient creativity and adaptability of the organization implementing it. Some of these challenges were relatively simple to resolve; others required that the Consortium change the demonstration's design.

A higher-than-expected dropout rate was a major challenge to implementation that also translated into evaluation challenges.

The dropout rate (19 percent in the treatment group during the first year) was higher than expected (Table 2). In winter 2002, the Consortium responded to this implementation challenge by increasing the target sample size by about 10 percent.

TABLE 2

DEMONSTRATION DROPOUT RATES,
BY SITE AND EVALUATON GROUP
(Percentages)

	New York City			Upstate New York			Both Sites	
	Treatment	Control	Total	Treatment	Control	Total	Treatment	Control
Disenrolled by the End of Year 1	22.6	3.7	13.3	15.5	2.7	9.1	18.8	3.2
Disenrolled by July 31, 2003	30.1	9.0	19.8	29.0	17.5	23.2	29.5	13.4

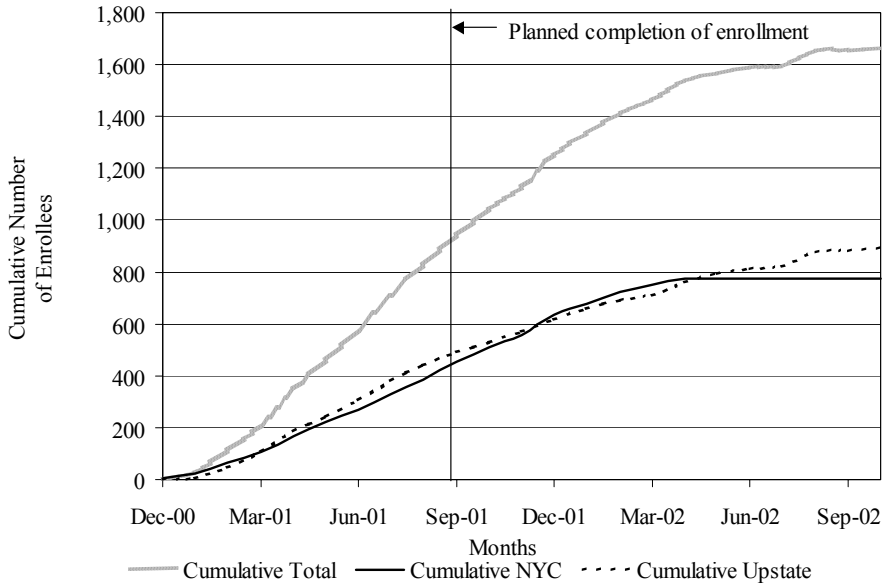
Source: MPR's calculations based on the IDEATel tracking status file (Columbia University 2003c).

The Consortium also extended the enrollment period to meet the new enrollment target, and to enable new upstate practices to join. These moves enabled the Consortium to complete recruitment in mid-April 2002 in New York City, and in mid-October 2002 in upstate New York, approximately 14 months after the originally projected date of August 2001 (Figure 3).

Because of the extended enrollment period relative to the original four-year demonstration period, eligible Medicare beneficiaries who enrolled at the end of the recruitment period (summer/fall 2002) received the intervention for only one year or less and, therefore, do not have survey follow-up data for the full two years, as originally planned, as of July 31, 2003—the cutoff for data for this evaluation. Thus, survey follow-up data are available on approximately

FIGURE 3

CUMULATIVE DEMONSTRATION ENROLLMENT



Source: Columbia University (2002c).

Note: The Consortium completed enrollment in NYC in April 2002, and in upstate New York in October 2002.

NYC = New York City.

82 percent of the 1,665 enrollees for the enrollees' first full year in the demonstration, and on approximately 35 percent of enrollees for their second full year (depending on the outcome measured) (Table 1).[4] In contrast, Medicare claims data for the period 2000–2003 are available for all 1,665 beneficiaries.

[4]These percentages are based on annual enrollee interviews (through July 31, 2003) that the Consortium provided to MPR. About 1,648 eligible beneficiaries had enrolled through July 2002 and therefore should have been interviewed; however, due to death and nonresponse, only 1,364 completed follow-up interviews. The Consortium continued collecting data for Year 1 between July 31, 2003, and the end of the demonstration's operations (October 31, 2003) in New York City; it continued collecting data uninterruptedly in the upstate site. As of February 2005, the Consortium had collected follow-up data on approximately 85 percent of enrollees for enrollees' first year in the demonstration, and on approximately 75 percent of enrollees for their second year (Columbia University 2004a and 2005).

Changes in the design of the HTUs created several new challenges that may have had lasting effects on the implementation of the demonstration.

Within 10 months of the demonstration's start, and without an interval between the award of the cooperative agreement and the actual start of funding, the Consortium had to create an HTU using off-the-shelf components because its subcontractor had stopped supplying the all-in-one device as originally proposed. It was ready to install the HTUs in the homes of the first demonstration participants by December 2000. By the end of the enrollee recruitment period (fall 2002), it had installed 794 HTUs. However, the changes to the technical design created several new challenges that affected the acceptability and use of the HTUs. Demonstration staff reported that some participants objected to having such a large object in their homes, and that some of those who objected refused to have the HTUs installed. In addition, the Consortium had to develop a *launch pad* to simplify operation of the HTU.

The Consortium also had to resolve several HTU maintenance problems during the demonstration's first phase, including software incompatibilities (between the HTU's software and the case management system), difficulties experienced by participants as they attempted to upload their clinical measurements (failure to receive confirmation that blood pressure and blood sugar readings had been transmitted), and the need to maintain hardware (replacement of batteries in glucose meters and blood pressure cuffs, and replacement of video cameras and speakers damaged by electrical storms). The Consortium successfully dealt with each of these problems. However, it is unclear whether the problems may have affected participants' experiences of the intervention before their resolution.

The demonstration's clinical procedures worked well throughout the first phase. The demonstration retained qualified nurse case managers. Communication between nurse case managers and primary care physicians seemed to have worked well.

The Consortium reported that, for the most part, the intervention ran smoothly, particularly during the demonstration's third and fourth years. The Consortium staffed the intervention with a stable, qualified, and empathetic cadre of nurse case managers. Moreover, Consortium staff reported that the protocols for televisits, case management supervision, and primary care physician communication worked well. Consortium staff also reported that participating physicians seemed to be receptive to the recommendations provided by nurse case managers about their patients. These recommendations were reviewed and signed off on by the demonstration's diabetologists before they were sent to the physicians.

Demonstration participants used the HTUs less frequently than expected.

Participants used their HTUs infrequently. Consortium staff reported that teaching participants how to use most of the HTU's functions was a slow, arduous process that, for some participants, was far from complete by the end of the first phase of the demonstration. An analysis of HTU use data for all participants indicates that virtually all the participants measured their blood pressure and blood sugar, and that they did so virtually every day. (Taking these measurements did not require logging in on the HTU, and most participants had been taking them before the demonstration began.) However, the analysis also showed that only a small group of technically savvy, highly motivated participants used the HTU's more complex functions. Most participants rarely used other features of the telemedicine system that required logging in, such as reading and sending electronic messages and entering medications or exercise data (Table 3). Minority participants used their HTUs less often than did white participants, as did participants with less education relative to those who completed at least high school (after controlling for other individual demographic and health characteristics).

TABLE 3

MEAN ANNUAL NUMBER OF TIMES HTU FUNCTION WAS USED DURING THE INTERVENTION, BY SITE
(Means)

HTU Function	All	Site	
		New York City	Upstate New York
Measure Blood Sugar	316.8	238.1	385.2
Measure Blood Pressure	237.0	212.1	258.7
Upload Blood Pressure or Blood Sugar Readings	19.1	14.3	23.3
Participate in Televisits	9.5	7.1	11.6
Monitor Clinical Readings	9.4	6.8	11.7
Read Electronic Messages	4.5	2.7	6.5
Enter Behavioral Goals	2.3	3.0	2.1
Enter Medications	1.8	1.6	1.9
Enter Exercise Activities	1.8	1.7	1.9
Send Electronic Messages	1.7	1.3	2.1
Consult American Diabetes Association Web Pages	1.5	1.1	1.9
Sample Size[a]	**781**	**359**	**422**

Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2003b).

[a]The number of participants using a function varies by the function.
HTU = home telemedicine unit.

After becoming aware that participants were not using their HTUs as intended, in spring 2002 (during the demonstration's third year), the Consortium leadership asked an expert on human–machine interactions to analyze patient interactions with the HTU (Kaufman et al. 2003a and 2003b). Based on the findings from that study, the Consortium retrained all participants on HTU use. The Consortium also installed a redesigned online tutorial in the HTUs that participants could watch whenever they needed instructions on how to use the system. The retraining took place between October 2002 and January 2003, but it may not have helped participants to feel

more comfortable with their HTUs; the device's use rate for several functions remained flat between December 2002 and July 2003—roughly the period after the Consortium retrained all participants.

Exposure to the intervention was uneven across sites, and less frequent than planned.

The frequency of televisits—a key component of the intervention—was substantially lower than planned and differed markedly between the two sites. Participants in the upstate site had one televisit every four weeks, about half the initially planned frequency of one televisit every two weeks; by contrast, those in the New York City site had a televisit substantially less frequently—about one visit every seven weeks (Table 3). The frequency of televisits in both sites would have been higher if participants had broken fewer appointments, particularly in New York City. The differences in estimates are consistent with reports by nurse case managers that a small number of participants in New York City spent their winter months outside New York State, and therefore were not available for televisits during that time. However, other factors probably are more important determinants of the difference in the number of televisits between the two sites. Although the average duration of a televisit (27 minutes) was within the planned duration for routine follow-up visits (between 15 and 30 minutes), the nurse case managers often spent some part of their televisit time during the second and third years of the demonstration addressing participants' concerns about the HTUs, rather than managing the participants' diabetes. It is unclear whether the nurse case managers' diversion to address technical issues limited the participants' exposure to the intervention.

Consortium staff believe that IDEATel is bridging the digital divide, and that the intervention was acceptable to participants, but a sizeable minority dropped out of the demonstration and most used only the basic functions of the system.

During their interviews, Consortium staff expressed the belief that the delivery of the IDEATel technology to a large number of homes in underserved communities represented a tremendous step forward in bridging the so-called *digital divide*. Even though the demonstration did deliver the IDEATel technology to 794 participants in medically underserved communities, it was not wholly successful in achieving this goal. Consortium staff also interpreted the fact that a large number of participants used several HTU functions as strong evidence that the technology was acceptable (Starren et al. 2003). However, the available evidence suggests that some participants may have found the technology unappealing; about seven percent refused to have HTUs installed in their homes and six percent dropped out of the study because they found the system difficult to use. Moreover, steep learning curves discouraged half of them from learning to use the more complex functions.[5] Although the high frequency with which participants measured their blood pressure and blood sugar suggests that the intervention has the potential to produce positive changes in clinical outcomes, in its current form, the HTU's effectiveness as a medium for delivering intensive nurse case management to a large number of Medicare beneficiaries with limited education remains unclear.

[5]Based on an analysis of an early cohort of participants (those whose HTUs were installed between December 2000 and November 2001), only between 6 and 35 percent of participants took less than one year to use the more complex functions, such as entering medications or consulting the American Diabetes Association web pages (Moreno et al. 2003).

The Consortium developed a physicians' syllabus about telemedicine and held a webcast for participating physicians.

The Consortium began work on the congressionally mandated objectives of physician education and development of telemedicine standards in 2002 (Columbia University 2003h). It developed a physicians' syllabus about telemedicine that was posted on the demonstration's website in early 2003, about two and a half years after the first participants were recruited. The Consortium reported that it notified all participating physicians about the existence of this practical guide on telemedicine. In addition, the Consortium held a webcast for participating physicians on April 22, 2003. The webcast offered continuing medical education credit.

The Consortium implemented the demonstration in managed care and fee-for-service environments.

Another mandated demonstration objective was to develop a "model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment." The Consortium's approach to meeting this objective was to enroll eligible Medicare beneficiaries in the demonstration regardless of whether they were enrolled in a Medicare managed care plan or in fee-for-service Medicare. Given the limited number of managed care plans operating in upstate New York, it probably would not have been possible for the Consortium to test whether the model was equally effective in managed care and fee-for-service environments (and the mandate does not explicitly require this test). Using Medicare enrollment data, MPR estimated that only about five percent of demonstration enrollees were enrolled for at least one month in managed care during the follow-up period. Thus, it was not possible to examine differences in how the demonstration was implemented in managed care and fee-for-service environments.

IDEATel had favorable effects on enrollees' diabetes care and communication with health care providers about their diet and care. However, it affected the self-efficacy of upstate enrollees only.

In both the New York City and upstate sites, the IDEATel intervention had large, positive effects on whether enrollees consulted with diabetes nurse educators or dietitians (including IDEATel's case managers) at least once since baseline, as well as on whether they tested their blood sugar daily. Upstate, the intervention increased the frequency of health care providers' discussions with enrollees about diet and exercise, and it improved enrollees' self-confidence in their ability to control their diabetes during the coming year (that is, their *self-efficacy*). However, it did not improve adherence to diet or exercise regimens. In New York City, the intervention resulted in an increase in the number of discussions that enrollees had with health care professionals, and somewhat better adherence to exercise regimens. However, it had no significant impacts on enrollees' views or beliefs about controlling their diabetes.

IDEATel had somewhat favorable effects on use of recommended medications among enrollees with baseline indications for treatment and, in some instances, more aggressive dosing and number of medications per enrollee.

In both sites, among enrollees with baseline indications for treatment (that is, elevated cholesterol levels, protein in the urine, high blood pressure, and poorly controlled blood sugar), intervention group members were somewhat more likely to have been prescribed appropriate medications than control group members, although most of these differences were not statistically significant because of small sample sizes. In the upstate site, among enrollees with poorly controlled blood sugar at baseline and prescribed insulin, treatment group members were treated more aggressively, as indicated by a higher average daily dose of insulin. However, the intervention had no effect in either site on the prescription of antiplatelet drugs, which are generally recommended for all persons with diabetes.

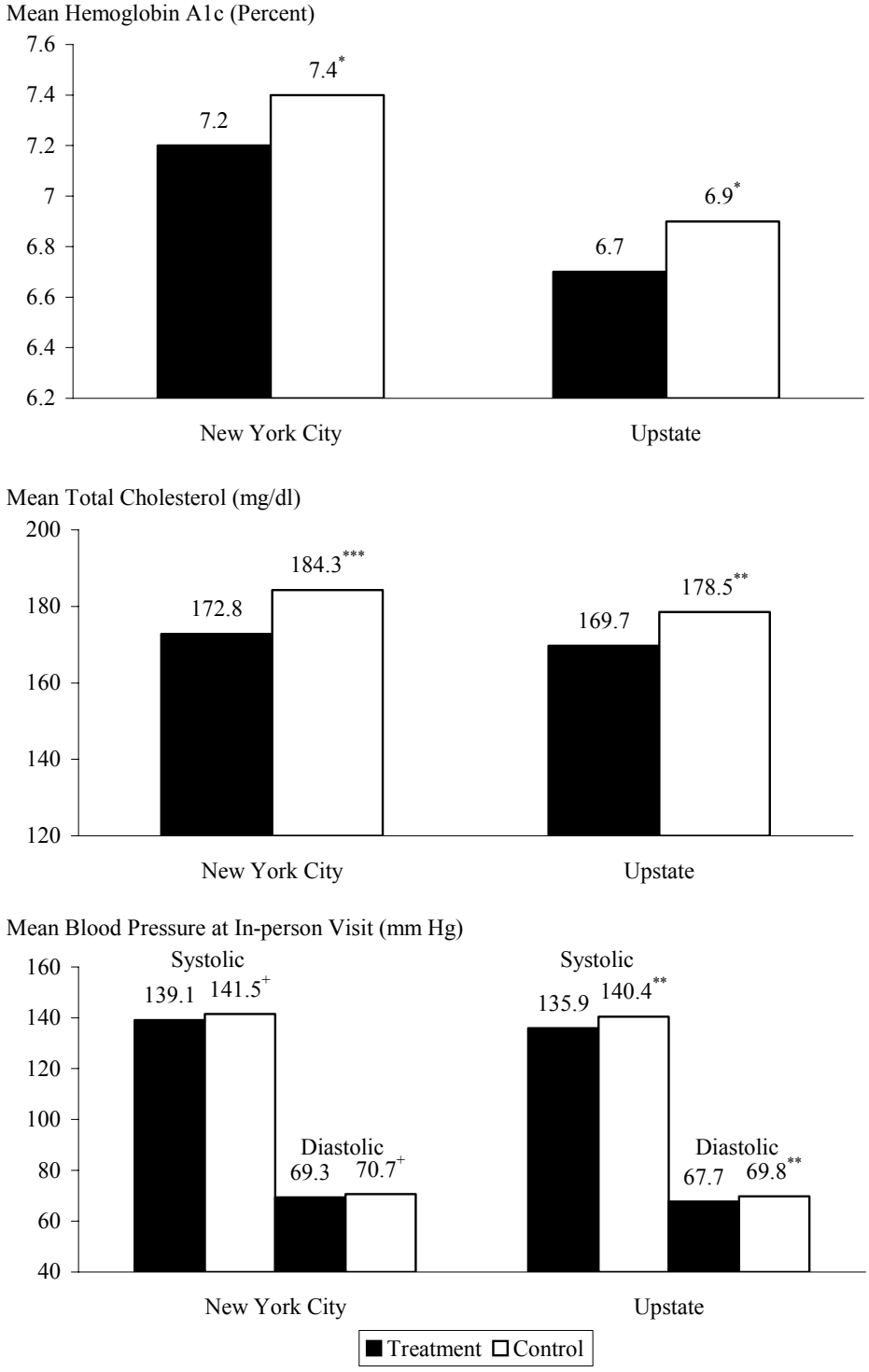
IDEATel had impacts on three key clinical measures.

The intervention had substantial, and statistically significant, favorable impacts on diabetes control and lipid levels at followup in both the New York City and upstate sites. In both sites, enrollees' blood sugar control was better than the control group's, and enrollees' average cholesterol level was about five to six percent lower than the control group's (Figure 4). A supplemental subgroup analysis showed that, in the upstate site only, the intervention led to a greater improvement in blood sugar control among participants whose blood sugar was more poorly controlled at baseline, than among those with better controlled blood sugar at baseline. The intervention also had impacts on the in-person blood pressure measurements, but more so in the upstate site. In the New York City site, enrollees' means were two percent less than the control mean for systolic and diastolic blood pressure, whereas differences in the upstate site were about three percent of the control mean for both systolic and diastolic blood pressure, and were highly significant. The Consortium had prespecified these three outcomes-diabetes control, lipid levels, and blood pressure control-as the main study outcomes.

The intervention had no clearcut effects in either site on several other important clinical outcomes. These included the ratio of microalbumin to creatinine (an indicator of diabetic kidney damage), 24-hour blood pressure measurements, and anthropometric measurements (such body mass index and waist to hip ratio).

FIGURE 4

IDEATel's IMPACTS ON KEY CLINICAL OUTCOMES



Source: IDEATel Year 1 in-person interview, laboratory measurement,and blood pressure measurement, conducted between December 2001 and October 2003 (Columbia University 2003d).

+ p<.10 * p<.05 ** p<.005 *** p<.001

IDEATel had limited impacts on the wide variety of health-related quality-of-life outcomes.

IDEATel may have had small, isolated effects on some of the numerous self-reported health-related quality-of-life outcomes, but in neither site did it have any major or broad-based impacts on these indicators. Likewise, the treatment and control groups in both sites were similarly satisfied with the health care professionals who cared for their diabetes.

It may be that treatment–control differences in quality-of-life measures will appear with longer followup. Prolonged control of the risk factors of diabetes over several years should help to prevent the visual, vascular, neurologic, and renal complications of this condition, which, in turn, should help enrollees to feel better than they would otherwise.

IDEATel has the potential to reduce the long-term complications of diabetes, assuming it can sustain its effectiveness over time.

The intervention demonstrated some positive effects on clinical indicators and, assuming it can sustain its effectiveness over time, has the potential to reduce the long-term complications of diabetes. The effects of IDEATel on the long-range outcomes of interest (that is, morbidity and mortality from diabetes) are unknown and can be projected only under a set of assumptions that may not be satisfied.

The demonstration did not generate savings in Medicare expenditures and was expensive to implement. The first phase of the demonstration cannot be considered cost-saving.

The implementation costs of the IDEATel demonstration were high (between $8,284 and $8,924 per participant per year, depending on the length of depreciation of the demonstration's design and HTU-removal costs). They exceeded the enrollees' total Medicare expenditures for all Part A and Part B services and were several times greater than the reported costs of other telemedicine and nurse case management interventions for people with diabetes. For several

reasons, the demonstration's implementation costs per participant may be higher than would have been observed in an ongoing telemedicine program operating at a larger scale. These reasons include the development and maintenance of a system designed for a demonstration serving medically underserved beneficiaries with limited computer experience, the lack of scale economies given the number of participants enrolled in the demonstration, the higher costs of living in New York City than in most areas of the country, and the extra costs to coordinate the intervention and research activities. Therefore, refinements to the demonstration's implementation may result in substantial decreases in cost per participant.

The intervention did not reduce the Medicare expenditures of treatment group members relative to those of control group members in either site (Table 4). This finding is not surprising, given that IDEATel did not reduce the level of service use. In fact, Medicare expenditures were higher (though not significantly so) for the treatment group, which may well have resulted from IDEATel meeting the latent demand for appropriate health services among medically underserved beneficiaries. When the demonstration's cost per participant is added to the Medicare expenditures of the treatment group members, the treatment group's costs are about two and one-half times larger than the control group's costs.

Thus, based on findings from the experience of enrollees through December 2003, the demonstration is far from being cost-saving. In fact, even if Medicare expenditures were eliminated by the intervention, the treatment group's costs would exceed the control group's costs in both sites.

TABLE 4
ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, BY SITE AND EVALUATION GROUP
(Means, in Dollars)

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Total Medicare	10,039	9,239	800 (.474)	7,969	6,832	1,137 (.127)
Medicare Part A	5,617	4,814	803 (.392)	4,208	3,545	663 (.261)
Medicare Part B	4,422	4,425	–3 (.992)	3,761	3,287	474 (.047)
Hospitalization	5,104	4,408	696 (.421)	3,680	3,001	679 (.200)
Skilled Nursing Care	270	180	90 (.436)	295	311	–16 (.874)
Emergency Room	86	79	7 (.482)	111	101	10 (.525)
Outpatient Hospital	1,226	1,259	–33 (.820)	864	687	177 (.064)
Home Health Care[a]	663	617	46 (.698)	309	302	7 (.926)
Durable Medical Equipment	342	323	19 (.774)	570	439	131 (.026)
Physician Office Visits	396	422	–26 (.336)	283	266	17 (.292)
Laboratory Services[b]	46	53	–7 (.397)	46	42	4 (.620)
Other Part B[c]	1,905	1,896	9 (.951)	1,759	1,619	140 (.356)
Sample Size[d]	**372**	**355**	**—**	**445**	**443**	**—**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c).

Notes: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the follow-up period (December 2003), and weighted by the length of the interval between randomization and December 2003 (see Appendix F). Means were predicted with linear regression models, which controlled for enrollees' baseline characteristics and outcomes. (See Appendix F, Section C, for the list of characteristics.)

The sum of Medicare costs, by type of service, is not equal to the total Medicare costs (or to the Part A or Part B components) because the list of services is not exhaustive.

[a]Includes both Part A and Part B expenditures.

[b]Refers to services rendered by a certified laboratory independent of an institution or a physician office.

[c]Refers to Part B-covered services, such as other physician services (for example, hospital visits, ophthalmology, and pathology); imaging services; laboratory services not independent of an institution or a physician office; minor procedures; medical supplies; therapy; and ambulance services.

[d]Refers to all enrollees in the study.

n.a. = not applicable.

Longer followup of demonstration enrollees will address whether IDEATel will show savings on Medicare costs in the long run.

As of the end of Phase I, the question remains as to whether the demonstration would begin to show savings in Medicare expenditures (exclusive of demonstration costs) if the enrollees were *followed for a longer period*. If it does not, the questions are whether the improvements in outcomes of treatment group members are worth the high costs of the intervention, and whether other disease management or care coordination interventions could have a similar clinical impact at a substantially lower cost. However, given the design of the demonstration, it will be difficult to compare IDEATel against other policy options, such as conventional nurse case management or nurse case management with less-sophisticated technological support. Other studies suggest that these simpler interventions can achieve impacts similar to or larger than those observed in IDEATel at substantially lower cost.

Congress extended the demonstration for four more years. The Consortium faces several logistical and technical challenges, which also may become challenges to the independent evaluation.

The Consortium's leadership requested, and has received, an extension to the demonstration for four additional years.[6] (The Consortium considers the initial four-year period of the demonstration as Phase I, and the extension as Phase II.) The Consortium has prepared a scope of work for the extension (Columbia University 2004b). It has re-enrolled more than half of the 1,247 Phase I treatment or control group enrollees who completed the Year 2 in-person interview

[6]The demonstration's second phase started on February 28, 2004.

(Columbia University 2004b, 2004c, and 2005).[7] Moreover, the Consortium has resumed televisits to participants in New York City (and continued them for participants in upstate New York). The extension will allow tests of whether following Phase I enrollees for much longer periods (two to six years) will show demonstration effects on several health outcomes, service use, and Medicare expenditures. In addition, the Consortium has begun enrolling, and randomizing, up to 400 new, Phase II-eligible Medicare beneficiaries in both sites.

One difficulty that the Consortium could face in implementing Phase II of the demonstration is that the legislation to authorize the extension was delayed in Congress for many months before passage. The Consortium's ability to continue the demonstration as implemented in Phase I in New York City, where Phase I operations ended in October 2003, may be limited by loss of enrollee interest during the interim, and by increased rates of enrollee drop out due to death or advancing illness (during Phase II). Moreover, from the evaluator's standpoint, IDEATel's extension may result in insufficient statistical power for detecting modest demonstration impacts on some survey-based outcomes at the end of the second phase because Phase I and Phase II cohorts cannot be pooled for analysis.[8]

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[7]This implies that, for conducting an *intention-to-treat analysis* (as originally proposed by the Consortium) of Medicare-covered services and expenditures, the impact analysis will estimate the treatment-control difference in outcomes for the original cohort of 1,665 enrollees and not only for the 1,247 enrollees who completed the Year 2 interview.

[8]This is primarily due to the differences in the stage of implementation of the demonstration when these two cohorts were randomized and began receiving the intervention.

CONCLUSIONS

The Consortium implemented a demonstration that both responded to the congressional mandate and addressed numerous design and implementation challenges. The intervention had positive impacts on several key clinical outcomes, but it had no impact on Medicare service use or expenditures over the three-year period examined. Furthermore, demonstration costs were high, exceeding the costs of all Medicare-covered services for enrollees. Thus, Phase I of the demonstration increased costs to CMS, and the high costs of the intervention per participant suggest that even complete elimination of all Medicare expenditures would lead to a net increase in expenditures.

As of this point of the evaluation, several factors limit the ability of MPR to draw policy-relevant conclusions:

- Results are available only for the first year after enrollment (with end-of-Year-2 data recently completed). Thus, if the intervention must operate for several years before effects on health outcomes and Medicare service use and expenditures appear, as seems likely for diabetic patients, a longer followup is necessary.
- Phase I of the demonstration was not designed to provide evidence on the marginal benefit of each of the intervention's components—that is, use of the HTU or interactions with the nurse case managers. Thus, MPR cannot determine whether the clinical impacts of the demonstration resulted from the telemedicine intervention, the intensive nurse case management, or both components.
- The demonstration's high implementation costs, together with the impossibility of separating the effects of the HTU from the effects of the intensive case management component, make it difficult to discern with certainty which of the intervention components would be most promising for the Medicare program. Thus, even if some cost savings appear over a longer followup, this evaluation will not be able to provide CMS with the critical information necessary to assess whether a less expensive version of this demonstration could produce sufficient Medicare savings to offset demonstration costs.

I. BACKGROUND AND PURPOSE OF THE REPORT

This is the second report to Congress about an independent evaluation of a large demonstration of home-based telemedicine services in New York State. It updates a report about early implementation experiences, submitted to Congress in spring 2003, and draws overall conclusions about the impacts of the demonstration during its first four years (hereafter, the *first phase* of the demonstration or *Phase I*) (U.S. Department of Health and Human Services 2003). The demonstration, as mandated by Congress, targets Medicare beneficiaries with diabetes who reside in medically underserved areas. This population is particularly likely to face substantial barriers to appropriate, timely care for this chronic condition. Telemedicine services offer the possibility of reducing these barriers, and of increasing the cost-effectiveness of diabetes care for the demonstration's target population. However, the target populations' generally low levels of education are a serious obstacle to the technology's success.

A. POLICY CONTEXT

Improving access to care and increasing the quality of care for underserved Medicare beneficiaries with diabetes are important policy objectives of the Medicare program. Diabetes is a leading cause of mortality, morbidity, and health care costs among older Americans (American Diabetes Association 2002a). Some of the serious health complications of the disease are loss of vision, kidney failure, nerve damage, coronary artery disease, cerebrovascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections (American Diabetes Association 2002b; and Nathan 1993). Fortunately, appropriate management and regular monitoring of people with diabetes can delay or avert the onset of many of these complications (American Diabetes Association 2002c).

Medicare beneficiaries who have diabetes and who live in medically underserved inner-city or rural areas are likely to have poor access to high-quality diabetes care. These areas, by definition, have an inadequate supply of health care providers, and their geography and lack of affordable transportation, primarily in rural areas, present additional barriers to access to medical care. The disproportionate incidence and severity of diabetes in minority senior populations, which represent a large share of the population living in underserved areas, compounds the effects of these barriers (Health Resources and Services Administration 2004). For example, both African Americans and Hispanics/Latino Americans have much higher rates of diabetes than do white Americans (Carter et al. 1996; Harris et al. 1998; and National Institutes of Health 1997), and much greater risks of severe complications and death (Carter et al. 1996; Gu et al. 1998; Harris 2001; Karter et al. 2002; and Resnick et al. 1999). Therefore, serving the populations with the greatest need of frequent medical attention for the monitoring and care of their diabetes is a major goal for the Medicare program.

Telemedicine, the use of telecommunications technology to deliver medical diagnostic, monitoring, and therapeutic services to health care users and providers who are separated geographically, may be a promising means of reducing access barriers for chronically ill Medicare beneficiaries. In particular, home telemedicine allows for regular health monitoring from, and delivery of care (such as early detection of health problems) to, people's homes. Potentially, such improved access to care could prevent the future need for the costly treatment of medical complications. To date, however, little hard evidence exists to demonstrate either the effectiveness or cost-effectiveness of home telemedicine.

B. CONGRESSIONAL MANDATES TO DEMONSTRATE AND EVALUATE TELEMEDICINE

To address the dearth of rigorous evidence about the effectiveness of telemedicine services for Medicare beneficiaries, Congress included in the Balanced Budget Act of 1997 a mandate for a demonstration project to test whether telemedicine networks and services can improve primary care for Medicare beneficiaries with diabetes mellitus. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 subsequently amended this mandate by clarifying that the target population should reside in medically underserved areas and by prohibiting cost sharing for demonstration services.[9]

Congress specified the following key aspects of the demonstration:

- ***Objectives of the Demonstration.*** The congressional mandate emphasizes that the demonstration should improve the access of beneficiaries with diabetes mellitus to care, adherence with appropriate guidelines, improve the beneficiaries' quality of life, and reduce costs. The mandate specifies the demographic characteristics of the target population of potentially eligible beneficiaries. It also emphasizes:
  - The development of a curriculum to train health professionals to use telemedicine services
  - The development of standards for the application of telemedicine services
  - The use of advanced telecommunication technologies in the provision of primary care services
  - The development of cost-effective delivery models of primary care services in the managed care and fee-for-service environments
- ***Type of Organization to Conduct the Demonstration.*** Congress also specified the nature of the organization to implement the demonstration, the organization's location relative to medical schools and tertiary care facilities, and the organization's responsibilities in conducting the demonstration.

[9]See Appendix A for copies of both laws.

- ***Services Covered by the Demonstration.*** The congressional mandate specified the allowable and unallowable costs of Medicare services to be provided under the demonstration.
- ***Budget for the Demonstration.*** Congress specified that $30 million would be available for the demonstration and its evaluation.
- ***Evaluation of the Demonstration.*** Congress required an evaluation of the demonstration that would assess the impact of the use of telemedicine on improving Medicare beneficiaries' access to health care services, reducing the costs of those services, and improving the quality of life of the beneficiaries.

The legislation also specified that interim and final evaluation reports be submitted to Congress. Although Congress did not specify a schedule for the interim reports, it required that the final report should be submitted within six months of the demonstration's conclusion. The law originally required that the demonstration be completed within four years. However, in fall 2003, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress authorized an extension of the demonstration for four more years and added $30 million to the budget for the demonstration and the evaluation.[10] This legislation did not modify any other aspect of the original authorization of the demonstration. Therefore, the schedule for the delivery of the final report has been delayed by four years; that report is due to Congress in August 2008.

C. PURPOSE OF THIS REPORT

This is the second interim report to Congress about the mandated evaluation of the demonstration, which a consortium led by Columbia University is operating. The Centers for Medicare & Medicaid Services (CMS) contracted with Mathematica Policy Research, Inc.

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[10]Appendix A also includes a copy of the legislation authorizing the extension of the demonstration.

(MPR) to perform the mandated evaluation independently of this consortium, although the consortium also is conducting its own internal evaluation. The mandated evaluation began 7 months after the award of the demonstration cooperative agreement, and its first phase will last 55 months. MPR also will evaluate the second phase of IDEATel; the evaluation of Phase II began on September 2004 and will last 48 months.

The current report updates the first report, submitted to Congress in spring 2003 (U.S. Department of Health and Human Services 2003). The first interim report examined the original design of the demonstration, the evolution of the demonstration, and the challenges that the consortium encountered while implementing the demonstration during the first 21 months of the project. The current report addresses the three major questions laid out in the legislation that mandated the demonstration: (1) whether the demonstration was implemented as intended by Congress; (2) whether participants used the technology through which the intervention was delivered; and (3) whether the demonstration had impacts on access to care, behavioral and physiologic outcomes, health services use, Medicare costs, quality of life, and satisfaction with care. The findings are based on data collected by the independent evaluator during telephone interviews in fall 2002 and fall 2003 with the consortium's leadership and with consortium staff who were involved with various aspects of the demonstration. This report also relies on data on clinical indicators and patient satisfaction that the consortium collected through summer 2003, as well as on Medicare enrollment and claims data for the period 1999-2003.[11] Finally, the report

[11]See Appendix B for a description of the study methodology.

synthesizes findings from the first interim report and presents conclusions about the first phase of the demonstration.

The report contains six chapters. Chapter II provides an overview of the demonstration and examines the way in which the consortium implemented the demonstration during its first phase, including the challenges to the demonstration's design and implementation that the consortium encountered, and the policy implications of those challenges. Chapter III summarizes the participants' use of the telemedicine technology that delivered the intervention. Chapter IV presents impact estimates on clinical, behavioral, and other health-related outcomes (including the use of Medicare-covered services). Chapter V focuses on the estimation of demonstration costs, using data collected by the consortium and by the independent evaluator, and estimates the impact of the demonstration on Medicare costs. Chapter VI summarizes the independent evaluation's findings on the implementation of the demonstration, use of the technology, and the demonstration's impacts on key outcomes during the first phase. It also draws conclusions from those findings and highlights their policy implications.

II. IMPLEMENTATION FINDINGS

Highlights of Findings

- The consortium successfully implemented the first phase of the demonstration. It recruited 1,665 eligible beneficiaries, installed home telemedicine units in 794 participants' homes, and conducted more than 11,000 televisits. During implementation, the consortium overcame numerous challenges, both large and small.
- The demonstration's higher-than-expected dropout rate among treatment group members raises the possibility that some of these participants may have found the intervention unappealing. Moreover, many participants did not receive as much of the intervention as planned in terms of either frequency or content.

This chapter provides an overview of the demonstration referred to as the Informatics for Diabetes Education and Telemedicine (IDEATel). The information presented in this chapter comes from data collected by the independent evaluator during in-person and telephone discussions with demonstration staff in 2001, 2002, and 2003, and from documents prepared by the consortium implementing the demonstration.[12]

Analysis of the demonstration's implementation finds that, although the demonstration was implemented successfully, the following five major challenges limit the ability of the independent evaluator to estimate the demonstration's impacts with much precision: (1) changes in the way that the intervention was delivered resulting from hardware and software difficulties, (2) delays in enrolling eligible Medicare beneficiaries, (3) uneven participant exposure to the

[12]See Appendix B, Table B.2, for a list of the demonstration staff interviewed in each year.

intervention, (4) the higher-than-expected enrollee dropout rate, and (5) changes in the demonstration's timeline.[13] A detailed discussion of these challenges follows.

A. DEMONSTRATION OVERVIEW

On February 28, 2000, CMS entered into a four-year, $28 million cooperative agreement with Columbia University to conduct the IDEATel demonstration. Columbia University assembled a consortium consisting of three types of organizations (hereafter referred to as the *Consortium*) to implement the demonstration: (1) ***core organizations*** that were responsible for the demonstration's design and implementation; (2) ***affiliated organizations*** that provided technical expertise or were sources of potential enrollees; and (3) ***subcontractors*** that provided hardware and software, trained enrollees, or provided technical support.[14]

The demonstration targeted Medicare beneficiaries with diabetes living in federally designated medically underserved areas and primary care health professional shortage areas in two sites in New York. The New York City site (led by Columbia University) enrolled enrollees from northern Manhattan and the Bronx. The upstate New York site (led by SUNY Upstate Medical University) enrolled Medicare beneficiaries from a 30,000 square mile area in upstate New York. The demonstration randomly assigned beneficiaries in each site equally to either the treatment group or the control group, with enrollment balanced between the two sites.

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[13]A detailed description of early implementation challenges and changes was presented in the first interim report to Congress (U.S. Department of Health and Human Services 2003).

[14]See Appendix C, Table C.1, for a list of Consortium members as of December 2003.

The demonstration had clinical goals as well as behavioral goals for participants and their physicians.[15] The three primary clinical goals were (1) control of blood sugar; (2) reduction or control of risk factors, such as smoking, obesity, physical inactivity, high blood pressure, and abnormal lipid levels; and (3) regular provision of preventive care.[16] To accomplish these goals, the demonstration sought to increase the frequency with which participants monitored their blood pressure and blood sugar, improve participants' adherence to medication regimens, increase the rate at which participants kept medical appointments, promote smoking cessation and weight loss, improve participants' diets, and increase the amount and frequency of participants' exercise. The demonstration's goals for physicians were to improve the quality of care provided by ensuring that the care was as consistent as possible with the recommendations of clinical practice guidelines. To implement its multi-pronged approach, the Consortium developed an intervention that provided remote clinical monitoring, videoconferencing, and web-based consulting. Figure II.1 illustrates the relationships among the components of the intervention.

The Consortium recruited eligible Medicare beneficiaries for the demonstration by seeking referrals from primary care physicians, rather than by approaching potential enrollees directly. This strategy enabled the demonstration to build relationships with the physicians, thereby increasing the likelihood that the physicians would follow the patient care recommendations generated by the demonstration's nurse case managers. In addition, this strategy was expected to

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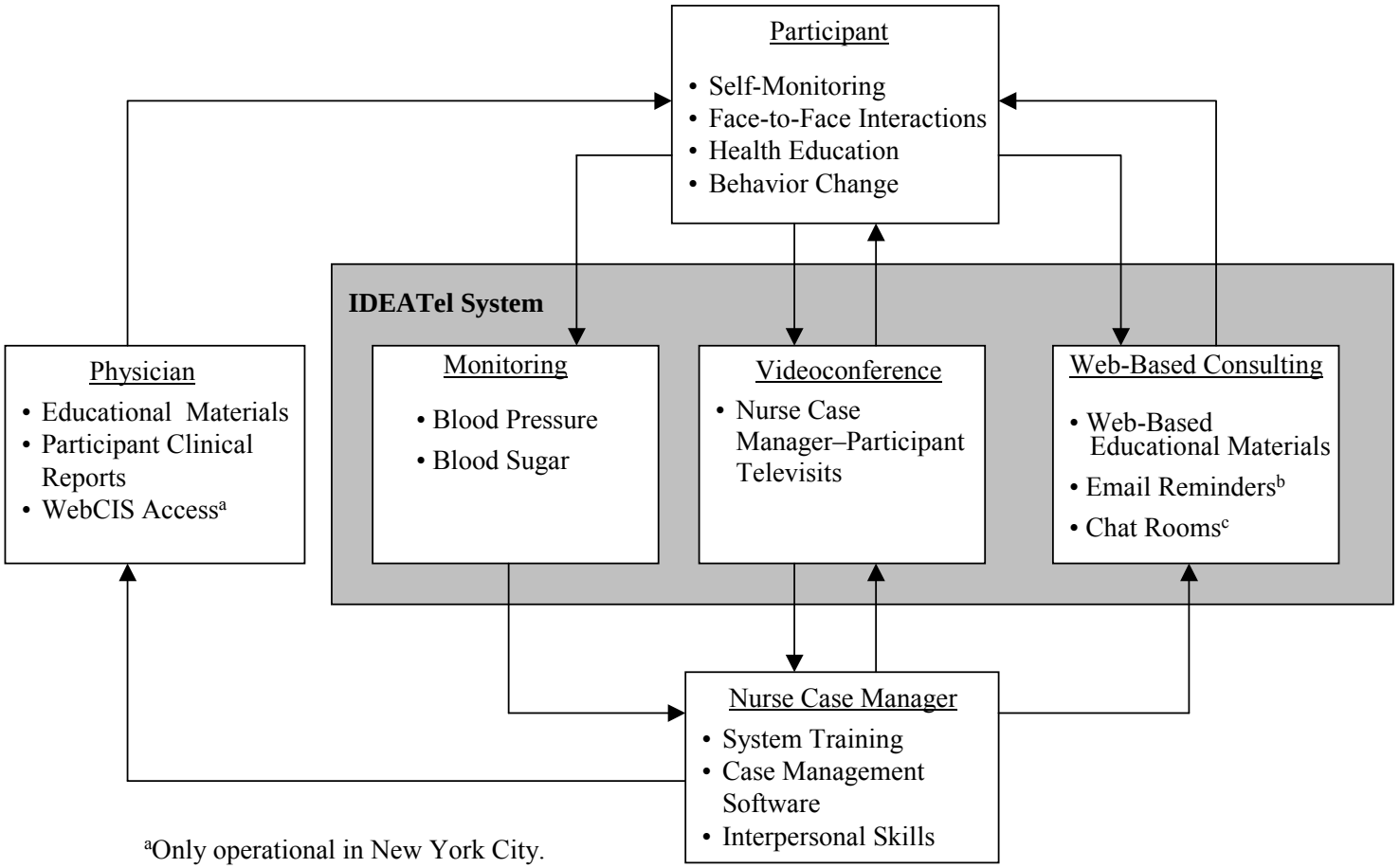
[15]An enrollee is an eligible Medicare beneficiary enrolled in the demonstration. A participant is an enrollee in the treatment group, regardless of whether he or she received the intervention and used the services offered.

[16]The key clinical outcomes of the demonstration are glycosylated hemoglobin level and blood pressure level.

FIGURE II.1

THE IDEATel SYSTEM INTERVENTION



[a]Only operational in New York City.

[b]Email reminders were not systematically implemented in the upstate site.

[c]Chat rooms were not implemented in either site.

Source: Synthesis from Columbia University (1998) and other demonstration materials.

WebCIS = Clinical Information System, Columbia-Presbyterian Medical Center, New York.

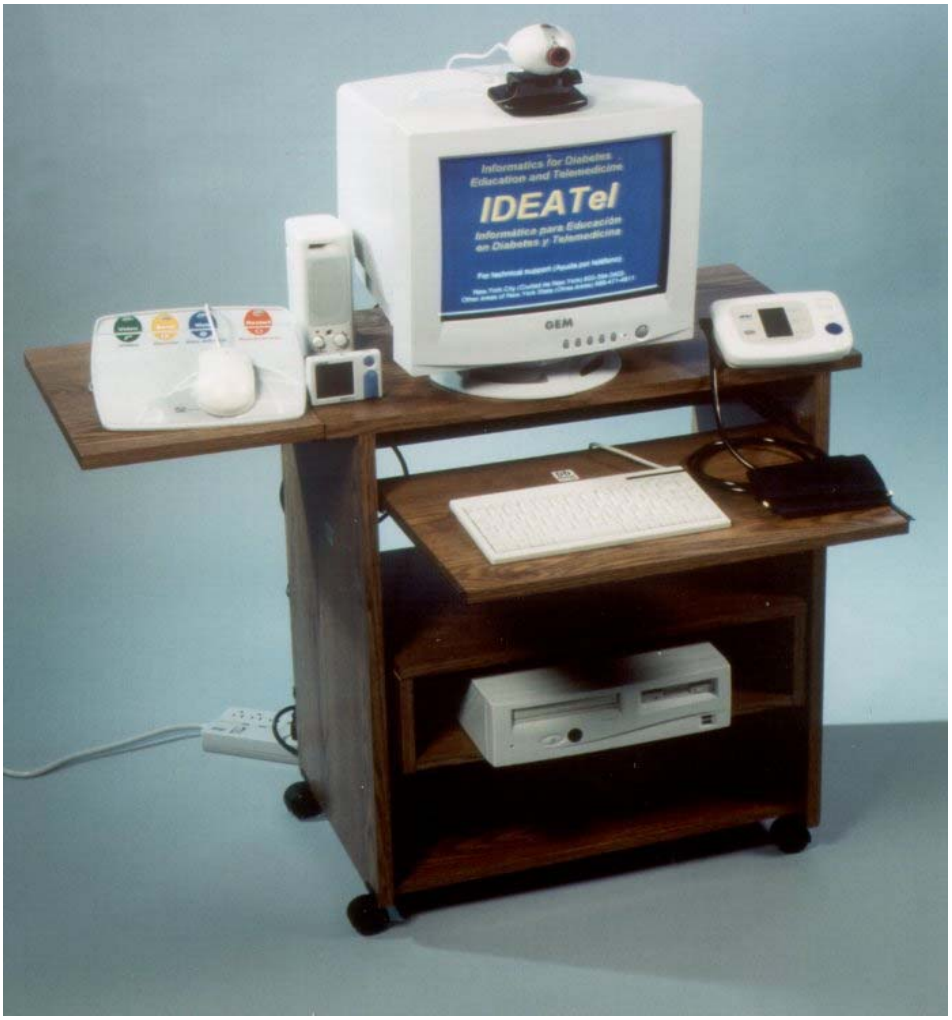
be more acceptable to potential enrollees, who would be more likely to respond to their primary care physicians' recommendation to enroll in the demonstration than to respond to a recruitment letter or telephone call from someone they never had contact with before. As mandated, the demonstration targeted Medicare beneficiaries with diabetes mellitus residing in medically underserved rural and inner-city areas in New York State. In addition, the Consortium developed inclusion and exclusion criteria to ensure that potential enrollees were physically and cognitively able to participate in the telemedicine intervention (U.S. Department of Health and Human Services 2003).

Beneficiaries randomized to the treatment group received a home telemedicine unit (HTU) and diabetes care management provided by a nurse case management team.[17] The HTU consisted of a personal computer with audio/video communication capabilities and devices for measuring blood sugar and blood pressure (Figure II.2). Enrollees in the treatment group used the HTUs to monitor their blood pressure and blood sugar, and to transmit these measurements to their nurse case managers. In addition, they and their nurse case managers used the HTUs to communicate via audio/video conferencing (televisits) and electronic mail. The participants also were instructed in how to use their HTUs to access web-based features of the intervention, such as educational materials and chat rooms accessible only to other participants. Control group beneficiaries received their usual care from their primary care physicians. They did not have HTUs, nor did they have any contact with the nurse case managers. As designed, the

[17] In New York City, a nurse case manager and a supervising endocrinologist formed the case management team. In the upstate site, a diabetes nurse educator and dietitian, a nurse case manager, and a supervising endocrinologist formed the team.

FIGURE II.2

IDEATel's HOME TELEMEDICINE UNIT



Source: Starren et al. (2003).

demonstration's goal was to answer the question of whether telemedicine, by providing intensive nurse case management services *that enrollees would not otherwise be able to receive in the medically underserved areas in which they resided* (emphasis added), improves clinical and other health outcomes (Columbia University 1998; and Shea 2002).

B. MAJOR CHALLENGES TO AND CHANGES IN THE DEMONSTRATION

The Consortium successfully implemented the first phase of the IDEATel demonstration. It enrolled 1,665 eligible Medicare beneficiaries, installed 794 HTUs in participants' homes, and conducted more than 11,000 televisits.[18] However, the Consortium faced numerous challenges, both large and small. Some were relatively simple to resolve; others required changes in the demonstration's design.[19] This section discusses five major challenges in the implementation of the demonstration that may have affected the Consortium's ability to achieve its intended effects.

1. Changes Due to Hardware and Software Difficulties

The telemedicine system used to deliver the demonstration's clinical intervention had four primary functions: (1) monitoring clinical measurements, (2) videoconferencing, (3) consulting web-based materials, and (4) securing provider-participant communications and data transmission. To support these functions, the Consortium installed in participants' homes HTUs consisting of a personal computer with internal modem, video camera, speakers, a microphone, web-browsing software, a glucose meter, and a blood pressure meter. The system included web-

[18]Section B.1 of Appendix B provides details about the number of participants in the treatment group who had an HTU installed in their homes.

[19]Appendix C, Table C.2, provides a more comprehensive list of implementation challenges and describes the timing and method of their resolution.

based educational materials from the American Diabetes Association, displays of trends in the participants' blood pressure and blood sugar in graph format, and tools to help participants to set exercise goals or other lifestyle changes.[20] Participants used the HTUs to transmit clinical data to and engage in televisits with their nurse case managers. The nurse case managers used case management software to document participants' progress between televisits, care plans, and follow-up monitoring contacts. Data security features ensured the confidentiality of all participants' clinical data and authenticated the identities of all users accessing the system (and was HIPAA [Health Insurance Portability and Accountability Act] compliant throughout).

The Consortium originally planned to use an all-in-one home telemedicine device available from its subcontractor, American TeleCare, Inc. However, by the start of the demonstration (February 2000), American TeleCare had stopped supplying this device. With no other product available to meet its needs, the Consortium quickly had to create a new HTU, using off-the-shelf components (a personal computer with a separate monitor and keyboard). Within 10 months of the demonstration's startup, the Consortium had redesigned the HTU, addressed compatibility issues with another vendor's case management software, and was ready to install the HTUs in the homes of the first demonstration participants.

Although the Consortium was able to overcome this early challenge, the changes made to the technical design created several new challenges that may have had lasting effects on the demonstration. First, the new HTU was considerably bigger than originally planned. The

[20]As planned, the system was to contain chat rooms and bulletin boards, but these features were never implemented fully.

Consortium found that it had to purchase computer carts to hold all the equipment, and to conceal wires and cords to prevent participants from tripping on them. Consortium staff reported that some participants objected to having such a large object in their homes. Some of these participants refused to have the HTU installed.

Second, the use of a personal computer made HTU operation more difficult than it would otherwise have been. To simplify the operation of the personal-computer-based HTU, the Consortium developed a four-button *launch pad* (Figure II.3). The four buttons enabled participants to (1) answer video calls from the nurse case managers, (2) electronically transmit blood pressure and blood sugar readings, (3) connect to the demonstration's website, and (4) restart or reboot the computer. The replacement of the simpler system with a personal-computer-based HTU may have created barriers to use of the technology for many participants who were functionally illiterate or had little or no experience with computers.

Finally, the Consortium had to resolve problems with the HTU's software. For example, incompatibilities between the software used by the HTUs and the case management software made it difficult for participants to navigate the HTU's web-based screens. In addition, the HTU's display did not alert participants to the status of their clinical data transmissions; consequently, some participants' blood pressure and blood sugar data were lost because the participants mistakenly shut off the HTUs before the data transmissions were complete. The problems, which probably were unrelated to the change in the HTU's platform, were discovered as the demonstration progressed. Although they eventually were resolved, they may have undermined participants' confidence in their ability to use the HTU, particularly if the participants believed that their difficulties were the result of their own lack of computer skills.

FIGURE II.3

HTU LAUNCH PAD

Source: Starren et al. (2003).

HTU = home telemedicine unit.

2. Delays in Enrolling Eligible Medicare Beneficiaries in the Demonstration

The Consortium initially planned to enroll 1,500 eligible Medicare beneficiaries between December 2000 and August 2001 (750 enrollees in each site equally divided between treatment and control groups) (U.S. Department of Health and Human Services 2003). In addition, the Consortium had anticipated that there would be an interval between the award of the cooperative agreement and the actual start of funding, and it had planned to initiate some tasks during that period, such as applying for institutional review board approvals. However, the start of the funding was concurrent with the award agreement. The lack of this interval posed substantial challenges to the Consortium, primarily with regard to the schedule for participant enrollment and the startup of the intervention.

As noted, the Consortium's initial recruitment strategy was to invite primary care physicians to take part in the demonstration, and to then ask the participating physicians to refer patients. According to Consortium staff, although they first contacted physicians with whom they had existing relationships, they still had to devote considerable time and effort to convincing the physicians to participate. Furthermore, before they could contact potential enrollees, the Consortium was required to obtain the approval of the institutional review boards of the hospitals in which the physicians practiced. Additional hurdles included difficulties identifying sufficient eligible Medicare beneficiaries and a higher-than-expected refusal rate among that group of beneficiaries. As a result, recruitment of enrollees, which took longer than expected, could not be completed by August 2001, as originally planned.

The Consortium responded to the higher-than-expected dropout rate during the first year of enrollment by increasing the target sample size by about 10 percent in winter 2002. The Consortium also extended the enrollment period to meet the new enrollment target, and to give

additional hospitals and physician practices in upstate New York sufficient time to join. In addition to enabling the Consortium to enroll the number of enrollees it deemed necessary given the design, the extension generated considerable goodwill among the upstate practices that were given extra time to enroll their patients. The Consortium completed enrollment in April 2002 for the New York City site, and in October 2002 for the upstate site, approximately 14 months after the original target date. The demonstration enrolled 1,665 enrollees (775 in New York City and 890 in the upstate site; Table II.1). Figure II.4 presents cumulative enrollments for the New York City and upstate sites, as well as for the demonstration as a whole.

Because of the extended enrollment period relative to the original four-year demonstration period, eligible Medicare beneficiaries who enrolled at the end of the recruitment period (summer/fall 2002) received the intervention for only one year or less and, therefore, do not have survey follow-up data for the full two years, as originally planned, as of July 31, 2003—the cutoff for data for this evaluation. Thus, survey follow-up data are available on approximately 82 percent of the 1,665 enrollees for the enrollees' first full year in the demonstration, and on approximately 35 percent of enrollees for their second full year (depending on the outcome measured).[21]

[21]These percentages are based on annual enrollee interviews (through July 31, 2003) that the Consortium provided to the independent evaluator. About 1,648 eligible beneficiaries had enrolled through July 2002 and therefore should have been interviewed; however, due to death and nonresponse, only 1,364 completed follow-up interviews. The Consortium continued collecting data for Year 1 between July 31, 2003, and the end of the demonstration's operations (October 31, 2003) in New York City; it continued collecting data uninterruptedly in the upstate site. As of February, 2005, the Consortium had collected follow-up data on approximately 85 percent of enrollees for enrollees' first year in the demonstration, and on approximately 75 percent of enrollees for their second year (Columbia University 2004a and 2005).

TABLE II.1

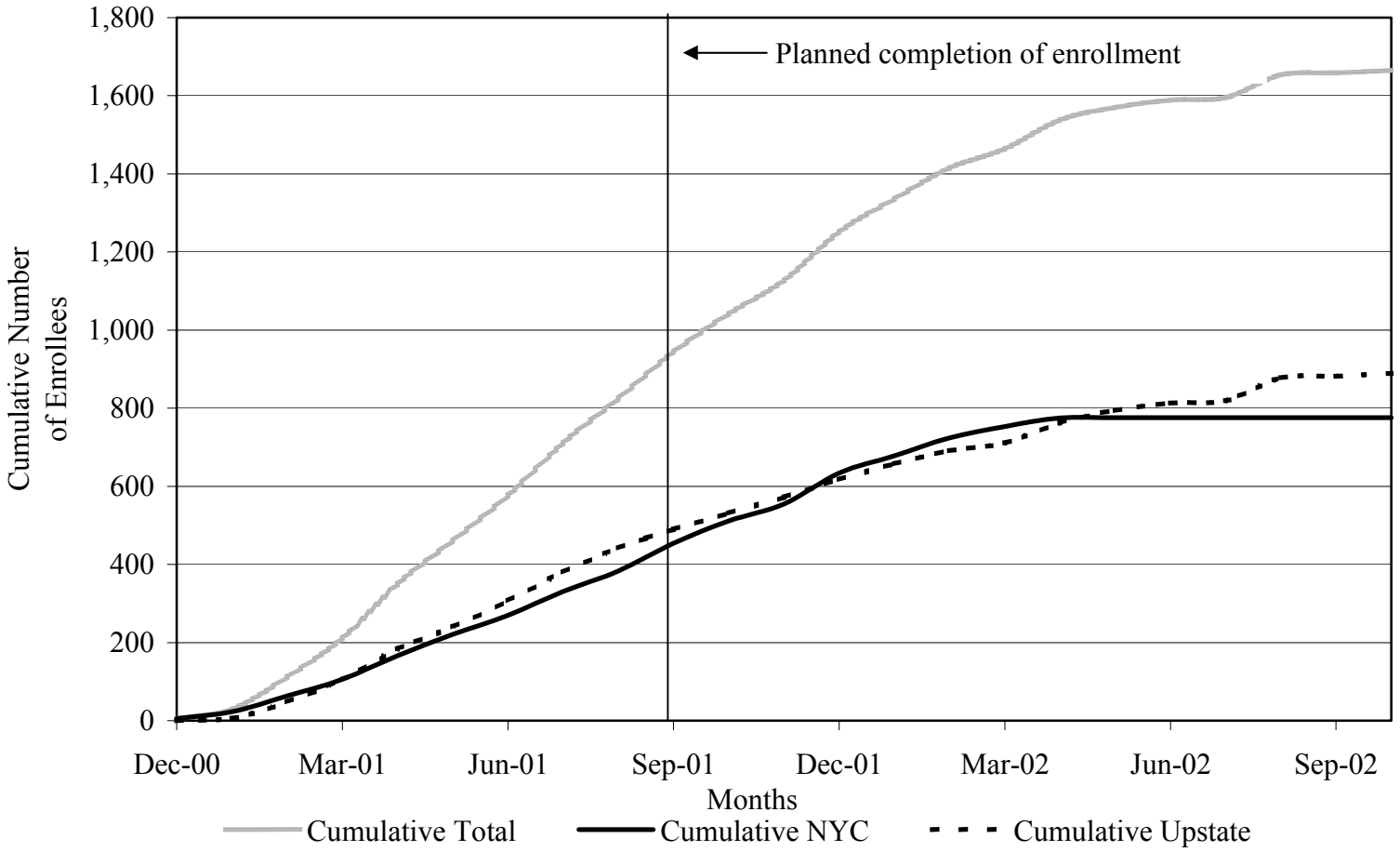
DISTRIBUTION OF IDEATel ENROLLEES, BY SITE AND EVALUATION GROUP
(Numbers)

	Evaluation Group		
Site	Treatment	Control	Total
New York City	397	378	775
Upstate New York	447	443	890
Total	**844**	**821**	**1,665**

Source: IDEATel tracking status file (Columbia University 2003c).

FIGURE II.4

CUMULATIVE DEMONSTRATION ENROLLMENT



Source: Columbia University (2002c).

Note: The Consortium completed enrollment in NYC in April 2002, and in upstate New York in October 2002.

NYC = New York City.

3. Uneven Participant Exposure to the Intervention

Other demonstrations of diabetes case management have provided in-person visits alone or telephone contacts alone. By contrast, IDEATel's intervention combined traditional diabetes case management, delivered via videoconference between nurse case managers and participants, with remote clinical monitoring and web-based educational resources. The demonstration's intervention consisted of four components: (1) interactions between participants and their nurse case managers through audio/video conference televisits; (2) participant interactions with the system through self-monitoring, consultation of web-based learning resources, and participation in chat rooms; (3) nurse case manager communications with participants' primary care physicians; and (4) education of primary care physicians in telemedicine (see Figure II.1). Although the Consortium implemented all four components, problems implementing the first two limited participants' exposure to the intervention.

The Consortium had planned for nurse case manager-participant televisits to occur every two weeks. However, the Consortium staff subsequently discovered that the participants' busy lives made it difficult to schedule the televisits. In addition, participants in New York City often failed to keep their scheduled televisit appointments. As a result, televisits occurred an average of every four to eight weeks, rather than every two weeks.[22]

The Consortium also had to resolve the implementation challenge of uneven HTU use across participants, in which some participants were frequent users, but others used their HTUs only infrequently. According to the nurse case managers, most participants were able to upload their

[22]Chapter III presents an analysis of the frequency and duration of televisits.

blood pressure and blood glucose measurements, and to connect to televisits, and many were able to monitor their clinical data. However, only about half were reported to be able to access and read electronic messages from their nurse case managers. Although about half also were reported to be able to access the web-based educational materials, based on their conversations with participants during televisits, the nurse case managers believed that few participants actually had used them. In addition, Consortium staff reported that few participants had used their HTUs to enter behavioral goals (such as exercise goals), record their exercise activity, or send messages to their nurse case managers.[23] The Consortium recently conducted a survey of participant satisfaction, but the independent evaluator has no information to explain why participants did not use those functions more frequently.[24]

The Consortium did not take steps to increase the frequency or duration of televisits, but it tried to increase participants' proficiency in using the HTUs. Consortium staff developed a video tutorial on use of the HTU and believed that the tutorial, combined with increasing familiarity with the HTUs, gradually would increase the participants' willingness and enthusiasm to use the devices over the first two years of the demonstration. However, by the third year of the demonstration, the staff realized that HTU use was not increasing as expected. To understand

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[23]The demonstration staff also reported that the chat rooms never became fully operational.

[24]At the end of the demonstration's first phase (September through November 2003), the Consortium conducted a survey of treatment group members' satisfaction with the intervention and, in particular, with the HTU. The data collected from the survey suggest that a large majority of participants believed that the intervention had improved their lives. However, the survey did not collect any data on the reasons why participants did not use their HTUs. Furthermore, only 363 participants (out of 844) completed interviews, and the respondents may have been the most active and motivated participants. The survey was conducted in person (in New York City) and by mail (in upstate New York).

participants' difficulties in using the HTU, the Consortium asked an expert on human-machine interactions from Columbia University's Department of BioInformatics to analyze participants' interactions with the HTUs for an early cohort of participants (roughly those enrolled during the demonstration's second year) (Kaufman et al. 2003a and 2003b).

Based on the expert's findings, the Consortium staff made several changes that they hoped would increase HTU use. They resolved software incompatibilities to increase the user-friendliness of the HTUs' screens; revised the video tutorial; and, most important, retrained all participants on the use of the HTU. The staff were able to train 203 of 359 (57 percent) participants in New York City and about 350 of 379 (92 percent) participants in upstate New York between July 2002 and January 2003.[25] This effort required the hiring of a new staff member to train some participants in New York City in Spanish, and the rehiring of the two nurse installers who originally installed the HTUs in upstate New York. However, the Consortium did not take these steps until the third year of the demonstration, and participants who were early enrollees received their retraining only a month or two before the scheduled end of their participation. Thus, although the demonstration staff believe that retraining increased HTU use, the timing probably had little effect on the early outcomes examined in this report.

The exposure to the intervention between participants in the New York City site and participants in the upstate New York site differed in several ways. New York City participants had fewer televisits because they broke their appointments at a higher rate. In addition, as discussed in Chapter III, televisits in New York City were shorter than upstate ones. Moreover, in the New

[25]These numbers refer to participants with HTUs as of July 1, 2002.

York City site, participants' televisits were with nurse case managers, one of whom was also a registered dietitian who provided some diet-related teaching. By contrast, in the upstate site, participants had televisits with nurse case managers and with a dietitian who *exclusively* provided diet-related teaching. Retraining also was conducted differently in the two sites. For example, in addition to the retraining provided to all participants, approximately 100 upstate participants received additional training on the HTU's more advanced functions. According to Consortium staff, these "high-end users" had requested help in sending email to friends and relatives or in conducting Internet searches. Advanced-level training was available to New York City participants, but few of them took advantage of this training since they were less familiar with computers from the outset. Therefore, differences in the implementation of the intervention in the New York City and upstate sites suggest that the two sites should be analyzed separately.

Televisits had been scheduled at regular intervals throughout the intervention period, although some participants broke their appointments. In contrast, as suggested by findings presented in Chapter III, participants used the other HTU functions primarily toward the end of the intervention period. These patterns of HTU use have two implications. First, participants received less exposure to the demonstration's intervention than had been planned, at least with regard to televisits. Second, because most components of the intervention were not used uniformly throughout the intervention period, it will be difficult to explain how the late timing of HTU use translated into the impacts on early outcomes.

4. Higher-than-Expected Enrollee Dropout Rate

According to its proposal, the Consortium expected that 15 percent of the treatment group and 20 percent of the control group would have dropped out by the end of Year 2. The actual

dropout rate one year after enrollment was 19 percent in the treatment group and 3 percent in the control group (Table II.2). As of July 31, 2003, 30 percent of the treatment group and 13 percent of the control group had dropped out (a statistically significant difference).[26] Table II.3 lists the reasons provided by the Consortium for enrollee dropout and the number of enrollees leaving the treatment and control groups in the two sites as of July 31, 2003. As noted, many participants left the demonstration during the first two years because of HTU-related problems.

As discussed in Section B.2, the Consortium addressed the higher-than-expected dropout rate in two ways. First, it enrolled approximately 10 percent more enrollees than the 1,500 it originally had targeted. This approach ensured that nurse case managers retained a full caseload but did not deal with the fact that treatment group members who dropped out received little exposure to the intervention. Second, the Consortium encouraged participants to remain in the demonstration. One of the study investigators personally telephoned participants who planned to drop out and their physicians to urge the participants to reconsider. In addition, the ultimate goal of the retraining effort described in the previous section was to make participants feel more positive and confident about using the HTU. Consortium staff reported that, by end of the third year of the demonstration, few people were dropping out for HTU-related reasons.

The high dropout rate in the treatment group raises the possibility that the intervention may have been unappealing to some participants. The oldest enrollees (aged 80 years or older) were

[26]These estimates were obtained from an analysis of time to dropout from the demonstration, using life-table methods.

TABLE II.2

DEMONSTRATION DROPOUT RATES, BY SITE AND EVALUATON GROUP
(Percentages)

	New York City			Upstate New York			Both Sites	
	Treatment	Control	Total	Treatment	Control	Total	Treatment	Control
Disenrolled by the End of Year 1	22.6	3.7	13.3	15.5	2.7	9.1	18.8	3.2
Disenrolled by July 31, 2003	30.1	9.0	19.8	29.0	17.5	23.2	29.5	13.4

Source: The independent evaluator's calculations based on the IDEATel tracking status file (Columbia University 2003c).

TABLE II.3

IDEATel FREQUENCY OF DROPOUTS, BY REASON AND SITE[a]
(Numbers and Percentages)

	New York City (n = 775)		Upstate New York (n = 890)	
Reason	Treatment (n = 397)	Control (n = 378)	Treatment (n = 447)	Control (n = 443)
Enrollee Refusal	27 (23%)	7 (23%)	36 (32%)	25 (46%)
Family Refusal	1 (<1%)	0 (0%)	2 (2%)	0 (0%)
Physician Refusal	1 (<1%)	1 (3%)	0 (0%)	0 (0%)
Cognitive Impairment	1 (<1%)	0 (0%)	0 (0%)	0 (0%)
Too Sick	7 (6%)	3 (10%)	22 (19%)	1 (2%)
Deceased	16 (13%)	14 (47%)	20 (18%)	20 (37%)
HTU Problem	29 (24%)	n.a. --	21 (18%)	n.a. --
Other[b]	38 (32%)	5 (17%)	13 (11%)	8 (15%)
Total	**120 (100%)**	**30 (100%)**	**114 (100%)**	**54 (100%)**

Source: IDEATel tracking status file (Columbia University 2003c).

Note: The reasons for dropping out are those reported by the Hebrew Home for the Aged at Riverdale, the demonstration's data coordination center. Numbers in parentheses correspond to the percentage distribution of reasons.

[a]As of July 31, 2003.

[b]The Consortium did not specify these reasons.

HTU = home telemedicine unit; n.a. = not applicable.

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63 percent more likely to drop out than were younger enrollees, as were enrollees whose diabetes had been diagnosed 15 or more years before (33 percent) relative to those who were diagnosed more recently.[27] By contrast, enrollees with the highest incomes ($40,000 or more annually) were nearly 65 percent less likely to drop out than were enrollees who reported lower incomes.[28]

5. Changes in the Demonstration Timeline

The Consortium proposed a four-year demonstration that consisted of a project start-up period, enrollment and intervention periods, and a data analysis and report writing period. It proposed a two-year intervention period during which enrollees would receive an in-person assessment at baseline, and at the end of their first and second years after randomization. Both the start-up and enrollment periods were extended for the reasons described previously.

Because enrollment ended later than planned, but the legislation specified the end date of the demonstration, many participants did not receive two full years of the intervention. The demonstration planned to stop televisits in September 2003 in New York City and in October 2003 in upstate New York (Columbia University 2003g). Subsequently, however, the Consortium reported that case management activities, including televisits, have continued uninterrupted in the upstate site until the time of this writing (Columbia University 2004a, 2004c,

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[27]Because enrollees whose diabetes had been diagnosed 15 or more years before account for nearly one-third of all dropout events due to death, the independent evaluator reran the analysis excluding this reason from its calculations. The findings indicate that the length of diabetes diagnosis is no longer an important predictor of dropping out, *all other things equal*. Instead, other factors, such as being a member of an ethnic minority or living alone, become statistically significant predictors of dropping out. These findings suggest caution when interpreting the contribution of a single factor to explaining the demonstration's high dropout rate.

[28]See Appendix C, Table C.3, for the estimated coefficients from the life-table regression.

and 2005). Thus, the last enrollees in New York City to enroll in the demonstration (summer 2002) received the intervention for only one year. In the absence of two years of data on each participant in both sites, and given the July 31, 2003, cutoff for data for this evaluation, the independent evaluator used Year 1 data only to assess the demonstration's impacts on clinical and other outcomes.

The Consortium's leadership requested, and has received, an extension to the demonstration for four additional years.[29] (The Consortium considers the initial four-year period of the demonstration as Phase I, and the extension as Phase II.) The Consortium has prepared a scope of work for the extension (Columbia University 2004b). It has reenrolled more than half of the 1,247 Phase I treatment or control group enrollees who completed the Year 2 in-person interview (Columbia University 2004b and 2004c). Moreover, the Consortium has resumed televisits to participants in New York City (and continued them for participants in upstate New York). The extension will allow tests of whether following Phase I enrollees for much longer periods (two to six years) will show demonstration effects on several health outcomes, service use, and Medicare expenditures. In addition, the Consortium has begun enrolling, and randomizing, up to 400 new, Phase II eligible Medicare beneficiaries in both sites.

One difficulty that the Consortium could face in implementing Phase II of the demonstration is that the legislation to authorize the extension was delayed in Congress for many months before passage. The Consortium's ability to continue the demonstration as implemented in Phase I in New York City, where Phase I operations ended on October 2003, may be limited by loss of

[29]The demonstration's second phase started on February 28, 2004.

enrollee interest during the interim, and by increased rates of enrollee drop out due to death or advancing illness (during Phase II). Moreover, from the evaluator's standpoint, IDEATel's extension may result in insufficient statistical power for detecting modest demonstration impacts on some survey-based outcomes at the end of the second phase because Phase I and Phase II cohorts cannot be pooled for analysis.[30]

C. SUMMARY AND DISCUSSION

1. Summary of Findings

The Consortium faced many challenges as it implemented the demonstration, but it also developed creative solutions to those problems. However, each change in the demonstration's original design created additional challenges for the intervention (and the independent evaluation) and, possibly, affected the demonstration's outcomes.

The implementation analysis identified two main findings. First, the demonstration's higher-than-expected dropout rate among treatment group members suggests that many participants found the intervention unappealing. Second, many participants did not receive as much of the intervention as planned, either in terms of frequency or content, in part because participants broke televisit appointments or would not make them when called, and in part because the use of several HTU functions was concentrated toward the end of the intervention period.

[30]This is primarily due to the differences on the stage of implementation of the demonstration when these two cohorts were randomized and began receiving the intervention.

2. Limitations of the Analysis

The implementation analysis is subject to two limitations. First, because the sources of information for the implementation analysis were interviews with Consortium staff, the findings (as in all qualitative studies) might have been influenced both by whether the independent evaluator correctly framed the interview questions and by whether the Consortium staff correctly interpreted the questions. Second, confidentiality constraints prevented the independent evaluator from interviewing demonstration participants or their physicians for preparation of this report.[31] Those interviews could have provided valuable insight into the implementation of the demonstration.

3. Further Considerations

Although the primary focus of the project was to bridge the *digital divide* facing Medicare beneficiaries in medically underserved areas by using web-based technologies to improve access to health care, the high dropout rate suggests that this objective has been only partially realized to date. Furthermore, the fact that older, sicker, and more economically disadvantaged enrollees were far more likely than their counterparts to drop out of the demonstration indicates that many of the most vulnerable Medicare beneficiaries are not willing or not able to take part in an web-based intervention. Thus, major challenges remain for the Consortium in achieving the goal of bridging the digital divide for those who might benefit the most from it.

[31]See Appendix B, Section A, for a summary of the independent evaluator's efforts to obtain approval to interview demonstration participants and their primary care physicians.

III. USE OF THE HOME TELEMEDICINE UNIT

Highlights of Findings

- About 95 percent of participants measured their blood sugar virtually every day and took their blood pressure an average of four or five times per week. This high level of use creates the potential for positive changes in clinical outcomes.
- Televisits, a key component for delivering the intervention, took place substantially less frequently than planned (10 times annually, versus the expected 24). The average duration of the visits (27 minutes) was close to the planned 15 to 30 minutes.
- While the retraining of participants at the end of the demonstration's third year (in fall 2002 and winter 2003) could have increased participants' confidence in their ability to use their HTUs, the use rate remained flat after the retraining.
- Several key features of the telemedicine system were rarely used. As a result, the majority of participants underutilized their HTUs.
- HTU use differed across sites, with upstate participants using most HTU functions substantially more frequently than their counterparts in New York City.

A. INTRODUCTION

In addition to standard diabetes management education, IDEATel had a unique goal for participants, and that is to make the *"HTU a part of [participants'] daily life just as the telephone is for most people"* (emphasis added) (Columbia University 1998). For participants, the intervention consisted of taking and uploading blood pressure and blood sugar measurements, videoconferencing, electronic messaging, and accessing web pages; thus, participants must have been as proficient as possible in the technology if they were to receive the full benefit of the demonstration (Demiris et al. 2001). Because the intervention hinged entirely on the use of the HTU, participants who took a long time to learn to use the device (or who never learned to use it) receive correspondingly less intervention.

To understand whether participants had the opportunity to derive significant benefit from the technology, this chapter examines the frequency of HTU use and the characteristics of people who are most likely to use the technology successfully. The analysis focuses on the participants' HTU use *on their own,* after they had received initial training by a nurse installer. The findings in this chapter rely on HTU-log-use data for 781 treatment group members (out of 844 in the group) whose HTUs were installed between December 2000 and October 2002.[32] The findings are based on the participants' experiences with the technology through the end of the follow-up period (July 31, 2003)—close to the end of the demonstration's first phase of operations (on or about October 2003). (Appendix B, Section B, provides a detailed summary of the data, study samples, and methods used in this chapter.)[33]

The analysis focuses on all the functions that the HTU enabled participants to perform, including uploading blood pressure and blood sugar measurements; monitoring clinical readings; participating in televisits; reading and sending electronic messages; consulting the demonstration's American Diabetes Association web pages; and entering medication use, exercise goals, and other behavioral goals. Participants did not have to log in to their HTUs to measure their blood pressure or blood sugar. However, to use the other functions of the HTU, several of which were the key features of a telemedicine system, they were required to log in.

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[32]As described in Appendix B, Section B.2, records of HTU installation are missing for 37 participants who dropped out of the demonstration before their HTUs were installed, and the records for 24 participants had missing installation dates. In addition, one participant had a valid installation date but dropped out before the HTU was installed, and another was dropped at the request of the Consortium, due to study ineligibility.

[33]Appendix D, Table D.1, reports the demographic and health characteristics of the sample at baseline.

(Table III.1 shows the steps that a participant must take to use each HTU function.) With the exception of televisits, which are initiated by nurse case managers, all the functions are self-initiated.[34] Because it is not possible to distinguish between HTU use guided by nurse installers and use without a nurse installer's assistance, the analysis excludes participants' HTU use on the day of the device's installation. That exclusion avoids counting the instances in which it was most likely that use was guided by the nurse installer. To account for substantial differences in the baseline demographic and health characteristics of participants in New York City and of participants in upstate New York, as well as for differences across the sites in the way that the intervention was implemented, the analysis is conducted separately for participants in the two sites.[35]

B. FREQUENCY OF HTU USE

Participants appear to have been at least somewhat motivated to use the HTU.[36] Virtually all of them measured their blood pressure or measured their blood sugar at least once between the day after HTU installation and the end of the follow-up period (96 and 95 percent, respectively; see Table III.2). Likewise, the vast majority (95 percent) participated in a televisit at least once during the follow-up period. Use of the more complex HTU functions was less widespread.

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[34]Nurse case managers conduct televisits to provide nutrition guidance and regular diabetes management. The HTU log-use data file distinguishes between initial and follow-up regular televisits. However, the analysis in this chapter does not distinguish between the types of visits.

[35]Chapter II describes differences in implementation of the intervention between the two sites.

[36]Participants were expected to be motivated; 59 percent of them reported at baseline that they joined the demonstration because they believed that the technology could help them. This reason is the one reported most frequently by participants to explain why they enrolled in the demonstration.

TABLE III.1

STEPS INVOLVED IN USING SPECIFIC HTU FUNCTIONS

HTU Function	Step[a]					
	Log In[b]	Operate Glucose Meter or Blood Pressure Cuff	Use Launch Pad[c]	Point to and Click Link	Point to and Click Drop-Down List	Enter Text or Numbers
1. Measure Blood Pressure	No	Yes	n.a.			
2. Measure Blood Sugar	No	Yes	n.a.			
3. Upload Clinical Readings	Yes	n.a.	Yes	No	No	No
4. Monitor Clinical Readings	Yes		No	Yes	Maybe	No
5. Participate in Televisits	Yes		Yes[d]	No	No	No
6. Read Electronic Messages	Yes		No	Yes	No	No
7. Send Electronic Messages	Yes		No	Yes	No	Yes
8. Consult American Diabetes Association Web Pages	Yes		Yes	Yes	No	No
9. Enter Medications	Yes		No	Yes	No	Yes
10. Enter Exercise Activities	Yes		No	Yes	No	Yes
11. Set Behavioral Goals	Yes		No	Yes	Yes	Yes

Source: Patient screen shots from Communi*Health*™ Diabetes Manager (Columbia University 2000).

Note: Pointing to a link or a drop-down list and clicking on a link or drop-down list requires the use of a mouse.

[a]The steps are displayed in sequential order, from left to right.

[b]Logging in requires entering a four-digit password.

[c]See Figure II.3.

[d]Participating in televisits requires pointing the videocamera in the direction of the participant.

HTU = home telemedicine unit; n.a. = not applicable.

TABLE III.2

ANY USE OF HTU FUNCTIONS DURING THE INTERVENTION, BY SITE
(Percentages)

HTU Function	All	Site		Difference (*p*-Value)
		New York City	Upstate New York	
Upload Blood Pressure or Blood Sugar Readings	96.3	95.3	97.1	1.9 (.172)
Measure Blood Pressure	95.9	94.7	96.9	2.2 (.128)
Measure Blood Sugar	95.0	93.0	96.7	3.7 (.023)
Participate in Televisits	94.5	92.2	96.4	4.2 (.012)
Monitor Clinical Readings	77.1	77.4	76.8	0.4 (.827)
Read Electronic Messages	53.3	57.1	50.0	7.1 (.047)
Send Electronic Messages	50.0	52.4	48.1	4.3 (.236)
Consult American Diabetes Association Web Pages	45.2	49.6	41.5	8.1 (.023)
Enter Medications	20.6	13.6	26.5	12.9 (.000)
Enter Exercise Activities	17.5	11.7	22.5	10.8 (.000)
Enter Behavioral Goals	11.0	6.4	14.9	8.5 (.000)
Sample Size	**781**	**359**	**422**	**—**

Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and baseline in-person interview, conducted between December 2000 and October 20002 (Columbia University 2003b).

HTU = home telemedicine unit.

More than three-quarters of the participants monitored their clinical readings (77 percent), about half read electronic messages or sent electronic messages (53 and 50 percent, respectively), and slightly less than half consulted the American Diabetes Association web pages (45 percent). Between 11 and 21 percent of the participants entered medications, exercise activities, or behavioral goals in their HTUs.

The two sites' use of the HTU differed considerably. Participants from the upstate site were about 4 percent more likely to measure their blood sugar at least once (97 versus 93 percent in New York City), and to participate in a televisit at least once (96 versus 92 percent; see Table III.2).[37] Upstate participants were twice as likely as New York City participants to use some of the HTU's more advanced functions, including entering medications (27 versus 14 percent), entering exercise activities (23 versus 12 percent), and entering behavioral goals (15 versus 6 percent). By contrast, New York City participants were slightly more likely to consult the American Diabetes Association web pages at least once (50 percent, versus 42 percent in the upstate site), and to read electronic messages (57 versus 50 percent). Differences between participants in the two sites in the likelihood of ever using the other HTU functions (measuring blood pressure, uploading and monitoring clinical readings, and sending electronic messages) were small and not statistically significant.

Participants were asked to attend televisits every two weeks (about 24 times per year), and more often, if necessary (Columbia University 1998). The frequency of self-monitoring recommended

[37]A majority of participants knew at baseline how to test their blood sugar (85 and 93 percent in New York City and in upstate New York, respectively). The findings presented here suggest that some participants who lacked the skills for testing their blood sugar at baseline may have learned how to do so as they used their HTUs.

to each participant depended on clinical circumstances and was determined by the nurse case managers, with support from the clinical guidelines and supervising diabetologist (U.S. Department of Health and Human Services 2003). As Table III.3 shows, the intensity of HTU use varied widely, depending on the function. For example, participants who measured their blood sugar did so virtually every day, on average. Participants who measured and recorded their blood pressure did so four or five times per week, on average. However, they uploaded those readings much less often—about once every three weeks. Participants used the televisit function, a key component of the intervention, substantially less often than had been proposed (about every five and a half weeks versus every two weeks). Likewise, they monitored their clinical readings about every six weeks. (As noted, no particular frequency of use of this function had been recommended.) The more complex HTU functions, which required dexterity to use the technology, were used infrequently (two to five times per year), as their use depended, in part, on the participants' proficiency with the technology and, in part, on their personal tastes.

Between-site differences in the average frequency of use of HTU functions (Table III.3) generally paralleled the between-site differences in the likelihood of any use of HTU functions (Table III.2). For example, participants in the upstate site used the HTU's glucometer an average of 385 times annually (or slightly more often than daily), and they used the blood pressure cuff to read their blood pressure an average of 259 times annually (or 0.7 times per day). Participants in New York City took these clinical readings significantly less frequently (238 and 212 measurements of blood sugar and blood pressure per year, respectively). Likewise, participants in the upstate site uploaded their clinical readings more frequently (23 times annually, versus 14 times annually in the New York City site) and monitored these readings more often (12 versus 7 times annually). Participants in the upstate site also monitored their clinical readings about twice

TABLE III.3

MEAN ANNUAL NUMBER OF TIMES HTU FUNCTION WAS USED DURING THE INTERVENTION, BY SITE
(Means)

HTU Function	All	Site		Difference (*p*-Value)
		New York City	Upstate New York	
Measure Blood Sugar	316.8	238.1	385.2	147.1 (.000)
Measure Blood Pressure	237.0	212.1	258.7	46.6 (.000)
Upload Blood Pressure or Blood Sugar Readings	19.1	14.3	23.3	9.0 (.000)
Participate in Televisits	9.5	7.1	11.6	4.5 (.000)
Monitor Clinical Readings	9.4	6.8	11.7	4.9 (.016)
Read Electronic Messages	4.5	2.7	6.5	3.8 (.000)
Enter Behavioral Goals	2.3	3.0	2.1	0.9 (.447)
Enter Medications	1.8	1.6	1.9	0.3 (.455)
Enter Exercise Activities	1.8	1.7	1.9	0.2 (.644)
Send Electronic Messages	1.7	1.3	2.1	0.8 (.019)
Consult American Diabetes Association Web Pages	1.5	1.1	1.9	0.8 (.010)
Sample Size[a]	**781**	**359**	**422**	**—**

Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2003b).

Notes: Estimates are annualized and weighted by the duration of enrollment between HTU installation and either the drop-out date or July 31, 2003, whichever came first.

With the exception of televisits, which were planned to take place every two weeks, no particular frequency of use of the HTU functions was recommended to participants. It was expected that some participants would be interested in some functions, whereas others would not be, and that the frequency of use would vary with participants' tastes and clinical circumstances.

[a]The number of participants using a function varies by the function.

HTU = home telemedicine unit.

as often as did participants in New York City (an average of about monthly versus an average of bimonthly).

Participants in the upstate site attended televisits more often than did participants in New York City. Participants attended an average of 12 televisits per year in the upstate site (or 1 televisit approximately every 4.3 weeks), compared with about 7 televisits per year (or 1 televisit every 7.3 weeks) among New York City participants. As noted, the frequency of televisits in the upstate site was about half the frequency recommended in the Consortium's proposal. By contrast, televisits in New York City occurred only about one-fourth as often as recommended. The frequency for both sites is about the same as was reported by the nurse case managers to the independent evaluator in the Year 2 telephone interviews. The use in both sites would have been higher if there had been fewer broken appointments.[38] Similarly, the estimates are consistent with reports by nurse case managers that a small number of participants in New York City spent their winter months outside New York State and therefore were not available for televisits for part of the year.

Consortium staff anecdotally reported that the length of the televisits was greater than planned.[39] However, the available data show that the televisit averaged 27 minutes overall, or roughly the same number of minutes as had been planned for routine follow-up visits (Table III.4).

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[38]Participants broke about one-quarter of all televisit appointments that the nurse case managers attempted to make. Consistent with the nurse case managers' reports, 37 percent of all recorded televisit appointments in New York City were broken, as were 17 percent of recorded appointments in the upstate site.

[39]That is, 45 to 60 minutes for the initial assessments and 15 to 30 minutes for routine follow-up visits (Columbia University 1998).

TABLE III.4

PATTERNS OF HTU USE DURING THE INTERVENTION, BY SITE

Use Pattern	All	Site		Difference (*p*-Value)
		New York City	Upstate New York	
Any Function (Percentage)[a]	96.9	96.4	97.4	1.0 (.420)
All HTU Functions (Percentage)[a]	4.9	3.3	6.2	2.9 (.061)
Number of Functions Used[a]	5.1	5.1	5.0	0.1 (.829)
Average Duration of Televisits (Minutes)[b]	26.6	22.8	29.8	7.0 (.000)
Average Duration of American Diabetes Association Web Page Consultation (Minutes)[b]	5.3	4.0	6.6	2.6 (.000)
Sample Size	**781**	**359**	**422**	**—**

Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2003b).

Note: Estimates of the number of functions used are weighted by the duration of enrollment between HTU installation and either the drop-out date or July 31, 2003, whichever came first.

[a]Excludes measurement of blood pressure and measurement of blood sugar, as neither function required system log-in.

[b]The number of participants participating in televisits or consulting the American Diabetes Association web pages varies by the function.

HTU = home telemedicine unit.

Between-site differences in the average length of televisits were substantial, with participants in the upstate site spending nearly 7 minutes more participating in a televisit than did their counterparts in New York City (30 versus 23 minutes).

Use of the more complex HTU functions, such as reading electronic messages and consulting the American Diabetes Association web pages, followed a pattern of infrequent use overall, and substantially more frequent use by participants in the upstate site. Moreover, participants in the upstate site spent an average of nearly three more minutes per consultation of the web pages than did participants in New York City (seven versus four minutes per consultation; Table III.4). Participants used functions that required entering data in the HTU, such as data on medications and exercise activities, fewer than three times annually, and the between-site differences were small and not statistically significant.

The breadth of HTU use varied widely across participants. Although virtually all participants (97 percent) used at least one of the HTU functions during the period between HTU installation and the end of followup, only about 5 percent used all nine HTU functions that required system log-in (Table III.4). Participants in the upstate site were nearly twice as likely as their counterparts in New York City to use all the HTU functions (six versus three percent), although the difference is only marginally significant. By contrast, between-site differences in the number of functions used were small and not statistically significant; between HTU installation and the end of followup, participants used about five HTU functions, on average. (These estimates exclude use of the two functions that did not require system log-in.)

Participants' HTU use also varied substantially over the 32-month period between the start of the demonstration (December 2000) and the end of the follow-up period (July 2003). For most functions, between 30 and 40 percent of all instances of use occurred during the last 8 months of

that interval (December 2002 through July 2003), which corresponds roughly to the period after the Consortium retrained all participants and the first half of the demonstration's last year. However, during the same interval, after an initial peak immediately after intervention startup, the use rate for several functions, such as televisits, remained flat (Figure III.1).[40] (Use rate is defined as instances of use per person-year of enrollment.)

C. DETERMINANTS OF HTU USE

The large between-site differences in the rate and intensity of use of the HTU functions persist even after controlling for the demographic and health characteristics of participants at randomization. To understand whether the differences across key subgroups arose from the influence of other characteristics, the independent evaluator conducted a regression analysis to examine the effect of each characteristic, while controlling for the effects of all the others.[41,42]

Only a few of the differences in characteristics were statistically significant after controlling for other characteristics. Specifically, participants in New York City who had completed high

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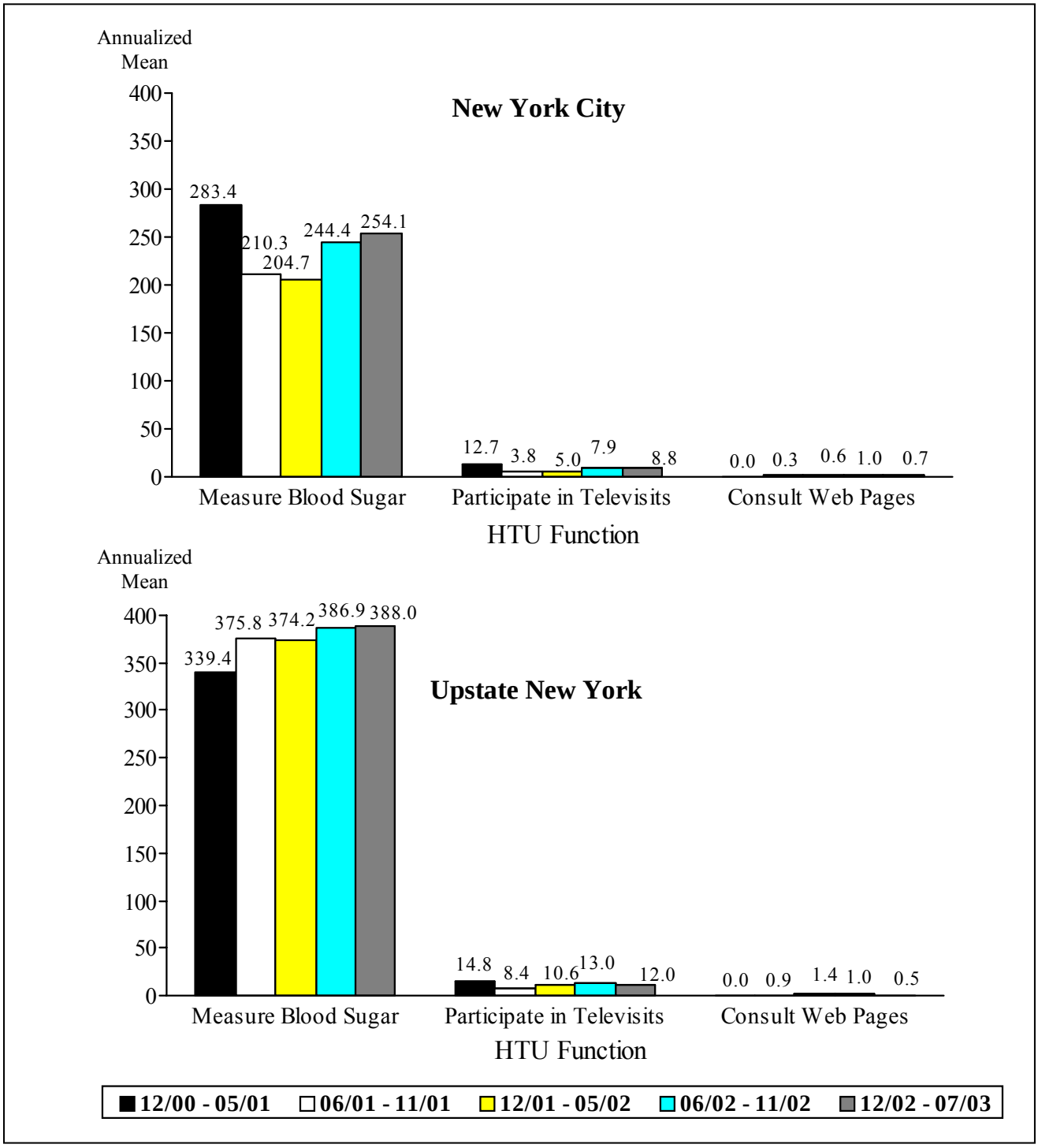
[40]These findings must be interpreted with caution, as participants who remain enrolled in the demonstration are likely to be more committed to using the HTU than are those who drop out of it.

[41]The regression analysis included the following demographic characteristics: age, race/ethnicity, sex, education, living arrangements, employment status, household income, prior knowledge of computers, length of Medicare enrollment, whether dually eligible for Medicare and Medicaid, and whether enrolled in a health maintenance organization in the month before randomization. The health characteristics were reason for Medicare entitlement and years since diabetes was diagnosed.

[42]An analysis of variance supports the decision to conduct the analysis for most HTU functions separately by site, given the large differences between participants in the two sites along so many dimensions (see Appendix B, Section B.4).

FIGURE III.1

MEAN ANNUAL NUMBER OF TIMES HTU FUNCTION WAS USED, BY PERIOD AND SITE



Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2003b).

Note: The estimates in this figure are rates of use of an HTU function for a given period. This rate is equal to the ratio of the total number of instances of use of an HTU function by all participants in a given period to the total number of person-months of enrollment in the demonstration during the same period. These estimates are annualized and thus should be interpreted as the mean annual number of times an HTU function was used per-person year of enrollment in each period.

school were more likely to use the HTU functions than were their counterparts with less education. Similarly, male participants seemed to be more likely to use some functions, such as measuring their blood pressure, than were female participants. In the upstate site, no single characteristic is significantly associated with HTU use. Although black and Hispanic/Latino participants in both sites used the HTU functions less often than did their white counterparts, this association is difficult to interpret, as virtually all participants in New York City identified themselves as belonging to racial or ethnic minorities, but fewer than 10 percent of participants in the upstate site were of black or Hispanic/Latino descent (see Appendix Table D.1). Thus, the high correlation between race and site makes it difficult to establish whether race/ethnicity accounts for the differences in HTU use, or whether the differences are explained by characteristics specific to the New York City site that were not included in the regression model.

D. SUMMARY AND DISCUSSION

1. Summary of Findings

The findings on the frequency of HTU use suggest that most participants used the functions that did not require system log-in (that is, measuring their blood pressure and blood sugar), and that were most familiar to them before the demonstration. Use of these functions may be more important in leading to positive changes in clinical outcomes than other HTU functions that are more complex and less widely used (Soumerai et al. 2004). Participants may have taken their clinical readings regularly because they were used to doing so as part of the self-initiated process of taking care of their diabetes. They also had no out-of-pocket expenses, whereas Medicare

beneficiaries who were not in the treatment group would have incurred copayments for supplies to measure their blood sugar.[43]

The frequency of televisits—a key component of the intervention—was substantially lower than planned and differed markedly between the sites. Participants in the upstate site had one televisit every four weeks, about half the planned frequency of one televisit every two weeks. Participants in New York City had a televisit substantially less frequently—about one visit every seven weeks. Particularly in New York City, the frequency of televisits in both sites would have been higher if participants had broken fewer appointments. The differences in estimates are consistent with reports by nurse case managers that a small number of participants in New York City spent their winter months outside of New York State and therefore were not available for televisits during that period. Although the average duration of a televisit (27 minutes) was close to the planned duration for follow-up visits, the nurse case managers spent an unknown part of that time during the second and third years of the demonstration addressing participants' concerns about the HTU, rather than managing the participants' diabetes. It is unclear whether the nurse case managers' diversion to address technical issues limited the participants' exposure to the intervention.

Other HTU features that required log-in of the telemedicine system were used only rarely. Only a small group of technically savvy, highly motivated participants (between 11 and 21 percent) used the HTU functions that are unique to the complex telemedicine system designed for the

[43] Enrollees in the treatment group, as well as those in the control group, had copayments for other services, such as physician office visits and other diabetes supplies and services not available as part of the telemedicine intervention.

IDEATel demonstration. In part, this might be because the participants had a limited understanding about how to operate their HTUs, or they may have lacked the technical support that would have helped them to use those functions. Moreover, lack of interest or failure to perceive the value of the more complex functions also might explain why the functions were used infrequently. The Consortium leadership investigated why the early cohort of participants (roughly those enrolled during the demonstration's second year) used the technology, particularly the televisits, infrequently (Kaufman et al. 2003a and 2003b). The studies found that aspects of the interface between participants and their HTUs were "sub-optimal and impeded the performance of certain tasks." They also determined that a range of participant-related factors, such as literacy and psychomotor skills, constituted barriers to productive use. Based on findings from that study, the Consortium retrained all participants on HTU use (see Chapter II). However, the findings presented here suggest that the majority of participants used the HTUs less than expected, and they raise concerns about the extent to which the full intervention was delivered to those participants.

HTU use varied substantially with participant characteristics. For example, minority participants used their HTUs less often than did white participants, as did less educated participants relative to those who completed at least high school (after controlling for other individual demographic and health characteristics). The differences were large enough during the demonstration's first phase that it remains unclear whether the demonstration achieved its goal of making the HTU as familiar to minority participants as the telephone.

2. Limitations of the Analysis

The analysis of HTU use has several limitations. First, although the use levels reported in this report should be considered reliable, it is not possible to measure the extent to which the

retraining efforts improved use levels. The independent evaluator was not able to obtain the exact date of each participant's retraining. Furthermore, in the absence of a suitable control group to account for secular trends against which to compare the changes in use before and after retraining, it is not possible to determine whether retraining increased most participants' use of the array of HTU functions. Second, because communications between participants and providers are confidential, the independent evaluator is unable to determine whether any instances of HTU use were self-initiated, or whether they occurred after reminders from nurse case managers during televisits or in electronic messages. Thus, it is unclear how much effort was required of Consortium staff to generate even the modest levels of use observed. Finally, it is possible that the number of data uploads have been underestimated, but the amount of underestimation is not known. During part of the demonstration's initial months of operations, software problems prevented participants from completing data uploads. Consortium staff did not provide the independent evaluator with an estimate of either the duration of this problem or the number of incomplete readings. Those early failures may have discouraged some participants from making future attempts to upload their clinical readings.

3. Further Considerations

Interviewed Consortium staff expressed the belief that the delivery of the IDEATel technology to a large number of homes in underserved communities is a tremendous step forward in bridging the so-called *digital divide*.[44] Similarly, they interpreted the use of a few HTU functions by a

[44]For context, in 2001, about one-third of Medicare beneficiaries nationwide had personal computers or Internet access at home. The fraction of black and Hispanic/Latino beneficiaries who had either of those technologies at home was substantially lower (about 20 percent) (Centers for Medicare & Medicaid Services 2004a).

large number of participants as strong evidence that the technology is acceptable (Starren et al. 2003). However, the available evidence suggests that some participants may have found the technology unappealing. About seven percent of the participants refused to have HTUs installed in their homes and six percent dropped out of the study because they found the system difficult to use. Moreover, steep learning curves discouraged about half of them from using the HTU's more complex functions.[45] Furthermore, the frequency of use of televisits—a key component of the intervention—was substantially lower than recommended by the demonstration. Although the high frequency of blood pressure and blood sugar monitoring suggests that the telemedicine device offers the potential to effect positive changes in clinical outcomes, in its current form, the HTU's effectiveness as a medium for delivering intensive nurse case management to a large number of Medicare beneficiaries with limited education remains unclear.

[45]Based on analysis of an early cohort of participants (that is, those whose HTUs were installed between December 2000 and November 2001), only between 6 and 35 percent of participants took less than one year to use the more complex functions, such as entering medications or consulting the American Diabetes Association web pages (Moreno et al. 2003).

IV. IDEATel IMPACT ESTIMATES ON BEHAVIORAL, PHYSIOLOGIC, AND OTHER HEALTH-RELATED OUTCOMES

Highlights of Findings

- In both the New York City and upstate sites, the IDEATel intervention had large, positive effects (increases of 30 to 40 percent) on treatment group members (1) seeing a diabetes nurse educator or dietitian at least once in the year since baseline, and (2) testing their blood sugar daily.

- Upstate, the intervention increased the frequency of health care providers' discussions with treatment group members about eating and exercise, and it improved treatment group members' efficacy in these areas. The intervention did not improve enrollees' adherence to their diet or exercise regimens. In New York City, treatment group members had somewhat more frequent discussions with health care professionals than did control group enrollees, and they reported somewhat better adherence to exercise regimens.

- Upstate, IDEATel increased treatment group members' general diabetes self-efficacy by a small but statistically significant amount. In New York City, IDEATel may have had a minor negative effect on the attitudes of a small proportion of participants toward certain daily tasks of managing diabetes (whether or not remembering to take medications, avoiding or limiting favorite foods, or planning meals were a "big hassle").

- IDEATel had no effects on treatment group members' use of Medicare-covered hospital, skilled nursing facility, home health care, or physician services. Neither did the intervention have any effects on enrollees' receipt of four recommended preventive services covered by Medicare (dilated eye examination, hemoglobin A1c testing, low-density lipoprotein [LDL] cholesterol testing, and urine microalbumin testing).

- In both sites, among enrollees with baseline indications for treatment (that is, elevated cholesterol levels, protein in the urine, high blood pressure, and poorly controlled blood sugar), intervention group members were somewhat more likely to have been prescribed appropriate medications than control group members, although most of these differences were not statistically significant because of small sample sizes. In the upstate site, among enrollees with poorly controlled blood sugar at baseline and prescribed insulin, treatment group members were treated more aggressively, as indicated by a higher average daily dose of insulin. However, the intervention had no effect in either site on the prescription of antiplatelet drugs, which are generally recommended for all persons with diabetes.

- In both sites, IDEATel lowered the in-person systolic and diastolic blood pressures as measured at the annual visits, although more so in the upstate site, where the treatment control-group difference was highly significant. These results were not

corroborated by the blood pressure data recorded by ambulatory blood pressure monitors, but the sample sizes for the ambulatory blood pressure monitors were small.

- In both sites, IDEATel had substantial and significant positive effects on treatment group members' lipid levels, and small but significant effects on their average hemoglobin A1c levels. The proportion with hemoglobin A1c levels higher than 8 percent was reduced by one-third in both sites. Apparent effects on urine albumin-to-creatinine ratios in both sites are difficult to interpret because a substantial number of enrollees are missing follow-up data and appear to be different from the enrollees with complete follow-up data.
- Some measures of general health status were better for treatment group members than for controls, in both sites.

A. INTRODUCTION AND EXPECTED EFFECTS

This chapter estimates the effects of the IDEATel intervention by comparing the Year 1 outcomes of demonstration enrollees who were randomly assigned to receive the intervention (the treatment group) with those of enrollees who were assigned to receive their usual care (the control group). As explained below, the intervention was expected to affect several types of outcomes: frequency and quality of enrollees' communications with health care professionals; self-care knowledge, attitudes, and behaviors; use of health services; physiologic outcomes; health-related quality of life; and satisfaction with diabetes care.

Data were drawn from interviews with enrollees, Medicare claims, and laboratory tests. Claims data were analyzed for the 1,664 randomly assigned enrollees.[46] Interview and laboratory data were analyzed for the subset of 1,364 enrollees who completed Year 1 interviews with demonstration staff. The analyses controlled for enrollees' baseline characteristics, including

[46]The tracking status file includes records for 1,666 enrollees randomized between December 5, 2000, and October 11, 2002. At the request of the Consortium, one enrollee was excluded because of ineligibility. Another enrollee had missing data in all baseline interview variables (Columbia University 2003c).

baseline measures of the outcomes in question. Because demonstration enrollees in New York City and upstate differed markedly from each other—as did some aspects of the intervention (Chapter II)—separate analyses were conducted for each site.[47] (Appendix B, Section C.4, provides a detailed description of the analytic methods.)

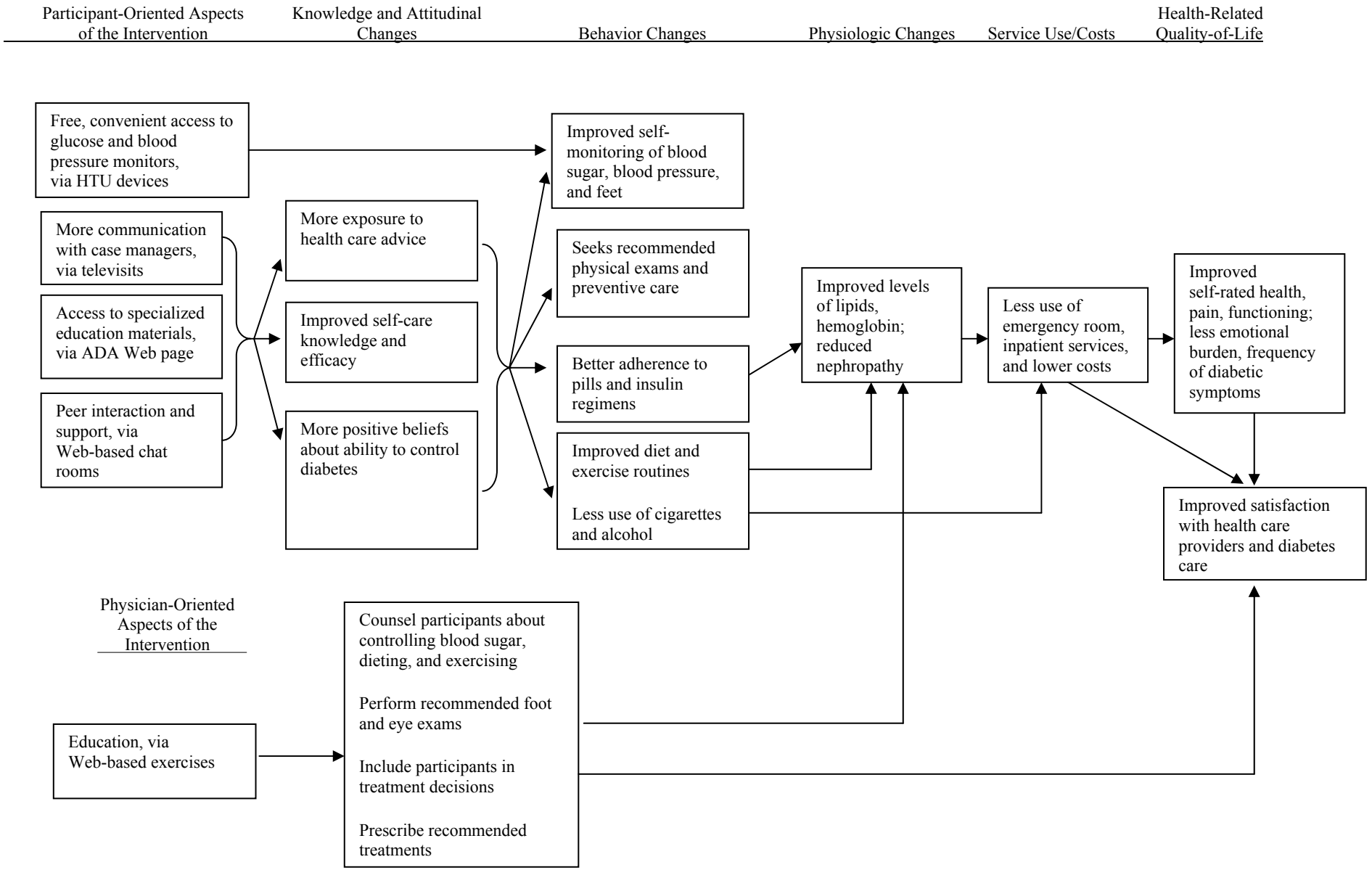
The collection of interview and laboratory data is summarized as follows. Members of both the treatment and control groups underwent a baseline assessment by Consortium study staff immediately before randomization, and then similar follow-up assessments one and two years after randomization. Each assessment consisted of a detailed structured interview; measurements of body dimensions and weight and of blood pressure; blood and urine tests; and setup of an ambulatory blood pressure monitor, a small blood-pressure–recording device worn for 24 hours after the annual assessment. The interview instruments included a number of scales, described in detail in Appendix B, for measuring subjective symptoms, attitudes, emotions, and functional capacities; in these scales, responses to individual questions were summed to create continuous scores. Most of the data presented in this chapter are from the Year 1 followups, because few enrollees had reached the end of their second year at the time of this analysis.

IDEATel might be expected to lead to program impacts through multiple pathways. (Figure IV.1 provides a graphic depiction of the production of expected impacts.) As described in Chapter II, IDEATel consists of a participant-focused component (the HTU and its functions) and a

[47] In its proposal, the Consortium mentioned plans for separate site-specific analyses as well.

FIGURE IV.1

EXPECTED EFFECTS OF THE IDEATel INTERVENTION



ADA = American Diabetes Association; HTU = home telemedicine unit.

physician-focused component (specialist- and guideline-based recommendations on diabetes care). Enrollees interacted with their HTUs by uploading readings from in-home glucose and blood pressure monitors; participating in televisits with nurse case managers; accessing web-based educational materials; and using the web-based *cyber-community* features of the device (the electronic messaging system, bulletin boards, and chat rooms). The regular use of these functions was expected to foster positive beliefs about the benefits of self-care (known as *outcome expectancies*), increase enrollees' knowledge about self-care, and strengthen confidence in specific self-care skills (known as *self-efficacy* for self-care skills). These changes, in turn, were expected to lead to behavioral changes, such as adhering more closely to diet, exercise, and foot care regimens; reducing or giving up the use of cigarettes and alcohol; monitoring blood pressure and blood sugar readings more frequently; and making and keeping medical appointments more faithfully.

The intervention's steady stream of feedback data and guideline-based recommendations was expected to lead physicians to prescribe better medical regimens. The data, combined with concrete suggestions, would lead the physicians to adjust their participating patients' medications in a more timely and responsive way, with more evidence-based regimens.

These changes in enrollees' and physicians' behaviors also were expected to lead to improved short-term physiologic outcomes, such as improved blood sugar control, reduction of blood pressure, and an improved cholesterol profile. Some of these physiologic changes might rapidly improve enrollees' health-related quality of life. For example, improvement in extremely high or extremely low blood sugar levels should cause people to feel better quickly. However, many effects on health and quality of life might not appear for some time. For example, although the intervention might avert nerve, kidney, and eye damage, heart attacks, strokes, and amputations

by improving enrollees' control of diabetes, blood pressure, and lipids, these effects might not become apparent for years.

IDEATel might have other effects on enrollees. Increasing enrollees' knowledge of and involvement in self-care, fostering positive attitudes and health behaviors in enrollees, and helping physicians improve their treatment of diabetes should all work to raise enrollees' overall satisfaction with their diabetes care. The improvements in health and well-being, in turn, would then have additional feedback effects on the enrollees' satisfaction with their diabetes care.

In its original supporting statement for OMB clearance (Health Care Financing Administration 2000), the Consortium listed glycosylated hemoglobin, blood pressure, and lipid levels as the three main study outcomes, thus imposing a hierarchy of importance on the outcomes.[48] This report, in contrast, presents the results of numerous outcomes beyond these three, without distinguishing between "primary" and "secondary" outcomes.

Clinical researchers and biostatisticians often prespecify a limited number of primary outcomes for clinical trials for two main reasons. First, they are concerned about increasing the risks of "false-positive" results or Type I errors; that is, the risk of multiple treatment-control comparisons producing apparent differences that are not true differences, but that arise only from chance (Schulz and Grimes 2005). Second, they wish to avoid the practice of "data-dredging," in which investigators conduct multiple treatment-control comparisons, but report only those that

[48] The supporting statement went on to say that "other important outcomes include receipt of recommended diabetes-specific health care services (dilated eye exam, monofilament foot exam), other recommended preventive services, smoking cessation in the subset who smoke, and satisfaction with care. Cost-effectiveness is assessed based on effectiveness, measures of health care utilization, and technology and service costs of the intervention."

turn out to be interesting and statistically significant, without mentioning the many other analyses.

Because their audience is policymakers and stakeholders, rather than scientists, clinicians, and journal editors, evaluators of complex programs and policies frequently take a different approach. Complex social and health programs may produce a host of effects, both intended and unintended, beyond the few primary endpoints of the program developers, which policymakers may need to consider. Such programs also commonly affect many stakeholders, not all of whom may agree on the relative importance of various outcomes. Thus, policy researchers and program evaluators often take a "triangulation" approach, in which quantitative results for all measurable outcomes are examined together with the qualitative analyses of the program's implementation, to arrive at an overall synthesis of the program's effects (Hatry and Newcomer 2004). Such an approach deals with isolated, apparently statistically significant results by checking their consistency with all of the other evaluation data, and with the overall pattern of findings. With its explicit intent to examine and synthesize all measurable outcomes simultaneously, this approach also avoids concerns over "data-dredging" or "data fishing expeditions."

B. BASELINE SAMPLE CHARACTERISTICS

At baseline, enrollees in the New York City and upstate sites differed from each other in many ways, several of which may have affected their IDEATel experiences. Only 5 percent of New York City enrollees had had experience with personal computers before enrolling in the demonstration, compared with 33 percent of upstate enrollees (Table IV.1). On average, New York City enrollees also had less formal education than did their upstate counterparts; one-quarter of New York City enrollees had 12 or more years of formal education, compared with

TABLE IV.1

CHARACTERISTICS OF ENROLLEES AT BASELINE, BY SITE
(Percentages, Unless Noted)

Characteristic	All Enrollees[a]		Respondents to the Year 1 Interview[b]	
	New York City	Upstate	New York City	Upstate
Age at Randomization (Years)				
55 to 64	10.7	13.3	10.9	11.7
65 to 69	37.0	30.2	37.1	31.5
70 to 74	26.5	25.7	26.9	26.4
75 to 79	18.2	17.5	17.6	17.4
≥80	7.6	13.3	7.4	13.0
Male	30.5	43.0	29.4	44.6
Race/Ethnicity				
African American, non-Hispanic/non-Latino	24.0	6.6	24.5	5.0
Hispanic	74.1	1.3	73.4	0.9
White, non-Hispanic/non-Latino	1.0	90.6	1.2	92.6
Other	0.9	1.5	0.9	1.5
Education (Years)				
≤11	75.9	36.7	75.0	33.8
12	17.1	37.9	17.8	39.6
≥13	7.0	25.4	7.2	26.6
Lived Alone	43.1	32.8	42.9	31.0
Employed	1.8	10.2	2.0	10.9
Household Income (Dollars)				
<10,000	83.2	18.1	83.1	16.1
10,001 to 20,000	9.6	31.8	9.3	30.6
20,001 to 30,000	1.0	19.6	1.0	21.6
≥30,001	0.5	15.6	0.6	17.4
Missing	5.7	14.9	6.0	14.3
Reason for Medicare Entitlement				
Old age	74.9	73.0	75.1	74.0
Disability	25.1	27.0	24.9	26.0
Duration of Medicare Enrollment (Years)				
<10	69.1	63.6	69.9	64.5
10 to 14	19.9	18.8	19.7	18.6
≥15	11.0	17.6	10.3	16.8
Dually Eligible	69.0	14.4	68.7	12.4

TABLE IV.1 *(continued)*

Characteristic	All Enrollees[a]		Respondents to the Year 1 Interview[b]	
	New York City	Upstate	New York City	Upstate
Medicare Expenditures in the Year Before Randomization (Mean Dollars)	7,002	5,414	6,992	5,100
Duration of Diabetes (Years)				
<5	28.6	32.3	28.6	34.1
5 to 9	19.6	21.1	19.8	21.5
10 to 14	17.8	16.7	17.2	15.7
≥15	33.9	29.9	34.5	28.7
Ever Used a Personal Computer	5.5	33.1	5.4	35.0
Enrolled in Health Maintenance Organization in the Month Before Randomization[c]	8.8	0.9	8.9	0.6
Systolic Blood Pressure (Mean mm Hg)	142.6	142.6	141.9	142.1
Systolic Blood Pressure>130 mm Hg (percentage)	66.1	69.7	65.7	69.1
Diastolic Blood Pressure (Mean mm Hg)	71.8	70.8	71.5	70.8
Diastolic Blood Pressure>80 mm Hg (percentage)	20.3	18.8	19.0	19.0
Body Mass Index (mean kg/m^2)	30.3	33.4	30.4	33.2
Overweight (percentage)	81.6	91.6	82.5	91.3
Obese (percentage)	45.2	65.9	46.5	65.1
Total Cholesterol (Mean mg/dl)	181.4	185.9	181.3	186.4
Mean LDL Cholesterol (Mean mg/dl)	105.4	108.9	105.6	109.2
LDL Cholesterol≥100 (percentage)	52.2	55.6	52.7	55.8
Mean Hemoglobin A1c (%)	7.8	7.0	7.8	7.0
Hemoglobin A1c≥7.0% (percentage)	59.2	44.5	59.7	44.5
Hemoglobin A1c≥8.0% (percentage)	36.5	16.0	36.7	15.8
Mean Urine Albumin-to-Creatinine Ratio	230.7	165.0	199.2	146.9
Insignificant Microalbuminuria (percentage)	50.8	51.9	52.5	51.4
Microalbuminuria (percentage)	34.0	36.9	33.9	37.9
Clinical Proteinuria (Percentage)	15.2	11.2	13.8	10.7
Sample Size	**774**	**890**	**687**	**677**

Source: IDEATel telephone screen and in-person baseline interviews, conducted between November 2000 and October 2002, and Medicare claims and enrollment records (Columbia University 2003c, 2003d, and 2003e).

[a]This sample was used in analyses based on Medicare claims.

[b]This sample was used in analyses based on interview responses, anthropometric measurements, and laboratory tests collected during the Year 1 interview. Actual sample sizes varied due to missing data—see Table B.13.

[c]Forty-eight enrollees were continuously enrolled in a health maintenance organization between randomization and December 2003 (see Appendix F, Section C, footnote 11).

about two-thirds of upstate enrollees. Nearly all New York City enrollees were Hispanic/Latino or black, whereas 9 out of 10 enrollees in upstate New York were white.

New York City enrollees' diabetes was in somewhat worse control than upstate enrollees', with mean hemoglobin A1c values of 7.7 and 7.0 respectively (in fact, upstate enrollees' diabetes was in quite good control).[49] Upstate enrollees were more overweight with a mean body mass index of 33, versus a mean body mass index of 31 among New York City enrollees.[50] Overall, IDEATel enrollees had only mildly to moderately abnormal values for hemoglobin A1c, blood pressure, cholesterol values, and other physiologic parameters.

C. RESULTS

1. Self-Reported Communication with Health Care Providers

In Year 1 interviews, treatment group members in both sites were much more likely than control group members to report that they had seen a diabetes nurse educator at least once since baseline. Compared with control group members, the proportions of treatment group members who said they had seen a nurse educator during that time were more than twice as large in New York City and more than six times as large upstate. In the upstate site, treatment group members also were

[49] In general, the target hemoglobin A1c value for people with diabetes who are otherwise healthy should be 7.0 or lower (see Appendix B).

[50] A body mass index over 25 is considered overweight, and an index over 30 is considered obese.

much more likely to say they had seen a dietitian. For both sites, data on HTU use suggest treatment–control differences were even larger than the interview responses indicate.[51]

Compared to control group members, treatment group members were more likely to report that the health care professionals who cared for their diabetes discussed exercise and diet with some frequency, but estimated effects were larger upstate than in New York City. In response to a question about the number of times that health care professionals had discussed each type of self-care during the year after randomization, upstate treatment group members were about twice as likely as their control group counterparts to report four or more discussions, and half as likely to report no discussions at all (Table IV.3). In New York City, more control group members than treatment group members reported that their health care providers had not talked to them about exercise or eating at all (about 43 percent and about 35 percent, respectively).[52]

IDEATel seemed to have had few effects on how frequently health care professionals included enrollees in decisions about the enrollees' diabetes (Table IV.3). The largest effects were

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[51]Judging from HTU-use data (Table III.2), most treatment group members in New York City and many in the upstate site did not count televisits with nurse case managers or dietitians as instances in which they "saw" such providers. Had more treatment group members included televisits in their responses, and assuming the control group's self-reports are fairly accurate, the estimated effects shown in Table IV.2 would be considerably larger.

[52]Table IV.3 also shows the results of a survey question about how often health care providers discussed control of blood sugar. Statistically significant differences favored the treatment group in both sites; however, the large proportions reporting that providers did not discuss this topic at all are surprisingly high and may suggest that the question was confusing. The question asked, "How many times in the past 12 months did any of the health care professionals who care for your diabetes discuss or refer you to someone who taught you how to keep your blood sugar near normal?" If people who were confused by the two-part question responded anyway, their responses might not provide valid measures of how often this key topic was discussed.

TABLE IV.2

ESTIMATED EFFECTS OF IDEATel ON APPOINTMENTS WITH NURSE EDUCATORS AND DIETITIANS, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Saw a Diabetes Nurse Educator at Least Once (Percent)	32.6	15.4	17.2 (.000)	76.1	11.5	64.5 (.000)
Number of consultations, if any (mean)	6.2	3.6	2.5 (.059)	7.2	1.9	5.3 (.000)
Saw a Dietitian (Percent)	21.7	22.0	-0.3 (.915)	77.4	16.3	61.1 (.000)
Number of consultations, among those with at least one dietitian consultation, if any (mean)	2.2	2.7	-0.5 (.724)	5.7	1.9	3.8 (.000)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly because of item nonresponse.

TABLE IV.3

ESTIMATED EFFECTS OF IDEATel ON ENROLLEE REPORTS OF PROVIDER PRACTICES, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
In the Past Year, Number of Times Health Care Professionals Discussed						
Exercise						
Four or more times	36.2	29.5	6.7 (.054)	47.0	24.3	22.8 (.000)
Not at all	35.2	43.2	–8.0 (.030)	26.0	49.5	–23.6 (.000)
Eating Habits						
Four or more times	27.6	22.5	5.1 (.113)	44.6	19.9	24.7 (.000)
Not at all	34.8	45.1	–10.3 (.005)	26.9	49.7	–22.8 (.000)
Controlling Blood Sugar						
Four or more times[a]	6.2	2.3	3.9 (.011)	24.8	6.6	18.2 (.000)
Not at all	74.7	81.3	–6.9 (.037)	39.4	75.6	–36.3 (.000)
In General, Number of Times Health Care Professionals[b]						
Offered Choices in Medical Care						
Always or almost always	57.4	58.7	–1.3 (.737)	35.9	34.0	1.9 (.596)
Never	19.8	23.8	–4.0 (.204)	43.5	43.2	0.3 (.946)
Discussed the Pros and Cons of Choices						
Always or almost always	53.9	47.2	6.7 (.081)	46.1	45.1	1.0 (.785)
Never	25.3	30.2	–4.9 (.150)	35.2	36.2	–1.0 (.777)

TABLE IV.3 (*continued*)

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Asked Enrollee to State Preferences						
Always or almost always	50.8	43.6	7.2 (.064)	36.7	34.3	2.3 (.506)
Never	31.0	34.3	–3.3 (.360)	47.7	48.0	–0.3 (.935)
Considered Preferences in Treatment Decisions						
Always or almost always	55.3	51.9	4.2 (.274)	50.7	48.0	2.7 (.457)
Never	21.8	26.4	–4.7 (.156)	33.9	34.6	–0.7 (.836)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]Effects for the New York City sample could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[b]These measures are derived from survey questions with five-point scales. The intermediate ratings (some or a little of the time) are not shown.

observed in the New York City sample; in that sample, treatment group members were about seven percentage points more likely than control group members to report that the health care professionals who cared for their diabetes always or almost always discussed the pros and cons of treatment choices and asked for their preferences.

2. Knowledge, Self-Efficacy, and Outcome Expectancies for Self-Care

In the upstate site, treatment group members did better than control group members on six measures of self-care knowledge (Table IV.4). The proportions of treatment group members who reported that they understood how to perform the specified self-care tasks "completely or pretty well" ranged from about 92 to 99 percent and were 5 to 7 percentage points higher than in the control group. In New York City, statistically significant treatment–control differences in self-care knowledge were observed only in foot care and testing of blood sugar levels; 94 percent of treatment group members reported understanding how to care for their feet, versus 88 percent of control group members, and 97 percent of the treatment group said they understood how to test blood sugar levels, versus 91 percent of the control group.

In the upstate site, treatment group members also scored higher than control group members on three of four measures of self-efficacy (self-assessed ability to accomplish certain tasks, such as following a diet or managing an exercise program; see Table IV.4). In New York City, however, differences between the groups were observed for only one self-efficacy area (managing blood sugar), with treatment group members scoring slightly higher than control group members.

The annual visit questionnaire also asked enrollees about their global attitudes about diabetes, and their perceptions of the day-to-day tasks of managing diabetes. The questionnaire asked about the following global attitudes: the degree of the harmfulness of diabetes to health, the benefits of diabetes control for health, and the degree of self-confidence in the ability to control

TABLE IV.4

ESTIMATED EFFECTS OF IDEATel ON SELF-CARE KNOWLEDGE AND EFFICACY, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Understands How to:[a]						
Take care of feet[b]	93.7	87.9	5.8 (.010)	96.2	89.8	6.4 (.001)
Address symptoms of low blood sugar[b]	89.9	89.2	0.7 (.776)	94.2	86.1	8.2 (.000)
Test blood sugar[c]	96.5	91.0	5.4 (.004)	99.4	94.6	4.8 (.000)
Exercise appropriately	82.4	80.7	1.8 (.545)	94.1	88.4	5.8 (.010)
Choose appropriate foods	89.8	88.6	1.1 (.640)	92.4	85.5	6.9 (.003)
Knows Target Blood Glucose Values	81.6	79.7	1.9 (.529)	89.1	79.5	9.7 (.000)
Self-Efficacy Scores[d] (Means)						
Managing weight and selecting foods	84.1	82.9	1.2 (.205)	86.0	82.6	3.4 (.000)
Following diet in general	76.7	75.3	1.4 (.417)	77.0	71.3	5.7 (.000)
Managing exercise	76.9	75.8	1.1 (.501)	75.4	72.8	2.5 (.109)
Managing blood sugar	89.1	86.7	2.4 (.029)	91.8	87.5	4.3 (.000)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]These measures include respondents who stated that they understood completely or pretty well.

[b]Effects for the New York City sample could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[c]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[d]These scores are the sum of responses to questions about enrollees' perceived ability to follow self-care regimens. The response values ranged from zero (to indicate definitely could not handle a task) to four (to indicate definitely could handle a task). The number of questions contributing to each score ranged from 3 to 10. The scores have been prorated to account for missing values, and normalized to scales from 0 to 100.

diabetes in the coming year. There were no treatment–control differences in any of these global attitudes in the New York City site (Table IV.5).

The data suggest that the intervention may have had a very small negative effect on some of the New York City participants' attitudes about the daily struggles with management of diabetes (Table IV.5). Although few enrollees reported that remembering to take medications was a "big hassle," the proportion of treatment group members who did so was higher than among control group members (eight versus four percent), a difference of borderline statistical significance ($p = 0.058$). Although not statistically significant, two of the other treatment–control differences for these "hassle" outcomes were in the same direction (avoiding or limiting favorite food, and planning meals), with the treatment group having higher proportions of participants rating these activities as big hassles. The treatment–control differences for the remaining outcomes (keeping a schedule, remembering to test blood sugar, organizing daily routine, and total time spent managing diabetes) were of smaller magnitude, with some favoring the treatment group and others the control group.

Among upstate enrollees, IDEATel also had no impacts on global attitudes toward diabetes. In the upstate site, IDEATel did have a statistically significant effect on enrollees' self-efficacy (Table IV.5). At followup, the proportion of treatment group members who felt sure that they would be able to control their diabetes was five percentage points higher than the proportion of control group members who felt this way. Finally, although nearly all of the estimated treatment–control differences in the "hassle" measures favored the treatment group (that is, with lower percentages of treatment group members viewing diabetes care activities as a big hassle), none of the differences were statistically significant (Table IV.5).

TABLE IV.5

ESTIMATED EFFECTS OF IDEATel ON SELF-REPORTED ATTITUDES ABOUT DIABETES, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Global Attitudes About Diabetes						
Beliefs About Harmfulness to Health						
Diabetes is very harmful	50.1	55.3	–5.2 (.154)	49.3	51.4	–2.1 (.573)
Diabetes is not at all harmful	22.0	20.1	2.1 (.524)	31.5	29.9	1.6 (.630)
Beliefs About Health Benefits of Diabetes Control						
Health will benefit a great deal	87.8	88.5	–0.7[a] (.786)	91.9	92.4	–0.5 (.802)
Health will not benefit a great deal	3.0	3.4	–0.4[a] (.722)	0.9	2.4	–1.5[a] (.131)
Confidence in Ability to Control Diabetes in the Next Year						
Feel sure can control diabetes	82.1	80.3	1.8 (.548)	85.8	80.5	5.3 (.051)
Not at all sure can control diabetes	5.1	6.1	-1.0[a] (.566)	4.2	7.1	–2.9[a] (.097)
Attitudes About Day-to-Day Diabetes Self-Care						
Avoiding or Limiting Favorite Food Is a Big Hassle	19.9	15.6	4.3 (.131)	14.7	19.2	–4.5 (.120)
Keeping a Schedule Is a Big Hassle	10.1	11.2	-1.1[a] (.617)	5.8	7.3	–1.5 (.422)
Remembering to Test Blood Sugar Is a Big Hassle	12.0	12.9	–0.9[a] (.745)	3.0	3.4	–0.4 (.764)
Planning Meals Is a Big Hassle	10.5	7.6	2.9[a] (.187)	4.3	3.8	0.5 (.065)
Organizing Daily Routine Is a Big Hassle	9.2	9.2	0.0[a] (.982)	2.7	3.6	–0.9[a] (.498)
Remembering to Take Medications Is a Big Hassle	7.9	4.4	3.5[a] (.058)	1.6	2.5	–0.9[a] (.408)
Total Time Spent Managing Diabetes Is a Big Hassle	8.6	8.0	0.6[a] (.800)	2.4	3.8	–1.4 (.338)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

TABLE IV.5 *(continued)*

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models which controlled for enrollees baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly because of item nonresponse.

[a]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

3. Self-Reported Behavior

a. Self-Monitoring

In both sites, IDEATel seemed to have large positive effects on the proportion of enrollees who tested their blood sugar daily, and smaller positive effects on the proportion who examined their feet daily (Table IV.6). In the New York City site, 68 percent of treatment group members reported that they tested their blood sugar at least daily during the week preceding their follow-up interview, compared with 54 percent of control group members. In the upstate site, 75 percent of treatment group members and 54 percent of control group members tested their blood sugar daily. The proportions of treatment group members who reported examining their feet daily were eight and six percentage points larger than those of control group members in New York City and upstate New York, respectively.

b. Making and Keeping Appointments

There were no treatment–control differences in either site on whether enrollees reported difficulty accessing any medical appointments they sought (Table IV.7). Overall, more than 70 percent of all enrollees reported that they could always get a routine health care appointment when they wanted one, and only 10 percent missed two or more appointments because of weather or other conditions beyond their control. In the upstate site, treatment group members were more likely than control group members to report that they had had their feet examined several times.

c. Reported Adherence to Medication, Diet, and Exercise Regimens

In New York City, more treatment group members than control group members reported adhering to their exercise regimens (a difference of 7 percentage points); despite the large difference, however, the percentage of treatment group members following an exercise regimen (55 percent) was still relatively low (Table IV.8). In the upstate site, no treatment–control

TABLE IV.6

ESTIMATED EFFECTS OF IDEATel ON SELF-MONITORING, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
In the Past Week						
Tested Blood Sugar Daily[a]	68.4	53.6	14.7 (.000)	74.5	53.7	20.9 (.000)
Examined Feet Daily	80.9	73.3	7.6 (.017)	73.2	67.4	5.8 (.077)
Sample Size	**338**	**349**	—	**338**	**339**	—

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly because of item nonresponse.

[a]This percentage was calculated from the average of the enrollees' responses to two questions. Possible responses ranged from zero to seven days.

TABLE IV.7

ESTIMATED EFFECTS OF IDEATel ON MAKING AND KEEPING APPOINTMENTS, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Gets Routine Health Care Appointment When Wants One[a]						
Always	81.1	77.1	4.0 (.198)	71.1	71.1	0.0 (.998)
Sometimes, rarely, or never	6.5	5.1	1.3 (.458)	6.6	6.0	0.6 (.744)
In the Past Year						
Missed or Did Not Schedule at Least Two Medical Appointments Because of Circumstantial Problems[b,c]	10.7	9.7	1.0 (.685)	9.4	9.2	0.2 (.909)
Number of Examinations of the Feet						
Four or more	42.5	43.9	–1.3 (.710)	40.8	33.3	7.5 (.028)
None	22.6	19.9	2.6 (.392)	20.6	23.7	–3.2 (.288)
Had at Least One Examination of the Feet with Monofilament	40.0	41.9	–1.9 (.613)	27.6	32.1	–4.4 (.191)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]This measure is derived from a survey question with a five-point scale. The intermediate rating (usually) is not shown.

[b]Effects for the New York City sample could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[c]Enrollees were asked about appointments they missed or did not schedule because of distance, road, or weather conditions, or because no one could accompany them.

TABLE IV.8

ESTIMATED EFFECTS OF IDEATel ON ADHERENCE TO SELF-CARE, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
In the Past Week						
Took Recommended Doses of Diabetes Pills Daily[a,b]	95.3	94.4	0.9 (.622)	97.7	95.1	2.7 (.101)
Administered Recommended Insulin Injections Daily[b,c]	95.2	99.1	–3.9 (.080)	98.0	97.1	0.9 (.659)
Adhered to Diet Daily[d]	57.7	59.5	–1.8 (.617)	46.6	42.1	4.4 (.206)
Adhered to Exercise Plan on Three or More Days[d]	54.8	47.4	7.4 (.040)	64.7	68.0	–3.4 (.333)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Sample sizes vary slightly because of item nonresponse.

[a]This question was answered by enrollees who were taking diabetes pills.

[b]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[c]This question was answered by enrollees who were taking insulin.

[d]This percentage was calculated from the average of the enrollees' responses to two questions. Possible responses ranged from zero to seven days.

differences in any of the outcomes relating to adherence to self-care regimens were observed. Regardless of site and treatment status, much larger proportions of enrollees reported adhering to their medication regimens during the week before their interviews than reported adhering to either diet or exercise regimens during that week. In fact, the control group's reported adherence to medication regimens was so high (above 94 percent, in both sites) that it left little room for positive program effects.

d. Use of Cigarettes and Alcohol

There were no significant treatment–control differences in measures of smoking cigarettes and drinking alcohol in either site; however, because so few enrollees smoked or drank, both statistical power for detecting intervention effects and room for intervention effects were very small (Table IV.9).[53] In New York City, there was a difference with borderline statistical significance between the two groups in the proportion of smokers reporting that they planned to quit within 30 days; in the treatment group, 15 of 19 smokers (79 percent) reported plans to quit, compared with only 14 of 26 smokers in the control group (54 percent). In the upstate site, a treatment–control difference in the use of cigarettes was driven by the fact that the treatment group included five heavy smokers who smoked 40 cigarettes per day, whereas only one control group member smoked that much. (No one reported smoking more than 40 cigarettes per day.)

[53]At the baseline and annual visits, the Consortium also performed laboratory tests on enrollees' urine specimens to measure cotinine. Cotinine is a substance produced by the body in its metabolism of nicotine and can be used to objectively distinguish smokers from nonsmokers. The number of smokers at baseline was so small, however, that the independent evaluator did not analyze these data.

TABLE IV.9

ESTIMATED EFFECTS OF IDEATel ON SELF-REPORTED USE OF CIGARETTES AND ALCOHOL, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
All Participants						
Currently Smokes Cigarettes[a]	5.6	8.3	–2.7 (.171)	8.3	7.9	0.5 (.636)
Currently Drinks Alcohol[b]	16.8	14.8	–1.9 (.403)	24.8	28.8	–4.0 (.148)
Current Users[c]						
Number of Cigarettes Smoked per Day in the Past Month (Mean)	11.1	8.2	2.9 (.299)	20.6	14.8	5.8 (.062)
Discussed Quitting Smoking with Health Care Professional in the Past Year (Percentage)	68.4	50.0	18.4 (.216)	53.9	53.6	0.3 (.984)
Plans to Quit Smoking in the Next 30 Days (Percentage)	79.0	53.9	25.1 (.089)	16.0	18.5	–2.5 (.811)
Usual Number of Drinks per Week (Mean)	1.5	2.2	–0.7 (.283)	3.5	3.3	0.2 (.815)
Among those who had at least one drink	4.0	5.0	–1.0 (.463)	7.2	6.0	1.2 (.337)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Sample sizes vary slightly because of item nonresponse.

[a]Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4).

[b]Effects for the New York City sample could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[c]Because of the small number of current users, logit models were not used to predict means. The results presented here are the unadjusted means and treatment–control differences.

4. Use of Medicare-Covered Health Services Overall, and Use of Recommended Preventive Care Services

IDEATel had no broad effect in either site on the likelihood that enrollees used either general Medicare-covered services or specific Medicare-covered recommended preventive care services for diabetes. With the exception of somewhat higher use of home health care and durable medical equipment by the treatment group in the upstate site, there were no real treatment–control differences across the broad range of general Medicare services studied, from inpatient hospital care to laboratory tests (Table IV.10). In the upstate site, the proportion of members using home health care was 22 percent in the treatment group, versus 17 percent in the control group, and the proportion using durable medical equipment was 84 percent in the treatment group, versus 76 percent in the control group.

Among the preventive services, treatment group members in the upstate site were slightly more likely to have had a dilated eye exam in the follow-up period (78 percent of the treatment group, compared to 73 percent of the control group). No other differences were seen for preventive services in either site. Except for a somewhat higher use of home health care services among New York City treatment group members and a slightly higher use of low-density lipoprotein cholesterol tests among upstate treatment group members, there were no major effects on the numbers of services used, among service users in either site (Table IV.11).

The results of Tables IV.10 and IV.11 reflect only services covered by Medicare, and thus received by participants outside of the study. In fact all participants, treatment and control group members alike, did undergo annual testing of lipid and urine microalbumin and creatinine tests at the annual evaluation visits, with results provided to all participants and their primary physicians. As evaluation and research data, however, these tests were paid for by the IDEATel study, and were not billed to Medicare. The results of Tables IV.10 and IV.11 thus show whether the

TABLE IV.10

USE OF SELECTED MEDICARE-COVERED SERVICES, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
General Medicare-Covered Services						
Hospitalization	31.2	33.9	-2.7 (.488)	47.9	42.7	5.2 (.128)
Skilled Nursing Facility Admission	4.0	1.7	2.3 (.059)	7.0	8.2	-1.2 (.525)
Home Health Care	24.8	26.9	-2.1 (.503)	22.1	16.8	5.3 (.044)
Skilled nursing visit[a]	100.0	94.7	5.3 (.029)	95.7	97.2	-1.5 (.614)
Aide visit[a]	58.4	55.8	2.6 (.718)	34.0	50.0	-16.0 (.040)
Therapy visit[a]	66.3	62.1	4.2 (.555)	56.4	58.3	-1.9 (.802)
Social worker visit[a]	18.0	22.1	-4.1 (.486)	4.3	6.9	-2.6 (.449)
Durable Medical Equipment	58.1	61.8	-3.7 (.293)	83.6	76.0	7.6 (.003)
Physician Office Visit	90.8	92.5	-1.7 (.418)	91.6	90.0	1.6 (.388)
Laboratory Test[b]	62.1	64.4	-2.3 (.495)	77.3	77.2	0.1 (.967)
Specific Recommended Preventive Care Services for Diabetes						
Dilated Eye Examination	90.2	88.2	2.0 (.385)	77.5	72.7	4.8 (.078)
Hemoglobin A1c Test	91.8	92.3	-0.5 (.776)	93.9	93.5	0.4 (.782)
Low-Density Lipoprotein Cholesterol Test	84.6	85.7	-1.1 (.708)	85.5	85.1	0.4 (.863)
Urine Microalbumin Test	74.2	77.0	-2.8 (.385)	75.4	73.6	1.8 (.534)
Sample Size	**372**	356	--	**446**	**442**	--

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c). Data correspond to 2000-2003.

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). Enrollees' data have been annualized (see Appendix F, Section B).

[a] Dependent variable(s) could not be modeled with logit regression; annualized unadjusted mean(s) and t-test(s) presented here.

[b] Refers to services rendered by a certified laboratory independent of an institution or a physician office.

TABLE IV.11

AMONG THOSE USING A SERVICE, MEAN NUMBER OF SERVICES USED, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
General Medicare-Covered Services						
Hospitalization	1.5	1.3	0.2 (.386)	1.2	1.3	-0.1 (.625)
Skilled Nursing Facility Admission[a]	0.72	0.52	0.2 (.164)	0.66	0.72	-.06 (.641)
Home Health Care[b]	36.7	24.7	12.0 (.083)	15.7	20.0	-4.3 (.372)
Skilled nursing visits[b]	10.7	7.2	3.5 (.055)	8.0	7.6	0.4 (.847)
Aide visits[b]	21.0	13.1	7.9 (.112)	4.1	8.6	-4.5 (.125)
Therapy visits[b]	4.9	4.2	0.7 (.418)	3.5	3.3	0.2 (.862)
Social worker visits[b]	0.13	0.19	-.06 (.382)	0.09	0.48	-0.39 (.187)
Physician Office Visit	8.0	8.6	-0.6 (.814)	8.0	8.1	-0.1 (.964)
Laboratory Test[c]	13.6	15.7	-2.1 (.344)	12.8	12.9	-0.1 (.840)
Specific Recommended Preventive Care Services for Diabetes						
Dilated Eye Examination	3.1	3.0	0.1 (.809)	1.5	1.7	-0.2 (.151)
Hemoglobin A1c Test	1.9	2.0	-0.1 (.280)	2.3	2.3	0.0 (.642)
Low-Density Lipoprotein Cholesterol Test	1.5	1.6	-0.1 (.372)	1.7	1.6	0.1 (.050)
Urine Microalbumin Test	1.5	1.8	-0.3 (.226)	1.7	1.6	0.1 (.433)
Sample Size	**372**	356	--	**446**	**442**	--

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c). Data correspond to 2000-2003.

Note: Means were predicted with linear regression, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4). The number of enrollees using a service varies by the service. Enrollees' data have been annualized (see Appendix F, Section B).

[a]Unadjusted annualized means of numbers of skilled nursing facility admissions and *t*-tests presented because of sample size limitations on regression models.

[b]Unadjusted annualized means of home health visits and *t*-tests presented because of sample size limitations on regression models.

[c]Refers to services rendered by a certified laboratory independent of an institution or a physician office.

intervention had any effects on monitoring and testing behavior of participants and their primary care physicians in routine care beyond the tests provided through the study. Although annual testing is the minimum frequency suggested in practice guidelines, testing more frequently than once per year may be indicated in individuals with poorly controlled lipid or blood sugar levels. The randomized design of the study means there should be an equal proportion of such poorly controlled individuals in both treatment and control groups, and one might thus expect more frequent testing among the treatment group, if primary care physicians were being encouraged by the nurse case managers' progress reports to monitor these clinical measurements more closely.

5. Patterns of Medication Use

a. Categories of Medications Studied

The independent evaluator assessed whether treatment group members were more likely than control group members to be prescribed recommended medication regimens for diabetes.[54] To make the assessment, the independent evaluator used data from the annual visit questionnaire, which asked enrollees detailed questions about prescribed medications and dosages. Appendix B, Section C.3, contains a more detailed explanation of the five main categories of medications studied; briefly, the five categories were:

1. ***ACE Inhibitors and ARBs.*** These are two different but related classes of blood-pressure–lowering medications. Beyond their blood-pressure–lowering effect alone, these medications have additional protective effects against diabetic kidney disease. They reduce the proteinuria that is a marker of kidney damage. They also may protect against heart attacks and stroke, independent of effects on blood pressure.

[54]As IDEATel is a Medicare demonstration, the discussion on medications focuses on Type 2 diabetes, the type predominantly seen in older people, and *diabetes* refers implicitly to Type 2 diabetes.

2. ***Antihypertensive Medications.*** This category includes all blood-pressure–lowering medications in general, including, but not limited to, ACE-inhibitors and ARBs. High blood pressure greatly increases risk for heart attack, kidney failure, and vascular disease stroke in people with diabetes.

3. ***Antiplatelet Agents.*** These medications inhibit the function of blood platelets, the blood elements that initiate blood clots. Platelets play a major role in the heart attacks and strokes to which people with diabetes are so prone; antiplatelet drugs reduce the risks of those events.

4. ***LDL-Cholesterol-Lowering Drugs.*** LDL cholesterol, the so-called *bad cholesterol* greatly increases risk for heart attacks, stroke, and vascular disease in people with diabetes. Drugs to lower LDL cholesterol reduce this risk.

5. ***Insulin and Oral Antihypoglycemic Agents.*** These drugs lower blood sugar levels. Controlling blood sugar reduces the nerve, kidney, and eye complications of diabetes.

The measurable *treatment targets* of these medications that will be examined in the discussion of clinical and laboratory outcomes (Section C.6) are proteinuria, blood pressure, LDL cholesterol, and hemoglobin A1c.

b. Analysis of Medication Use

For each medication category, the independent evaluator restricted its analysis of patterns of medication use to demonstration enrollees with indications for the category's use. For example, the use of ACE-inhibitors and ARBs was studied only in patients with proteinuria at the baseline study visit, the use of hypoglycemic drugs was studied in patients with poor blood sugar control at baseline (hemoglobin A1c levels higher than eight percent), and the use of antihypertensive agents was studied in people with high baseline blood pressure readings. Within these subgroups defined by indications for treatment, the independent evaluator thus conducted treatment–control comparisons, by site, of rates of prescription of the recommended medications.

In addition to determining whether the recommended medications were prescribed, the independent evaluator also studied the mean dosages of the medications that were prescribed,

and for some of the medication categories, the number of different medications in that category prescribed per person. (The mean dosages are measured in milligrams, or mg, except for insulin, which is measured in units.) With the exception of the antiplatelet drugs, larger doses of the medications lead to larger reductions in the treatment targets (the effects of antiplatelet medications are not highly dependent on dose). Two or more different medications from the same category (such as two antihypertensive drugs or two oral antihypoglycemic agents) may have a greater effect than one medication alone.

Although a multitude of individual patient characteristics will influence physicians' and patients' decisions on prescription and dosing of medications, the random assignment design of the demonstration should result in an equal distribution of these characteristics, measured and unmeasured, between the treatment and control groups. Such patient characteristics might include clinical contraindications to drugs, potential for drug interactions, comorbidities, financial resources, susceptibility to side effects, preferences, or known drug allergies. Because of these individual factors, rates of prescription of medications with even the most solid research evidence and clearcut guideline recommendations supporting their use will likely never be 100 percent, nor will dosing necessarily reach maximal doses achieved in clinical trials with carefully selected participants. However, random assignment should remove any treatment–control imbalance in these factors as a potential source of bias in comparisons between the two groups.

A more serious potential limitation of using prescription rates, prescribed dosages, or numbers of medications, however, is that they may be confounded by patient adherence, which may in turn be affected by the intervention. If treatment group members have higher adherence to medications, diet, or exercise than control group members, they may achieve their physicians' desired clinical targets with lower prescribed dosages or fewer medications than the control

group. It is important to remember, however, that the intervention had no discernable effect on patients' self-reported adherence to oral medications in either site, or on adherence to insulin injections in the upstate site (with self-reported adherence to insulin possibly slightly lower among treatment group members in the New York City site) (Table IV.8).

Because each medication category included a number of medications, each with its own tablet or capsule sizes and dosing ranges, the independent evaluator developed a single number to summarize dosages across the different medications within a medication category. The independent evaluator converted dosages into percentages of maximum effective doses.[55] The daily prescribed doses for each medication of interest were divided by that medication's maximum recommended daily dose. Person-level means were then calculated, followed by treatment and control group means across persons. Appendix B, Section C.3, provides a simple example of how this person-level mean of percentage of maximum dose is calculated.

For two reasons, treatment–control differences in rates of medication prescription and average daily doses are discussed here, even if they are not statistically significant. First, the statistical power of the medication analyses was limited, as the samples were already reduced by restricting analyses to enrollees with specific indications for medications (for example, only enrollees with proteinuria or high baseline hemoglobin A1c); furthermore, the number of enrollees taking

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[55]For all drugs except sulfonylurea drugs and metformin, the maximum effective dose was the maximum dose listed by the drug's manufacturer on the drug's package insert. For the sulfonylurea drugs (glimepiride, glipizide, glyburide, and chlorpropamide), however, the maximum effective dose was set at 50 percent of this maximum listed dose, because there is little marginal clinical benefit in increasing the dosages of these drugs beyond this level. For the same reasons, the maximum effective dose of metformin was set at 1,000 mg twice daily (2,000 mg daily), even though the package insert states that the maximum dose is 2,500 mg.

particular medications was smaller still. In addition, the variation of prescribed doses within each drug or drug category was often quite large. Second, statistically insignificant differences in rates of medication prescription and dosing still could produce significant effects on the treatment targets of proteinuria, blood pressure, LDL cholesterol, and blood sugar.

c. Results

ACE-Inhibitors and ARBs. In the New York City site, slightly more treatment group members than control group were prescribed this category of medication (78 percent, compared to 76 percent; Table IV.12). Among sample members receiving these medications, treatment group members were prescribed a slightly higher dose of one drug (losartan, by two mg—about 5 percent more relative to the control group), and substantially larger doses of another (quinapril, by six mg—about 20 percent higher than the control group). The overall mean percentages of maximum dose were the same (both about 58 percent).

Upstate treatment group members also were more likely to have been prescribed these medications (86 percent, compared with 79 percent of control group members). Dosing differences were mixed, with higher doses for the treatment group for two drugs (quinapril and enalapril), and lower doses for two others (lisinopril and losartan); the overall mean percentage of maximum recommended dose was lower among the treatment group (51 percent, compared with 56 percent for the control group; Table IV.12).

Antihypertensive Medications. The proportion of New York City treatment group members receiving any antihypertensive drug (95 percent) was significantly higher than that of the control group (87 percent), although rates in both groups were high. Treatment group members were also receiving slightly more drugs (an average of 2.3 medications per enrollee, compared with

TABLE IV.12

USE OF SELECTED MEDICATIONS, BY SITE

Outcome	New York City			Upstate		
	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)
ACE-Inhibitor or ARB in Patients with Baseline Proteinuria[a]						
Percentage of Group Prescribed	78.0	75.5	2.5 (.642)	85.5	78.6	6.9 (.155)
Mean Dosage of Five Most Common Medications, Among Those Prescribed the Medication (mg)[b]						
Lisinopril	31.2	30.3	0.9 (.825)	17.3	21.0	–3.7 (.431)
Enalapril	19.0	24.8	–5.8 (.286)	21.3	16.4	4.9 (.443)
Losartan	34.7	33.0	1.7 (.847)	40.0	55.2	–15.2 (.360)
Quinapril	33.7	27.8	5.9 (.459)	38.9	35.4	3.5 (.698)
Ramipril	11.3	10.7	0.6 (.889)	8.3	8.7	–0.4 (.884)
Mean Percentage of Maximum Recommended Dosage, for all Medications (Percent)	58.6	58.4	0.2 (.971)	50.8	55.7	–4.9 (.468)
Other Antihypertensive Medications in Patients with Baseline Hypertension[c]						
Percentage of Group Prescribed	94.6	87.3	7.3 (.007)	88.9	86.5	2.4 (.420)
Mean Number of Medications, Among Those Prescribed the Medication	2.3	2.2	0.1 (.904)	2.2	2.1	–0.1 (.730)
Mean Dosage of Five Most Common Medications, Among Those Prescribed the Medication (mg)[b]						
Metoprolol	31.6	28.0	3.6 (.438)	47.7	52.1	–4.4 (.569)
Lisinopril	31.9	34.3	-2.4 (.547)	17.3	17.6	–0.3 (.920)
Quinapril	38.9	37.8	1.2 (.910)	30.3	36.3	–6.0 (.356)

TABLE IV.12 *(continued)*

Outcome	New York City			Upstate		
	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)
Enalapril	20.5	23.7	–3.2 (.365)	25.4	15.7	9.6 (.045)
Losartan	33.6	29.7	3.9 (.535)	27.2	53.4	–26.2 (.034)
Mean Percentage of Maximum Recommended Dosage, for all Medications (Percent)	46.6	50.3	–3.7 (.232)	41.5	38.8	2.7 (.317)
Antiplatelet Medications in All Patients						
Percentage of Group Prescribed	42.9	40.1	2.8 (.459)	14.8	16.8	–2.0 (.471)
LDL–Lowering Agents in Patients with Baseline High LDL[d]						
Percent of Group Prescribed	49.4	40.4	9.0 (0.89)	56.5	47.2	9.3 (.077)
Mean Number of Medications, Among Those Prescribed the Medication	1.0	1.0	0.0 (—)[f]	1.0	1.0	–0.0 (.881)
Mean Dosage of Five Most Common Medications, Among Those Prescribed the Medication (mg)[b]						
Atorvastatin	25.9	25.3	0.6 (.896)	20.6	21.5	–0.9 (.806)
Simvastatin	32.1	27.7	4.4 (.540)	24.3	23.3	1.0 (.825)
Pravastatin	23.3	30.0	–6.7 (.260)	39.2	32.1	7.1 (.419)
Lovastatin	33.3	40.0	–6.7 (—)[f]	40.0	20.0	20.0 (—)[f]
Fluvastatin	—	—	—	62.9	57.6	5.3 (.742)
Mean Percentage of Maximum Recommended Dosage, for all Medications (Percent)	34.2	34.0	.13 (.976)	36.4	34.1	2.3 (.600)
Hypoglycemic Medications in Patients with Baseline Hemoglobin A1c Higher than Eight Percent						
Percentage Prescribed Either Insulin or Oral Medication	100.0	98.4	1.6 (.161)	100.0	92.0	8.0 (.034)
Percentage Prescribed Oral Medications Only	57.3	52.0	5.3 (.400)	48.2	40.0	8.2 (.403)
Percentage Prescribed Insulin Only	31.5	32.0	–.50 (.947)	19.4	19.7	–.30 (.955)
Mean Number of Oral Medications, Among Those Prescribed Oral Medications	1.87	1.57	.30 (.003)	1.76	1.80	–.04 (.802)

TABLE IV.12 *(continued)*

Outcome	New York City			Upstate		
	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)	Treatment Group Mean	Control Group Mean	Difference (*p*-Value)
Mean Dosage of Selected Medications, Among Those Prescribed the Medication (mg)[b]						
Metformin	1,501.0	1,463.0	38.8 (.745)	1,533.0	1,450.0	83.0 (.655)
Glipizide	12.4	13.8	–1.4 (.348)	12.1	11.5	0.6 (.868)
Glyburide	8.8	8.2	0.6 (.685)	10.3	10.9	–.06 (.841)
Rosiglitazone	6.6	6.5	0.1 (.887)	6.3	6.0	0.3 (.870)
Mean Daily Insulin Dosage, Among Those Prescribed Insulin (Units)	100.9	109.7	–8.8 (.530)	66.8	45.2	22.6 (.038)
Mean Percentage of Maximum Recommended Dosage, for All Oral Medications (Percent)	73.0	76.3	–3.3 (.491)	84.3	83.7	0.6 (.958)

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Results are unadjusted mean values; comparisons are tested with *t*-tests and chi-squared statistics.

[a]Baseline urine albumin-to-creatinine ratio of ≥30 mg/g. In New York City, 266 enrollees with baseline proteinuria (127 treatment, 139 control). In upstate site, 250 enrollees with baseline proteinuria (124 treatment and 124 control).

[b]Medications are listed in descending order of frequency.

[c]Baseline systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg. In New York City, 456 enrollees with baseline hypertension (220 treatment, 235 control). In upstate site, 472 enrollees with baseline hypertension (235 treatment and 237 control).

[d]HCTZ and triamterene not included because dosing less important.

[e]Baseline LDL cholesterol ≥100 mg/dl. In New York City, 355 enrollees with baseline LDL (172 treatment, 183 control). In upstate site, 366 enrollees with baseline LDL (186 treatment and 180 control).

[f]*t*-statistic and *p*-value could not be calculated because enrollees in either the treatment or control group (or both groups) all have the same value. For example, all control group members had the identical dose of lovastatin of 40 mg daily.

[g]No enrollees were taking this medication.

In New York City, 251 enrollees with high baseline hemoglobin A1C (124 treatment, 127 control). In upstate site, 104 enrollees with high baseline hemoglobin A1c (43 treatment, 50 control).

ACE-Inhibitor = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; LDL = low-density lipoprotein.

2.2 per control group member). The overall mean percent of maximum dose was lower in the treatment group than in the control group (47 versus 50 percent); however, the treatment group's doses were higher for two of the five most commonly prescribed drugs (metoprolol and losartan).

In the upstate site, slightly more treatment group members than control group members also received antihypertensive drugs (89 and 87 percent, respectively). Despite lower mean treatment group dosages for three drugs (metoprolol, quinapril, and losartan), the overall mean percent of maximum dose was slightly higher for the treatment group (42 percent, compared with 39 percent for the control group).

Antiplatelet Drugs. The rates of prescription of these recommended drugs among the New York City enrollees was about the same in the treatment group and the control group (43 and 40 percent, respectively); the difference was not significant. The rates of antiplatelet drug prescription for the treatment and control groups in the upstate site also were comparable (15 and 17 percent, respectively), although both rates were markedly lower than in New York City.

LDL-Cholesterol–Lowering Drugs. The proportion of treatment group members in New York City receiving LDL-cholesterol–lowering drugs was 9 percentage points higher than the proportion of control group members receiving these drugs (49 and 40 percent, respectively). Among those prescribed medications in this category, no clear treatment–control group pattern was observed in either the number of drugs per person (one medication per person in each group) or the mean dosages between treatment and control group members.

As in the New York City site, treatment group members in the upstate site were more likely than control group members to have been prescribed LDL-cholesterol–lowering drugs (57 versus 47

percent), with no difference in the average number of drugs per person. Compared with the control group, treatment group members prescribed pravastatin, lovastatin, or fluvastatin received higher daily average doses, and the mean percent of maximum dose for the treatment group was slightly higher (36 percent, compared with 34 percent for the control group).

Hypoglycemic Drugs. In New York City, nearly all enrollees prescribed hypoglycemic drugs were prescribed either insulin or an oral drug (100 percent of the treatment group and 98 percent of the control group). More treatment group members than control group members were taking oral medications only, and, among enrollees taking any oral medications, the mean number of drugs per person was significantly higher in the treatment group than in the control group (1.9 versus 1.6 medications per person). The mean dosage of one of the medications, metformin, was slightly higher for the treatment group (1,500 mg) than for the control group (1,460 mg).

In the upstate site, 100 percent of the treatment group members were receiving a hypoglycemic drug, compared with 92 percent of control group, a difference that was statistically significant. As in New York City, a somewhat higher proportion of the treatment group than of the control group was taking oral medications only (48 and 40 percent, respectively). Among enrollees prescribed metformin, treatment group members were prescribed a mean dosage of roughly 1,530 mg, compared with 1,450 mg among control group members. The average daily insulin dose was substantially and significantly higher for the treatment group (68 units per day) than for the control group (45 units per day).

6. Clinical and Laboratory Outcomes

The demonstration collected numerous clinical and laboratory measures. The following is a brief list of the measures. Appendix B, Section C.2, contains additional explanations of their relevance and the rationale for their collection.

- ***Blood Pressure.*** Each measurement consisted of a systolic and diastolic reading, measured in millimeters of mercury (mmHg). Blood pressures were measured in the demonstration by two methods:
  - *In Person.* In-person measurements were taken by Consortium staff at the annual visits.
  - *Ambulatory Blood Pressure Monitoring.* These monitors were small devices worn by enrollees over 24-hour periods following each annual visit. In addition to mean waking and sleeping systolic and diastolic blood pressures, the presence or absence of normal nocturnal *dipping* was determined for each enrollee. (The normal decline of nocturnal systolic blood pressure is at least 10 percent of waking systolic blood pressure.)
- ***Anthropometry.*** At each annual visit, Consortium staff performed the following series of anthropometric, or body, measurements:
  - *Body Mass Index (BMI),* in units of kilograms per meter squared (kg/m^2). People with BMIs over 25 kg/m^2 are overweight, and those with BMIs over 30 kg/m^2 are considered obese.
  - *Waist Girth*, in centimeters, cm
  - *Waist-to-Hip Ratio,* a unitless ratio
- ***Laboratory Values***
  - *Cholesterol.* Reported as levels of total blood cholesterol, LDL cholesterol, and high-density lipoprotein (HDL) cholesterol.[56] Levels of triglycerides are also reported. These blood lipids are measured in milligrams per deciliter (mg/dl).
  - *Hemoglobin A1c.* Hemoglobin A1c is reported as a percentage of total hemoglobin. Although normal ranges vary by the laboratory performing the test, the upper limit of normal is roughly 6.0 percent. The normal range for

[56]As described in Appendix B, HDL cholesterol levels were actually calculated from the measured levels of total and LDL cholesterol, and of triglycerides.

the IDEATel laboratory is 4.4 to 6.4 percent. For each patient with diabetes, decisions on how aggressively to control blood sugar levels should consider the risks and benefits of tight versus loose control, and thus, goal or target values of hemoglobin A1c should be individualized for specific patients. For example, the 1999 version of the Veterans Health Administration Guidelines recommends taking into account the patient's life expectancy or "physiologic age," whether the patient has major comorbidities, and whether the patient has already developed eye, kidney, or nerve damage from diabetes. The VHA guidelines suggest target hemoglobin A1c levels between seven (for more aggressive control) and nine (for less tight control). For this report, besides analyzing hemoglobin A1c as a continuous variable, hemoglobin A1c was also analyzed as two binary variables—whether seven or greater, and whether eight or greater. These two thresholds correspond respectively to "goal" and "action suggested" levels recommended by the American Diabetes Association (2002d).

- *Urine Microalbumin.* Results are expressed as milligrams of albumin per gram of creatinine (mg/g). Dividing by the creatinine corrects for varying urine volume and concentration. Ratios of urine albumin to creatinine of less than 30 mg/g are considered normal; ratios ranging from 30 mg/g to 300 mg/g are called microalbuminuria; and ratios of 300 mg/g and higher are called clinical proteinuria.

a. Results

Blood Pressure. In the New York City site, treatment group members' in-person blood pressure readings were lower than those of control group members by amounts that were almost statistically significant (2.0 mmHg lower for systolic blood pressure, and roughly 1.5 mmHg lower for diastolic blood pressure, *p*-values of 0.10 and 0.06 respectively; Table IV.13). There were no statistically significant treatment–control differences on the ambulatory blood pressure monitoring results. The number of enrollees completing the Year 1 ambulatory blood pressure monitoring was small, however (among treatment group members, only 87 of 338 attending the Year 1 annual visit, and among control group members, only 98 of 349).

In the upstate site, the treatment group had better in-person blood pressure measurements than did the control group (Table IV.13). Treatment group members' in-person systolic blood pressure was a little less than five millimeters of mercury lower than that of the control group

TABLE IV.13

ESTIMATED EFFECTS OF IDEATel ON BLOOD PRESSURE AND ANTHROPOMETRIC MEASUREMENTS, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
In-Person Blood Pressure Measurements						
Systolic Blood Pressure (mmHg)	139.1	141.5	–2.4 (.099)	135.9	140.4	–4.5 (.003)
Systolic blood pressure >130 mmHg (percentage)	66.3	67.4	–1.1 (.753)	57.8	63.1	–5.3 (.139)
Diastolic Blood Pressure (mmHg)	69.3	70.7	–1.4 (.059)	67.7	69.8	–2.1 (.002)
Diastolic blood pressure >80 mmHg (percentage)	12.9	16.7	–3.8 (.132)	9.8	17.7	–7.9 (.003)
Ambulatory Blood Pressure Monitoring[a]						
Waking						
Systolic blood pressure (mmHg)	138.2	139.0	–0.8 (.721)	130.6	132.5	–1.9 (.244)
Diastolic blood pressure (mmHg)	71.7	73.6	–1.9 (.152)	67.7	68.9	–1.2 (.202)
Sleeping						
Systolic blood pressure (mmHg)	133.0	131.3	–1.7 (.513)	122.3	122.9	–0.6 (.737)
Diastolic blood pressure (mmHg)	66.0	66.6	–0.6 (.679)	61.2	60.8	0.4 (.723)
Nocturnal Non-Dipping in Systolic Blood Pressure (Percentage)	83.9	74.5	9.0 (.118)	60.3	65.0	–4.7 (.402)
Anthropometric Measurements						
Body Mass Index (kg/m^2)	30.8	30.7	0.1 (.864)	33.0	33.2	–0.2 (.452)
Overweight (percentage)[b]	85.3	82.3	3.0 (.151)	92.2	90.1	2.1 (.190)
Obese (percentage)[c]	47.5	46.1	1.4 (.508)	65.2	64.0	1.2 (.588)
Waist-to-Hip Ratio	0.93	0.93	0.00 (.645)	0.95	0.96	–0.01 (.336)
$\geq$1.0 males, $\geq$0.85 females (percentage)	62.6	65.1	–2.5 (.392)	64.9	63.7	1.2 (.665)
Waist Girth (cm)	104.3	103.9	0.4 (.521)	110.9	111.0	–0.1 (.851)
$\geq$102 cm males, $\geq$ 88 cm females (percentage)	78.6	79.2	–0.6 (.789)	85.8	84.9	0.9 (.577)
Sample Size	**336**	**348**	**—**	**338**	**334**	**—**

Source: IDEATel Year 1 in-person interview, blood pressure measurement, and anthropometry, conducted between December 2001 and October 2003 (Columbia University 2003d).

TABLE IV.13 *(continued)*

Notes: Means were predicted with either logit models (binary outcome) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4).

[a]Sample sizes for ambulatory blood pressure monitoring are—New York City: treatment 73, control 94; Upstate: treatment 124, control 121 (See Table B.13).

[b]Overweight is defined as having a body mass index of 25 or more.

[c]Obese is defined as having a body mass index of 30 or more.

mmHg = millimeters of mercury.

members; their diastolic blood pressure was two millimeters of mercury lower. The difference in diastolic blood pressure meant that, compared to the control group, eight percentage points fewer treatment group members had diastolic blood pressure readings over 80 millimeters of mercury. No significant differences were seen in the readings on 24-hour ambulatory blood pressure monitoring; again, sample sizes for the 24-hour recordings were small.

Anthropometry. None of the anthropometric measures were significantly different between treatment and control group members in either site (Table IV.13).

Laboratory Values. The IDEATel intervention had significant and substantial favorable impacts on the laboratory outcomes in both sites (Table IV.14). In the New York City site, the intervention led to substantial and highly significant improvements in lipid values, with relative reductions in the treatment group's total and LDL cholesterol levels that were 6 and 10 percent lower than the respective control group means (Table IV.14). Fewer treatment group members than control group members had high LDL cholesterol levels (100 mg/dl or more; 43 versus 57 percent). In addition, the treatment group's mean triglyceride level was 12 mg/dl lower than the control group's (an eight percent reduction relative to the control group mean).

The intervention also had a small beneficial effect on glycemic control in New York City. The mean hemoglobin A1c level was 0.2 units lower among treatment group members than among control group members, leading to a significantly lower percentage of treatment group members with hemoglobin A1c levels above 8 percent (19 percent, compared to 28 percent in the control group).

The mean urine albumin-to-creatinine ratio in the treatment group appeared lower than that of the control group (178 mg/g compared with 248 mg/g, a difference of 70 mg/g), a difference of

TABLE IV.14

ESTIMATED EFFECTS OF IDEATel ON LABORATORY RESULTS, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Lipids (mg/dl)						
Mean Total Cholesterol	172.8	184.3	–11.5 (.000)	169.7	178.5	–8.8 (.003)
Mean LDL Cholesterol	97.3	108.5	–11.2 (.000)	95.7	101.1	–5.4 (.040)
Mean HDL Cholesterol	49.9	50.7	–0.8 (.279)	45.5	45.9	–0.4 (.599)
Mean Triglycerides	138.9	150.8	–11.8 (.019)	171.3	194.6	–23.3 (.001)
High LDL Cholesterol (≥100; Percent)	43.4	56.6	–13.2 (.000)	39.8	43.3	–3.5 (.337)
Diabetes Control						
Mean Hemoglobin A1c (%)	7.2	7.4	–0.2 (.039)	6.7	6.9	–0.2 (.031)
Hemoglobin A1c ≥7.0% (percent)	50.9	55.7	–4.8 (.148)	31.3	36.1	–4.8 (.159)
Hemoglobin A1c >8.0% (percent)	19.0	27.9	–8.9 (.002)	9.7	14.5	–4.8 (.046)
Diabetic Nephropathy[a]						
Mean Urine Albumin-to-Creatinine Ratio	178.3	248.3	–70.0 (.094)	111.9	143.6	–31.7 (.337)
Insignificant microalbuminuria (percent)[b]	54.8	51.7	3.1 (.470)	57.0	58.4	–1.4 (.726)
Microalbuminuria (percent)[c]	32.6	31.7	0.9 (.470)	34.0	34.8	–0.8 (.726)
Clinical proteinuria (percent)[d]	12.6	16.7	–4.1 (.470)	8.9	6.8	2.1 (.726)
Sample Size	**333**	**347**	**—**	**309**	**314**	—

Source: IDEATel Year 1 in-person interview, blood pressure measurement, and anthropometry, conducted between December 2001 and October 2003 (Columbia University 2003d).

Notes: Means were predicted with either logit models (binary outcome) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4).

HDL = high-density lipoprotein; LDL = low-density lipoprotein.

[a]Sample sizes for urine albumin-to-creatinine ratios are—New York City: treatment 219, control 254; Upstate: treatment 206, control 207 (see Table B.13).

TABLE IV.14 *(continued)*

[b]Urine microalbumin-to-creatinine ratio <30.

[c]Urine microalbumin-to-creatinine ratio ≥30 but <300.

[d]Urine microalbumin-to-creatinine ratio ≥300.

borderline statistical significance (*p*-value of .09). However, for unclear reasons, a large proportion of enrollees were missing follow-up data from the first annual visit, and their baseline data suggest that treatment group members with missing data were systematically different from control group members with missing data, so even this borderline significant favorable effect on proteinuria may be the result of bias from differential dropout.[57]

In the upstate site, the treatment group had a total cholesterol level that was nearly 9 mg/dl lower than that of the control group (about five percent of the control group mean), and an LDL cholesterol level that was a little over 5 mg/dL lower (about five percent of the control group mean). The treatment group also had a substantially lower mean triglyceride level (a 23 mg/dl absolute difference, and a 12 percent reduction relative to the control group mean).

The IDEATel intervention also had a favorable impact on mean hemoglobin A1c levels in the upstate site. At followup, the treatment group's mean hemoglobin A1c level was 0.2 percentage units lower than the control group's (about 3 percent relative to the control group mean), a significant difference. If a hemoglobin A1c level of greater than 8 percent is defined as high, then 10 percent of the treatment group had high levels, compared with 15 percent of the control group—a 33 percent difference relative to the control group. There were no significant treatment–control difference in the results for the albumin-to-creatinine ratios.

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[57] Ninety of the treatment group members were missing follow-up data, and their mean baseline albumin-to-creatinine was 328 mg/g, significantly higher than the mean baseline value of 163 mg/g for the 219 treatment group members with follow-up data. The 53 control group members missing follow-up data had a mean baseline urine microalbumin-to-creatinine of 139 mg/g, significantly lower than the mean baseline urine microalbumin-to-creatinine value of 285 mg/g for the 254 control group members with complete follow-up data.

7. Health-Related Quality of Life

The IDEATel intervention had some isolated effects on the numerous self-reported health-related quality-of-life outcomes collected through the in-person interviews, but no broad-based impacts were observed in either site. In New York City, treatment group members were more likely than control group members to rate their health as better than compared to three months prior to the interview (53 versus 43 percent), and less likely to rate their health as worse relative to three months before (13 versus 18 percent; Table IV.15). These favorable effects are counterbalanced by a higher proportion of treatment group members (41 percent) than control group members (34 percent) rating their health as fair or poor relative to their peers, by a slightly higher proportion of treatment than control group members with cardiovascular symptoms (15 versus 13 percent), and by the lack of effects in the scores for a number of scales (measuring any bodily pain, depression, difficulties with emotional adaptation to diabetes, and a variety of diabetes symptoms). In the upstate site, treatment group members were less likely than control group members to rate their health as fair or poor (18 versus 25 percent). Treatment group members also had lower scores on the visual symptoms subscales of the Diabetes Symptom Checklist (8 versus 10 points, and on the total symptom checklist score (134 versus 143 points; Table IV.15), but these were of borderline statistical significance.

8. Satisfaction with Diabetes Care

In New York City, the few statistically significant effects on satisfaction were dispersed among the study topics. By contrast, in upstate New York, treatment group members reported higher levels of satisfaction than did control group members with regard to two overarching measures. They were somewhat more likely than control group members to state that the overall quality of

TABLE IV.15

ESTIMATED EFFECTS OF IDEATel ON SELF-REPORTED QUALITY-OF-LIFE OUTCOMES, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Self-Rated Health						
Health Rating[a]	72.7	72.0	0.7 (.621)	73.5	73.3	0.2 (.814)
Health Excellent or Very Good	13.3	9.5	3.8 (.096)	36.6	34.0	2.6 (.430)
Health Fair or Poor	56.8	62.9	–6.1 (.068)	17.8	24.8	–6.1 (.018)
Health Excellent or Very Good Compared with Peers	31.4	28.5	2.9 (.376)	48.5	49.5	–1.0 (.790)
Health Fair or Poor Compared with Peers	40.7	34.1	6.6 (.013)	14.0	14.4	–0.4 (.857)
Health Better than Three Months Ago	52.9	43.1	9.8 (.008)	27.5	27.4	0.1 (.966)
Health Worse than Three Months Ago	11.9	18.3	–6.4 (.018)	9.8	10.9	–1.1 (.649)
ADL Score[b]	25.6	26.3	–0.7 (.625)	18.8	19.8	–1.0 (.387)
Pain and Depression						
Bodily Pain in the Past Four Weeks	48.3	53.5	–5.2 (.793)	69.8	69.9	–0.1 (.984)
Pain Score, if Pain[c]	49.2	53.4	–4.2 (.136)	45.2	46.4	–1.2 (.560)
Depression Score	22.6	23.6	–1.0 (.397)	15.4	15.9	–0.5 (.529)
Diabetes Symptoms						
Problem Areas in Diabetes Score	14.0	13.1	0.9 (.328)	7.1	7.7	–0.6 (.339)

TABLE IV.15 *(continued)*

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Diabetes Symptom Checklist Subscales						
Hyperglycemic symptoms	38.8	39.3	–1.1 (.545)	31.0	32.8	–1.8 (.270)
Hypoglycemic symptoms	12.0	12.3	–0.3 (.827)	12.4	13.1	–0.7 (.526)
Psychological symptoms (0 to 200)[d]	41.1	43.8	–1.2 (.233)	45.5	48.1	–2.6 (.269)
Cardiovascular symptoms	15.5	13.0	2.5 (.024)	11.9	12.7	–0.8 (.429)
Neuropathic symptoms (0 to 200)[e]	38.7	37.6	1.1 (.774)	24.4	26.1	–1.7 (.340)
Vision problems	18.6	17.5	1.1 (.466)	7.8	9.9	–2.1 (.057)
Diabetes Symptom Checklist Total Score	160.0	164.6	–4.6 (.478)	133.8	142.8	–9.0 (.083)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel in-person interviews, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with either logit models (binary outcomes) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4).

[a]Rated on a scale from 0 to 100, where 0 = death and 100 = best possible health. Respondents were also asked to rate their health on a scale where 0 is a state of worst possible health (great pain and discomfort due to permanent chronic disease) and 100 is best possible health. Means for this scale were two or three points lower than the ratings anchored by death, but there were no significant treatment–control differences in either site.

[b]From the Comprehensive Assessment and Referral Evaluation (CARE) Interview Schedule (Teresi et al. 1984). This score is the sum of responses to 27 questions about whether enrollees were able to perform normal activities without difficulty or without help from others, as well as data on whether the enrollees could touch their toes and could raise their arms overhead (as observed by the interviewer). The response values varied from question to question; they included 0/1 responses (yes/no), 0/1/2 responses (definitely/probably/definitely not), and five-point scales to indicate the degree of independence.

[c]Sample sizes for pain score—New York City: treatment 180, control 186; Upstate: treatment 237, control 235.

[d]The overall psychological symptom score is shown here. There were also subscales for psychological fatigue symptoms and psychological cognitive symptoms; no significant treatment–control differences were found in these subscales in either site.

[e]The overall neuropathic symptom score is shown here. There were also subscales for neuropathic pain symptoms and neuropathic sensory symptoms; no significant treatment–control differences were found in these subscales in either site.

ADL = activities of daily living.

their diabetes care was very good or excellent (79 versus 72 percent), and that they definitely intended to follow their health care providers' advice (79 versus 70 percent; Table IV.16).

9. Effects on Subgroups

It seems reasonable that IDEATel might have greater benefits for enrollees with more education and computer experience. The independent evaluator conducted subgroup analyses to explore whether the intervention had differential effects on selected outcomes for enrollees with 12 or more years of formal education compared with those with fewer years of education, and for enrollees with personal computer experience before enrollment compared to those with none. These subgroup analyses were conducted for key outcomes in the areas of access to care, provider practices, self-care knowledge, self-monitoring, adherence to self-care, and satisfaction with diabetes care. In general, these subgroup analyses either revealed no significant subgroup effects or no discernible pattern of effects (see Appendix E, Tables E.1 through E.4). However, given the small size of the subgroups, only very large differences would have been detected.

At the suggestion of the Consortium, a subgroup analysis was conducted to see whether IDEATel effects differed by whether enrollees' diabetes was under better or worse control at baseline (defined as a baseline hemoglobin A1c of less than seven, versus seven or greater). There was no discernable subgroup effect for the New York City site. In the Upstate site, however, there was a significant differential effect. The intervention had a larger lowering of hemoglobin A1c among enrollees with baseline hemoglobin of seven or greater, than among those with a baseline hemoglobin less than seven (Appendix E, Table E.5)

TABLE IV.16

ESTIMATED EFFECTS OF IDEATel ON SATISFACTION WITH DIABETES CARE, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
How Well Doctors and Health Care Professionals Who Cared for Enrollees' Diabetes:[a]						
Showed Concern, Courtesy, Respect, and Sensitivity						
Very good or excellent	67.1	64.0	3.1 (.384)	85.0	81.3	3.7 (.185)
Fair or poor[b]	5.7	6.0	–0.3 (.840)	3.6	3.3	0.3 (.838)
Disclosed All Pertinent Information						
Very good or excellent	49.7	46.8	2.9 (.446)	81.3	78.2	3.0 (.299)
Fair or poor	16.2	12.4	3.8 (.166)	5.7	7.4	–1.7 (.383)
Answered Questions About Diabetes						
Very good or excellent	55.6	50.0	5.6 (.139)	73.8	71.1	2.7 (.410)
Fair or poor	10.9	11.8	–0.9 (.701)	5.4	9.7	–4.3 (.036)
Gave Test Results When Promised						
Very good or excellent	49.6	49.2	0.3 (.931)	76.6	74.3	2.3 (.474)
Fair or poor	11.4	13.1	–1.7 (.489)	9.4	9.1	0.3 (.887)
Reviewed and Explained Test and Laboratory Results						
Very good or excellent	52.8	51.9	0.9 (.821)	67.9	66.9	1.0 (.762)
Fair or poor	15.1	12.1	3.0 (.245)	11.3	10.3	1.0 (.659)
Explained and Included Enrollee in Treatment Decisions						
Very good or excellent	47.3	46.7	0.6 (.876)	68.2	64.5	3.7 (.275)
Fair or poor	17.7	16.4	1.3 (.646)	16.7	18.8	–2.2 (.440)
Explained Side Effects of Medications						
Very good or excellent	50.0	42.3	7.7 (.015)	61.7	57.7	4.0 (.270)
Fair or poor	21.5	21.8	–0.2 (.939)	19.5	24.2	–4.7 (.123)

TABLE IV.16 *(continued)*

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Explained What to Expect from Diabetes or Its Treatment						
Very good or excellent	49.5	42.6	6.9 (.074)	58.8	60.5	–1.7 (.625)
Fair or poor	23.8	23.5	0.3 (.930)	19.4	21.7	–2.2 (.441)
Made Sure They Could Be Reached Easily in Emergencies						
Very good or excellent	46.4	44.7	1.7 (.671)	69.3	62.0	7.3 (.048)
Fair or poor	18.2	16.0	2.3 (.443)	13.3	17.5	–4.2 (.138)
General Measures of Satisfaction						
Rating of Quality of Diabetes Care in the Past Year[a]						
Very good or excellent	56.9	56.3	0.6 (.862)	79.0	72.1	6.9 (.030)
Fair or poor	9.0	9.3	–0.3 (.891)	3.8	7.1	–3.3 (.054)
Would Recommend Doctor/Health Care Professional Based on Personal Manner[c]	92.5	94.7	–2.2 (.241)	93.8	91.0	2.9 (.146)
Intends to Follow Doctor's/Health Care Professional's Advice[d]	80.4	82.8	–2.4 (.411)	78.7	69.7	8.9 (.006)
Sample Size	**338**	**349**	**—**	**338**	**339**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for enrollees' baseline characteristics (see Appendix B, Section C.4).

[a]This measure is derived from a survey question with a five-point scale. The intermediate rating (good) is not shown.

[b]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[c]Includes those who stated that they probably or definitely would recommend their doctor or health professional.

[d]Includes those who stated that they definitely intended to follow their doctor's or health care professional's advice.

10. Projected Long-Range Effects of IDEATel

Unfortunately, there are no clearcut answers to the key policy question of whether and how well IDEATel's favorable impacts on intermediate physiologic outcomes will translate into the prevention of the clinical complications of diabetes, and ultimately into health care cost savings. The current study's duration of followup is too short to answer this question directly, and there are no published studies of people with diabetes that have both long enough followup, and that have measured clinical risk factors, clinical outcomes, and health costs, to help address this question.

A few studies can provide at least a crude idea of the potential effects of IDEATel on just cardiovascular events. As IDEATel's enrollees generally do not have advanced complications of diabetes, such as severe kidney disease, amputations, severe heart disease, strokes, or blindness, the demonstration may be best described as a *secondary prevention* intervention, or a set of actions to slow or stop the progress of a disease during its early stages.[58] As in the IDEATel intervention, secondary prevention for people with diabetes focuses on improving blood sugar control, lipid levels, hypertension, obesity, and physical inactivity. The independent evaluator

[58]In contrast, *tertiary prevention* (actions to slow or stop the progress of a disease during its advanced stages) diabetes disease management programs would be appropriate for people with advanced diabetes who have already developed complications, and would focus on the prevention or delay of such additional late-stage complications as wound infections, limb amputations, severe congestive heart failure, complete loss of vision, and initiation of dialysis. Given the high baseline risks and high costs of such adverse events among people with severe end-stage diabetes, such a program could conceivably achieve substantial benefits in health outcomes and medical savings (compared to an untreated group) over a relatively short three-to five-year time period. *Primary prevention* would involve preventing or delaying people from ever developing diabetes in the first place.

thus examined two well-known, recent studies relevant to secondary prevention in people with diabetes—Wilson et al. (1998) and Stevens et al. (2001).

Using data from the Framingham study, Wilson et al. (1998) developed a regression equation that predicts an individual's risk for angina, heart attack, or cardiac death over a 10-year period, given the person's baseline age, gender, presence or absence of diabetes, blood pressure, smoking status, and LDL and HDL cholesterol values. The independent evaluator used the Framingham formula and the individual-level risk variables to project risks for the IDEATel treatment and control groups (in the case of IDEATel, all enrollees have the value of "yes" for diabetes). The projected 10-year rates of cardiac outcomes in the New York City site were 15.1 percent for the treatment group and 16.6 for the control group, for an absolute difference of 1.5 percentage points, or a 9 percent reduction relative to the control group mean. Expressed another way, roughly 67 Medicare beneficiaries would need to participate in IDEATel over a 10-year period in order to prevent one occurrence of angina, heart attack, or cardiac death.[59] In the upstate site, the treatment and control group's risks were 16.7 and 17.3 percent, respectively, a difference of 0.6 percentage points, or about 3.5 percent relative to the control group mean. This translates into an NNT of 167 Medicare beneficiaries. There are numerous potential sources of inaccuracy in applying the Framingham formula to the IDEATel enrollees. For instance, the Framingham study included relatively small numbers of people with diabetes, and the model thus only includes diabetes only as a binary (yes or no) variable, with no consideration of the severity or duration of the diabetes. Additional limitations are that the Framingham cohort is

[59] This is an example of the "number needed to treat," or NNT, a popular way in the clinical literature of summarizing binary outcome results for a clinical trial. It is simply the reciprocal of the difference of the control and treatment group means, in this case 1.5 percent.

substantially younger than the IDEATel study population, and comprises primarily white, middle-aged, lower-middle-class people, somewhat like the IDEATel upstate cohort, but quite unlike the New York City cohort.

Researchers with the United Kingdom Prospective Diabetes Study (UKPDS) developed a regression model exclusively for use with people with diabetes that predicts individual-level risk for fatal or nonfatal heart attacks or sudden death over varying time periods (Stevens et al. 2001).[60] The regression formula incorporates the severity of diabetes, as measured by hemoglobin A1c, and time since diagnosis of diabetes, as well as age, gender, ethnicity, blood pressure, and total cholesterol to HDL cholesterol ratio. Applying the UKPDS formula to the IDEATel data yields a predicted incidence of the outcomes in the New York City cohort of 12.9 percent in the treatment group and 15.8 percent in the control group, a difference of 2.9 percentage points, equivalent to a NNT of 34 beneficiaries. The calculated incidences in the upstate cohort are 24.1 percent in the treatment group and 26.7 percent in the control group, a difference of 2.6 percentage points and an NNT of 38 beneficiaries. The UKPDS model may also be inaccurate when applied to the IDEATel population. The UKPDS study enrollees were again much younger than IDEATel enrollees (people over age 55 were excluded from the study), and their ethnic make-up of white, Asian Indian, and Afro-Caribbean people was different than that of the IDEATel enrollees.[61]

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[60] Somewhat surprisingly, Protopsaltis et al. (2004) report that the Framingham formula may be more accurate in people with diabetes than the UKPDS score, which was derived specifically in a study of people with diabetes.

[61] The independent evaluator also reviewed the Steno-2 Study (Gaede et al. 2003). This was a randomized clinical trial in 160 patients of a multifactorial strategy of intensive lowering of

Despite providing rough ideas of how IDEATel's impacts on intermediate outcomes might translate into reduction of cardiovascular events, these studies still provide no information on IDEATel's potential effects on the numerous other complications of diabetes—end-stage renal disease and dialysis, blindness, and lower extremity vascular complications and amputations. The studies also provide no information on the potential cost savings from prevention of cardiovascular events or on possible cost savings from prevention of any of the other diabetes complications.[62]

D. SUMMARY AND DISCUSSION

1. Summary of Findings

The IDEATel intervention's overall effects were positive, although the intervention did not have impacts across all of the numerous outcomes measured. Treatment group members in both sites reported more frequent contact with diabetes nurse educators or dietitians, discussions with

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(continued)

blood pressure, hemoglobin A1c, and cholesterol levels, and increasing use of aspirin and ACE-inhibitors with a mean followup of eight years. The intervention achieved much larger reductions in blood pressure, hemoglobin A1c, and cholesterol than in the IDEATel study, and an impressive near-halving of cardiovascular events (only 24 percent of the intervention group suffered a cardiovascular event, compared to 44 percent of the control group, an NNT of five patients). The Steno-2 patients were quite different from the IDEATel enrollees, however, and unlike the Framingham and UKPDS researchers, the Steno-2 investigators have not published a regression formula with which to predict probabilities of future events based on baseline values of risk factors. It is thus difficult to apply the Steno-2 results to the IDEATel population.

[62]Another approach in the literature is to develop computer simulation models of populations of people with diabetes. These models use probabilities gathered from various published studies (or even expert opinions) to simulate random health events over time in people with diabetes (The CDC Diabetes Cost-Effectiveness Group 2002; and Eastman et al. 1997). Such simulations thus allow researchers to generate hypothetical data on the long-term incidence of multiple clinical events and their costs, even in the absence of actual data. Such an approach was beyond the scope of the evaluation.

providers on diet and exercise, and better understanding and performance of blood sugar monitoring and of self-examinations of the feet. Treatment group members were more likely to receive recommended medications, and in some instances, more aggressive dosing and numbers of medications per person. IDEATel enrollees in both sites experienced improvements in blood lipid values, hemoglobin A1c levels, and self-assessed general health status. Positive impacts for other outcomes (providers' inclusion of patients in decision making; enrollees' self-efficacy with respect to their diabetes, attitudes about diabetes, adherence to exercise regimens, satisfaction with diabetes care; and reduction of microalbuminuria) were observed only among enrollees in one or the other of the sites. Finally, no detectable impacts were observed for the following outcomes: enrollees' beliefs about diabetes (outcome expectancies), making and keeping of appointments, adherence to medication regimens, and use of Medicare-covered services.

In order to consider the policy implications of the results, it is useful to consider how specific components of the complex and multifaceted IDEATel intervention might be responsible for the observed effects. For example, it may have been the intervention's provision of free glucometers to treatment group members, in conjunction with reminders by the nurse case managers, that was primarily responsible for the much larger proportion of the treatment group that performed daily blood sugar testing.[63] It may also have been reminders by the nurse case managers to perform foot checks that led to the smaller positive impacts on daily foot examinations. Provision of glucometers is not linked to installation of the HTU, and reminders by nurse case managers may

[63] During early interviews, a member of the Consortium staff told us that the manufacturer was also donating glucometer test strips. In later interviews, Consortium staff told us that free glucose strips were not routinely dispensed to all participants, and provided only occasionally and under special circumstances to enrollees in the upstate site.

be accomplished through telephone calls, although the visual aspect of the televisits may have made the reminders more compelling.

As discussed, the large treatment–control difference in how often treatment group members saw nurse educators and dietitians may have been inherent in the IDEATel intervention itself. The intervention consisted in large part of regular televisits with health care professionals. Thus, after people started participating regularly in televisits, these results are not surprising.

It is noteworthy that, apart from a modest effect on adherence to exercise among the New York City treatment group, there were no impacts on self-reported adherence to medications or diet. The self-reported rates of medication adherence were so high that it would have been difficult to see any large treatment–control differences, but dietary adherence was in the 45 to 60 percent range for all enrollees, allowing for the detection of moderate-sized effects. Possible explanations for the lack of effects include the insensitivity of the self-reported adherence measures, ineffective behavioral counseling by the nurse case managers, and inadequate time devoted to behavioral counseling. The lack of effects on BMI and anthropometric measures support the lack of major dietary and exercise behavioral changes. It is possible that, with the pressures of having to review HTU use with participants, discuss blood sugar and blood pressure readings, and provide basic diabetes education, the nurse case managers did not have much time to devote to educational counseling. If true, the HTU may in fact have been a distraction, and regular conventional telephone contact with nurse case managers might have been more effective.

There were no differences in use of either all Medicare-covered services or specific recommended preventive care services. One would not necessarily expect to see differences in the use of general health care services. Few, if any, enrollees were traveling on a regular basis to

offices or clinics to receive ongoing diabetes education anyway, so the HTU was not intended to substitute for such services, and the televisits were not meant to substitute for enrollees' visits with their physicians. As discussed, the demonstration's first phase was of too short a duration and too small a size to see any intervention effects on reduction of health care use from prevention of heart attacks, strokes, kidney failure, eye damage, and so on.

The intervention's provision of free annual hemoglobin A1c, lipid, and urine microalbuminuria testing to both treatment and control group members (with results forwarded to enrollees' physicians) would have tended to blunt any treatment–control differences in these three outcomes. It is slightly disappointing, however, that no obvious impacts were seen in dilated eye examinations, as one might expect the nurse case managers to do a better job of keeping track of these preventive visits, and of encouraging participants to see their eye doctors. Perhaps participants did not follow through with their eye doctors despite reminders by the nurse case managers, or perhaps, again, with multiple competing time pressures, including reviewing HTU use, the nurse case managers gave lower priority to reminders about eye examinations.

IDEATel did have some effect on enrollees' medication regimens. The effect was primarily to increase the proportion of treatment group members receiving recommended medications relative to the control group, rather than to lead to more aggressive dosing among people already prescribed the medications. There was clear variation in New York City and upstate sites in the treatment–control differences of the medication use outcomes. For example, unlike in upstate, in New York City, the treatment group had higher mean number of oral hypoglycemic medications per person than the control group, whereas unlike in New York City, the upstate treatment group had higher daily insulin dosage than the control group. These site differences suggest that the

New York City and upstate IDEATel staff did have differing approaches to the intervention, and support the decision to analyze the data by site.

In both sites, the IDEATel nurse case managers and diabetologists were able to use the home blood glucose and blood pressure monitoring to recommend better medication regimens for treatment group members, and their recommendation notes mailed to the enrollees' physicians apparently influenced the physicians to start recommended medications. It is unclear to what extent this pathway—enrollees uploading measurements to the IDEATel staff, and the staff generating recommendation letters to participants' physicians—depended on the HTUs, and whether similar effects might have been achieved with simpler, non-HTU–based blood sugar and blood pressure home monitoring devices capable of uploading data (such devices are discussed further below).

The introduction to this chapter discussed the effects on the clinical and laboratory values that could result from both intervention-induced improvements in self-care (improved adherence to medication, diet, and exercise) and improved medical treatment. As noted, there were no impacts on self-reported adherence, and the observed effects on the clinical and laboratory outcomes roughly corresponded to the observed effects on the medication regimens. Reductions in hemoglobin A1c were more dramatic in the upstate site, where treatment group members not only had a significantly greater proportion taking any hypoglycemic treatment, but also a higher mean insulin dosage. There were suggestions that more treatment group members than control group members were prescribed antihypertensive and LDL-cholesterol lowering drugs, and there were positive effects for the treatment group on in-person blood pressure and lipid values. As mentioned, the results for urine albumin-to-creatinine are difficult to interpret because of missing data, and cannot be correlated with the ACE-inhibitor and ARB prescription patterns.

Unlike many ongoing diabetes disease management programs operated by health care institutions or commercial vendors, IDEATel did not have a comprehensive quality improvement or feedback mechanism to guide the intervention (Chen et al. 2000; and Wagner et al. 2001). There was a limited CQI mechanism in place to improve program performance in physician acceptability and satisfaction. The results of the annual telephone acceptability and satisfaction surveys of participating physicians (conducted over 2002-2004) were provided to the nurse case managers, as were comments and suggestions from physicians as they were received. This information was used to modify the form of some of the communications with physicians during the course of the intervention between 2002 and 2004. A more extensive CQI program might have measured program performance in several key processes and outcomes. Examples of process measures might be numbers of contacts per nurse case manager per day, numbers of broken appointments, or numbers of participants using HTU features. Examples of outcomes measures might be enrollee adherence, hemoglobin A1C levels, or blood pressure measurements. The CQI program would feed these reports back to the staff implementing the program, probably more frequently than annually, and staff would follow an established, systematic process to analyze these reports and improve program-wide performance (Berwick 1990; Goldfield and Nash 1989). One would expect such a quality improvement feedback feature to be incorporated into IDEATel, should it ever become an ongoing program in Medicare.

Finally, there were modest effects on a few general health and symptom scores favoring the treatment group. Televisits with the IDEATel nurse case managers may have reduced enrollees' feelings of loneliness and social isolation, which, in turn, may have led to some of the modest improvements. If so, the question arises as to whether similar effects could be achieved with regular telephone calls, and without the HTUs.

2. Limitations of the Analysis

One potential shortcoming of these impact analyses is that the truncated, one-year follow-up period for a large proportion of enrollees (rather than the originally planned two years) might have biased the results.[64] For example, the novelty of the intervention may have been the factor motivating participants during the first year of followup, but the novelty, and thus any effectiveness of the intervention, might have faded during a second year. In that case, analysis based on only the first year of data would overestimate longer-term intervention impacts. Conversely, the likelihood of participants' successful behavior change might increase steadily as a function of duration of exposure to the HTUs and nurse case managers, and the analysis based on the Year 1 data would underestimate program effects. With even more time, participants might eventually begin making regular use of the web resources, electronic messaging, chat rooms, and bulletin boards, and to begin deriving benefits from these features. Among commercial disease management vendors and purchasers, it is often held that even a basic diabetes disease management program, based on nurse case managers alone without any technological enhancements, must operate for at least a few years before starting to show effects on enrollee and provider behaviors (Beaulieu et al. 2003).

Analyses to explore these potential biases suggest that, in general, the estimated impacts are not sensitive to the duration of followup. The independent evaluator used Year 2 data to estimate impacts on the 585 demonstration enrollees who completed Year 2 in-person interviews in time for this analysis and used the last-available data to estimate impacts on the 1,364 enrollees who

[64] As discussed in Chapter II, enrollment took longer than anticipated. Many enrollees entered the demonstration late, thus limiting the duration of their follow-up periods.

completed either Year 1 or Year 2 interviews. For most outcomes, impact estimates were similar whether they were measured with Year 1, Year 2, or last-available data (Appendix B, Section C.4). In New York City, however, Year 2 impacts (n = 287) on enrollees' ratings of their health care professionals and of the overall quality of their diabetes care were larger than Year 1 impacts (n = 687). The independent evaluator was not able to determine whether the observed effects reflect improved satisfaction over time or only unmeasured differences between enrollees who completed Year 2 interviews and enrollees who completed only Year 1 interviews. There is no analytic strategy that can compensate for the missing data for the urine albumin-to-creatinine ratio.

It is possible that the IDEATel intervention affected physicians' care for the control group members, as well, thus blunting any treatment control-group effects. Physicians were not blinded to treatment groups, were well aware of the identity of their control participants, and received labs from the study for both control and treatment group members. Physicians told IDEATel staff that they had applied knowledge and materials from the IDEATel recommendations on intervention patients to other patients. Some physicians even admitted to entering a "friendly competition" to see whether they could control their patients' blood sugar, blood pressure, and lipid levels better than the study personnel. There is a large literature showing that improving physicians' practice to better conform to evidence-based guidelines is possible but difficult (Davis and Taylor-Vaisey 1997; and Cabana et al. 1999), and it is unclear whether brief written recommendations on IDEATel treatment group members (a subset of all patients with diabetes in a physician's practice) would lead physicians to change their treatment for control group members as well.

A major improvement in the follow-up outcome values of the control group compared to baseline values would suggest (though, in the absence of a well-matched comparison group of patients of non-participating physicians, not prove) that participating physicians did indeed alter their treatment of control group members. A simple comparison of the Year 1 values to the baseline values for control group members shows improvement for patients in the upstate site, but not the New York City site. The Consortium did not detail whether their anecdotes of physicians changing their practices or entering into "friendly competition" came from physicians in the upstate site, the New York City site, or both. In the end, whether the intervention altered participating physicians' care of control group members cannot be determined from the study, but it is certainly possible, in which case intervention impacts would have been larger if such "contamination" could have been eliminated.

Finally, the current findings may also reflect a cohort effect. In contrast to the present generation of elderly, whose lifetime exposure and current use of computer technology is limited, the next generation of elderly (the *baby boomer* generation), will have had markedly greater familiarity with computers. The near-elderly (those aged 50 to 64) already show much higher use of the Internet and online health resources than those 65 years or older (Rideout et al. 2005), and their attitudes toward health and technology are also likely to be very different from the current generation of elderly. The acceptability and effectiveness of the IDEATel intervention may thus be substantially higher among the next wave of elderly. Whether this is the case is a question that the current study cannot answer, however.

3. Further Considerations

Although the results of the independent evaluator's analysis suggest that IDEATel does indeed have positive effects, the intervention must be considered in the context of viable policy

alternatives. In this case, as the target population is Medicare beneficiaries with diabetes in underserved areas, the main policy options are programs for diabetes that use technology allowing remote contact with isolated people. The simplest such technology is merely conventional telephone calls, but other technologies have been developed as well.

Studies of other programs coupling diabetes support with telephonic or remote monitoring technology generally are of much smaller size and scope than the IDEATel demonstration, but they provide strong evidence of their effectiveness. Examples of rigorous random assignment studies of interventions based on nurse case managers using only frequent telephone calls to enrollees are those of Aubert et al. (1998), The California Medi-Cal Type 2 Diabetes Study Group (2004), and Taylor et al. (2004). The first two studies reported significant treatment–control differences in hemoglobin A1c of 1.7 and 1.9 percent, respectively, and the third resulted in 42 percent of the treatment group with a hemoglobin A1c below 7.5 percent, compared with 25 percent of the control group. The second study also achieved a significant LDL cholesterol reduction (116 mg/dl, versus 121 mg/dl in the control group). The two other studies showed cholesterol reductions that did not reach statistical significance.

Other researchers have developed automated interactive telephone systems. Piette et al. (2000 and 2001) studied an intervention in which a computer system called enrollees and asked a series of questions, using a recorded human voice. Enrollees answered by depressing the buttons on their regular touch-tone telephones, and the system branched to different questions depending on the responses received. In a randomized study, significant positive effects were found on self-reported self-care, self-efficacy, days of disability, communication with providers, and hemoglobin A1c (a 0.3 percent reduction). Other nonrandomized studies using such automated interactive telephone systems with people with diabetes have also found positive effects on blood

sugar control and patient satisfaction. These systems also have the potential to help enrollees improve their diets (Delichatsios et al. 2001).

There are simple glucometers that can record blood sugar measurements and upload data through a basic modem connection to a standard telephone line. A number of small studies have found positive effects on behaviors and hemoglobin A1c levels (Shultz et al. 1992; Ahring et al. 1992; and Meneghini et al. 1998). A related device is a hand-held electronic diary that allows the participant to record not only blood sugars but also diet, and to upload these data (Tsang et al. 2001).

Newer or less well-studied technologies include wireless paging devices that remind people to take their medications (Facchinetti and Korman 1998) or allow text messaging (Dunbar et al. 2003), cell-phone text messaging systems with medication reminders and personalized health information (Franklin et al. 2003), and numerous commercially available home telemedicine units that connect to a telephone jack (American TeleCare, Inc. 2004; LifeLink Monitoring Corp. 2004; Viterion TeleHealthcare 2004; and Cybernet Medical 2004). Basic commercial units are small, simple to use, permit text messaging, and permit uploading of blood pressure and blood sugar readings; more advanced systems allow televisits and coupling with automated telephone response systems. Rigorous data on the effectiveness of these devices are fewer, but what information exists suggests that patients find the devices acceptable and easy to use (Dembner 2003; Schuerenberg 2003; Howington 2004; and Bakken 2003). Commercial disease management vendors that serve managed care plans have increasingly been using such commercial devices (Disease Management News 2002). The Veterans Administration has several active telemedicine and home telehealth programs that use commercial products, and it is planning to expand the programs to cover 25,000 veterans nationwide by the end of 2004

(Dembner 2003; and Department of Veterans Affairs 2004). The main differences between these commercial home units and the IDEATel HTUs are that the commercial units do not require the installation of a PC-based unit in the home and do not offer patients the Internet- and web-based features that the IDEATel HTUs have, such as web browsing, chat rooms, and bulletin boards; however, some of the commercial units do use the Internet for data transmission and display for health care providers.

Unfortunately, in the absence in this demonstration of an intervention arm featuring non-HTU-based diabetes support, it is difficult to cleanly disentangle any marginal effects of the HTU (Hersh et al. 2002). In the preceding discussion, none of the intervention effects appeared to depend exclusively on the unique features of the HTU (that is, the Web-based features). As we saw in Chapter III, participants limited their use of the HTUs almost entirely to functions that required no log-in, suggesting that the observed results might well have been achieved without the web, chat room, and electronic messaging functions of the HTUs that necessitated their customized, personal-computer-based design.

In summary, the IDEATel intervention does demonstrate some positive effects and, assuming it can sustain its effectiveness over time, has the potential to reduce the long-term complications and costs of diabetes. Given the design of the demonstration, it is difficult to compare IDEATel directly against other policy options, such as nurse case management with telephone calls, computer-generated automated voice response systems, or commercially available home telemedicine units. Other studies suggest that these simpler interventions can achieve impacts similar to or larger than the ones observed in this independent evaluation of the IDEATel demonstration. The effects of IDEATel on the long-range outcomes of interest (that is, morbidity and mortality from diabetes) are unknown and can be projected only under a set of

assumptions that may not hold. Furthermore, any health benefits or cost savings that IDEATel may generate in the long term will have to be weighed against the costs of the intervention.

V. THE DEMONSTRATION'S COSTS AND COST IMPACTS

Highlights of Findings

- The implementation costs of the IDEATel demonstration were high (about $9,392 per participant per year), as they were relative to the costs of comparable home-based telemedicine programs.
- Total and service-specific annual mean Medicare expenditures generally were higher for treatment group members than for control group members, but the differences were relatively small and not statistically significant. Thus, Phase I of the demonstration led to significantly higher total costs than would have been incurred in the absence of the demonstration.

This chapter presents estimates of the cost of implementing the IDEATel intervention, estimates of the impact of the demonstration on enrollees' Medicare expenditures, and a discussion of whether the demonstration achieved cost savings.[65] The estimates of the demonstration's costs are based on data provided by the Consortium and information obtained by the independent evaluator. Medicare claims data were available for the entire Phase I intervention period (that is, for December 2000 through December 2003).

A. THE INDEPENDENT EVALUATOR'S METHODS TO ESTIMATE THE DEMONSTRATION'S COSTS

Because the Consortium provided the independent evaluator with most, but not all, of the demonstration's budget data, the independent evaluator created estimates of the demonstration's costs, based on information obtained from seven sources: (1) the budget data provided by the Consortium, (2) the Consortium's technical proposal and progress reports (Columbia University

[65]Appendix F presents a detailed description of the methods used to estimate the demonstration's costs, Medicare expenditures, and impact of the demonstration on costs.

1998, 2002a, 2003e, 2003g, and 2004c), (3) a paper published by the demonstration team (Starren et al. 2002), (4) information that the independent evaluator collected during site visits to and telephone calls with Consortium staff, (5) the website of the Columbia University Health Sciences Division's Office of Grants and Contracts (Columbia University 2003f), (6) the input of a consultant in telemedicine, and (7) the independent evaluator's research on the market prices of the goods and services used in the demonstration. The cost estimates have been built from the bottom up by identifying and then pricing out every component of the demonstration.

A cooperative agreement between CMS and Columbia University (total budget $28,159,066) funded all the costs of the demonstration—both *intervention-related* (for example, the purchase of hardware and software, training of case managers, and costs associated with conducting televisits) and *research-related* (for example, costs associated with randomizing enrollees, collecting data on enrollees, and conducting data analysis).[66] If all these costs were included in a cost-savings analysis, the cost of the intervention would be overstated. Therefore, the independent evaluator estimated the costs of implementing the demonstration's intervention as if it were an *ongoing* telemedicine program. The cost of an ongoing program would include all the demonstration's costs related to the implementation of the intervention, but it would exclude research-related costs. The costs of designing the intervention and closing it out (that is, de-installing the HTUs from participants' homes) should be included, but depreciated over a period of several years. The independent evaluator estimated the costs of an ongoing program both with and without design and HTU de-installation costs.

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[66]Neither physicians nor enrollees received compensation for their involvement in the demonstration. However, enrollees were reimbursed for expenses incurred while traveling to the demonstration offices for the baseline and two annual data collection visits.

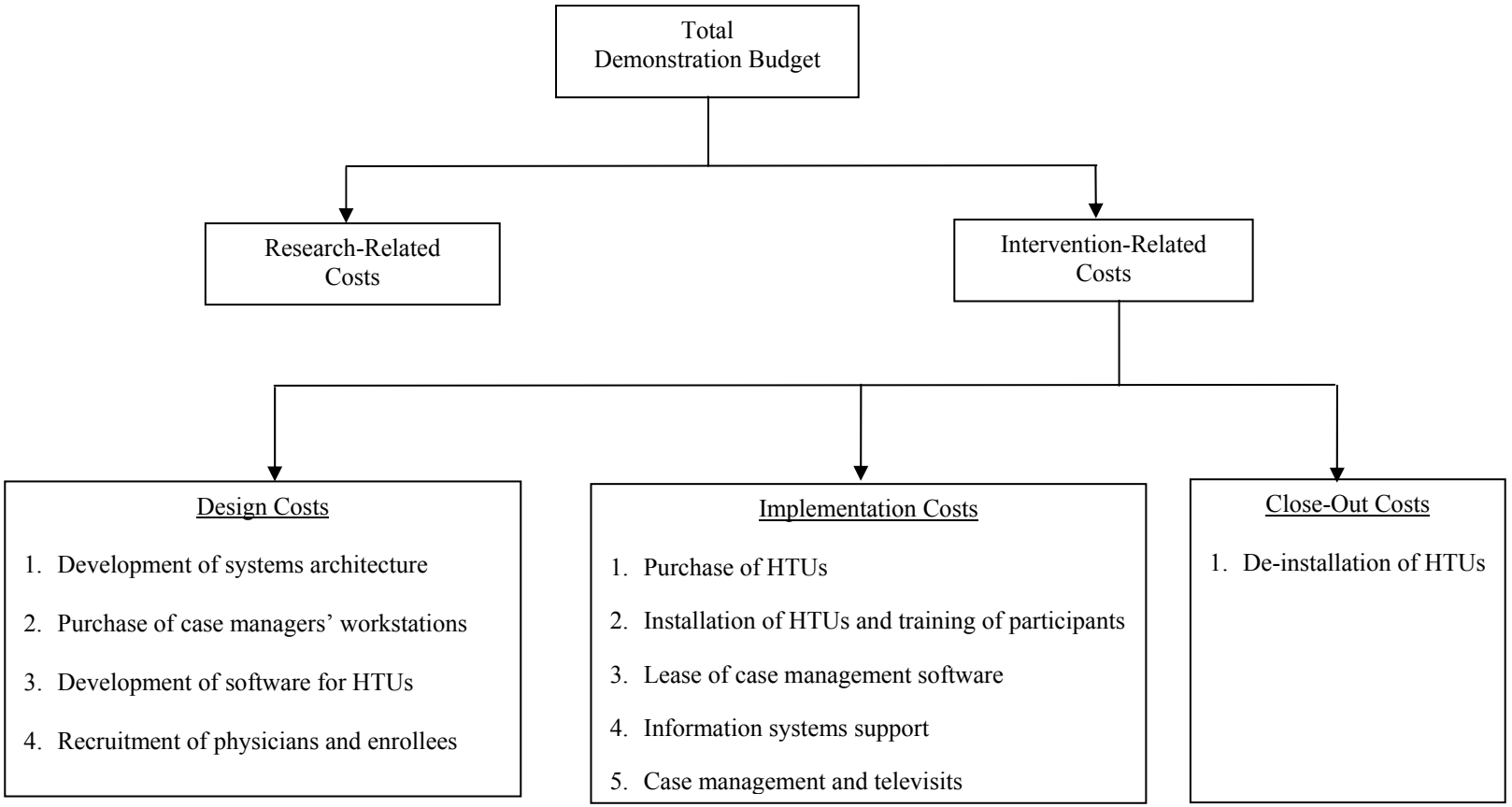
To estimate the costs of implementing the demonstration, the independent evaluator identified and classified dozens of activities into several groups. The independent evaluator first classified the demonstration's activities as research- or intervention-related (Figure V.1).[67] It then classified the intervention-related activities into three stages: (1) design, (2) implementation, and (3) close out (that is, HTU de-installation). It grouped the design activities into four broad categories: (1) development of systems architecture, (2) purchase of case managers' workstations, (3) development of software for HTUs, and (4) recruitment of physicians and enrollees. Likewise, it grouped the implementation activities into eight broad categories: (1) purchase of HTUs, (2) installation of HTUs and training of participants, (3) lease of case management software, (4) provision of information systems support, (5) case management and televisits, (6) enrollee screening and assessment, (7) quality improvement, and (8) project management and other direct costs. Finally, the independent evaluator classified all HTU de-installation activities into a single category.

The Consortium provided data on the cost of the HTUs and the total dollar value of its subcontracts with American TeleCare, Inc., the American Diabetes Association, the Hebrew Home for the Aged at Riverdale, and Siemens Medical Solutions Health Services Corporation. It also provided de-identified salary and percent effort data for most demonstration staff members. For all other aspects of the demonstration for which it had no data, the independent evaluator used estimates of specific goods, services, and individual staff members' salaries to estimate the

[67]See Appendix Table F.1 for a description of the allocation of specific demonstration components as intervention related or research related, such as project management.

FIGURE V.1

CLASSIFICATION OF THE DEMONSTRATION'S COSTS



Source: The independent evaluator's methodology used to estimate demonstration costs (see Appendix F

HTU = home telemedicine unit.

costs of the different demonstration components.[68] The estimate used 2001 as the base year for estimating costs. The independent evaluator also calculated the percentage of the estimated total budget spent on each component. Because the estimated total demonstration cost and the actual amount of the cooperative agreement differed, the independent evaluator apportioned the award amount ($28,159,066) according to each component's estimated percentage of the total budget.[69] If the independent evaluator has failed to account for any costs, this approach will correct for that omission, assuming that the omitted costs are distributed across the demonstration components in the same pattern as are observed costs.

B. ESTIMATED COST OF IMPLEMENTING THE DEMONSTRATION

The estimated cost of the demonstration's intervention is $17,223,353, or about 61 percent of the demonstration's total budget (Table V.1). The bulk of intervention-related costs are split between the design stage (15 percent of the total budget) and the implementation stage (46 percent), with only a small fraction of costs (less than 1 percent) related to HTU de-installation. As expected, case management and televisits is one of the most costly components of implementation, representing approximately 11 percent of total demonstration costs. The costs of purchasing the HTUs, installing the HTUs and training participants, supporting the information systems, and managing the program each represent between 5 and 13 percent of the

[68]The Consortium provided data on the level of effort for all but a few demonstration staff, and salary data for about half of them. It also provided data on the costs for all subcontracts. However, the Consortium did not provide data on the costs of goods and services, such as telecommunications equipment.

[69]The evaluator's independent estimate of the total cost of the demonstration is $28,863,942 (see Appendix F, Table F.2).

TABLE V.1

ESTIMATED COST OF THE IDEATel DEMONSTRATION,
BY COMPONENT AND STAGE OF IMPLEMENTATION

Component		Estimated Cost[a] (Percentage of Total)	
Research-Related Costs			**$10,935,713 (39)**
Intervention-Related Costs			**$17,223,353 (61)**
Design Stage		$4,307,346 (15)	
Development of systems architecture	$1,989,252 (7)		
Purchase of case managers' workstations	$38,570 (<1)		
Development of software for HTUs	$2,076,033 (7)		
Recruitment of physicians and participants	$203,491 (<1)		
Implementation Stage		$12,905,572 (46)	
Purchase of HTUs	$3,598,340 (13)		
Installation of HTUs and training of participants	1,512,555 (5)		
Lease of case management software	285,749 (1)		
Information systems support	2,421,982 (9)		
Case management and televisits	3,044,144 (11)		
Participant screening and assessment	164,611 (<1)		
Quality improvement	99,720 (<1)		
Project management and other direct costs	1,778,470 (6)		
Close-Out Stage (De-Installation of HTUs)		$10,435 (<1)	
Total Demonstration Costs			**$28,159,066 (100)**

Source: The independent evaluator's estimates based on information obtained from the Consortium's technical proposal (from which information on staff hours had been deleted) and progress reports; a paper published by the demonstration team; information collected during site visits by the independent evaluator; the Web site of the Office of Grants and Contracts for Columbia University's Health Sciences Division; input of a consultant in telemedicine; input from the Consortium on the salaries of demonstration staff, the staff's level of effort, and the value of subcontracts; and the independent evaluator's research on market prices. (See Appendix F, Section A, for more information on the methods used to estimate costs.)

[a]Costs include estimated institutional overhead for Columbia University and SUNY Upstate Medical University.

HTU = home telemedicine unit.

total budget. Each of the costs of the remaining implementation-stage components is less than one percent of the total budget.

The implementation-stage costs ($12,905,572; Table V.1), divided by the total number of treatment group enrollees randomized (n = 844), provides an estimate of the implementation cost per participant.[70] The cost per treatment group participant for the implementation stage only is $15,291. The *annual* cost per participant is obtained by dividing this amount by two, which corresponds to the length of intervention stage (that is, $7,645 per participant per year; Table V.2). Of course, these costs are for a demonstration program, and they may be higher than those that would be experienced by an ongoing telemedicine program. Furthermore, an ongoing program would depreciate its start-up costs over several years.

The independent evaluator added the costs of the demonstration's design and HTU de-installation stages ($4,317,781, or $5,116 per participant over the length of the intervention) and created different scenarios under which the start-up costs could be depreciated.[71] If the design and HTU de-installation costs were depreciated over the four years of the demonstration's first phase, these costs would equal $1,279 per participant per year. Under this scenario, the annual cost per participant would be $8,942 (= $7,645 + $1,279; Table V.2). If the design and HTU de-installation costs were depreciated over the full eight years that the demonstration will

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[70]If the independent evaluator had used the actual number of HTUs installed (n = 794), the estimates of the total cost per participant would have been about six percent higher. Thus, the estimates presented here may be regarded as conservative estimates of the demonstration's implementation costs.

[71]It is debatable whether design costs need to be included in the calculation of the annual cost per participant since they would go towards zero per person, per year if the demonstration were to become permanent.

TABLE V.2

ESTIMATES OF IMPLEMENTATION COSTS PER PARTICIPANT AND IMPLEMENTATION COSTS PLUS DESIGN AND CLOSE-OUT COSTS PER PARTICIPANT
(Dollars)

		Implementation Cost plus Design/Close-Out Costs	
	Implementation Costs Only	Depreciated Over Four Years	Depreciated Over Eight Years
Annual Implementation Cost per Participant	7,645	8,924	8,284

Source: The independent evaluator's estimates based on information obtained from the Consortium's technical proposal (from which information on staff hours had been deleted) and progress reports; a paper published by the demonstration team; information collected during site visits by the independent evaluator; the Web site of the Office of Grants Contracts for Columbia University's Health Sciences Division; input of a consultant in telemedicine; input from the Consortium on the salaries of demonstration staff, the staff's level of effort, and the value of subcontracts; and the independent evaluator's research on market prices. (See Appendix F, Section A, for more information on the methods used to estimate costs.)

last (over Phase I and Phase II), they would equal $639 per participant per year. Thus, under this scenario, the annual cost per participant for the intervention would be $8,284 (= $7,645 + $639; Table V.2).

C. IMPACT ON MEDICARE EXPENDITURES

To estimate demonstration impacts on Medicare expenditures, the independent evaluator used claims data to calculate Medicare expenditures for each enrollee from the time of the enrollee's randomization until December 31, 2003.[72] This impact analysis uses the full sample of 1,665 eligible Medicare beneficiaries enrolled in the demonstration (that is, it is an *intention-to-treat* analysis).[73,74]

Mean annual Medicare expenditures were higher for treatment group members than for control group members in both sites, but differences are not statistically significant. In the New York City site, the mean annual Medicare expenditures for treatment group members were $10,039, versus $9,239 for control group members (Table V.3). Similarly, in the upstate site, expenditures for treatment group members exceeded the expenditures for control group members

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[72]Impacts are based on Medicare expenditures alone. Although the Consortium collected some data on expenditures paid by other sources (such as Medicaid and supplemental insurance policies), and some data on enrollees' out-of-pocket expenditures, the data are incomplete and of variable quality. Therefore, they have not been included in this analysis.

[73]One enrollee was excluded from the analysis because her dropout date preceded her randomization date.

[74]Appendix F, Section D, presents a sensitivity analysis of the demonstration's impacts on Medicare expenditures to different specifications of the study sample. It also examines the sensitivity of the estimates to capping expenditures greater than the 98th percentile. Finally, the appendix discusses impact estimates by subgroups defined by the intensity of use of the intervention using a propensity score methodology to account for the endogeneity of use of services.

TABLE V.3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, BY SITE AND EVALUATION GROUP (MEANS, IN DOLLARS)

Component/Service	New York City			Upstate New York		
	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Total Medicare	10,039	9,239	800 (.474)	7,969	6,832	1,137 (.127)
Medicare Part A	5,617	4,814	803 (.392)	4,208	3,545	663 (.261)
Medicare Part B	4,422	4,425	–3 (.992)	3,761	3,287	474 (.047)
Hospitalization	5,104	4,408	696 (.421)	3,680	3,001	679 (.200)
Skilled Nursing Care	270	180	90 (.436)	295	311	–16 (.874)
Emergency Room	86	79	7 (.482)	111	101	10 (.525)
Outpatient Hospital	1,226	1,259	–33 (.820)	864	687	177 (.064)
Home Health Care[a]	663	617	46 (.698)	309	302	7 (.926)
Durable Medical Equipment	342	323	19 (.774)	570	439	131 (.026)
Physician Office Visits	396	422	–26 (.336)	283	266	17 (.292)
Laboratory Services[b]	46	53	–7 (.397)	46	42	4 (.620)
Other Part B[c]	1,905	1,896	9 (.951)	1,759	1,619	140 (.356)
Sample Size[d]	**372**	**355**	**—**	**445**	**443**	**—**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c).

Notes: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the follow-up period (December 2003), and weighted by the length of the interval between randomization and December 2003 (see Appendix F). Means were predicted with linear regression models, which controlled for enrollees' baseline characteristics and outcomes. (See Appendix F, Section C, for the list of characteristics.)
The sum of Medicare costs, by type of service, is not equal to the total Medicare costs (or to the Part A or Part B components) because the list of services is not exhaustive.

[a]Includes both Part A and Part B expenditures.

[b]Refers to services rendered by a certified laboratory independent of an institution or a physician office.

[c]Refers to Part B-covered services, such as other physician services (for example, hospital visits, ophthalmology, and pathology); imaging services; laboratory services not independent of an institution or a physician office; minor procedures; medical supplies; therapy; and ambulance services.

[d]Refers to all enrollees in the study.

n.a. = not applicable.

($7,969 versus $6,832). The treatment-control difference for upstate enrollees ($1,137) is about 40 percent higher than the difference for enrollees in New York City ($800), but it is not statistically significant.

In both New York City and upstate sites, treatment group members had somewhat higher expenditures for Medicare Part A services (primarily inpatient hospital care). Expenditures for Part B services (physician office visits and outpatient care) are higher for treatment group members in the upstate site but about the same for treatment and control group members in New York City (Table V.3). There were few statistically significant differences between treatment and control group members, but treatment group members had higher expenditures in most Medicare cost categories with the exception of physician office visits and laboratory services in New York City, and skilled nursing facility care in the upstate site.[75]

D. ANALYSIS OF COST SAVINGS

Given that there were no savings in Medicare Part A and B expenditures *over the period studied,* there is obviously no cost at which the intervention could satisfy the legislative goal to "…improve patient quality-of-life and *reduce overall health care costs*"(emphasis added).[76] The net effects of the demonstration on Medicare costs are equal to the treatment–control difference in Medicare expenditures plus the demonstration costs described in this chapter. Adding the per-participant cost of the demonstration to the average total expenditures for Medicare-covered

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[75]See Appendix G, Table G.1, for impact estimates for both sites combined. The pattern of treatment–control differences, by Medicare expenditures component and type of service, is similar to the pattern described here for each site.

[76]See Appendix A for a copy of the legislation.

services of the treatment group members results in per-participant costs that are significantly higher for treatment group members ($18,963 and $16,893 in New York City and upstate New York, respectively; see Table V.4) than for control group members in both sites.[77,78]

The demonstration's costs also are several times higher than the costs of comparable home-based telemedicine programs for patients with diabetes that used televisits with nurse case managers in addition to in-home visits, and which were reported as having the "potential to effect cost savings" (Table V.5) (Dansky et al. 2001; and Johnston et al. 2000). Thus, from the perspective of the Medicare budget and other telemedicine initiatives for beneficiaries with diabetes, IDEATel is an expensive intervention.

Although highly unlikely, the demonstration may have resulted in savings outside the Medicare program. For example, nearly 40 percent of treatment group members were dually eligible for Medicare and Medicaid at randomization. If the demonstration reduced the use of Medicaid-covered health care services (such as nursing homes) or, perhaps, of prescription medications, it may have generated savings to the Medicaid program. In addition, enrollees' out-of-pocket expenses (their Medicare deductibles and copayments or their costs for non-Medicare- or

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[77]See Appendix G, Table G.3, for the impacts of the demonstration on total Medicare costs for the full sample.

[78]For context, mean annual per-enrollee costs ($17,221) are well above the average Medicare expenditures per beneficiary in the United States and in New York State ($5,841 and $7,483, respectively) (Centers for Medicare & Medicaid Services 2004b). Treatment group expenditures also are high relative to the average Medicare expenditures for a sample of beneficiaries with diabetes ($6,525) (Krop et al. 1999). See Appendix G, Table G.2, for details about these estimates.

TABLE V.4

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, DEMONSTRATION SERVICES, AND TOTAL SERVICES
(Means, in Dollars)

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Total Medicare-Covered Services	10,039	9,239	800 (.474)	7,969	6,832	1,137 (.127)
Total Demonstration Services	8,924	0	n.a.	8,924	0	n.a.
Total Services	18,963	9,239	9,724 (.000)	16,893	6,832	10,061 (.000)
Sample Size[a]	**372**	**355**	**—**	**445**	**443**	**—**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c), and Table V.2.

Notes: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the follow-up period (December 2003), and weighted by the length of the interval between randomization and December 2003 (see Appendix F). Means were predicted with linear regression models, which controlled for enrollees' baseline characteristics and outcome. (See Appendix F, Section C, for the list of characteristics.)

[a]Refers to all enrollees in the study.

n.a. = not applicable.

TABLE V.5

ANNUAL COST PER PARTICIPANT IN INTENSIVE NURSE CASE MANAGEMENT TELEMEDICINE INTERVENTIONS
(Dollars)

Study	Annual Cost per Participant
IDEATel[a] (n = 844)	
As a demonstration program (excludes design costs)	7,645
As an ongoing program (includes design costs)	8,284–8,924
Randomized Study of Elderly Patients with Diabetes Discharged from a Hospital and Referred to a Large, Urban Home Health Agency[b] (n = 86)	415
Quasi-Experimental Study of Patients Diagnosed with Diabetes (or Other Chronic Conditions) in a Home Health Department[c] (n = 102)	1,830

Source: Table V.2, Dansky et al. (2001), and Johnston et al. (2000).

Note: All three studies used home telemedicine units supplied by American Telecare, Inc.

[a]Data correspond to 2000–2002.

[b]Data correspond to 1997–1998. The hospital and home health agency were in Pennsylvania.

[c]Data correspond to 1996–1997. No reference time period was reported for the cost estimates (for example, whether the estimates were annualized). The other conditions are congestive heart failure, chronic obstructive pulmonary disease, cerebral vascular accident, cancer, and secondary diagnoses of anxiety or being in need of wound care. The home health department was in Sacramento, California.

non-Medicaid-covered expenses) may have decreased. Unfortunately, the independent evaluator was not able to analyze Medicaid data or data on enrollees' out-of-pocket expenses.[79]

E. SUMMARY AND DISCUSSION

1. Summary of Findings

The demonstration's estimated annual implementation cost per participant is high relative to total Medicare expenditures for all Part A and Part B services. It also is high relative to the costs of comparable home-based telemedicine programs that used televisits with nurse case managers for people with diabetes. For several reasons, the demonstration's implementation cost per participant may be higher than what would be observed in an ongoing telemedicine program operating on a larger scale. First, the demonstration's intervention is technically more complex and therefore likely to be more costly to implement than would other disease management or telemedicine programs. In addition, the information systems designed for the demonstration may be more costly to maintain than would a stand-alone system. Second, the Consortium implementing the demonstration—led by an academic medical center—has not been subject to the pressure to control costs that might be found in a managed care organization or a for-profit vendor implementing the same kind of intervention. Third, the costs of living are higher in New York (particularly in New York City) than in most other areas of the country. Thus, labor and space costs for the demonstration are higher than they would be if the intervention were implemented in lower-cost areas. Fourth, as noted in Chapter III, the majority of demonstration participants had not had experience with personal computers before enrolling in the

[79]The independent evaluator could not analyze Medicaid claims data because analysis of such data was never intended for this study—that is, the Consortium did not request Medicaid claims data for demonstration enrollees.

demonstration. Thus, system redesign and participant training costs are higher than if the demonstration had served a younger cohort of Medicare beneficiaries, who are likely to have more experience with computers, given the rapid and widespread adoption of electronic health technologies by the U.S. population in recent years. Finally, it also is possible that the demonstration's costs are higher than would be observed in an ongoing program because of a lack of scale economies. (For example, the demonstration's system architecture could support many more participants than the number currently enrolled.) The demonstration also may have had to bear extra costs to coordinate the intervention and research activities. Therefore, refinements to the demonstration's implementation may result in substantial decreases in cost per participant.

The finding that the intervention was not able to generate any savings in Medicare expenditures for treatment group members is not surprising, given that IDEATel did not reduce the level of services use (Chapter IV). Higher levels of use of Medicare-covered services among treatment group members may well have resulted from IDEATel meeting the latent demand for appropriate health services among medically underserved beneficiaries. It may be that favorable treatment-control differences in Medicare expenditures will appear with longer follow-up periods. As noted in Chapter IV, prolonged control of diabetes risk factors over several years should help enrollees to avoid the visual, vascular, neurologic, and renal complications of diabetes, which should then reduce the use of Medicare-covered services and, consequently, expenditures. However, treatment group members had *higher* Medicare expenditures than did the control group members. Thus, for the intervention to produce savings in the long run and, therefore, to become cost-saving, it would have to substantially reduce expenditures for hospitalization services among treatment group members.

2. Limitations of the Analysis

This analysis of the impacts of the demonstration on Medicare costs has several minor limitations. First, because the Consortium provided the independent evaluator with most, but not all, of the demonstration's budget data, the independent evaluator's estimates of the demonstration's costs should be regarded as approximations of the true costs of implementing IDEATel. Second, because the independent evaluator was not able to analyze either Medicaid data or data on enrollees' out-of-pocket expenses, it could not address whether the demonstration generated savings outside of Medicare, although such savings seem highly unlikely given the absence of effects on Medicare services and costs during Phase I. Finally, because of the large variability of Medicare expenditures and the relatively small sample sizes available from each site, the statistical power for detecting demonstration impacts might be insufficient. However, the absence of effects on Medicare service use and the fact that treatment-control differences were *positive* for key services in both sites suggest that inadequate sample size does not explain why the estimates in costs show no reduction.

3. Further Considerations

From a cost perspective, Phase I of the demonstration cannot be considered cost-saving. However, given the demonstration's impacts on selected enrollees' clinical outcomes (discussed in Chapter IV), the demonstration could be considered moderately effective clinically. Nevertheless, questions remain as to whether the demonstration would begin to show savings for

a longer follow-up period or, if not, whether other disease management or care coordination interventions could have a similar clinical impact at substantially lower cost.[80]

[80]An analysis of enrollees who were continuously enrolled in the demonstration for 24 months after randomization (n = 1,010) suggests no clear trend in the impacts of the demonstration on Medicare expenditures over time. While in New York City the treatment-control difference in total Medicare expenditures declined between the first and second year of enrollment, in the upstate site this difference increased substantially. None of the differences involved in the comparison are statistically significant (see Appendix F, Section D.1).

VI. CONCLUSIONS

The current report updates one on the first 21 months of this demonstration that the independent evaluator submitted to Congress in spring 2003. It also addresses the three major issues laid out in the legislation that mandated the demonstration: (1) whether the demonstration was implemented as intended by Congress; (2) whether participants used the technology through which the intervention was delivered; and (3) whether the demonstration had impacts on access to care, service use, behavioral and physiologic outcomes, Medicare costs, quality of life, and satisfaction with care.

In contrast to the first report, which examined the implementation of the demonstration and therefore relied exclusively on qualitative data collected during site visits in fall 2001 and winter 2002, the findings in the current report draw on several qualitative and quantitative data sources. First, the independent evaluator held telephone discussions with demonstration staff in the second and third years of the demonstration to collect data to update the implementation analysis. However, the Consortium's confidentiality restrictions regarding human subjects prevented the independent evaluator from interviewing either members of the treatment group or the participants' primary care physicians.[81] The interviews could have provided valuable insight into the implementation of the demonstration. Second, the current report draws on various data that the Consortium collected during the demonstration's first phase (February 2000 through

[81]These discussions are planned for winter 2007. As of this writing, the Consortium has secured institutional review board approval to seek consent from Phase II members of the treatment group and their physicians to release contact information to the independent evaluator.

February 2004). The new data include the numbers and characteristics of people enrolled in and leaving the demonstration, HTU use, enrollees' outcomes at randomization and at followup, participants' satisfaction with the intervention and with their HTUs, characteristics of referring physicians, costs of designing and implementing the demonstration, and Medicare expenditures and service use between 1999 and 2003.

The Consortium effectively implemented IDEATel, despite early hardware and software problems.

The Consortium successfully implemented the first phase of the IDEATel demonstration. It confirmed that the numerous challenges that arose at each stage of the implementation of the demonstration's first phase could be overcome with sufficient creativity and adaptability of the organization implementing it. Some of these challenges were relatively simple to resolve; others required that the Consortium change the demonstration's design.

A higher-than-expected dropout rate was a major challenge to implementation that also translated into evaluation challenges.

The dropout rate (19 percent in the treatment group during the first year) was higher than expected. In winter 2002, the Consortium responded to this implementation challenge by increasing the target sample size by about 10 percent.

The Consortium also extended the enrollment period to meet the new enrollment target, and to enable new upstate practices to join. These moves enabled the Consortium to complete recruitment in mid-April 2002 in New York City, and in mid-October 2002 in upstate New York, approximately 14 months after the originally projected date of August 2001.

Because of the extended enrollment period relative to the original four-year demonstration period, eligible Medicare beneficiaries who enrolled at the end of the recruitment period

(summer/fall 2002) received the intervention for only one year or less and, therefore, do not have survey follow-up data for the full two years, as originally planned, as of July 31, 2003—the cutoff for data for this evaluation. Thus, survey follow-up data are available on approximately 82 percent of the 1,665 enrollees for the enrollees' first full year in the demonstration, and on approximately 35 percent of enrollees for their second full year (depending on the outcome measured).[82] In contrast, Medicare claims data for the period 2000–2003 are available for all 1,665 beneficiaries.

Changes in the design of the HTUs created several new challenges that may have had lasting effects on the implementation of the demonstration.

Within 10 months of the demonstration's start, and without an interval between the award of the cooperative agreement and the actual start of funding, the Consortium had to create an HTU using off-the-shelf components because its subcontractor had stopped supplying the all-in-one device as originally proposed. It was ready to install the HTUs in the homes of the first demonstration enrollees by December 2000. By the end of the enrollee recruitment period (fall 2002), it had installed 794 HTUs. However, the changes to the technical design created several new challenges that affected the acceptability and use of the HTUs. Demonstration staff reported that some participants objected to having such a large object in their homes, and that

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[82]These percentages are based on annual enrollee interviews (through July 31, 2003) that the Consortium provided to the independent evaluator. About 1,648 eligible beneficiaries had enrolled through July 2002 and therefore should have been interviewed; however, due to death and nonresponse, only 1,356 completed follow-up interviews. The Consoritum continued collecting data for Year 1 between July 31, 2003, and the end of the demonstration's operations (October 31, 2003) in New York City; it continued collecting data uninterruptedly in the upstate site. As of February, 2005 the Consortium had collected follow-up data on approximately 85 percent of enrollees for enrollees' first year in the demonstration, and on approximately 75 percent of enrollees for their second year.

some of those who objected refused to have the HTUs installed. In addition, the Consortium had to develop a *launch pad* to simplify operation of the HTU.

The Consortium also had to resolve several HTU maintenance problems during the demonstration's first phase, including software incompatibilities (between the HTU's software and the case management system), difficulties experienced by participants as they attempted to upload their clinical measurements (failure to receive confirmation that blood pressure and blood sugar readings had been transmitted), and the need to maintain hardware (replacement of batteries in glucose meters and blood pressure cuffs, and replacement of video cameras and speakers damaged by electrical storms). The Consortium successfully dealt with each of these problems. However, it is unclear whether the problems may have affected participants' experiences of the intervention before their resolution.

The demonstration's clinical procedures worked well throughout the first phase. The demonstration retained qualified nurse case managers. Communication between nurse case managers and primary care physicians seemed to have worked well.

The Consortium reported that, for the most part, the intervention ran smoothly, particularly during the demonstration's third and fourth years. The Consortium staffed the intervention with a stable, qualified, and empathetic cadre of nurse case managers. Moreover, Consortium staff reported that the protocols for televisits, case management supervision, and primary care physician communication worked well. Consortium staff also reported that participating physicians seemed to be receptive to the recommendations provided by nurse case managers about their patients. These recommendations were reviewed and signed off on by the demonstration's diabetologists before they were sent to the physicians.

Demonstration participants used the HTUs less frequently than expected.

Participants used their HTUs infrequently. Consortium staff reported that teaching participants how to use most of the HTU's functions was a slow, arduous process that, for some participants, was far from complete by the end of the first phase of the demonstration. An analysis of HTU use data for all participants indicates that virtually all the participants measured their blood pressure and blood sugar, and that they did so virtually every day. (Taking these measurements did not require logging in on the HTU; most participants had been taking them before the demonstration began.) However, the analysis also showed that only a small group of technically savvy, highly motivated participants (between 11 and 21 percent) used the HTU's more complex functions. Most participants rarely used other features of the telemedicine system that required logging in, such as reading and sending electronic messages and entering medications or exercise data. Minority participants used their HTUs less often than did white participants, as did participants with less education relative to those who completed at least high school (after controlling for other individual demographic and health characteristics).

After becoming aware that participants were not using their HTUs as intended, in spring 2002 (during the demonstration's third year), the Consortium leadership asked an expert on human–machine interactions to analyze patient interactions with the HTU. Based on the findings from that study, the Consortium retrained all participants on HTU use. The Consortium also installed a redesigned online tutorial in the HTUs that participants could watch whenever they needed instructions on how to use the system. The retraining took place between October 2002 and January 2003, but it may not have helped participants to feel more comfortable with their HTUs; the device's use rate for several functions remained flat between December 2002 and July 2003—roughly the period after the Consortium retrained all participants.

Exposure to the intervention was uneven across sites, and less frequent than planned.

The frequency of televisits—a key component of the intervention—was substantially lower than planned and differed markedly between the two sites. Participants in the upstate site had one televisit every four weeks, about half the initially planned frequency of one televisit every two weeks; by contrast, those in the New York City site had a televisit substantially less frequently—about one visit every seven weeks. The frequency of televisits in both sites would have been higher if participants had broken fewer appointments, particularly in New York City. The differences in estimates are consistent with reports by nurse case managers that a small number of participants in New York City spent their winter months outside New York State, and therefore were not available for televisits during that time. However, other factors probably are more important determinants of the difference in the number of televisits between the two sites. Although the average duration of a televisit (27 minutes) was within the planned duration for routine follow-up visits (between 15 and 30 minutes), the nurse case managers often spent some part of their televisit time during the second and third years of the demonstration addressing participants' concerns about the HTUs, rather than managing the participants' diabetes. It is unclear whether the nurse case managers' diversion to address technical issues limited the participants' exposure to the intervention.

Consortium staff believe that IDEATel is bridging the digital divide, and that the intervention was acceptable to participants, but a sizeable minority dropped out of the demonstration and most used only the basic functions of the system.

During their interviews, Consortium staff expressed the belief that the delivery of the IDEATel technology to a large number of homes in underserved communities represented a tremendous step forward in bridging the so-called *digital divide*. Even though the demonstration did deliver the IDEATel technology to 794 participants in medically underserved communities, it was not

wholly successful in achieving this goal. Consortium staff also interpreted the fact that a large number of participants used several HTU functions as strong evidence that the technology was acceptable. However, the available evidence suggests that some participants may have found the technology unappealing; about seven percent refused to have HTUs installed in their homes and six percent dropped out of the study because they found the system difficult to use. Moreover, steep learning curves discouraged half of them from learning to use the more complex functions.[83] Although the high frequency with which participants measured their blood pressure and blood sugar suggests that the intervention has the potential to produce positive changes in clinical outcomes, in its current form, the HTU's effectiveness as a medium for delivering intensive nurse case management to a large number of Medicare beneficiaries with limited education remains unclear.

The Consortium developed a physicians' syllabus about telemedicine and held a webcast for participating physicians.

The Consortium began work on the congressionally mandated objectives of physician education and development of telemedicine standards in 2002 (Columbia University 2003h). It developed a physicians' syllabus about telemedicine that was posted on the demonstration's website in early 2003, about two and a half years after the first participants were recruited. The Consortium reported that it notified all participating physicians about the existence of this practical guide on

[83]Based on an analysis of an early cohort of participants (those whose HTUs were installed between December 2000 and November 2001), only between 6 and 35 percent of participants took less than one year to use the more complex functions, such as entering medications or consulting the American Diabetes Association Web pages.

telemedicine. In addition, the Consortium held a webcast for participating physicians on April 22, 2003. The webcast offered continuing medical education credit.

The Consortium implemented the demonstration in managed care and fee-for-service environments.

Another mandated demonstration objective was to develop a "model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment." The Consortium's approach to meeting this objective was to enroll eligible Medicare beneficiaries in the demonstration regardless of whether they were enrolled in a Medicare managed care plan or in fee-for-service Medicare. Given the limited number of managed care plans operating in upstate New York, it probably would not have been possible for the Consortium to test whether the model was equally effective in managed care and fee-for-service environments (and the mandate does not explicitly require this test). Using Medicare enrollment data, the independent evaluator estimated that only about five percent of demonstration enrollees were enrolled for at least one month in managed care during the follow-up period. Thus, it was not possible to examine differences in how the demonstration was implemented in managed care and fee-for-service environments.

IDEATel had favorable effects on enrollees' diabetes care and communication with health care providers about their diet and care. However, it affected the self-efficacy of upstate enrollees only.

In both the New York City and upstate sites, the IDEATel intervention had large, positive effects on whether enrollees consulted with diabetes nurse educators or dietitians (including IDEATel's case managers) at least once since baseline, as well as on whether they tested their blood sugar daily. Upstate, the intervention increased the frequency of health care providers' discussions with enrollees about diet and exercise, and it improved enrollees' self-confidence in their ability

to control their diabetes during the coming year (that is, their *self-efficacy*). However, it did not improve adherence to diet or exercise regimens. In New York City, the intervention resulted in an increase in the number of discussions that enrollees had with health care professionals, and somewhat better adherence to exercise regimens. However, it had no significant impacts on enrollees' views or beliefs about controlling their diabetes.

IDEATel had somewhat favorable effects on use of recommended medications among enrollees with baseline indications for treatment and, in some instances, more aggressive dosing and number of medications per enrollee.

In both sites, among enrollees with baseline indications for treatment (that is, elevated cholesterol levels, protein in the urine, high blood pressure, and poorly controlled blood sugar), intervention group members were somewhat more likely to have been prescribed appropriate medications than control groups members, although most of these differences were not statistically significant because of small sample sizes. In the upstate site, among enrollees with poorly controlled blood sugar at baseline and prescribed insulin, treatment group members were treated more aggressively, as indicated by a higher average daily dose of insulin. However, the intervention had no effect in either site on the prescription of antiplatelet drugs, which are generally recommended for all persons with diabetes.

IDEATel had impacts on three key clinical measures.

The intervention had substantial, and statistically significant, favorable impacts on diabetes control and lipid levels at followup in both the New York City and upstate sites. In both sites, enrollees' blood sugar control was better than the control group's, and enrollees' average cholesterol level was about five to six percent lower than the control group's. A supplemental subgroup analysis showed that, in the upstate site only, the intervention led to a greater

improvement in blood sugar control among participants whose blood sugar was more poorly controlled at baseline, than among those with better controlled blood sugar at baseline. The intervention also had impacts on the in-person blood pressure measurements, but more so in the upstate site. In the New York City site, enrollees' means were two percent less than the control mean for systolic and diastolic blood pressure, whereas differences in the upstate site were about three percent of the control mean for both systolic and diastolic blood pressure, and were highly significant. The Consortium had prespecified these three outcomes-diabetes control, lipid levels, and blood pressure control-as the main study outcomes.

The intervention had no clearcut effects in either site on several other important clinical outcomes. These included the ratio of microalbumin to creatinine (an indicator of diabetic kidney damage), 24-hour blood pressure measurements, and anthropometric measurements (such body mass index and waist to hip ratio).

IDEATel had limited impacts on the wide variety of health-related quality-of-life outcomes. IDEATel may have had small, isolated effects on some of the numerous self-reported health-related quality-of-life outcomes, but in neither site did it have any major or broad-based impacts on these indicators. Likewise, the treatment and control groups in both sites were similarly satisfied with the health care professionals who cared for their diabetes.

It may be that treatment–control differences in quality-of-life measures will appear with longer followup. Prolonged control of the risk factors of diabetes over several years should help to prevent the visual, vascular, neurologic, and renal complications of this condition, which, in turn, should help enrollees to feel better than they would otherwise.

IDEATel has the potential to reduce the long-term complications of diabetes, assuming it can sustain its effectiveness over time.

The intervention demonstrated some positive effects on clinical indicators and, assuming it can sustain its effectiveness over time, has the potential to reduce the long-term complications of diabetes. The effects of IDEATel on the long-range outcomes of interest (that is, morbidity and mortality from diabetes) are unknown and can be projected only under a set of assumptions that may not be satisfied.

The demonstration did not generate savings in Medicare expenditures and was expensive to implement. The first phase of the demonstration cannot be considered cost-saving.

The implementation costs of the IDEATel demonstration were high (between $8,284 and $8,924 per participant per year, depending on the length of depreciation of the demonstration's design and HTU-removal costs). They exceeded the enrollees' total Medicare expenditures for all Part A and Part B services and were several times greater than the reported costs of other telemedicine and nurse case management interventions for people with diabetes. For several reasons, the demonstration's implementation costs per participant may be higher than would have been observed in an ongoing telemedicine program operating at a larger scale: the development and maintenance of a system designed for a demonstration serving medically underserved beneficiaries with limited computer experience; the lack of scale economies given the number of participants enrolled in the demonstration; the higher costs of living in New York City than in most areas in the country; the extra costs to coordinate the intervention and research activities, among others. Therefore, refinements to the demonstration's implementation may result in substantial decreases in cost per participant.

The intervention did not reduce the Medicare expenditures of treatment group members relative to those of control group members in either site. This finding is not surprising, given that

IDEATel did not reduce the level of service use. In fact, Medicare expenditures were higher (though not significantly so) for the treatment group, which may well have resulted from IDEATel meeting the latent demand for appropriate health services among medically underserved beneficiaries. When the demonstration's cost per participant is added to the Medicare expenditures of the treatment group members, the treatment group's costs are about two and one-half times larger than the control group's costs.

Thus, based on findings from the experience of enrollees through December 2003, the demonstration is far from being cost-saving. In fact, even if Medicare expenditures were eliminated by the intervention, the treatment group's costs would exceed the control group's costs in both sites.

Longer followup of demonstration enrollees will address whether IDEATel will show savings on Medicare costs in the long run.

As of the end of Phase I, the question remains as to whether the demonstration would begin to show savings in Medicare expenditures (exclusive of demonstration costs) if the enrollees were *followed for a longer period*. If it does not, the questions are whether the improvements in outcomes of treatment group members are worth the high costs of the intervention, and whether other disease management or care coordination interventions could have a similar clinical impact at a substantially lower cost. However, given the design of the demonstration, it will be difficult to compare IDEATel against other policy options, such as conventional nurse case management or nurse case management with less-sophisticated technological support. Other studies suggest that these simpler interventions can achieve impacts similar to or larger than those observed in IDEATel at substantially lower cost.

Congress extended the demonstration for four more years. The Consortium faces several logistical and technical challenges, which also may become challenges to the independent evaluation.

The Consortium's leadership requested, and has received, an extension to the demonstration for four additional years.[84] (The Consortium considers the initial four-year period of the demonstration as Phase I, and the extension as Phase II.) The Consortium has prepared a scope of work for the extension (Columbia University 2004b). It has reenrolled more than half of the 1,247 Phase I treatment or control group enrollees who completed the Year 2 in-person interview (Columbia University 2004b, 2004c, and 2005).[85] Moreover, the Consortium has resumed televisits to participants in New York City (and continued them for participants in Upstate New York). The extension will allow tests of whether following Phase I enrollees for much longer periods (two to six years) will show demonstration effects on several health outcomes, service use, and Medicare expenditures. In addition, the Consortium has begun enrolling, and randomizing, up to 400 new, Phase II-eligible Medicare beneficiaries in both sites.

One difficulty that the Consortium could face in implementing Phase II of the demonstration is that the legislation to authorize the extension was delayed in Congress for many months before passage. The Consortium's ability to continue the demonstration as implemented in Phase I in New York City, where Phase I operations ended on October 2003, may be limited by loss of enrollee interest during the interim, and by increased rates of enrollee drop out due to death or

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[84]The demonstration's second phase started on February 28, 2004.

[85]This implies that, for conducting an *intention-to-treat analysis* (as originally proposed by the Consortium) of Medicare-covered services and expenditures, the impact analysis will estimate the treatment-control difference in outcomes for the original cohort of 1,665 enrollees and not only for the 1,247 enrollees who completed the Year 2 interview.

advancing illness (during Phase II). Moreover, from the evaluator's standpoint, IDEATel's extension may result in insufficient statistical power for detecting modest demonstration impacts on some survey-based outcomes at the end of the second phase because Phase I and Phase II cohorts cannot be pooled for analysis.[86]

CONCLUSIONS

The Consortium implemented a demonstration that both responded to the congressional mandate and addressed numerous design and implementation challenges. The intervention had positive impacts on several key clinical outcomes, but it had no impact on Medicare service use or expenditures over the three-year period examined. Furthermore, demonstration costs were high, exceeding the costs of all Medicare-covered services for enrollees. Thus, Phase I of the demonstration increased costs to CMS, and the high costs of the intervention per participant suggest that even complete elimination of all Medicare expenditures would lead to a net increase in expenditures.

As of this point of the evaluation, several factors limit the ability of the independent evaluator to draw policy-relevant conclusions:

- Results are available only for the first year after enrollment (with end-of-Year-2 data recently completed). Thus, if the intervention must operate for several years before effects on health outcomes and Medicare service use and expenditures appear, as seems likely for diabetic patients, a longer followup is necessary.
- Phase I of the demonstration was not designed to provide evidence on the marginal benefit of each of the intervention's components—that is, use of the HTU or

[86]This is due primarily to the differences in the stage of implementation of the demonstration when these two cohorts were randomized and began receiving the intervention.

interactions with the nurse case managers. Thus, the independent evaluator cannot determine whether the clinical impacts of the demonstration resulted from the telemedicine intervention, the intensive nurse case management, or both components.

- The demonstration's high implementation costs, together with the impossibility of separating the effects of the HTU from the effects of the intensive case management component, make it difficult to discern with certainty which of the intervention components would be most promising for the Medicare program. Thus, even if some cost savings appear over a longer followup, this evaluation will not be able to provide CMS with the critical information necessary to assess whether a less expensive version of this demonstration could produce sufficient Medicare savings to offset demonstration costs.

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APPENDIX A

ENABLING LEGISLATION FOR THE DEMONSTRATION AND THE EVALUATION

.

SEC. 4207. INFORMATICS, TELEMEDICINE, AND EDUCATION DEMONSTRATION PROJECT.

42 USC 1395b–1

(a) PURPOSE AND AUTHORIZATION.—

(1) IN GENERAL.—Not later than 9 months after the date of enactment of this section, the Secretary of Health and Human Services shall provide for a demonstration project described in paragraph (2).

(2) DESCRIPTION OF PROJECT.—

(A) IN GENERAL.—The demonstration project described in this paragraph is a single demonstration project to use eligible health care provider telemedicine networks to apply high-capacity computing and advanced networks to improve primary care (and prevent health care complications) to medicare beneficiaries with diabetes mellitus who are residents of medically underserved rural areas or residents of medically underserved inner-city areas.

(B) MEDICALLY UNDERSERVED DEFINED.—As used in this paragraph, the term ''medically underserved'' has the meaning given such term in section 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3)).

(3) WAIVER.—The Secretary shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (d).

(4) DURATION OF PROJECT.—The project shall be conducted over a 4-year period.

(b) OBJECTIVES OF PROJECT.—The objectives of the project include the following:

(1) Improving patient access to and compliance with appropriate care guidelines for individuals with diabetes mellitus through direct telecommunications link with information networks in order to improve patient quality-of-life and reduce overall health care costs.

(2) Developing a curriculum to train health professionals (particularly primary care health professionals) in the use of medical informatics and telecommunications.

(3) Demonstrating the application of advanced technologies, such as video-conferencing from a patient's home, remote monitoring of a patient's medical condition, interventional informatics, and applying individualized, automated care guidelines, to assist primary care providers in assisting patients with diabetes in a home setting.

(4) Application of medical informatics to residents with limited English language skills.

(5) Developing standards in the application of telemedicine and medical informatics.

(6) Developing a model for the cost-effective delivery of primary and related care both in a managed care environment and in a fee-for-service environment.

(c) ELIGIBLE HEALTH CARE PROVIDER TELEMEDICINE NETWORK DEFINED.—For purposes of this section, the term ''eligible health care provider telemedicine network'' means a consortium that includes at least one tertiary care hospital (but no more than 2 such hospitals), at least one medical school, no more than 4

facilities in rural or urban areas, and at least one regional telecommunications provider and that meets the following requirements:
(1) The consortium is located in an area with a high concentration of medical schools and tertiary care facilities in the United States and has appropriate arrangements (within or outside the consortium) with such schools and facilities, universities, and telecommunications providers, in order to conduct the project.
(2) The consortium submits to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the use to which the consortium would apply any amounts received under the project and the source and amount of non-Federal funds used in the project.
(3) The consortium guarantees that it will be responsible for payment for all costs of the project that are not paid under this section and that the maximum amount of payment that may be made to the consortium under this section shall not exceed the amount specified in subsection (d)(3).
(d) COVERAGE AS MEDICARE PART B SERVICES.—
(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, services related to the treatment or management of (including prevention of complications from) diabetes for medicare beneficiaries furnished under the project shall be considered to be services covered under part B of title XVIII of the Social Security Act.
(2) PAYMENTS.—
(A) IN GENERAL.—Subject to paragraph (3), payment for such services shall be made at a rate of 50 percent of the costs that are reasonable and related to the provision of such services. In computing such costs, the Secretary shall include costs described in subparagraph (B), but may not include costs described in subparagraph (C).
(B) COSTS THAT MAY BE INCLUDED.—The costs described in this subparagraph are the permissible costs (as recognized by the Secretary) for the following:
(i) The acquisition of telemedicine equipment for use in patients' homes (but only in the case of patients located in medically underserved areas).
(ii) Curriculum development and training of health professionals in medical informatics and telemedicine.
(iii) Payment of telecommunications costs (including salaries and maintenance of equipment), including costs of telecommunications between patients' homes and the eligible network and between the network and other entities under the arrangements described in subsection (c)(1).
(iv) Payments to practitioners and providers under the medicare programs.
(C) COSTS NOT INCLUDED.—The costs described in this subparagraph are costs for any of the following:
(i) The purchase or installation of transmission equipment (other than such equipment used by health professionals to deliver medical informatics services under the project).
(ii) The establishment or operation of a telecommunications

common carrier network.
(iii) Construction (except for minor renovations related to the installation of reimbursable equipment) or the acquisition or building of real property.
(3) LIMITATION.—The total amount of the payments that may be made under this section shall not exceed $30,000,000 for the period of the project (described in subsection (a)(4)).
(4) LIMITATION ON COST-SHARING.—The project may not impose cost sharing on a medicare beneficiary for the receipt of services under the project in excess of 20 percent of the costs that are reasonable and related to the provision of such services.
(e) REPORTS.—The Secretary shall submit to the Committee on Ways and Means and the Committee Commerce of the House of Representatives and the Committee on Finance of the Senate interim reports on the project and a final report on the project within 6 months after the conclusion of the project. The final report shall include an evaluation of the impact of the use of telemedicine and medical informatics on improving access of medicare beneficiaries to health care services, on reducing the costs of such services, and on improving the quality of life of such beneficiaries.
(f) DEFINITIONS.—For purposes of this section:
(1) INTERVENTIONAL INFORMATICS.—The term ''interventional informatics'' means using information technology and virtual reality technology to intervene in patient care.
(2) MEDICAL INFORMATICS.—The term ''medical informatics'' means the storage, retrieval, and use of biomedical and related information for problem solving and decision-making through computing and communications technologies.
(3) PROJECT.—The term ''project'' means the demonstration project under this section.

H.R.3075
Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Referred to Senate Committee after being Received from House)

SEC. 512. MISCELLANEOUS CHANGES AND STUDIES.

(c) PROMOTING PROMPT IMPLEMENTATION OF INFORMATICS, TELEMEDICINE, AND EDUCATION DEMONSTRATION PROJECT- Section 4207 of BBA is amended--

(1) in subsection (a)(1), by adding at the end the following: `The Secretary shall make an award for such project not later than 3 months after the date of the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. The Secretary shall accept the proposal adjudged to be the best technical proposal as of such date of the enactment without the need for additional review or resubmission of proposals.';

(2) in subsection (a)(2)(A), by inserting before the period at the end the following: `that qualify as Federally designated medically underserved areas or health professional shortage areas at the time of enrollment of beneficiaries under the project';

(3) in subsection (c)(2), by striking `and the source and amount of non-Federal funds used in the project';

(4) in subsection (d)(2)(A), by striking `at a rate of 50 percent of the costs that are reasonable and' and inserting `for the costs that are related';

(5) in subsection (d)(2)(B)(i), by striking `(but only in the case of patients located in medically underserved areas)' and inserting `or at sites providing health care to patients located in medically underserved areas';

(6) in subsection (d)(2)(C)(i), by striking `to deliver medical informatics services under' and inserting `for activities related to'; and

(7) by amending paragraph (4) of subsection (d) to read as follows:

`(4) COST-SHARING- The project may not impose cost sharing on a Medicare beneficiary for the receipt of services under the project. Project costs will cover all costs to patients and providers related to participation in the project.'.

SECTION. 1. MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

SEC. 417. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of the Balanced Budget Act of 1997 (Public Law 105-33) is amended—
(1) In subsection (a)(4), by striking "4-year" and inserting "8-year"; and
(2) in subsection (d)(3), by striking "$30,000,000" and inserting "60,000,000".

APPENDIX B

STUDY METHODOLOGY

This appendix describes the study methodology that the independent evaluator used for this report. The first section focuses on the data and methods used in the implementation analysis. The second section summarizes the technical aspects of the analysis of HTU use. Finally, the third section summarizes the technical approach used to estimate the demonstration's impacts on behavioral, clinical, and other health-related outcomes. (The approach that the independent evaluator used to estimate demonstration costs and the impact of the demonstration on Medicare expenditures and costs are reported in Appendix F.)

A. IMPLEMENTATION ANALYSIS

The implementation analysis relies on data collected during a series of site visits and telephone conferences during which key informants involved in the IDEATel demonstration were interviewed. The independent evaluator developed a protocol to collect information about the demonstration's original design, its evolution, and the reasons for the changes that were made. The protocol evolved over the years to better address the changes in the design and implementation of the demonstration. The core protocol contained questions about the Consortium; targeting, recruitment, and retention of physicians and enrollees; the technology used in the demonstration; the clinical intervention; and the Consortium's evaluation of the demonstration. Table B.1 presents the protocol used during the last round of telephone interviews.[87] The protocols were reviewed and revised after the interview with the Consortium's chief principal investigator had been conducted.

[87]The core protocol for a previous round of telephone interviews is available from the independent evaluator. The core protocol for the site visit interviews is available in the first interim report to Congress (U.S. Department of Health and Human Services 2003).

TABLE B.1

PROTOCOL FOR YEAR 3 INTERVIEWS WITH
IDEATel DEMONSTRATION STAFF

CONSORTIUM These questions address changes in the composition and functioning of the consortium.		
CON-1.	What is the biggest challenge the project faced in the last year? Was it resolved? If so, how?	
CON2.	Have the roles or responsibilities of the Consortium members changed in the last year?	
CON.3	Which members of the Consortium are still actively involved in demonstration activities and which have completed their responsibilities to the project?	
CON-4.	Which staff members are currently working on the demonstration? Will they continue their work through February 2004?	
CON-5.	Which staff left the demonstration in the last year? When did they leave? Were their responsibilities taken over by other staff members?	
CON-6.	Have you hired any new staff or added new positions in the last year? If so, who?	☐ No ☐ Yes. Probe: Who, when, and why?
CON-7.	What types of issues has the Data Safety and Monitoring Board focused on in the last year? Were there any changes to the membership of the board?	

CONSORTIUM These questions address changes in the composition and functioning of the consortium.		
	How many times have they met? Will they have another meeting before the end of February 2004?	
CON-8.	Jay Saunders was the keynote speaker at the April Web cast to physicians. Have any of the other consultants to the demonstration played a role this year?	☐ No ☐ Yes. Probe: Who? How were they involved?
CON-9.	How well has the Consortium functioned in the past year?	
CON-10.	Does the Steering Committee still hold regular weekly meetings?	☐ No ☐ Yes. Probe: What issues are discussed?
CON-11.	In addition to the Steering Committee, there were several other groups that held regular meetings. Have these other groups (technical implementation group, clinical group, case management software group) continued their meetings? If not, when were these meetings discontinued? Why?	Technical group still meets? ☐ No. Probe: When stopped meeting? Why? ☐ Yes. Probe: What issues are discussed? Clinical group still meets? ☐ No. Probe: When stopped meeting? Why ☐ Yes. Probe: What issues are discussed? Case management software group still meets? ☐ No. Probe: When stopped meeting? Why ☐ Yes. Probe: What issues are discussed?
CON-12.	Have any new groups begun to meet in the last year?	☐ No ☐ Yes. Probe: What is the composition of the group? How often do they meet? What issues do they address? Who leads the group?

TARGETING, RECRUITMENT, RETENTION		
These questions address the population targeted for the demonstration, inclusion and exclusion criteria, sources of referral to the demonstration, and participant enrollment and retention.		
TRR-1.	Did the demonstration's enrollment criteria identify the types of participants you wanted to enroll?	☐ No. Probe: What characteristics did the enrolled participants have that you would have preferred to have excluded? ☐ Yes.
TRR-2.	How many participants dropped out of the demonstration after July 31, 2003? In the treatment vs control group? Upstate vs New York City? Have you had any new thoughts on why participants dropped out?	Treatment group: _____ Control group: _____ New York City: _____ Upstate: _____
TRR-3.	Last year we talked about strategies you were using to prevent participants from dropping out. These included better training to make participants more comfortable with the HTU and calls to participants and their physicians to try to dissuade them from dropping out. Were these strategies successful? Have you developed any new strategies?	☐ No. Why not? ☐ Yes.
TRR-4.	What types of physician concerns or questions have you had to address in the past year?	
TRR-5.	Have any physicians dropped out? Why?	☐ No ☐ Yes. How many? Why?

TECHNOLOGY		
This set of questions is about the technology involved in the telemedicine demonstration. These questions are meant to help us understand the key components of the overall system that uses the telemedicine technology to improve participant outcomes and generate data for research.		
TEC-1.	Did you make any changes to the hardware or software in the last year? The demonstration's progress report for 2/28/03-8/31/03 mentions that you were in the process of installing a second upgrade to the HTU software.	☐ No ☐ Yes. What? Why? Probe: Is this the upgrade that you began to install last winter? ☐ Yes. ☐ No. What was the purpose of this upgrade?
TEC-2.	Have there been any changes in the subcontractors providing system components and services?	☐ No. ☐ Yes. Which ones?
TEC-3.	Did the HTU perform as intended? Were you able to resolve maintenance problems (for example, the need to replace batteries) with the blood pressure and blood glucose monitors?	☐ Yes. ☐ No. Why? ☐ Yes. ☐ No. Why?
TEC-4.	Are any HTUs still in active use?	☐ No. ☐ Yes. Probe: How many? Why?
TEC-5.	How are HTUs being deinstalled? How many have been deinstalled? Who is doing the deinstallation? What does the deinstallation process involve? How long does it take? Who handles disconnection of the ISP?	

TEC-6.	Some demonstration participants completed their two year intervention period and others had to stop their intervention because the demonstration came to an end. Did the process of deinstalling the HTUs differ for these two groups of participants?	☐ No. ☐ Yes. How?
TEC-7.	What are you doing with the deinstalled HTUs?	
TEC-8.	About 10 percent of participants had four or fewer years of education. How did this affect their use of the HTU?	

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-1.	How many nurse case managers are currently working on the project?	Probe: Are any demonstration staff now in contact with patients? ☐ No. ☐ Yes. Who? For what purpose?
INA-2.	Did any nurse case managers leave the project between December 2002 and August 2003?	☐ No. ☐ Yes. How many?
INA-3.	Did you hire any new nurse case managers after December 2002?	☐ No. ☐ Yes. How many?
INA-4.	Did the nurse case managers' responsibilities change in the last year?	☐ No. ☐ Yes. How?
INA-5.	At the point of highest enrollment, for how many participants was each nurse case manager responsible? What was the range of the caseload for the nurse case managers?	
INA-6.	Were there any changes to the intervention in the last year?	Probe: Changes in the frequency or duration of televisits? Changes in the materials on the ADA website? Changes in any other materials? Changes in the goals that nurse case managers worked on with

		participants? ☐ No. ☐ Yes. What?
INA-7.	Did the participant no-show rate for televisits change in the past year?	☐ No. ☐ Yes. How?
INA-8.	Last year you mentioned that the program was developing a database to track whether physicians were following the nurse case managers' recommendations. Did you implement this database?	☐ No. Why not? ☐ Yes. Probe: Did you find that physicians were heeding the recommendation and changing their behavior?
INA-9.	Last year the program retrained participants on the use of the HTU. When was retraining completed? In New York City? Upstate?	New York City: _____ Upstate: _____
INA-10.	How many participants were retrained in New York City? Upstate?	New York City: _____ Upstate: _____
INA-11.	Did you attempt to retrain all treatment group participants?	☐ No. Probe: Why? Had some completed their 2 year intervention period by then? Did some refuse retraining? Why? ☐ Yes.
INA-12.	Did the retraining have an impact on participants' comfort with the HTU or their proficiency in using the HTU's functions?	☐ No. Probe: Why not? ☐ Yes. Probe: How do you know?
INA-13.	How were participants prepared for the end of the demonstration?	Probe: Did you prepare a protocol? ☐ No. ☐ Yes. How did participants respond when you told them the demonstration was ending?

		Did the demonstration give the participants any equipment from the HTUs (glucose meters, blood pressure meters)? Did you refer participants to any other disease management or social service programs?
INA-14.	Overall, what impact do you think the demonstration had on participants?	Probe: Do you think the demonstration has impacts on participants: Knowledge of their condition: ☐ No. ☐ Yes. Why? Compliance with medication regimens: ☐ No. ☐ Yes. Why? Ability to keep appointments with physicians or other providers ☐ No. ☐ Yes. Why? Diet regimen: ☐ No. ☐ Yes. Why? Weight loss goals: ☐ No. ☐ Yes. Why? Exercise regimen: ☐ No. ☐ Yes. Why? Smoking cessation goals: ☐ No. ☐ Yes. Why? Glucose control: ☐ No. ☐ Yes. Why? Self care goals or motivation to do self-care: ☐ No. ☐ Yes. Why? Probe: What aspect of the intervention had the greatest effect? The least effect?
INA-15.	How many physicians participated in the Web cast held in April 2003? How long did the Web cast last? What topics were covered?	

EVALUATION ACTIVITIES The questions in this section deal with the randomization, data collection, and analysis processes.		
REA-1.	How many physicians responded to the first round of the physician survey? How many to the second round? Why was the physician survey not repeated in NYC?	First round: _____ Second round: _____
REA-2.	What are the Consortium's plans for conducting a survey of participant satisfaction?	
REA-3.	What is the Consortium's schedule for data analysis?	
REA-4.	The response rate for the quarterly telephone interviews decreases considerably over the two-year follow-up period. Do you have any data on reasons why these interviews could not be completed – such as patients could not be contacted or refused to be interviewed?	

The independent evaluator developed short protocols from the core protocol to be used when interviewing the principal investigators, a system designer, two recruitment managers, three diabetologists, a data coordination manager, a systems manager, an installation manager, a dietitian, three nurse case managers, and a participant trainer. Table B.2 lists the staff who were interviewed, their titles, and the dates of the interviews.

The interviews with demonstration leadership and staff took place during fall–winter 2001, fall 2002, and fall 2003. The telephone conference calls with staff from American TeleCare, Inc. (based in Eden Prairie, Minnesota) also took place during the same periods. Two-person teams from the independent evaluator conducted the telephone interviews; the same set of interviewers conducted all rounds of interviews. In-person interviews were restricted to a maximum duration of 45minutes; telephone interviews were restricted to 30 minutes.

The independent evaluator did not interview demonstration physicians or participants during the first round of site visits because Consortium leadership would not permit these interviews in the absence of institutional review board approval. Time constraints prevented the independent evaluator from seeking this approval. Likewise, the independent evaluator did not seek approval for the fall 2002 follow-up telephone interviews; the goal of the interviews was to speak with a subset of the people interviewed during the first round. Although the independent evaluator sought approval from Columbia University's institutional review board for the final round of follow-up telephone interviews, it was not granted. The institutional review board's director deemed that the demonstration's data confidentiality provisions precluded the release of identifiable data to any third party not associated with the Consortium.

TABLE B.2

IDEATel DEMONSTRATION STAFF INTERVIEWED
FOR THE IMPLEMENTATION ANALYSIS

Interviewee	Title	Year of Interview		
		2001	2002	2003
Steven Shea	Project director/principal investigator Professor of medicine and director, Division of General Internal Medicine, Columbia University	X	X	X
Ruth Weinstock	Co-principal investigator Professor of medicine and chief, Division of Diabetes, Endocrine, and Metabolism, SUNY Upstate Medical University Director, Joslin Center for Diabetes	X	X	X
Justin Starren	Co-principal investigator Assistant professor of Medical Informatics, Columbia University	X	X	X
Jeanne Teresi	Senior research associate, Hebrew Home for the Aged at Riverdale Senior research scientist, Columbia University	X	X	X
Walter Palmas	Assistant professor of clinical medicine, Columbia University	X	X	X
Charlyn Hilliman	Implementation manager, Columbia University	X	X	X
Robin Goland	Associate professor of medicine, Columbia University Director, Naomi Berrie Diabetes Center	X	X	X
Paul Knudson	Associate professor of medicine, SUNY Upstate Medical University Associate medical director, Joslin Center for Diabetes	X		
Roberto Izquierdo	Associate medical director, Joslin Center for Diabetes Clinical associate professor, SUNY Upstate Medical University			X
Phil Morin	Project manager, upstate New York	X		
Lesley Field	Project manager, New York City	X		
Carina Lagua	Dietitian, upstate New York	X	X	X
Susan Fox	Nurse case manager, upstate New York	X		
Jessica Rivera	Nurse case manager, New York City	X	X	
Renee Bachman	Nurse case manager, New York City	X		
Armando Velázquez	Participant trainer, New York City		X	
Richard Abbruscato	Vice president, Engineering & Manufacturing, American TeleCare, Inc.	X		
Karen Boril	Project manager, American TeleCare, Inc.	X	X	X

Source: Interviews with Consortium staff members conducted in 2001, 2002, and 2003.

Within two weeks after an interview, one of the interviewers prepared notes taken during the interview and had them reviewed by all members of the evaluation team. All the notes were transferred to the core protocol and were discussed during meetings of the team. The independent evaluator also requested and obtained additional documentation from the Consortium about specific aspects of the demonstration discussed during the interviews with demonstration staff.

B. ANALYSIS OF HTU USE

This section summarizes the technical aspects of the analysis of HTU use. Technical aspects covered include the data sources, the measures of HTU use, the study samples, and the statistical methods used to analyze the HTU log-use data.

1. Data Sources

The interactions of treatment group participants with their HTUs included contacts with (1) the clinical database in which participants uploaded and viewed their own clinical data; (2) the nurse case managers with whom participants had televisits and exchanged electronic messages; and (3) the demonstration's Web pages, in which participant searched for information about their diabetes and entered behavioral goals.[88] The Consortium logged HTU use in five different databases:

[88]Although chat rooms and bulletin boards also were planned to be part of IDEATel's web-based system, demonstration staff reported that these features were not implemented. Thus, the HTU log database does not record any instance of their use.

1. ***The ACCESS database*** logged the times and dates of visits to the demonstration's Web-based, case management system and database (that is, the case management software licensed to the Consortium by Siemens Medical Solutions Health Services Corporation [formerly Shared Medical Systems], a unit of Siemens Health Services).

   Four groups used the case management system: (1) participants; (2) nurse case managers; (3) primary care physicians; and (4) administrators (that is, Consortium technical staff). Participants accessed the system to view measurements (for example, their own clinical readings), read and send electronic messages, enter data on exercise and medications, and enter behavioral goals (Columbia University 2000c). Nurse case managers accessed it to monitor data on participants, and to read and send electronic messages, among other functions.[89] Primary care physicians accessed the database to view data on their patients who were participating in the demonstration. Administrators accessed it to monitor use of the system by authorized individuals.

2. ***The UPLTEST database*** logged the dates and times that participants measured their blood pressure and blood sugar, as well as the dates and times that they uploaded these readings to the demonstration's clinical repository.

3. ***The VISITS database*** logged the dates and times of the audio/video conferences (the televisits) between nurse case managers and participants, as well as the length of each televisit. Nurse case managers always initiated televisits.

4. ***The MESSAGE database*** logged the dates and times of electronic messages sent by participants and nurse case managers using the demonstration's secure system. The log recorded messages both to and from participants and nurse case managers.

5. ***The ADA database*** logged the dates and times of participants' visits to the IDEATel Web site, the length of a session, and the pages visited during the session. The Web site included the pages that the American Diabetes Association designed for the demonstration.

The Consortium also maintained the DEMO database, which contained identifying and demographic data about all treatment group enrollees, as well as the dates on which the treatment

[89]The case management software includes alerts and reminders to the nurse case managers about readings showing unsafe blood sugar and blood pressure levels, based on clinical algorithms; an electronic messaging feature to communicate with participants; and web-based graphic trend displays of enrollees ' measurements, selected goals, and self-reported progress toward achievement of the goals.

group members' HTUs were installed. The Consortium used the TRACKING database to track the enrollment status of enrollees.

The Consortium provided the independent evaluator with the HTU log databases and the TRACKING file during fall 2003 (Columbia University 2003b). The HTU log data correspond to 820 participants (out of 844 participants in the treatment group) whose HTUs were installed between December 15, 2000 (the beginning of the HTU installation period), and February 11, 2003 (the end of the installation period).[90,91] The HTU log databases include logs of all events recorded between December 4, 2000, and July 31, 2003.[92] The number of records and the range of dates of the events provided in each database are shown in Table B.4. Figure B.1 depicts the process for constructing the files for the analysis of HTU use.

2. Measures of HTU Use

The independent evaluator developed measures of the frequency and duration of use of specific HTU functions over a period after installation. The independent evaluator developed measures

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[90]There is no record of HTU installation for 24 participants who dropped out of the demonstration before their HTU was installed. In addition, the dates of installation were missing on 37 records, 21 of which also had missing identification numbers. All records with missing installation dates were excluded from the analysis. In addition, one participant had a valid installation date but dropped out before the HTU was installed. This case also was excluded from the analysis. Finally, one participant was dropped at the request of the Consortium, due to study ineligibility. (Table B.3 summarizes the HTU installation status as of July 31, 2003.)

[91]Two participants had their HTUs installed several weeks after the last enrollee was randomized in October 11, 2002. Because Consortium staff confirmed that the installation dates were valid, the independent evaluator included these cases in the analysis.

[92]Because the system logged tests of the HTU conducted by the nurse technician in charge of installation or by the nurse case manager during training, several databases logged HTU use before the date of installation. These records were excluded from the analysis.

TABLE B.3

NUMBER OF HTUs INSTALLED,
BY SITE

Status	Site		Total
	New York City	Upstate	
Active	279	305	584
De-Installed	85	124	210
Total	**364**	**430**	**794**

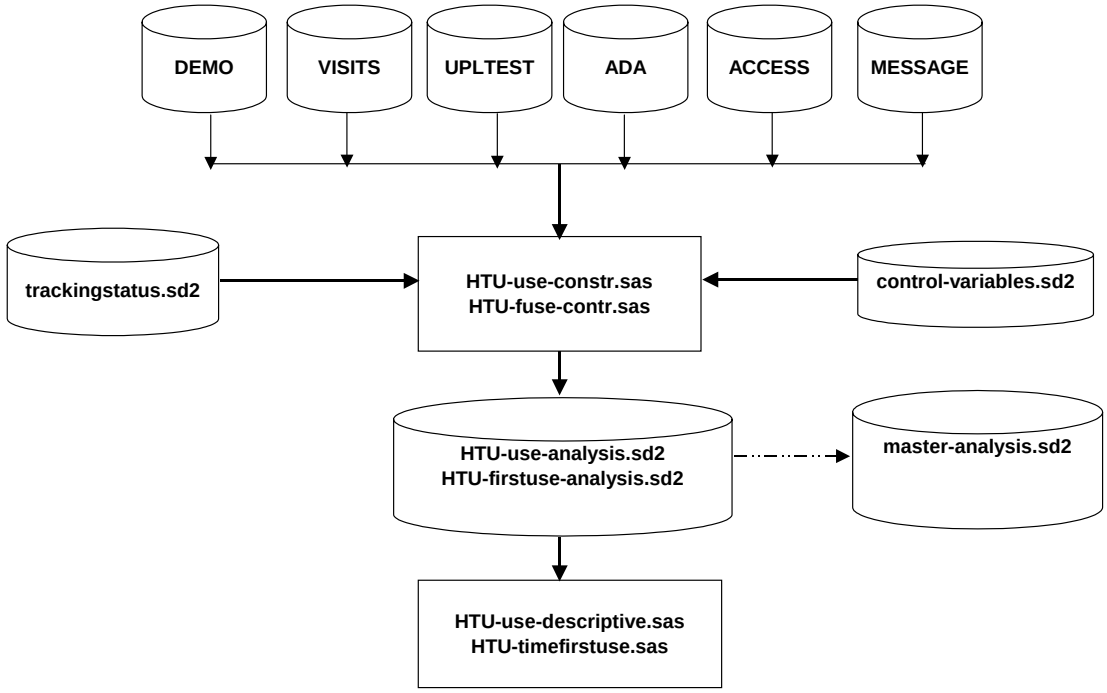
Source: Email communication from Charlyn Hilliman, April 21, 2004.

Note: As of July 31, 2003.

HTU = home telemedicine unit.

FIGURE B.1

CONSTRUCTION OF FILES FOR THE ANALYSIS OF TIME TO FIRST USE AND FREQUENCY OF HTU USE



Source: Columbia University (2003b, 2003c, and 2003d).

HTU = home telemedicine unit.

TABLE B.4

NUMBER OF RECORDS AND RANGE OF DATES
ON RECORDS OF HTU USE, BY DATABASE

Database	Number of Records	First Date on Record	Last Date on Record
ACCESS	170,879	December 4, 2000	July 31, 2003
UPLTEST	693,582	December 4, 2000	July 31, 2003[a]
VISITS	15,970	December 4, 2000	July 31, 2003
MESSAGE	5,591	December 4, 2000	July 31, 2003
ADA	6,826	July 12, 2001	July 29, 2003

Source: Consortium database on HTU use (Columbia University 2003b).

[a]Corresponds to the cut-off date of the blood pressure or blood sugar measurements. The last date on record on which participants uploaded these measurements is September 19, 2003.

HTU = home telemedicine unit.

of frequency of use for the following key HTU functions: (1) measurement of blood pressure; (2) measurement of blood sugar; (3) uploading of blood pressure or blood sugar measurements; (4) monitoring of clinical readings; (5) participating in a televisit; (6) reading electronic messages; (7) sending electronic messages; (8) consulting the American Diabetes Association Web pages; (9) entering medications; (10) entering exercise activities; and (11) entering goals (for example, goals in the areas of physical activity, diet, medication, monitoring, quality of life, or social habits).[93] The measures of frequency of use consist of counts of events per specified period, where the events are defined according to the definitions provided in Table B.5. The table also shows the source files and variables used to construct each measure. These definitions take into account the fact that participants could drop out of the demonstration before using an HTU function, or before the end of the follow-up period (in July 2003). The independent evaluator calculated annualized rates by multiplying the count of events by 12/*m*, where *m* denotes the number of months of enrollment from HTU installation through the end of the follow-up period.

The independent evaluator constructed a measure of the length of each televisit and the amount of time spent consulting the American Diabetes Association Web pages. These measures consist of the average duration of a televisit or a session spent consulting the Web pages per specified period among

[93]As explained in Chapter III, the analysis excludes enrollees ' HTU use on the day of the device's installation. This convention was adopted to avoid counting instances of use guided by the nurse installer, at least when such instances were most likely to have occurred.

those who used this function. Finally, the independent evaluator developed counts of the number of HTU functions that each participant used during the study period.[94]

3. Study Sample

The study sample for the analysis of frequency of HTU use consists of 781 participants whose HTUs were installed between December 15, 2000, and February 11, 2003. This group's experience with HTU use was followed through July 31, 2003.

4. Methods

For the analysis of frequency of HTU use, the independent evaluator fitted a weighted linear regression model (that is, an analysis of variance) to each measure of use, controlling for participants' characteristics at the time of randomization, one at a time, using STATA (StataCorp 2003). The independent evaluator also fitted this type of model, separately for each site, with all the characteristics included.[95] Weights were equal to the length of the period between HTU installation and either dropout or July 31, 2003, whichever came first. Similar analyses were conducted for the duration of the session devoted to consulting the American Diabetes Association web pages and the duration of a televisit. The independent evaluator used an *F*-test to ascertain differences across groups. (A *t*-test was used in instances in which the group included only two categories.)

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[94]These estimates were weighted by the duration of the period between HTU installation and either dropout or July 31, 2003, whichever occurred first.

[95]A Chow test was used to determine whether the analysis needed to be conducted pooling the data across sites or separately for each site (Gould 2003).

TABLE B.5

DEFINITION OF MEASURES OF PARTICIPANTS' FREQUENCY OF HTU USE, BY FUNCTION

HTU Function	Source Files	Source Variables	Definition
Measure Blood Pressure or Blood Sugar	DEMO TRACKING UPLTEST	INSTALLED_DATE DROPDATE TEST_TYPE TEST_DATE	Count of events [a reading of blood pressure (TEST_TYPE = BP) or blood sugar (TEST_TYPE = GLUCOSE) was made (TEST_DATE)] between the day after the installation date and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period (July 31, 2003) was reached
Upload Blood Pressure or Blood Sugar	DEMO TRACKING UPLTEST	INSTALLED_DATE DROPDATE DATETIME	Count of events [a data upload was recorded (DATETIME)] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Monitor Blood Clinical Readings	DEMO TRACKING ACCESS	INSTALLED_DATE DROPDATE TYPE_NAME DATETIMES PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed one of the following three pages: PageTitle=Glucose, Blood Pressure, or Graph of Daily Data] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Participate in a Televisit	DEMO TRACKING VISITS	INSTALLED_DATE DROPDATE DOI NOTETYPE	Count of events [a televisit was recorded (DOI and NOTETYPE = Initial, Followup, or Nutrition)] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Read Electronic Messages	DEMO TRACKING ACCESS	INSTALLED_DATE DROPDATE DATETIMES TYPE_NAME PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed the following page: PageTitle=Show Message] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Send Electronic Messages	DEMO TRACKING MESSAGES ACCESS	INSTALLED_DATE DROPDATE MESSAGE_DATE DATETIMES TYPE_NAME PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed the following page: PageTitle=Compose Message *and* the time that a message was logged (MESSAGE_DATE) was within 10 minutes after the time that the compose page was accessed] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached

TABLE B.5 *(continued)*

HTU Function	Source Files	Source Variables	Definition
Consult the American Diabetes Association Web Pages	DEMO TRACKING ADA	INSTALLED_DATE DROPDATE LOGIN_DATETIME	Count of events [an American Diabetes Association Web page was accessed (LOGIN_DATETIME)] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Enter Medications	DEMO TRACKING ACCESS	INSTALLED_DATE DROPDATE DATETIMES PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed the following page: PageTitle=Medicine] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Enter Exercise	DEMO TRACKING ACCESS	INSTALLED_DATE DROPDATE DATETIMES PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed the following page: PageTitle=Exercise or Enter Exercise] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Enter Goals	DEMO TRACKING ACCESS	INSTALLED_DATE DROPDATE DATETIMES PAGETITLE	Count of events [the participant (TYPE_NAME=Patient) accessed the following page: PageTitle=Add Goal] between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached
Number of HTU Functions Used	DEMO TRACKING	INSTALLED_DATE DROPDATE	Count of whether the participant used all, none, or a specific number of the functions defined above between the day after installation and the day that the first of the following two events took place: (1) the participant dropped out of the demonstration, or (2) the end of the follow-up period was reached.

Source: Specifications developed on the basis of file layout of databases provided by Columbia University (2000, 2003b, and 2003c).

HTU = home telemedicine unit.

C. ESTIMATION OF THE DEMONSTRATION'S IMPACTS ON CLINICAL AND OTHER HEALTH-RELATED OUTCOMES

This section summarizes the technical aspects of the analysis of the demonstration's impacts on physiologic and other health-related outcomes. The section covers the data sources, the study samples, and the statistical methods used to analyze the data provided by the Consortium.

1. Data Sources

The Hebrew Home for the Aged at Riverdale was the demonstration's coordinating center for recruitment, enrollment, randomization, and data processing and reduction. Table B.6 summarizes the demonstration's enrollee data collection activities, their periodicity, and contents.

Screening data (eligibility assessment and followup of nonrespondents) were collected at baseline, by telephone. The telephone screen questions were asked of all potential enrollees who agreed to enroll in the demonstration. Demonstration staff at both sites used paper forms to collect the data, which were then forwarded to the Hebrew Home for the Aged at Riverdale for processing. The screening interview focused on identifying whether a potential enrollee met any of the demonstration's exclusion criteria, including cognitive impairments, visual impairments, severity of diabetes, health status, and residence. It also asked the potential enrollee about demographic characteristics, and whether he or she had experience with personal computers. In addition, it asked people who chose not to enroll to provide a reason for their decision, and it collected from these individuals demographic characteristics and information about access to care, health status, diabetes treatment and care, and attitudes about life.

TABLE B.6

ENROLLEE DATA COLLECTION ACTIVITIES,
THEIR PERIODICITY, AND CONTENTS

Data Collection Activity	Periodicity	Contents
Screening (Telephone) Interview	At recruitment	Eligibility assessment and nonrespondent followup
In-Person Visit	Baseline, one-year followup, and two-year followup	Clinical assessment (anthropometrics, resting blood pressure, urine collection for measurement of microalbuminuria, drawing of blood for measurement of glycosylated hemoglobin and lipid levels, and a 24-hour blood pressure recording), health care service use, quality of life, process of care, demographic characteristics, functional status, vision impairment, health status, severity of disease, and social support
Telephone Interview	Every quarter between in-person visits	Health care service use, assessment of family support, smoking status, and quality of life
Medicare Claims	Once in 2003 and once in 2004	Medicare claims data for demonstration participants for the period 1999 through 2003

Source: Columbia University (2002b).

Data were collected in person from all treatment and control group enrollees on three occasions: (1) during the baseline visit, (2) during the Year 1 follow-up visit, and (3) during the Year 2 follow-up visit.[96] In New York City, these visits were conducted at the Columbia-Presbyterian Medical Center. In the upstate site, the visits were conducted at the Clinical Research Unit at

SUNY Upstate Medical University, Bassett Healthcare, Olean General Hospital, Samaritan Medical Center, Arnot Ogden Medical Center and, occasionally, at regional rural health centers or at the offices of enrollees' primary care physicians. The visits were conducted at the homes of demonstration enrollees only if the enrollees were unable to travel to one of the regional demonstration clinics. The baseline interview preceded randomization to the treatment or control group. Each in-person visit consisted of a detailed structured interview and a clinical assessment. The interview questions asked about enrollees' general health, comorbidities, severity of diabetes, diabetes self-care activities, prescribed medications, physical activities, activities of daily living, health beliefs, depression, use of alcohol and tobacco, access to care, and satisfaction with care. The clinical assessment included anthropometric measures (that is, measurements of weight, height, and waist and hip circumferences); measurement of resting heart rate and blood pressure; and collection of blood and urine specimens. At the end of the interview, an ambulatory blood pressure monitor was attached to enrollees. The monitor is a device about the size of a small personal cassette tape player that may be worn on a strap around the neck and shoulders or attached to a belt around the waist. It is connected by a tube under the clothing to a blood pressure cuff on the arm. The device inflates the cuff and measures and records blood pressure and pulse rate every 20 minutes. Enrollees wore these devices for a 24-

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[96]As of July 31, 2003, data collection of the baseline interview had been completed. Data collection for the first annual interview was near completion by that date as well (see Chapter II).

hour period while performing their usual day- and nighttime activities. They then either dropped them off with the IDEATel data collection staff or mailed them back in a shipping pouch that had been given to them.

During the intervals between the in-person annual assessments, all demonstration enrollees were interviewed quarterly, using computer-assisted telephone interviews. The interviews, which were conducted by staff from the Hebrew Home for the Aged at Riverdale, focused primarily on the enrollees' health care use. The quarterly survey instrument collected data on diabetes care and treatment; the costs associated with diabetes care and treatment; health insurance coverage; frequency of physician visits; frequency of emergency room visits; number of hospitalizations; and use of specialist services, including mental health services. It also elicited information about health status, changes in the enrollees' ability to conduct activities of daily living, diet and exercise regimens, satisfaction with life, and satisfaction with care. The independent evaluator did not use the quarterly telephone data for analyzing either service use or the health-related quality of life and satisfaction outcomes, as it had the more accurate Medicare claims data to analyze enrollees' service use and cost, and the annual interview data to analyze enrollees' health status, functional status, adherence to treatment, and satisfaction with care.

Consortium staff reported that both the interviewers who conducted the in-person interviews and those who performed the telephone data collection were blind to the study status of the enrollees.[97]

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[97]However, demonstration staff did mention that interviewers might be able to determine whether a respondent was in the treatment group from the respondent's responses to the quarterly telephone interview's questions about service use. It is unclear whether this knowledge would bias the interviews.

The Hebrew Home for the Aged at Riverdale also was responsible for extracting Medicare claims data on all demonstration enrollees. Data have been extracted for the period 1999 through 2003 to estimate Medicare expenditures for all enrollees for the year before enrollment into the demonstration (beginning in December 2000 in New York City, and in January 2001 in the upstate site).[98] These data were also used to estimate the demonstration's impacts on Medicare-covered services and expenditures (see Appendix F, Section B, for a discussion of the methods for calculating Medicare expenditures).

Finally, the Consortium used a database to track the enrollment status of demonstration enrollees (see Section B.1 above). The database included each enrollee's date of randomization, age at randomization, and group membership (that is, whether he or she was assigned to the treatment or the control group). If an enrollee dropped out of the demonstration, the Consortium staff recorded the reasons for and the date of the dropout. The Consortium attempted to complete data collection on all randomized enrollees, regardless of whether the enrollees had dropped out or not (that is, it collected data for an *intention-to-treat* analysis).

The demonstration's confidentiality constraints required the Consortium to process and merge all relevant demonstration data files, and to strip them of all personal identifiers, including Medicare number. In addition, because the independent evaluator did not have access to the identifiers necessary for linking enrollees' Medicare claims data and demonstration data, the Consortium

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[98]The Consortium used CMS's Medicare Data Extract System to access the enrollees' claims records and it used the Enrollment Data Base workbench to extract descriptive information on the Medicare beneficiaries who are enrolled in the demonstration. The independent evaluator provided technical assistance to staff from the Hebrew Home for the Aged at Riverdale in the processing and downloading of these data.

created an identification number for linking Medicare claims data with other demonstration data (for example, the screener and baseline interviews). Figure B.2 depicts the process used to combine the various databases for constructing measures of enrollee characteristics and outcomes at baseline and one year later.

During fall 2003 and fall 2004, the Consortium provided the independent evaluator with all databases, including Medicare enrollment and claims data for the period 1999 through 2003.[99] The independent evaluator processed all the files in SAS (SAS Institute, Inc. 1999).

2. Enrollees' Characteristics and Outcomes

This section describes the operational definitions for the various enrollee characteristics considered in this report, including demographic characteristics; behavioral and clinical outcomes, access-to-care outcomes, use-of-services outcomes, and quality-of-life and satisfaction-with-care outcomes.[100] The reader is reminded that, because IDEATel is a Medicare demonstration, the study focused on Type II diabetes, the type seen predominantly among older people, and that the term "diabetes" in the following discussion refers implicitly to Type II diabetes.

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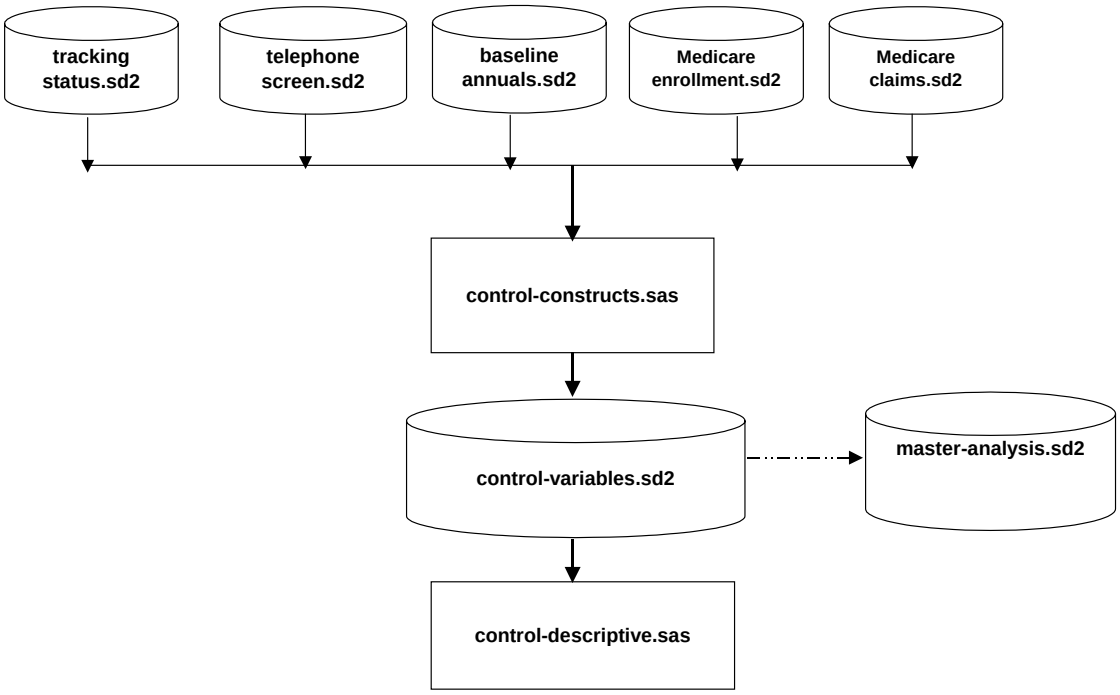
[99]The Consortium also provided the data file for the first round of the physician survey (216 completed interviews), and for the second round (35 completed interviews). Finally, the Consortium provided data on 363 participants who completed a participant satisfaction survey.

[100]For simplicity's sake, the term *outcome* is used regardless of whether a characteristic is referred to as a baseline or a follow-up measure.

FIGURE B.2

CONSTRUCTION OF CONTROL VARIABLES FOR THE IMPACT ANALYSES AND ANALYSIS OF HTU USE



Source: Columbia University (2003b, 2003c, and 2003d).

HTU = home telemedicine unit.

a. Demographic Characteristics

The telephone screener and the first annual interview were used to construct measures of enrollees' characteristics at baseline, including age at randomization, race/ethnicity, sex, number of years of education, highest degree completed, marital status, household size, living arrangements, whether the enrollee was born in the United States, primary language, whether the enrollee was employed, annual household income, and whether the enrollee knew how to use personal computers before joining the demonstration. Medicare enrollment and claims data were used to construct measures of Medicare eligibility and expenditures at baseline, including length of Medicare enrollment as of the date of randomization, reasons for initial Medicare entitlement, whether the enrollee was eligible for both Medicare and Medicaid (dually eligible), and Medicare expenditures during the year preceding randomization. (See Appendix F, Section C, for a detailed description of the methods to calculate Medicare expenditures.)

b. Behavioral Outcomes

The annual interviews collected data on the following six broad domains of behavioral outcomes: (1) education and knowledge, (2) health beliefs, (3) perceived burden of illness, (4) perceived diabetes management self-efficacy, (5) adherence to diabetes self-care activities, and (6) habits.[101] Table B.7 lists these domains, briefly describes and explains each one, and presents representative questions for each one.

[101]Self-efficacy is the belief that one has the ability, capacity, and confidence to successfully accomplish certain activities, such as diabetes self-care activities.

TABLE B.7

BEHAVIORAL OUTCOMES

Domain	Description and Explanation	Representative Question(s)	Comments
Education and Knowledge	Enrollees' self-reported understanding of various aspects of diabetes self-care (6 questions)	How well do you understand what to do for symptoms of low blood sugar?	Each question analyzed separately
Health Beliefs	Enrollees' self-reported beliefs about the importance of diabetes self-care for health (3 questions)	On a scale of 0 to 10, where 0 is not a great deal of benefit, and 10 is a great deal of benefit, how much do you think your health will benefit if you control your diabetes?	Each question analyzed separately
Perceived Burden of Illness	Enrollees' perceptions of the difficulty of diabetes self-care (7 questions)	On average, over the past four weeks, how much of a problem or hassle has it been to remember to test your blood for sugar?	Each question analyzed separately
Perceived Diabetes Management Self-Efficacy	Enrollees' self-reported beliefs about their ability, capacity, and confidence to perform certain behaviors (21 questions)	I think I'm able to keep my weight under control. I think I'm able to get sufficient physical activity, for example, taking a walk or biking.	Analyzed as four subscales; responses totaled to form four scores (weight and specific nutrition, medications and general nutrition, exercise, and blood sugar management)
Adherence to Diabetes Self-Care Activities	Enrollees' self-reported performance of recommended self-care activities (14 questions)	On how many of the last seven days did you take your recommended insulin injections? How many of the last seven days have you followed a healthful eating plan?	Four questions analyzed separately. Otherwise, analyzed as four subscales; responses totaled or averaged to form four scores (diet, exercise, blood sugar testing, and foot care)
Habits	Enrollees' self-reports of past and current cigarette smoking (16 questions), past and current use of other tobacco products (15 questions), and past and current alcohol intake (11 questions)	On average, during the past month, how many cigarettes did you smoke per day? Are you seriously considering quitting smoking in the next six months? In the past month, what is the largest number of drinks you had in one day?	Each question analyzed separately

Source: Columbia University (2002b).

Note: Data for all of these measures were collected during the annual in-person interviews.

Some of the measures in the interview instrument were scales, which are collections of related questions that are constructed by summing the responses from individual questions. For example, the 21 questions about perceived diabetes management self-efficacy fall into four subscales: (1) managing weight and selecting foods, (2) following diet and medication routines, (3) exercise, and (4) managing blood sugar. The 14 questions about adherence to diabetes self-care activities likewise form four subscales: (1) diet, (2) exercise, (3) blood sugar testing, and (4) foot care. These scores and scales were analyzed as continuous variables.

c. Physiologic Outcomes

All data for the physiologic outcomes come from the annual, in-person interviews. The outcomes are (1) blood levels of hemoglobin A1c and lipids; (2) urine levels of protein and creatinine; (3) blood pressure and heart rate measured by the conventional, in-person method and by ambulatory blood pressure monitors; and (4) anthropometric measures—body mass indices, calculated from measurements of enrollees' heights and weights, and waist-to-hip ratios and waist girths, calculated from measurements of enrollees' waist and hip circumferences. Table B.8 lists the physiologic outcomes, their normal or desirable ranges, and the units of their measurement.

Hemoglobin A1c is a measure of the control of blood sugar levels. It is a substance in the blood formed when glucose (sugar) molecules passively attach to hemoglobin, the protein normally found in red blood cells that helps to transport oxygen in the blood. More hemoglobin A1c is formed when blood glucose levels remain high for a prolonged period, and red blood cells last about three months in the circulation. Thus, in people with diabetes, hemoglobin A1c provides a measure of how well blood sugar has been controlled during the three or four months preceding the time that the measure was taken. It is a key test to follow in caring for people with diabetes.

TABLE B.8

PHYSIOLOGIC OUTCOMES

Outcome Measures	Normal or Desired Range	Units of Measurement	Method of Measurement
Hemoglobin A1c	≤7.0	None (expressed as a percentage)	Blood sample
Lipid Levels			
Triglycerides	≤150	Milligrams per deciliter (mg/dl)	Blood sample (participant must have fasted overnight)
HDL cholesterol	≥45		
LDL cholesterol	≤100		
Ratio of Urine Albumin to Creatinine	≤30	Milligrams per gram (mg/g)	Random urine sample
Blood Pressure			
Systolic blood pressure	≤130	Millimeters of mercury (mmHg)	Recordings from conventional and ambulatory monitors
Diastolic blood pressure	≤80		
Body Mass Index	18–24	Kilograms per meter squared (kg/m^2)	Anthropometry—standardized measurements of height and weight

Source: Columbia University (2002b).

Note: Data for all of these outcomes were collected at each annual in-person interview.

HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Hemoglobin A1c is reported as a percentage of total hemoglobin; the upper normal level of which is roughly 6.0 to 6.5 percent, depending on the specific laboratory (the upper limit of normal for IDEATels' laboratory is 6.4 percent). Recommendations for target hemoglobin A1c levels will vary depending on age and other health problems, with looser control recommended for those with shortened life expectancy, advanced age, or complicating medical problems; regardless, hemoglobin A1c levels generally should be below nine percent, with an even lower goal of seven percent for an otherwise healthy person (VA/DoD 1999). In people with diabetes, sustained elevations of hemoglobin A1c are associated with diabetic eye, kidney, and nerve damage. Cholesterol is one of the fatty substances (or lipids) found in the blood. Cholesterol results are commonly reported as levels of total blood cholesterol, as well as levels of two important varieties of cholesterol, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol. High levels of LDL cholesterol increase the risk of cardiovascular disease, whereas high levels of HDL seem to protect against cardiovascular events. In fact, LDL cholesterol has been called the *bad cholesterol*, and HDL cholesterol the *good cholesterol*. Another important blood lipid is triglycerides. Elevated levels of triglycerides also may increase risks for cardiovascular disease. In the IDEATel demonstration, blood was drawn at the annual visits for these lipid tests. The unit of measurement for total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides is milligrams per deciliter (mg/dl).

An important marker of kidney damage in diabetes is the abnormal leakage of the blood protein albumin into the urine (proteinuria or albuminuria). In the earliest stages of kidney damage, small but still abnormal quantities of albumin are detectable in the urine, called microalbuminuria. As kidney function worsens, larger quantities are present, sometimes called clinical proteinuria.

Enrollees provided a single urine specimen voided at the time of the annual visit; the laboratory measured both the amount of albumin and a substance called creatinine in the specimen. Creatinine is normally found in the urine and is an indirect measure of the flow and concentration of urine. Calculating the ratio of albumin to creatinine in a random urine specimen allows estimation of the amount of albumin that would have been excreted during a 24-hour period. Results are expressed as milligrams albumin per grams creatinine (mg/g). Urine albumin-to-creatinine ratios of less than 30 mg/g are considered normal; ratios ranging from 30 mg/g to 300 mg/g are called microalbuminuria, and ratios of 300 mg/g and higher are called clinical proteinuria.

Body mass index (weight in kilograms divided by height in meters squared) is a measure of weight corrected for body size. Many people with diabetes are obese, and weight loss often leads to improved control of diabetes, blood pressure, and lipid levels.

Waist circumference is a measure of abdominal fat content. Abdominal fat appears to have adverse effects on the body's sensitivity to insulin and on lipid metabolism, and abdominal fat that is out of proportion to total body fat is an independent risk factor for heart attacks and strokes. Men whose waist circumferences are greater than 102 cm, and women with waists over 88 cm are at increased risk for cardiovascular events (Centers for Disease Control and Prevention 2004).

The waist-to-hip ratio is another measure of abdominal fat content. For men and for women, waist-to-hip ratios greater than 0.90 and greater than 0.80, respectively, increase risk (Centers for Disease Control and Prevention 2004).

d. Access to Care

Measures of access to care were constructed from a series of questions asked during the annual in-person interviews (Table B.9). The questions asked enrollees whether they had been unable to schedule or had to miss scheduled medical or nurse appointments during the preceding year because of various potential access barriers, such as transportation and weather conditions. The in-person interviews also contained a question on whether enrollees were worried about experiencing an episode of low blood sugar while they lacked any access to help.

e. Use of All Medicare-Covered Services and Use of Selected Medicare-Covered Services

Measures of use of all Medicare-covered services for the period between randomization and December 31, 2003 were constructed from the services recorded in Medicare claims data. A second set of variables that measured the use only of recommended services covered by Medicare was also constructed from the claims data. These variables included whether or not the enrollee received services for dilated eye examinations, and for laboratory testing for levels of hemoglobin A1c, LDL cholesterol, and urine microalbumin. Table B.10 lists these variables from the Medicare data.

f. Use of Medications

Data on medications came from the annual interviews. Enrollees were asked to provide the names of all the prescription and over-the-counter medications they were taking at the time, and the daily frequency and dosage of each medication. The analyses focused on five main categories of medications: (1) two different but related classes of blood-pressure–lowering medications, called angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARBs), (2) all blood-pressure–lowering medications (antihypertensive medications) in general, including, but not limited to ACE inhibitors and ARBs, (3) drugs to

TABLE B.9

OUTCOMES MEASURES FOR ACCESS TO CARE

Measure	Definition and Comment
Data Source: Annual In-Person Interview	
	In the past 12 months, about how many times did your provider…
Dietary Counseling	…discuss your eating habits and advise you on how to adjust your eating…?
	Whether or not occurred at least once[a]
Exercise Counseling	…discuss the importance of exercise with you?
	Whether or not occurred at least once[a]
Foot Examination	…examine your feet?
	Whether or not occurred at least once[a]
Foot Examination with Nylon Monofilament	…examine your feet using a monofilament—a tool that looks like a fishwire?
	Whether or not occurred at least once[a]
Reported Problems with Access to Care	During the past year, about how often did you not schedule or have to miss medical or nurse appointments because of lack of transportation, too far to travel, bad weather or road conditions, or lack of someone to accompany you? (Numeric answer)
	During the past month, how often have you been worried that your blood sugar would be too low, and that no one would be able to help you? (Numeric answer)
	Whether or not occurred at least once[a]
Data Source: Medicare Claims Data	
Dilated Eye Examination	CPT codes for dilated eye examination Whether or not occurred at least once within the past 12 months
Measurement of Hemoglobin A1c Level	CPT codes for hemoglobin A1c
	Whether or not occurred at least once within past 6 months[b]

Source: Columbia University (2002b).

[a]Depending on frequency distributions or clinical appropriateness, alternative definitions were considered, such as whether occurred at least twice, and so on, and may be reported in the tables of results.

[b]The annual hemoglobin A1c test performed for the demonstration at the annual in-person visits is considered as one of these tests. Specifying a frequency of hemoglobin A1c testing of at least once every six months, corresponding to biennial testing, is more stringent than the standard adopted for diabetes care by CMS's Health Care Quality Improvement Project (Jencks et al. 2000) but is in accord with recommendation by the American Diabetes Association (2002d).

CPT = *Current Procedural Terminology* (American Medical Association 2001).

TABLE B.10

OUTCOME MEASURES FOR MEDICARE-COVERED SERVICES USED DURING THE PERIOD BETWEEN RANDOMIZATION AND DECEMBER 31, 2003

Measure	Comments
Physician Office Visits	Specified combination of BETOS, type of service, and place of services codes Counts per specified periods of time
Laboratory Use[a]	Specified combination of BETOS, type of service, and place of services codes Counts per specified periods of time
Hospital Outpatient Care Outpatient clinic visits Emergency room visits	Hospital claims for outpatient services Counts per specified periods of time
Acute Hospital Inpatient Stays	Hospital claims for inpatient services Whether had any in specified periods of time[b]
Medicare Home Health Care	Claims from home health agencies Whether received any in specified periods of time[b]
Durable Medical Equipment Use	Claims from suppliers of durable medical equipment Whether received any in specified periods of time[b]
Skilled Nursing Facility Care	Claims from skilled nursing facilities Whether received any in specified periods of time[b]

Source: Columbia University (2002b).

[a]Refers to services rendered by a certified laboratory independent of an institution or a physician office.

[b]Between randomization and December 31, 2003.

BETOS = Berenson-Eggers Types of Service Codes, a system for classifying HCPCS (Health Care Finance Administration Common Procedure Coding System) codes for professional services.

lower LDL cholesterol levels (LDL-cholesterol–lowering drugs), (4) drugs to lower blood sugar levels (insulin injections and oral antihypoglycemic agents), and (5) medications to inhibit the function of blood platelets (antiplatelet agents). Table B.11 lists the categories studied and the medications within each category.

ACE-inhibitors and ARBs. These are two classes of blood-pressure–lowering medications (antihypertensive medications). Although reducing high blood pressure with any antihypertensive medications slows the progression of diabetic kidney disease, ACE inhibitors and ARBs appear to have protective effects against diabetic kidney disease specific to their classes that are independent of and beyond their blood-pressure–lowering effect(Hollenberg 2004; Zandbergen et al. 2003). ACE inhibitors and ARBs have been shown to reduce albuminuria, and to slow the worsening of diabetic kidney disease. National guidelines on diabetes treatment, including the ones used by the IDEATel case managers and endocrinologists, thus specifically recommend the use of ACE inhibitor and ARB drugs in people who have diabetes with any proteinuria (both microalbuminuria and clinical proteinuria;VA/DoD Clinical Practice Guideline Working Group 2003 update; American Diabetes Association 2004).

Antihypertensive Medications. High blood pressure, or hypertension, is extremely common in people with diabetes and greatly increases the risks of such complications of diabetes as stroke, coronary artery disease, peripheral vascular disease, diabetic retinal disease, and diabetic kidney disease. Controlling blood pressure with a variety of antihypertensive medications is thus a key component of diabetes care.

LDL-Cholesterol–Lowering Drugs. Diabetes causes abnormal blood cholesterol and lipid levels, which, in turn, sharply increase risks of the same vascular complications listed above (that is, stroke, heart disease, and so on). Solid evidence has shown that treating people who have

TABLE B.11

CATEGORIES AND NAMES OF MEDICATIONS

ACE-Inhibitors and ARBs[a]

Benazepril
Benazepril/amlodipine
Captopril
Enalapril
Enalapril/Hctz[b]
Fosinopril
Lisinopril
LISINOPRIL/HCTZ
Perindopril
Quinapril
Quinapril/HCTZ
Ramipril
Trandolapril
Trandolapril/verapamil
Candesartan
Irbesartan
Irbesartan/HCTZ
Losartan
Losartan/HCTZ
Olmesartan
Telmisartan
Valsartan
Valsartan/HCTZ

Antihypertensive Medications

ACE-Inhibitors and ARBs above
Acebutolol
Amiloride
Amiloride/HCTZ
Atenolol
Betaxolol
Bisoprolol
Bisoprolol/HCTZ
Carteolol
Carvedilol
Chlorothiazide
Clonidine
Diltiazem
Doxazosin
Guanfacine
Hctz
HCTZ/Triamterene
Hydralazine
Indapamide
Isradipine
Labetalol
Methyldopa
Metolazone
Metoprolol
Minoxidil
Nadolol
Nadolol/Bendroflumethiazide
Nicardipine
Nifedipine
Nisoldipine
Pindolol
Prazosin
Propranolol
Spironolactone
Terazosin
Timolol
Torsamide
Triamterene
Verapamil

LDL-Cholesterol-Lowering Drugs

Atorvastatin
Cholestyramine
Colesevelam
Ezetimibe
Fluvastatin
Lovastatin
Lovastatin/niacin
Pravastatin
Simvastatin

TABLE B.11 (*continued*)

Anti-Platelet Medications	
Aspirin	Dipyridamole
Clopidogrel	Aspirin/dipyridamole
Hypoglycemic Drugs	
Acarbose	Metformin
Chlorpropamide	Miglitol
Glimepiride	Nateglinide
Glipizide	Pioglitazone
Glyburide	Repaglinide
Glyburide/metformin	Rosiglitazone
Insulin[c]	

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

[a]ACE-Inhibitors=Angiotensin Converting Enzyme Inhibitors and ARBs=Angiotensin Receptor Blockers.

[b]HCTZ=hydrochlorothiazide.

[c]Includes: Insulin (insulin, Humulin, and Novolin) regular, NPH, Lente, and Ultra; pre-mixed insulin (Insulin NPH/Regular, Humulin 70/30, Novolin 70/30), insulin aspart (NovoLog), NovoLog mix 70/30, insulin lispro (Humalog), Humalog Mix 75/25, insulin glargine, insulin pumps (insulin or Humalog).

diabetes with drugs that lower levels of a specific type of cholesterol particle in the blood, LDL cholesterol, substantially reduces the risk of cardiovascular and other vascular complications in these patients (Snow et al. 2004; Vijan et al. 2004; American Diabetes Association 2004; Heart Protection Study Collaborative Group 2003).

Hypoglycemic Drugs. One of the cardinal manifestations of diabetes is elevated blood sugar, and a number of clinical trials have shown that maintaining blood sugar levels as close to normal as possible delays the onset of diabetic damage to the retinas, the kidney, and nerve function (American Diabetes Association 2004). Blood sugar can be controlled with a combination of diet, weight control, and medications. Medications include oral medications and insulin injections.

Anti-Platelet Medications. These drugs, which interfere with platelet function, are recommended for all people who have diabetes and who are older than age 40 (assuming they have no contraindication). Platelets are the blood cells that initiate blood clots, but they also contribute to vascular events, such as stroke and heart attack. Studies have shown that platelets in people with diabetes are abnormally prone to form clots, and that anti-platelet drugs prevent cardiovascular events (American Diabetes Association 2004). Aspirin is the main anti-platelet drug. Other drugs are available for those who cannot take aspirin, although their benefits have been less well studied.

The independent evaluator restricted the analysis of the five medication categories to demonstration enrollees with indications for their use. For example, the independent evaluator studied the use of ACE inhibitors and ARBs in enrollees who, at their baseline study visit, were shown to have proteinuria; similarly, the use of hypoglycemic drugs was studied in enrollees who had poor blood sugar control at baseline (hemoglobin A1c levels higher than eight percent),

and the use of antihypertensive medications was studied in those with high baseline in-person blood pressure readings (systolic and diastolic blood pressure higher than 130 or 80 mm Hg, respectively).

The independent evaluator analyzed the rates of prescription of the medications in the treatment and control groups. The highest achievable rate of prescription of recommended medications in each group was not expected to be 100 percent, as some patients were expected to have allergies or other contraindications for given drugs. However, the random assignment nature of the demonstration distributed these individual patient factors equally between the treatment and control groups, so that treatment–control differences in rates of medication prescription do provide an unbiased estimate of how well each group's physicians followed treatment guidelines for diabetes. Additional efforts to sort through individual enrollees' clinical characteristics to determine eligibility or ineligibility for particular medications were therefore unnecessary.

The independent evaluator also examined the mean dosages of the medications (in milligrams, or mg, except for insulin dosage, which is measured in units) that were prescribed, and for some of the medication categories, the number of different medications in that category prescribed per person. With the exception of the antiplatelet drugs, larger doses of the medications lead to larger reductions in the treatment target measures (proteinuria, LDL cholesterol, blood pressure, and hemoglobin A1c). The effects of antiplatelet medications are not very dependent on dose. Two or more different medications from the same category (such as two anthihypertensive drugs or two OHAs) may have a greater effect than one. Any intervention effects that might be seen in the treatment targets could thus be from an increased proportion of treatment group enrollees receiving recommended drugs, a higher intensity of dosing among those receiving drugs, prescription of more drugs per person, or a combination of these reasons. Although individual

enrollee factors, such as severity of hypertension, degree of blood sugar elevation, and responsiveness to medication, will influence the dosages of medicines and the numbers of medications per person prescribed, the randomized design of the study again means that treatment–control differences in medication dosing provide an unbiased indication of the aggressiveness and attention with which the target measures in each group are being addressed. In the case of combination medications, in which two different drugs are combined into a single tablet or capsule, the independent evaluator counted each drug separately. For example, the oral hypoglycemic combination medication glyburide/metformin was counted as two separate prescriptions of glyburide and metformin.

In order to prepare the raw data on medication doses collected by the demonstration staff for analysis, the independent evaluator developed a number of rules of thumb. In dealing with the lack of decimal points, the evaluator based decisions on the tablet or capsule sizes available from the manufacturer, and on commonly prescribed doses. For example, doses of metformin recorded as "10MG" or "1MG" were assumed to represent 1000 mg, since 1000 mg is an available tablet size and commonly prescribed dose. Similarly, a dose of the combined medication losartan/hydrochlorothiazide recorded as "012.5MG" was analyzed as losartan 50 mg and hydrochlorothiazide 12. mg, since this is a tablet size produced by the manufacturer. Doses recorded, for example, as "1.5 TAB" or "2 CAP" were set to missing. Doses that seemed implausible, and doses for which two possibilities could not be distinguished (for example, "00025MG" where both 2.5 mg and 25 mg were possible), were also set to missing.[102]

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[102] An example of an implausible dose is the medication diltiazem, recorded as "10MG" taken twice daily. Diltiazem is only available in tablet strengths of 30, 60, 90, and 120 mg and is taken

Since each medication category included a number of different medications, each with its own tablet or capsule sizes and dosing ranges, the independent evaluator developed a single number to summarize dosages across the different medications within a medication category. The independent evaluator converted dosages into percentages of maximum recommended doses. The daily prescribed doses for each medication of interest were divided by that medication's maximum recommended daily dose. Person-level means were then calculated, followed by treatment and control group means across enrollees.

For example, suppose the control group consisted only of two members, the first whom was prescribed 10 mg of ramipril per day and 240 mg of valsartan per day. Ramipril is an ACE inhibitor with a maximum recommended daily dose of 20 mg; valsartan is an ARB with a maximum recommended daily dose of 320 mg. The percentages of maximum dosage for this person would be 50 percent for the ramipril, and 75 percent for the valsartan; the person-level mean would be the average of 50 and 75, or 62.5. Suppose the second control group member was prescribed a daily dose of 120 mg of valsartan; the percentage of maximum dosage would be 50 percent for the valsartan, and, with only one medication, the person-level mean would be 50 percent as well. The control group mean would then be the average of the two person-level values of 62.5 and 50, or 56.3.[103]

(continued)

four times daily; as a long-acting formulation it is available in tablet strengths of 120, 180, 240, 300, and 360 mg and generally taken once daily.

[103] To assess the sensitivity of calculating dosages this way, a medication-level analysis was conducted, in which group means were calculated with each *medication prescription* as one

To analyze the insulin doses the independent evaluator also recoded the raw data. Insulin doses with slashes were assumed in general to indicate a combined injection of intermediate and short-acting insulin. For example, "HUMULIN N" with a dose of "40/20 IU" and a daily frequency of "2" was assumed to indicate a mixture of 40 units of intermediate insulin with 20 units of short-acting insulin (or 60 units) given twice daily, or a total of 120 units daily. An exception was if the medication name indicated a pre-mixed insulin, in which case the slash in the dosage was taken to mean two separate doses. Thus, "NOVOLIN 70/30" (a type of combined intermediate/short acting insulin pre-mixed in a ratio of 70 to 30) with a dose of "45/22IU" and a daily frequency of "2" was translated as Novolin 70/30 given as two doses, the first 45 units, and the second 22 units, for a total of 67 units daily. Following these rules only two cases were ambiguous—both were "INSULIN," one with a dose of "70/30UI" and the other "70/30MG," and both were given with a frequency of "2." Although these could have been cases of pre-mixed 70/30 insulin given twice daily with information on dose missing, they were interpreted rather as 100 units each dose, for a total of 200 units daily.

Doses with dashes were interpreted as indicating a range of doses. For example, "INSULIN 70/30" with a dose of "12-20U" given once daily was understood as a varying dose between 12 to 20 units, and was assigned the average value of 16 units. Doses such as "VARIES" or "SLIDING" (presumably indicating a "sliding scale," where the enrollee adjusted doses according to glucometer results) were set to missing, as were doses or medication names such as

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(continued)

observation. Using the example presented here, the control group mean would be the average of the three *medication* values of 50, 75, and 50, or 58.3.

"141-180" and "181-220" (again presumably referring to glucometer ranges for a sliding scale). Finally, two enrollees with "INSULIN PUMP," and two other enrollees with doses that seemed implausibly high ("500U" and "1000U") had their doses set to missing.

g. Quality of Life and Satisfaction with Care

All data on enrollees' quality of life and satisfaction come from the annual, in-person interviews. The interview instruments contained both quality-of-life scales and individual questions. (As mentioned, the quality-of-life scales are collections of related questions analyzed by summing responses from individual questions into one or more scores.) The instruments also contained questions on satisfaction with care. Table B.12 lists each measure and the ways in which it was analyzed. Variables constructed as scores were prorated to account for missing component values, and scores were normalized to a scale from 0 to 100.

3. Study Samples

The study sample for the descriptive analysis at baseline consisted of 1,664 enrollees.[104] For the impact analyses based on enrollees' in-person interviews and laboratory tests, the study sample consisted of the 1,364 treatment and control group enrollees who completed Year 1 interviews.

[104]The tracking status file includes records for 1,666 individuals randomized between December 5, 2000, and October 11, 2002. At the request of the Consortium, one enrollee was excluded because of ineligibility. Another enrollee had missing data in all baseline interview variables.

TABLE B.12

OUTCOME MEASURES FOR PARTICIPANTS' QUALITY OF LIFE
AND SATISFACTION WITH CARE

Domain	Description and Explanation	Representative Question(s)	Comments
Self-Rated Health	Enrollees' ratings of overall health, using five categories ranging from excellent to poor (3 questions)	In general, how would you rate your health at the present time?	Also asks enrollees to compare themselves with others their age, and to compare their health with their health from three months previously Each question analyzed separately
Visual Analog Scales	Enrollees' ratings of overall health, using a visual scale marked from 0 to 100 (2 questions)	This scale shows the potential range of your sense of health and well-being between 0, death, and 100, best possible health and well-being. Please point to the place on the line where you would rate your sense of health and well-being right now.	Also asks with permanent pain and disability as 0, and freedom from pain and disability as 100 Each question analyzed separately
Pain	Severity of pain and degree of interference with functioning (3 questions)	During the past four weeks, how much did pain interfere with your normal work?	One question analyzed separately. Two others analyzed as a single scale; responses totaled to form a single score
Frequency of Diabetes Symptoms	Frequency of multiple separate symptoms related to diabetes in the past month, using eight response categories (continuously, several times a day,…, not at all; 34 questions)	In the past month, how frequently have you experienced… tingling or prickling in the legs or feet?	Analyzed as eight subscales; responses totaled to form eight scores (hyperglycemic, hypoglycemic, neuropathic pain, sensibility, fatigue, cognitive distress, cardiovascular, and ophthalmologic)
Activities of Daily Living and Instrumental Activities of Daily Living	Ability to perform basic and more complex activities required for day-to-day life (27 questions plus 2 questions on physical exercise)	Do you have any difficulty reaching down to put on your socks?	Analyzed as a single scale; responses totaled to form a single score

TABLE B.12 (*continued*)

Domain	Description and Explanation	Representative Question(s)	Comments
Problem Areas in Diabetes	Reports of problems with diabetes-related psychosocial distress, using five response categories ranging from not a problem to a very serious problem (14 items)	Consider the degree to which each of these items may have distressed or bothered you during the past month… …worrying that diabetes limits your social relationships and friendships	Analyzed as a single scale; responses totaled to form a single score
Depression Scale from Short Form Comprehensive Assessment and Referral Evaluation	Reports of numerous feelings and physical symptoms associated with depression (28 to 45 questions, depending on responses and branching logic)	Have you been depressed or sad in the past month? Have you cried in the past month?	Analyzed as a single scale; responses totaled to form a single score
Satisfaction with Care, from American Diabetes Association Patient Satisfaction Survey	Reports of providers' behavior, using five response categories ranging from all of the time to none of the time, and ratings of various aspects of care, using five response categories ranging from excellent to poor (17 questions)	How often do the doctors or health care professionals who take care of your diabetes…take your preferences into account when making treatment decisions? How are the doctors or health care professionals who take care of your diabetes at…answering your questions about your diabetes?	Each question analyzed separately

Source: Columbia University (2002b).

Note: Data for all of these measures were collected during the annual in-person interviews.

For measures derived from Medicare claims, the study sample consisted of the 1,664 treatment and control group members who were randomized and completed baseline interviews regardless if they subsequently dropped out the study.[105] This sample is the intention-to-treat sample described in Chapters IV and V, and Appendix F. (Table B.13 presents the sample sizes, by type of outcome, at different time points in the study.) As with the calculation of Medicare expenditures described in Appendix F, durations of enrollment were calculated for each enrollee from their date of enrollment to the end of the claims data, December 31, 2003, subtracting any months of membership in a Medicare managed care plan. Enrollees' outcomes were annualized and analyzed in weighted regressions in which the weights were proportional to the duration of enrollment.

4. Methods

To control for residual treatment and control group differences that might have persisted despite random assignment, and to improve statistical precision, the independent evaluator used regression models to conduct the impact analyses presented in Chapter IV. In its original study design, the Consortium had planned for the two sites to be analyzed separately, and, in fact, the independent evaluator found in its implementation analysis that the substantial differences between the interventions and enrollees in the two sites warranted separate site-specific analyses.

The dependent variables in these regressions were the numerous outcomes discussed in the preceding section, the main independent variable of interest was the intervention status, and the

[105]The tracking status file includes records for 1,665 individuals randomized between December 5, 2000, and October 11, 2002. One enrollee had missing data in all baseline interview variables and was therefore excluded from the analysis.

TABLE B.13

SAMPLE SIZES BY TYPE OF OUTCOME AT DIFFERENT FOLLOW-UP POINTS IN THE DEMONSTRATION

	New York City		Upstate	
Type of Outcome	Treatment	Control	Treatment	Control
Interview Data				
Baseline	397	377	447	443
Year 1	338	349	338	339
Year 2	149	138	143	155
In-person Blood Pressure and Anthropometry				
Baseline	395	375	447	440
Year 1	336	348	338	334
Year 2	149	139	141	154
Ambulatory Blood Pressure				
Baseline	300	303	314	321
Year 1	73	94	124	121
Year 2	15	6	30	27
Cholesterol and Hemoglobin A1c				
Baseline	390	369	433	426
Year 1	333	347	309	314
Year 2	149	138	134	147
Urine Microalbumin-to-Creatinine Ratio				
Baseline	318	312	345	330
Year 1	219	254	206	207
Year 2	111	115	90	111
Utilization Outcomes-Medicare Claims Data[a]	370	354	445	442

Source: IDEATel Year 1 and Year 2 in-person interviews, anthropometric, and laboratory data, collected between December 2001 and October 2003; and Medicare claims data (Columbia 2003a and 2003c).

Note: Because treatment-control comparisons are based on analyses of covariance, sample sizes for Year 1 are for enrollees who have baseline and Year 1 data. Results in the report are based on these enrollees. Sample sizes may vary slightly from specific outcome to outcome, for example, sample sizes for waist-to-hip ratio may not be exactly the same as for body mass index. Sample sizes for Year 2 are likewise for enrollees who have baseline and Year 2 data; Year 2 sample sizes are presented for informational purposes only.

[a]Sample sizes correspond to the intention-to-treat sample. Complete Medicare claims data were available on these enrollees through December 31, 2003, and so the number of months of observation for each sample member varied depending on when the enrollee entered the study. The analysis of the claims-based utilization outcomes weighted each sample member's outcomes proportionally to the months of observation, and annualized all outcomes to a 12 month period (see Appendix F).

remaining independent variables included the baseline value of the outcome variable and a standard set of control variables (an approach often called the analysis of covariance).[106, 107]

The standard set of control variables are those listed in Table IV.1. Ordinary least squares regression models were used for the continuous outcome variables, and logit regression models were used for the binary outcomes. An ordinal logistic regression model was used for outcomes of whether an enrollee had no proteinuria, microalbuminuria, or clinical proteinuria. For the urine albumin-to-creatinine-ratio, the dependent variable was the natural logarithm of the measure, because of the skewed distribution of the measure. The values reported in Chapter IV are predicted treatment and control group means calculated from the coefficients of the estimated models. The statistical significance of the treatment effect was determined from the *p*-value for the coefficient of the treatment–control indicator variable.

Any case with a missing value for a dependent variable was dropped for the analysis of that variable. The analyses were conducted using Year 1 outcomes for enrollees with Year 1 data, Year 2 outcomes for the small subset that had actual Year 2 data, and a *last observation carried forward* approach in which actual Year 2 outcomes were used where present, but missing Year 2 outcomes were imputed by inserting the Year 1 outcomes. Results from these three approaches

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[106]For the Medicare-claims–based access outcomes, which consisted of service use during the period between randomization and December 31, 2003, the corresponding baseline control variable was the use of the same service during the year preceding randomization.

[107]A few categorical variables were constructed differently for the New York City and upstate regression models. For example, race/ethnicity was constructed as black/Hispanic/white for New York City, and as minority/nonminority for upstate New York, to reflect the degree of heterogeneity in the respective sites. In addition, models used in the analysis of the upstate site did not control for enrollment in a health maintenance organization, because very few enrollees were enrolled in managed care plans.

were compared and found to lead to the same conclusions, and Chapter IV presents the results from the analysis using Year 1 outcomes.

Cases with missing values for a control variable were dropped from analysis if fewer than three percent of cases were missing that variable. If three percent or more of cases were missing values for a control variable, those cases were included with a dummy variable to indicate the missing value. In fact, this strategy was necessary only for the income variables, as they were the only control variables for which more than three percent of cases were missing data. The few instances in which logit models could not be estimated because of small cells or collinearity are indicated in the tables in Chapter IV, and unadjusted means are presented and compared, using a *t*-test.

Impacts for subgroups were estimated by including two interaction terms in a single model. The subgroup indicators were defined by baseline measures of enrollees' years of education and previous use of personal computers and were interacted with the treatment-status indicator.[108]

The medication analyses were not amenable to analysis of covariance, as there were enrollees taking medications at the follow-up interviews who had not been taking the medications at baseline. The independent evaluator determined that the remaining control variables used in the other regression analyses would not affect the prescription of medication; consequently,

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[108]When estimating impacts for subgroups defined by years of education and previous computer use, the variance of the estimated impact was approximated by calculating the variance of the difference in the predicted probabilities for a treatment and control group member with all independent variables set at their sample means. A *t*-statistic was then constructed and used to test whether the estimated impact was significantly different from zero.

unadjusted means are presented and compared, using *chi-squared* statistics to test for equality of binary and count outcomes, and using *t*-tests for continuous outcomes.

APPENDIX C

SUPPLEMENTAL TABLES
TO CHAPTER II

TABLE C.1

IDEATel CONSORTIUM MEMBERSHIP AS OF DECEMBER 2003

Organization Type	Organization Name
Core Organization	Columbia University Division of General Medicine
	Columbia University Department of Bioinformatics[a]
	Hebrew Home for the Aged at Riverdale
	Naomi Berrie Diabetes Center
	SUNY Upstate Medical University
	Joslin Diabetes Center (Syracuse)
Affiliated Organization	American Diabetes Association
	Arnot Ogden Medical Center
	Bassett Healthcare
	Delaware Valley Hospital
	Family Health Network of Central New York
	Guthrie Healthcare System (New York State offices only)
	Harlem Hospital Center
	Harlem Renaissance HealthCare Network
	Hudson Headwaters Health Network
	Kaledia Health Diabetes Center
	Lee Memorial Hospital
	Lourdes Hospital
	Olean General Hospital
	St. Luke's-Roosevelt Hospital Center
	Samaritan Medical Center
	SUNY Buffalo
	Syracuse Veterans Affairs Medical Center
	United Health Care
Subcontractor	American TeleCare, Inc.
	Crosshair Technologies
	MCI WorldCom
	MedStar/Penn Labs
	Siemens Medical Solutions Health Services Corporation
	Space Labs Medical Data
	SUNY Stony Brook
	Verizon

Source: Interviews with Consortium staff members conducted in 2001, 2002, and 2003.

[a]The Department of Bioinformatics recently changed its name from the Department of Medical Informatics.

TABLE C.2

IMPLEMENTATION CHALLENGES AND CHANGES IN THE DEMONSTRATION DESIGN

Challenge	Aspect of Demonstration Involved	Change in Demonstration Design	Status of Challenge[a]
Challenges Recognized in Year 1 and Year 2			
Physician and participant recruitment were taking longer than expected.	Consortium Physician and participant recruitment	To increase the number of participating physicians and thereby increase the pool of potential patient participants, added more organizations to the Consortium	Change made in Year 2 Addition of new affiliated hospitals slowed by IRB approval. Recruitment of community physicians was labor-intensive. Challenge eventually resolved
CareSoft Inc. stopped offering its case management software as a stand-alone product.	Consortium Technical design	Contracted with Siemens Medical Solutions Health Services Corporation to provide case management software	Change made in Year 1 Challenge resolved
Bell Atlantic spun off the corporate division that had been working on the demonstration's data security features.	Consortium Technical design	Contracted directly with Crosshair Technologies, Inc. (the former Bell Atlantic division) to use the same personnel for data security work	Change made in Year 1 Challenge resolved
American TeleCare, Inc. subcontracted to Gentiva Health Care, Inc. to install HTUs. The per-unit cost of installing HTUs was higher than budgeted.	Consortium	Responsibility for HTU installation taken over by American TeleCare, Inc.	Change made in Year 2 Challenge resolved
The yield of participants from patient lists provided by physicians was low.	Physician and participant recruitment	Changed demonstration's inclusion and exclusion criteria to increase the number of Medicare beneficiaries eligible to participate	Change made in Year 2 Yield of participants remained low
The proposed "all-in-one" HTU model no longer was available.	Technical design	Changed hardware specifications to utilize off-the-shelf components to construct an HTU	Change made in Year 1 Challenge resolved

TABLE C.2 (*continued*)

Challenge	Aspect of Demonstration Involved	Change in Demonstration Design	Status of Challenge[a]
The multiple components of new HTUs, along with cords and wires, created logistical problems for installation and participant use.	Technical design	Added a cart to hold HTU components and hide cords and wires	Change made in Year 1 Challenge resolved
Participants with low computer literacy had difficulty using the redesigned HTU.	Technical design	Created a four-button launch pad to help participants turn the HTU on and off, initiate televisits, upload clinical measurements, and launch the Web browser	Change made in Year 1 Challenge resolved
Participants were concerned about electricity use and background noise generated by the HTUs.	Technical design	Modified functioning of the restart button on the launch pad to enable participants to turn off the HTU	Change made in Year 2 Challenge resolved
Participants had difficulty learning to use both the basic and advanced HTU functions.	Technical design Intervention	Created a video tutorial to guide participants though use and features of the HTU	Change made in Year 2 Continued difficulty with HTUs
Participants in New York City broke appointments for televisits at a high rate.	Intervention	Used support staff at Berrie Diabetes Center to call participants and remind them of scheduled televisits	Change made in Year 2 Appointments continued to be broken
Challenges Ongoing or Recognized in Year 3			
Physician and participant recruitment continued to take longer than expected.	Consortium Physician and participant recruitment Internal evaluation	Added more organizations to the Consortium Extended the enrollment period	Change made in Year 3 Recruitment completed
The endocrinologist supervising nurse case managers in the upstate site requested a new role.	Consortium	Endocrinologist given the role of providing technical assistance. Responsibility of supervising the nurse case managers given to another endocrinologist	Change made in Year 3 Challenge resolved
Telergy, Inc., a supplier of telecommunications services for the demonstration, went out of business.	Consortium Technical design	Contracted with MCI WorldCom to provide the services	Change made in Year 3 Challenge resolved
The demonstration needed oversight for safety reasons.	Consortium	Created an independent Data Safety and Monitoring Board	Change made in Year 3 Challenge resolved

TABLE C.2 (*continued*)

Challenge	Aspect of Demonstration Involved	Change in Demonstration Design	Status of Challenge[a]
The participant dropout rate was higher than expected.	Physician and participant recruitment Internal evaluation	Increased the target sample size	Change made in Year 3 Ongoing problems with the dropout rate
The software used by HTUs and case management software were incompatible in some ways.	Technical design	Upgraded the HTU software to increase compatibility with the case management software	Change made in Year 3 Challenge resolved
Intermittent problems occurred when participants tried to upload blood pressure and blood sugar data from the HTUs.	Technical design	Upgraded the HTU software	Change made in Year 3 Challenge resolved
Batteries in the blood pressure and blood sugar meters began to fail; technical problems developed in some speakers and videocameras in the HTUs.	Technical design	Implemented a maintenance schedule to replace batteries	Change made in Year 3 Challenge resolved
The data telecommunications line connecting the upstate site with the clinical information system at Columbia University had insufficient capacity.	Technical design	Contracted with MCI WorldCom to add another data telecommunications line	Change made in Year 3 Challenge resolved
Participants continued to have difficulty using both the basic and advanced HTU functions.	Intervention	Conducted a qualitative study of participants' interactions with the HTU. Based on the findings, revised the video tutorial, revised and shortened the user manual, and retrained all participants in the use of the HTU	Change made in Year 3 Challenge ongoing

TABLE C.2 (*continued*)

Challenge	Aspect of Demonstration Involved	Change in Demonstration Design	Status of Challenge[a]
Challenges Ongoing or Recognized in Year 4			
The vice president of engineering and manufacturing at American TeleCare, Inc. left the company.	Consortium	None made	No change in the Consortium's relationship with American TeleCare, Inc., which already had a limited role in Year 4 Challenge resolved
Both nurse case managers in the New York City site left the demonstration in September 2003.	Intervention	None made	Televisit component of intervention stopped for New York City participants in September 2003; other HTU functions still used
Participants continued to drop out at a high rate.	Internal evaluation	Increased target sample size and extended the enrollment period in Year 3 Retrained all participants in Year 3 in the use of the HTU to make them more comfortable with its use	Participant recruitment completed in Year 3 Retraining completed in Year 3 Continued dropout in Year 4, but at a slower rate
Demonstration staff had to clean and prepare the large volume of data needed for the evaluation.	Internal evaluation	None made	Data cleaning completed in Year 4 Challenge resolved
Delays in participant recruitment resulted in the Consortium having less than two years of follow-up data on some participants.	Internal evaluation	Consortium leadership asked for extension to the demonstration Data analysis will use all available endpoints to measure impacts on participants	Extension granted in December 2003 Analysis proceeding with a combination of Year 1 and Year 2 outcomes data

Source: Interviews with Consortium staff members conducted in 2001, 2002, and 2003.

[a]As reported by Consortium staff during site visits in Year 2, and during telephone calls in Year 3.

IRB = institutional review board, HTU = home telemedicine unit.

TABLE C.3

ESTIMATED EXPONENTIATED COEFFICIENTS OF HAZARD MODEL OF TIME TO DROPOUT

Characteristic	Exponentiated Coefficient	Standard Error	*p*-Value[a]
Intervention Group			
Treatment	3.217	.404	.000
(Control)			
Site			
New York City	1.038	.298	.897
(Upstate site)			
Age at Randomization (Years)			
55 to 64	.948	.244	.835
(65 to 69)			
70 to 74	1.058	.169	.726
75 to 79	1.267	.218	.169
≥80	1.636	.310	.009
Sex			
Male	.965	.128	.787
(Female)			
Race/Ethnicity			
Minority[b]	.764	.219	.347
(White, non-Hispanic/non-Latino)			
Education (Years)			
≤11			
12	.747	.110	.048
≥13	.848	.169	.410
Missing	.000	.000	.000
Lived Alone			
Yes	1.091	.137	.489
(No)			
Employed			
Yes	.829	.228	.496
(No)			
Missing	3.829	3.741	.170
Household Income (Dollars)			
<5,000	1.376	.435	.312
(5,001 to 10,000)			
10,001 to 20,000	1.140	.218	.492
20,001 to 30,000	1.027	.269	.918
30,000 to 40,000	.661	.301	.364
≥40,001	.347	.175	.036
Missing	1.284	.287	.263
Reason for Medicare Entitlement			
(Old age)			
Disability	.956	.168	.797

TABLE C.3 (*continued*)

Characteristic	Exponentiated Coefficient	Standard Error	*p*-Value[a]
Dually Eligible			
Yes	1.119	.181	.488
(No)			
Duration of Diabetes (Years)			
(<5)			
5 to 9	1.200	.211	.302
10 to14	1.290	.237	.165
≥15	1.332	.199	.056
Missing	.994	.537	.990
Had Experience with Computers Before Randomization			
Yes	.898	.172	.573
(No)			
Missing	.771	.397	.614
Log-Likelihood		–2,199.055	
Chi-Square (Degrees of Freedom)		2,351.530 (29)	
Sample Size		**1,662**	

Source: Consortium tracking status file linked to both the IDEATel telephone screen and baseline, in-person interviews and Medicare enrollment and claims data (Columbia University 2003a, 2003c, and 2003d).

Notes: All characteristics were measured at the time of randomization, unless otherwise noted. Entries in parenthesis correspond to the omitted (or baseline) group, which has a coefficient equal to zero. Exponentiated coefficients are interpreted as *relative risks* of dropping out IDEATel, with a risk of one for the omitted group.

[a]For a *t*-test of significance of the coefficient.

[b]Includes African-American, non-Hispanic/non-Latino; Hispanic/Latino; and other.

APPENDIX D

SUPPLEMENTAL TABLE
TO CHAPTER III

TABLE D.1

CHARACTERISTICS OF PARTICIPANTS FOR ANALYSIS OF HTU USE, BY SITE
(Percentages, Unless Noted)

Characteristic	All	Site		Difference (*p*-Value)
		New York City	Upstate New York	
Age at Randomization (Years)				
55 to 64	12.2	10.3	13.7	3.4 (.048)
65 to 69	34.1	36.8	31.8	5.0
70 to 74	27.3	28.4	26.3	2.1
75 to 79	16.7	17.6	15.9	1.7
≥80	9.9	6.9	12.3	5.4
Race/Ethnicity				
African American, non-Hispanic/non-Latino	14.6	23.1	7.4	15.7 (.000)
Hispanic/Latino	35.3	74.9	1.7	73.2
White, non-Hispanic/non-Latino	48.7	0.6	89.6	89.0
Other	1.4	1.4	1.4	0.0
Born in the United States				
Yes	62.6	22.3	96.9	74.6 (.000)
No	37.4	77.7	3.1	74.6
Primary Language				
English	63.6	24.7	96.7	72.0 (.000)
Spanish	35.1	74.7	1.4	73.3
Other	1.3	0.6	1.9	1.3
Sex				
Male	37.8	30.6	43.8	40.2 (.000)
Female	62.2	69.4	56.2	13.2
Marital Status				
Single/never married	12.2	19.5	5.9	13.6 (.000)
Married/living with significant other	43.2	29.3	55.0	25.7
Separated/divorced	16.1	23.1	10.2	12.9
Widowed	28.4	28.1	28.7	0.6
Missing	0.1	0.0	0.2	0.2
Lived Alone				
Yes	36.5	42.6	31.3	11.3 (.001)
No	63.5	57.4	68.7	11.3
Education (Years)				
0	2.3	4.7	0.2	4.5 (.000)
1 to 11	53.0	73.3	35.8	37.5
12	28.3	16.2	38.6	22.4
≥13	16.3	5.6	25.4	19.8
Missing	0.1	0.3	0.0	0.3

TABLE D.1 *(continued)*

Characteristic	All	Site: New York City	Site: Upstate New York	Difference (*p*-Value)
Employed				
Yes	6.3	1.1	10.7	9.6 (.000)
No	93.6	98.6	89.3	9.3
Missing	0.1	0.3	0.0	0.3
Annual Household Income (Dollars)				
<5,000	3.6	6.4	1.2	5.2 (.000)
5,001 to 10,000	46.1	78.8	18.3	60.5
10,001 to 20,000	21.1	9.8	30.8	21.0
20,001 to 30,000	11.3	0.8	20.1	19.3
30,001 to 40,000	3.7	0.0	6.9	6.9
≥40,001	5.0	0.3	9.0	8.7
Missing/refused/did not know	9.2	3.9	13.7	9.8
Knew How to Use Computers				
Yes	18.8	4.2	31.3	27.1 (.000)
No	79.8	95.0	66.8	28.2
Missing	1.4	0.8	1.9	1.1
Reason for Medicare Entitlement				
Old age	74.0	75.8	72.5	3.3 (.301)
Disability	26.0	24.2	27.5	3.3
Length of Medicare Enrollment (Years)				
<1	4.9	6.7	3.3	3.4 (.040)
1 to 4	30.4	31.2	29.6	1.6
5 to 9	32.3	31.5	32.9	1.4
10 to 14	17.9	19.2	16.8	2.4
≥15	14.6	11.4	17.3	5.9
Average Medicare Expenditures in the Year Before Randomization (Dollars)	6,156	7,011	5,414	1,597 (.009)
Enrolled in a Health Maintenance Organization				
Yes	4.9	9.2	1.2	8.0 (.000)
No	95.1	90.8	98.8	8.0
Dually Eligible				
Yes	38.4	67.4	13.7	53.7 (.000)
No	61.6	32.6	86.3	53.5
Duration of Diabetes (Years)				
<5	30.9	29.5	32.0	2.5 (.314)
5 to 9	19.3	20.1	18.7	1.4
10 to14	17.8	17.6	18.0	0.4
≥15	30.6	32.3	29.2	3.1
Missing	1.4	0.6	2.1	1.5

TABLE D.1 *(continued)*

Characteristic	All	Site: New York City	Site: Upstate New York	Difference (*p*-Value)
Diabetes Treatment				
Pills alone	14.2	14.5	14.0	0.5 (.766)
Insulin alone	64.9	63.0	66.6	3.6
Insulin and pills	15.0	16.7	13.5	3.2
Diet alone	5.3	5.3	5.2	0.1
Missing/refused	0.6	0.6	0.7	0.1
Sample Size	**781**	**359**	**422**	**—**

Source: Consortium database on HTU use linked to both the IDEATel telephone screen and in-person baseline interviews, conducted between November 2000 and October 2002, and Medicare claims and enrollment records (Columbia University 2003a, 2003b, 2003c, and 2003d).

HTU = home telemedicine unit.

APPENDIX E

SUPPLEMENTAL TABLES
TO CHAPTER IV

TABLE E.1

ESTIMATED EFFECTS OF IDEATel ON KEY OUTCOMES,
BY YEARS OF EDUCATION
(New York City Sample)

Outcome	<12 Years			≥12 Years		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator at Least Once in the Past Year	34.2	15.5	18.7 (.000)	30.5	16.0	14.5 (.031)
Saw a Dietitian at Least Once in the Past Year[*]	24.9	22.3	2.6 (.476)	14.5	23.3	–8.9 (.112)
Provider Practices						
Health Care Professionals Discussed Diabetes Topic Four or More Times in the Past Year:						
Exercise[**]	33.7	30.9	2.8 (.534)	45.5	25.5	20.1 (.007)
Eating[*]	25.2	23.9	1.3 (.782)	35.1	18.9	16.3 (.015)
Controlling blood sugar[a]	6.9	2.0	4.9 (.007)	4.0	3.2	0.8 (.781)
Self-Care Knowledge						
Understands How to:						
Take care of feet[a]	93.4	86.9	6.5 (.014)	94.7	90.4	4.2 (.305)
Address symptoms of low blood sugar[a]	88.5	88.4	0.1 (.957)	94.7	91.4	3.3 (.415)
Test blood sugar[a]	95.4	89.9	5.5 (.018)	100.0	93.7	6.3 (.027)
Exercise appropriately	81.1	80.9	0.2 (.961)	85.8	79.0	6.8 (.275)
Choose appropriate foods[**]	88.4	90.4	–2.0 (.453)	93.8	83.1	10.7 (.043)
Knows Target Blood Glucose Values	79.6	77.6	2.0 (.574)	86.7	86.4	0.3 (.959)
Self-Monitoring						
Tested Blood Sugar Daily in the Past Week	69.1	52.7	16.4 (.000)	62.0	50.9	11.1 (.162)
Examined Feet Daily in the Past Week	81.8	72.8	9.0 (.013)	76.6	75.5	1.1 (.866)

TABLE E.1 *(continued)*

Outcome	<12 Years: Predicted Treatment Group Mean (Percent)	<12 Years: Predicted Control Group Mean (Percent)	<12 Years: Estimated Effect (*p*-Value)	≥12 Years: Predicted Treatment Group Mean (Percent)	≥12 Years: Predicted Control Group Mean (Percent)	≥12 Years: Estimated Effect (*p*-Value)
Adherence to Self-Care						
Took Recommended Doses of Diabetes Pills Daily in the Past Week[a]	94.5	94.9	–0.4 (.866)	98.3	93.1	5.3 (.150)
Administered Recommended Insulin Injections Daily in the Past Week[a]	94.9	98.7	–3.8 (.179)	96.2	100.0	–3.8 (.240)
Adhered to Diet Daily in the Past Week	58.1	61.9	–3.7 (.432)	55.4	51.4	4.0 (.575)
Adhered to Exercise Plan on Three or More Days in the Past Week	55.5	47.3	8.2 (.056)	51.6	47.6	4.0 (.609)
Satisfaction with Diabetes Care						
Rated Quality of Diabetes Care in the Past Year as Very Good or Excellent[*]	53.9	57.0	–3.1 (.431)	65.9	53.1	12.8 (.099)
Intends to Follow Health Care Provider's Advice	80.5	82.5	–2.0 (.561)	80.4	83.0	–2.6 (.682)
Sample Size	**261**	**253**	**—**	**76**	**95**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for participants' baseline characteristics (see Table IV.1). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–control differences.

[*]The estimated effects for the two subgroups were statistically different from each other at the .10 level, two-tailed test.

[**]The estimated effects for the two subgroups were statistically different from each other at the .05 level, two-tailed test.

TABLE E.2

ESTIMATED EFFECTS OF IDEATel ON KEY OUTCOMES,
BY YEARS OF EDUCATION
(Upstate Sample)

Outcome	<12 Years			≥12 Years		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator at Least Once in the Past Year	69.1	9.3	59.8 (.000)	78.3	12.5	65.8 (.000)
Saw a Dietitian at Least Once in the Past Year	68.7	16.3	52.4 (.000)	80.6	16.6	64.0 (.000)
Provider Practices						
Health Care Professionals Discussed Diabetes Topic Four or More Times in the Past Year:						
Exercise	41.3	26.2	15.2 (.014)	50.1	22.6	27.5 (.000)
Eating	42.3	20.4	21.8 (.113)	46.1	19.0	27.1 (.000)
Controlling blood sugar	28.0	10.3	17.7 (.001)	23.1	4.9	18.2 (.000)
Self-Care Knowledge						
Understands How to:						
Take care of feet	93.5	90.2	3.3 (.442)	97.3	89.9	7.4 (.002)
Address symptoms of low blood sugar	95.5	81.2	14.3 (.001)	93.6	87.9	5.7 (.019)
Test blood sugar[a]	99.1	91.6	7.5 (.009)	99.6	96.2	3.3 (.014)
Exercise appropriately	93.6	82.3	11.3 (.012)	94.6	91.3	3.3 (.119)
Choose appropriate foods	85.6	79.1	6.5 (.206)	95.4	88.4	7.0 (.007)
Knows Target Blood Glucose Values	86.7	70.2	16.5 (.003)	90.5	84.2	6.3 (.038)
Self-Monitoring						
Tested Blood Sugar Daily in the Past Week**	67.5	57.4	10.1 (.113)	76.6	50.5	26.0 (.000)
Examined Feet Daily in the Past Week**	66.6	71.4	–4.8 (.407)	76.1	65.0	11.1 (.007)

TABLE E.2 (*continued*)

Outcome	<12 Years			≥12 Years		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Adherence to Self-Care						
Took Recommended Doses of Diabetes Pills Daily in the Past Week[a]	97.8	95.7	2.1 (.423)	97.7	94.7	3.0 (.149)
Administered Recommended Insulin Injections Daily in the Past Week[a]	96.9	100.0	–3.1 (.270)	98.6	95.2	3.3 (.269)
Adhered to Diet Daily in the Past Week	40.2	40.9	–0.7 (.921)	49.6	42.7	7.0 (.107)
Adhered to Exercise Plan on Three or More Days in the Past Week	62.5	65.2	–2.8 (.660)	66.2	69.4	–3.2 (.464)
Satisfaction with Diabetes Care						
Rated Quality of Diabetes Care in the Past Year as Very Good or Excellent	82.2	67.6	14.6 (.011)	77.2	74.3	3.0 (.452)
Would Recommend Doctor/Health Care Provider Based on Personal Manner	92.4	90.5	1.9 (.643)	94.4	91.1	3.3 (.211)
Intends to Follow Health Care Provider's Advice	74.9	70.2	4.8 (.465)	80.7	69.1	11.7 (.005)
Sample Size	**220**	**213**	**—**	**110**	**123**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for participants' baseline characteristics (see Table IV.1). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment–contro1 differences.

[**]The estimated effects for the two subgroups were statistically different from each other at the .05 level, two-tailed test.

TABLE E.3

ESTIMATED EFFECTS OF IDEATel ON KEY OUTCOMES,
BY PRIOR EXPERIENCE WITH PERSONAL COMPUTERS
(New York City Sample)

Outcome	Did Not Have Prior Experience			Had Prior Experience		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator At Least Once in the Past Year	33.1	15.6	17.5 (.000)	34.9	15.9	19.0 (.200)
Saw a Dietitian At Least Once in the Past Year	21.4	22.4	–1.0 (.718)	33.1	24.8	8.3 (.581)
Provider Practices						
Health Care Professionals Discussed Diabetes Topic Four or More Times in the Past Year:						
Exercise**	38.3	29.1	9.1 (.015)	12.3	33.0	–20.7 (.099)
Eating	28.7	22.3	6.3 (.072)	13.5	26.9	–13.5 (.317)
Controlling blood sugar[a]	6.5	2.5	4.0 (.013)	0.0	0.0	0.0 (—)
Self-Care Knowledge						
Understands How to:						
Take care of feet[a]	93.7	88.0	5.7 (.013)	93.3	90.9	2.4 (.792)
Address symptoms of low blood sugar[a]	90.0	89.1	0.9 (.699)	85.7	95.2	–9.5 (.331)
Test blood sugar[a]	96.3	91.3	5.0 (.009)	100.0	90.0	9.1 (.238)
Exercise appropriately	82.6	80.2	2.4 (.371)	74.9	86.9	–12.0 (.422)
Choose appropriate foods	89.7	88.3	1.4 (.556)	90.5	94.1	–3.6 (.696)
Knows Target Blood Glucose Values	81.7	79.3	2.5 (.449)	73.5	86.7	–13.1 (.374)
Self-Monitoring						
Tested Blood Sugar Daily in the Past Week	67.4	53.0	14.4 (.000)	67.7	40.1	27.6 (.099)
Examined Feet Daily in the Past Week	80.5	73.2	7.3 (.027)	85.7	79.8	5.8 (.683)

TABLE E.3 (*continued*)

Outcome	Did Not Have Prior Experience			Had Prior Experience		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Adherence to Self-Care						
Took Recommended Doses of Diabetes Pills Daily in the Past Week[a]	95.2	94.1	1.1 (.567)	100.0	100.0	0.0 (—)
Administered Recommended Insulin Injections Daily in the Past Week[a]	94.9	99.1	–4.2 (.075)	100.0	100.0	0.0 (—)
Adhered to Diet Daily in the Past Week	56.4	59.0	–2.5 (.504)	81.3	67.9	13.4 (.415)
Adhered to Exercise Plan on Three or More Days in the Past Week	54.6	46.9	7.7 (.041)	53.1	56.7	–3.6 (.837)
Satisfaction with Diabetes Care						
Rated Quality of Diabetes Care in the Past Year as Very Good or Excellent[***]	58.6	55.4	3.2 (.369)	26.8	70.7	–44.0 (.010)
Intends to Follow Health Care Provider's Advice	81.3	83.1	–1.8 (.545)	65.2	74.9	–9.7 (.563)
Sample Size	**321**	**326**	**—**	**15**	**22**	**—**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003).

Note: Means were predicted with logit models, which controlled for participants' baseline characteristics (see Table IV.1). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment-control differences.

[**]The estimated effects for the two subgroups were statistically different from each other at the .05 level, two-tailed test.

[***]The estimated effects for the two subgroups were statistically different from each other at the .01 level, two-tailed test.

TABLE E.4

ESTIMATED EFFECTS OF IDEATel ON KEY OUTCOMES,
BY PRIOR EXPERIENCE WITH PERSONAL COMPUTERS
(Upstate Sample)

Outcome	Did Not Have Prior Experience			Had Prior Experience		
	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percent)	Predicted Control Group Mean (Percent)	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator at Least Once in the Past Year	77.5	10.1	67.4 (.000)	70.5	13.8	56.8 (.000)
Saw a Dietitian in the Past Year*	79.2	14.6	64.6 (.000)	71.7	19.6	52.0 (.000)
Provider Practices						
Health Care Professionals Discussed Diabetes Topics Four or More Times in the Past Year						
Exercise*	50.9	22.7	28.3 (.000)	40.1	25.9	14.3 (.017)
Eating	44.8	19.2	25.6 (.000)	45.2	20.3	24.9 (.000)
Controlling blood sugar	24.6	4.9	19.7 (.000)	24.7	9.9	14.9 (.003)
Self-Care Knowledge						
Understands How to:						
Take care of feet	96.2	89.3	69.3 (.005)	96.0	91.6	4.4 (.223)
Address symptoms of low blood sugar	93.5	86.3	7.1 (.006)	95.9	84.7	11.2 (.008)
Test blood sugar[a]	99.1	93.3	5.8 (.002)	100.0	96.7	3.3 (.055)
Exercise appropriately**	92.7	90.5	2.2 (.493)	97.7	83.8	13.8 (.006)
Choose appropriate foods	93.7	86.5	7.2 (.006)	88.7	83.1	5.6 (.207)
Knows Target Blood Glucose Values	89.2	75.8	13.5 (.020)	89.2	81.1	8.1 (.020)
Self-Monitoring						
Tested Blood Sugar Daily in the Past Week	76.6	53.3	23.3 (.000)	67.7	51.3	16.4 (.010)
Examined Feet Daily in the Past Week*	74.5	64.3	10.2 (.014)	70.3	72.8	–2.5 (.676)

TABLE E.4 (*continued*)

Outcome	Did Not Have Prior Experience: Predicted Treatment Group Mean (Percent)	Did Not Have Prior Experience: Predicted Control Group Mean (Percent)	Did Not Have Prior Experience: Estimated Effect (*p*-Value)	Had Prior Experience: Predicted Treatment Group Mean (Percent)	Had Prior Experience: Predicted Control Group Mean (Percent)	Had Prior Experience: Estimated Effect (*p*-Value)
Adherence to Self-Care						
Took Recommended Doses of Diabetes Pills Daily in the Past Week[a]	97.6	96.3	1.3 (.484)	97.8	92.9	4.9 (.116)
Administered Recommended Insulin Injections Daily in the Past Week[a]	100.0	97.0	3.0 (.169)	94.3	97.0	–2.7 (.592)
Adhered to Diet Daily in the Past Week	47.9	45.0	2.9 (.524)	43.5	36.1	7.3 (.236)
Adhered to Exercise Plan on Three or More Days in the Past Week	65.3	69.6	–4.3 (.316)	64.3	64.8	–0.4 (.937)
Satisfaction with Diabetes Care						
Rated Quality of Diabetes Care in the Past Year as Very Good or Excellent	79.7	73.4	6.3 (.114)	77.9	69.3	8.6 (.154)
Would Recommend Doctor/Health Care Provider Based on Personal Manner	94.5	93.1	1.4 (.505)	91.7	85.7	6.0 (.181)
Intends to Follow Health Care Provider's Advice[**]	76.4	73.1	3.3 (.416)	83.1	63.4	19.6 (.000)
Sample Size	**108**	**121**	**--**	**230**	**218**	**--**

Source: IDEATel Year 1 in-person interview, conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with logit models, which controlled for participants' baseline characteristics (see Table IV.1). Sample sizes vary slightly from measure to measure because of item nonresponse.

[a]Effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment-control differences.

[*]The estimated effects for the two subgroups were statistically different from each other at the .10 level, two-tailed test.

[**]The estimated effects for the two subgroups were statistically different from each other at the .05 level, two-tailed test.

TABLE E.5

ESTIMATED EFFECTS OF IDEATeL ON HEMOGLOBIN A1C,
BY WHETHER BASELINE HEMOGLOBIN A1C LESS THAN 7.0 OR NOT

	Baseline Hemoglobin A1c<7			Baseline Hemoglobin A1c≥7			
	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Estimated Difference of Subgroup Differences (*p*-Value for Subgroup Effect)
New York City							
Mean Hemoglobin A1c	7.2	7.3	-0.2 (0.260)	7.3	7.5	-0.2 (0.067)	0.06 (.760)
Sample Size	**134**	**140**		**199**	**207**		
Upstate							
Mean Hemoglobin A1c	6.6	6.6	-.03 (.800)	6.9	7.2	-0.4 (.003)	0.4 (.040)
Sample Size	**172**	**176**		**137**	**138**		

Source: IDEATel Year 1 in-person interview conducted between December 2001 and October 2003 (Columbia University 2003d).

Note: Means were predicted with a linear regression model that controlled for enrollees' baseline characteristics (see Appendix B, Section C.4), and that included an interaction term between treatment-control status and whether baseline hemoglobin A1c was <7.0 or not.

APPENDIX F

THE METHODS USED BY THE INDEPENDENT EVALUATOR TO ESTIMATE DEMONSTRATION IMPACTS ON COSTS

This appendix describes the study methodology that the independent evaluator used to estimate the demonstration's impact on costs. The first section focuses on the methodology used to estimate the demonstration's costs, the second section summarizes the methods used to estimate Medicare expenditures, and the third section describes the approach for estimating impacts on Medicare costs. In the last section of the appendix, the independent evaluator presents a sensitivity analysis of the impacts on costs of different specifications of the study sample and subgroups defined by intensity of use of the intervention.

A. CALCULATION OF THE DEMONSTRATION'S COSTS

The independent evaluator estimated the demonstration's costs based on information obtained from seven sources: (1) the budget data provided by the Consortium, (2) the Consortium's technical proposal and progress reports to CMS (Columbia University 1998, 2002a, 2003e, 2003g, and 2004c), (3) a paper published by the demonstration team (Starren et al. 2002), (4) information that the independent evaluator collected during site visits and telephone calls, (5) the website of the Office of Grants and Contracts for Columbia University's Health Sciences Division (Columbia University 2003f), (6) the input of a consultant in telemedicine, and (7) the independent evaluator's research on market prices of the goods and services used in the demonstration.[109] The estimates were built from the bottom up, by identifying and then pricing out every aspect of the demonstration.

[109]The Consortium's technical proposal contained a description of its approach to the demonstration and a general sense of the level of effort for certain staff members (Columbia University 1998). However, information on staff hours had been deleted from the copy of the proposal given to the independent evaluator.

1. Intervention Costs Versus Research Costs

The independent evaluator's first step in developing the cost estimates was to define the demonstration's *intervention-related* and *research-related* activities. The independent evaluator used notes taken during site visits to and telephone calls with Consortium staff to identify all the activities occurring in the demonstration (see Appendix B, Section A). The notes detailed the order in which activities were undertaken, the organizations and staff involved, the nature of the work delegated to subcontractors, the structure of the intervention, and the Consortium's own internal evaluation. Some activities, though research-related in the context of the demonstration, still would be necessary activities in an ongoing telemedicine program. For example, in the demonstration, data on treatment and control group enrollees were collected for research purposes, but an ongoing telemedicine program would collect a subset of these data for quality improvement and reporting purposes. Thus, the independent evaluator classified a portion of some research-related activities as intervention-related.[110]

2. Intervention-Related Costs

The independent evaluator's second step in developing the cost estimates was to classify the intervention-related activities into three stages: (1) design, (2) implementation, and (3) closeout (or HTU de-installation). The independent evaluator defined ***design-stage costs*** as one-time costs associated with setting up the intervention. Among the design costs are costs incurred while developing the HTU software, designing the system architecture to connect Consortium members, and the costs of transferring participant data to a central repository. Although a

[110]All costs for control group members (for example, the cost for screening and randomization, and other data collection) were classified as research costs and were therefore excluded from the cost estimates.

telemedicine program would have ongoing costs for marketing and patient screening, the demonstration's costs for physician and enrollee recruitment were included as design-stage, rather than implementation-stage, costs. The independent evaluator defined ***implementation-stage costs*** as ongoing costs that would be incurred for leasing the case management software. Implementation-stage costs also included activities related to the purchase of the HTUs, installation of the devices in the participants' homes, and training of participants on how to use the HTUs. The independent evaluator defined ***close-out stage (or HTU de-installation) costs*** as those associated with removing the HTUs from participants' homes.

The independent evaluator estimated the costs of an ongoing telemedicine program under different scenarios. The first estimate included costs associated with implementation-stage activities only. The second estimate included design-stage and close-out-stage activities but depreciated those costs over four years and over eight years (see Table V.2).[111]

3. Classification of Demonstration Components

The independent evaluator's third step in developing the cost estimates was to classify the demonstration's intervention-related activities into broad categories or components within each stage. It grouped the design activities into four components: (1) development of systems architecture, (2) purchase of case managers' workstations, (3) development of software for HTUs, and (4) recruitment of physicians and enrollees. Likewise, it grouped the implementation activities into eight broad components: (1) purchase of HTUs, (2) installation of HTUs and

[111]The independent evaluator used the straight-line method to calculate depreciation. It assumed that the products of the design- and close-out stages had no salvage value at the end of the depreciation period.

training of participants, (3) lease of case management software, (4) information systems support, (5) case management and televisits, (6) screening and assessment of enrollees, (7) quality improvement, and (8) project management and other direct costs. The independent evaluator classified HTU de-installation activities as a single component.

4. Specific Assumptions

As a final step, the independent evaluator estimated the cost of each demonstration component from the Consortium's budget data, estimates of salaries for the different labor categories of staff members for which data were not available, and estimates of the costs of specific goods and services. This section describes, for each demonstration component, specific assumptions related to the salaries of demonstration staff members and the costs of goods and services.

a. Salaries of Demonstration Staff Members

During its site visits and telephone calls, the independent evaluator asked about the number and types of staff employed by the demonstration. The interviews detailed the staff members' responsibilities and percentage of time devoted to the project during each year.[112] To estimate compensation of demonstration staff about whom no data were available, the evaluator relied on information about the background and qualifications of each staff member and on published salary information (U.S. Bureau of Labor Statistics 2003; and Watson Wyatt Data Services 2002). The independent evaluator also asked for each staff member's starting date with the

[112]Although the level of effort for many staff members has varied from year to year, the independent evaluator assumed that the allocation of the staff members' efforts between intervention- and research-related activities did not change over time.

demonstration, and whether the staff member had been hired to work on the demonstration for the entire four-year period. An institutional base salary was estimated for each staff member for Year 1 of the project (2000–2001). The independent evaluator assumed that all staff would receive a salary increase of approximately three percent per year. Fringe benefits were added to the base salary at a rate of 25.6 percent for Year 1 and were increased by approximately 0.2 percent per year (Columbia University 2003f).

In addition to the salaries and benefits paid to demonstration staff, the independent evaluator also assumed that the Consortium paid consultancy fees to the three members of the Data Safety and Monitoring Board, which became active in Year 3 (2002–2003). It is assumed that the Board met once each in Years 3 and 4 (2003–2004), and that each member received a flat fee for his or her participation.

b. Costs for Goods and Services

The independent evaluator estimated the costs of equipment and supplies, as well as other direct costs, such as telephone, printing, and travel. Specific assumptions are detailed in this section, by stage and by component.

Design-Stage Activities. Many of the demonstration's design-stage costs are included in the ***development of system architecture*** component. The component includes the salaries of the development team working within Columbia University's Department of BioInformatics, the costs for the various servers and routers required to store and transfer data, and the cost of developing data security measures to prevent unauthorized users from accessing demonstration data. This component also includes minimal costs for additional telephone lines in the participants' homes, splitters, and ground fault circuit interrupts.

In estimating the cost of ***purchasing the case mangers' workstations,*** the independent evaluator used information obtained during the interviews with the demonstration staff. These interviews described how the nurse case managers each used two workstations simultaneously during the televisits, and how they used document cameras to convey information to participants.

Development of the software for the HTUs was another major component of the design stage. Most of the cost of American TeleCare Inc.'s subcontract is included in this component.[113] The independent evaluator assumed that the company made the software for the HTUs available to the Consortium for a fixed, one-time fee. However, it is also assumed that the company charged the demonstration an additional fee for the development of the video tutorial and the redesign of the HTU software in Year 3, as these tasks were not necessarily included at the time of the original subcontract negotiation. Finally, this component includes the cost of the Consortium's subcontract with the American Diabetes Association to develop the web pages (including adaptation of educational materials).

The ***physician and enrollee recruitment*** component includes salaries for the physicians and project managers who spent the majority of their time on this task. It also includes the cost of salary support for the physicians at the demonstration's affiliated hospitals in upstate New York who were active in the recruitment efforts.

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[113]The tasks performed by American TeleCare, Inc., the demonstration's major subcontractor, cut across more than one demonstration component. All the costs of this subcontract, including the company's project management costs and fee, were divided across the relevant demonstration components.

Implementation-Stage Activities. ***Purchasing HTUs*** was one of the first tasks of the implementation stage. Because the HTUs were assembled from off-the-shelf parts, each component was priced separately. The Consortium received the glucose meters free of charge from the vendor for use in the demonstration. However, the independent evaluator identified a price for these units under the assumption that an ongoing program would have to purchase this equipment. Because the unit cost of the HTU provided to the evaluator was substantially higher than the cost estimate obtained by pricing each component ($3,361 versus $1,040), the independent evaluator did not attempt to reconcile the difference. Instead, the evaluator used the higher HTU unit cost in all other calculations. The independent evaluator added the costs related to the purchase of the public key infrastructure, mail client license, and *launch pad* for the HTU, which were assumed to vary with the number of HTUs installed.

Most of the costs associated with ***HTU installation and participant training*** were included in American TeleCare, Inc.'s subcontract. This component includes the subcontractor's staff time to perform test televisits during participant training and retraining, configuration of the HTUs, HTU installation and training performed by Gentiva nurses, shipping of the HTUs from American TeleCare, Inc. to the New York City and upstate sites, and courier costs to transport the HTUs from central warehouses in New York City and upstate New York to the participants' homes.[114] It also includes the cost of the retraining visits conducted in the upstate site by American TeleCare, Inc.'s nurses, the cost of the retraining visits conducted in New York City by Columbia University staff, and travel costs for the staff who conducted the retraining.

[114]Gentiva was the installation subcontractor to American TeleCare, Inc.

The cost of ***leasing the case management software*** assumes that the Consortium's subcontract with Siemens Medical Solutions Health Services Corporation (formerly Shared Medical Systems) included an upfront cost for customization of screen layouts and report generation, with a fixed monthly fee thereafter for the use of the software.

Another implementation-related component is ***information systems support,*** which includes the salaries for Columbia University's Department of BioInformatics staff who were members of the demonstration's implementation team. It also includes technical support provided by American TeleCare, Inc. for the nurse case managers and participants.

The ***case management and televisit*** task includes the salaries of the nurse case managers, the salaries of support staff at the Berrie Diabetes Center and the Joslin Diabetes Center, and the time of the diabetologists to oversee the work of the nurse case managers. This implementation-stage component includes telecommunications fees for participants to access the Internet; and Internet access fees and fees for data communication lines linking Columbia University, SUNY Upstate Medical University, and the Hebrew Home for the Aged at Riverdale. It also includes two 1-800 telephone lines for use by participants when calling their nurse case managers and 1-500 telephone numbers for upstate participants to access the Internet service providers. Finally, this component includes the costs of mailing information to enrollees and their physicians.

The ***enrollee screening and assessment*** component includes salaries for the research assistants (in New York City) and nurses (in upstate New York) who performed the in-person assessments of enrollees at baseline, in Year 1, and in Year 2 (see Appendix B, Section C.1). It includes the cost of the equipment and supplies necessary to collect the assessment data, and the cost of the Consortium's subcontract with Spacelabs Medical Data and SUNY Stony Brook to obtain ambulatory blood pressure data, and with Medstar/Penn Labs to obtain laboratory data on the

enrollees . This component includes reimbursement of enrollees' travel expenses (in New York City), and reimbursement of nurses' travel expenses incurred while traveling to the homes of an estimated 25 percent of upstate enrollees who could not come to clinics for the assessments. It also includes the cost of providing breakfast or lunch to enrollees on the day of their assessments.

The ***project management*** component includes salaries for the demonstration's principal investigators and their support staff. Also included under project management are fees for the three consultants on the Data Safety and Monitoring Board. It also includes the cost of computer time (based on the number of staff hours). In addition, this component includes other direct costs incurred by Columbia University and SUNY Upstate Medical University (for example, travel and supplies).

Close-Out Activities. The last component of the demonstration is ***HTU de-installation*** at the conclusion of the two-year intervention period. It includes the costs of having an American TeleCare, Inc. nurse travel to the participants' homes to remove the HTUs, and of shipment of the HTUs to a central collection point. The independent evaluator did not assume that the demonstration's close-out phase would include costs for referring enrollees to other disease management programs or social service agencies.

Other Costs. Indirect costs charged to the demonstration by Columbia University (63.5 percent) and SUNY Upstate Medical University (52 percent) were applied to salaries and wages, fringe benefits, computer time, and other direct costs (such as travel expenses). Supplies purchased by Columbia University and costing less than $2,000 were also included in the calculation, as were all supplies purchased by SUNY Upstate Medical University (Columbia University 2003f; and Email from Ruth Weinstock, May 17, 2005). Subcontract and equipment costs (that is, items

having a unit cost equal to or greater than $2,000 purchased by Columbia University) were not included in the calculation of indirect costs.

5. Estimation of Demonstration Costs

The independent evaluator used the estimated costs of goods, salaries, and services for each activity to estimate the cost of each demonstration component. It allocated the cost of each component as research-related or as intervention-related according to the percentages listed in Table F.1. By summing the cost of each component, the independent evaluator estimated the cost of the demonstration to be $28,863,942 (in 2001 dollars, the base year).

Because the estimated demonstration cost and the actual amount of the cooperative agreement differ, the independent evaluator apportioned the award amount ($28,159,066), using the estimated percentages of the total cost for each component (Table F.2). If the independent evaluator failed to account for any costs, this approach will correct for the omission, if the omitted costs are distributed across the demonstration components in the same pattern as are observed costs.

6. Sensitivity Analysis of Demonstration Costs

The independent evaluator examined the sensitivity of demonstration costs to variations in the assumptions about labor and equipment costs with Monte Carlo simulation methods, using *Crystal Ball 7.0* (Decisioneering 2004). These methods allow for the simultaneous variation of several cost inputs (Spiegelhalter and Best 2002). The independent evaluator assumed variation in three groups of costs: (1) the HTU's software and hardware costs, including lease of the case management software and the development of the American Diabetes Association website; (2) labor costs for the development of the software for the HTUs; and (3) labor costs for case management and televisits. (A summary of the assumptions is available from the independent

TABLE F.1

ALLOCATION OF DEMONSTRATION COMPONENTS AS INTERVENTION RELATED OR RESEARCH RELATED
(Percentages)

Demonstration Component	Cost Allocation	
	Intervention-Related	Research-Related
Design Stage		
Development of systems architecture	100	0
Purchase of case managers' workstations	100	0
Development of software for HTUs	100	0
Recruitment of physicians and enrollees	10	90
Implementation Stage		
Purchase of HTUs	100	0
Installation of HTUs and training of participants	100	0
Lease of case management software	100	0
Information systems support	100	0
Case management and televisits	100	0
Screening and assessment of enrollees	10	90
Quality improvement[a]	10	90
Project management and other direct costs	50	50
Close-Out Stage (HTU De-Installation)	10	90

Source: The independent evaluator's estimates based on information obtained from the Consortium's technical proposal (from which information on staff hours had been deleted) and progress reports; a paper published by the demonstration team; information collected during site visits by the independent evaluator; the Web site of the Office of Grants and Contracts for Columbia University's Health Sciences Division; the input of a consultant in telemedicine; the input from the Consortium on salaries of demonstration staff, the staff's level of effort, and the value of subcontracts; and the independent evaluator's research on market prices.

[a]The research-related portion of this demonstration component is defined as "enrollee randomization and internal evaluation."

HTU = home telemedicine unit.

TABLE F.2

ALLOCATION OF ESTIMATED DEMONSTRATION COSTS TO ACTUAL COOPERATIVE AGREEMENT AMOUNT

Demonstration Component	Independent Evaluator's Cost Estimate (1)	Estimated Percentage of Total Demonstration Costs[a] (2)	Allocation of Estimated Percentage to Actual Cooperative Agreement Amount (3)
Research-Related Costs	**$11,209,455**	**39**	**$10,935,713**
Intervention-Related Costs	**17,654,487**	**61**	**17,223,353**
Design Stage	4,415,167	15	4,307,346
Development of systems architecture	2,039,047	7	1,989,252
Purchase of case managers' workstations	39,535	<1	38,750
Development of software for HTUs	2,128,000	7	2,076,033
Recruitment of physicians and enrollees	208,585	<1	203,491
Implementation Stage	13,228,624	46	12,905,572
Purchase of HTUs	3,688,414	13	3,598,340
Installation of HTUs and training of participants	1,550,418	5	1,512,555
Lease of case management software	292,902	1	285,749
Information systems support	2,482,609	9	2,421,982
Case management and televisits	3,120,345	11	3,044,144
Screening and assessment of enrollees	168,732	<1	164,611
Quality improvement[b]	102,216	<1	99,720
Project management and other direct costs	1,822,988	6	1,778,470
Close-Out Stage (HTU De-Installation)	10,697	<1	10,435
Total Demonstration Costs	**$28,863,942**	**100**	**$28,159,066**

Source: The independent evaluator's estimates based on information obtained from the Consortium's technical proposal (from which information on staff hours had been deleted) and progress reports; a paper published by the demonstration team; information collected during site visits by the independent evaluator; the Web site of the Office of Grants and Contracts for Columbia University's Health Sciences Division; the input of a consultant in telemedicine; the input from the Consortium on salaries of demonstration staff, the staff's levels of effort, and the value of subcontracts; and the independent evaluator's research on market prices.

[a]These percentages are estimated from column (1).

[b]The research-related portion of this demonstration component is defined as "enrollee randomization and internal evaluation."

HTU = home telemedicine unit.

evaluator upon request, although salary information that can be linked to a specific individual's name or job title cannot be disclosed.) The cost outputs considered in the simulations were: (1) total intervention costs; (2) total design costs; and (3) annual cost per participant, including and excluding the design and HTU-deinstallation costs depreciated over four years of the demonstration's first phase.

The analysis found that the total intervention-related and per-participant costs are highly sensitive to the assumptions made about the HTU's software and hardware costs, which account for more than 90 percent of the variability in intervention and per participant costs. Moreover, these cost outcomes were not sensitive to variation in labor costs for case management and televisits, which explain less than one percent of the variance. In addition, unsurprisingly, nearly three-quarters of the total design costs are explained by the software development costs. These findings must be interpreted cautiously because the assumptions about the distribution of input costs are based on a heuristic interpretation of the demonstration's cost components.

B. CALCULATION OF MEDICARE EXPENDITURES

The independent evaluator calculated Medicare expenditures for each enrollee from claims data for the period 1999–2003.[115] It added expenditures for all episodes of care between randomization and the end of the study period (December 31, 2003) for the 1,665 enrollees in the

[115]The independent evaluator also calculated expenditures per enrollee for the year before randomization; as an indicator of recent use of health services, that amount also is a good predictor of expenditures and utilization during the follow-up period. The independent evaluator used this variable as a control in the estimation of regression-adjusted means of outcomes.

full sample (the *intention-to-treat* sample).[116] However, as noted in Chapter V, the independent evaluator constructed alternative samples to assess the sensitivity of the demonstration's impacts on Medicare expenditures. In these instances, it added expenditures for all episodes of care between randomization and the date of the event that defined the study period for each sample, such as the end of a six-month period of continuous enrollment after randomization (see Section D below).

The independent evaluator calculated annualized expenditures for each enrollee by multiplying the sum of expenditures for the study period by 12/*m,* where *m* denotes the number of months of enrollment from randomization through the end of the event that defined the study period for each sample (for instance, December 31, 2003, for the intention-to-treat sample).

In addition, because about five percent of enrollees were enrolled in a health maintenance organization for at least one month during the post-randomization period, and no claims records were available for Medicare beneficiaries enrolled in managed care, the independent evaluator adjusted the annualized expenditures per enrollee accordingly.[117] This adjustment is justified, as IDEATel would not be expected to have an effect on the capitation payment that Medicare pays the health maintenance organizations for providing health services to demonstration enrollees in

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[116]For claims for service episodes that straddled the dates on which the study period began or ended, the independent evaluator prorated the expenditures, using the percentage of the length of the episode that fell within the study period.

[117]Specifically, the independent evaluator excluded from the analysis enrollees who were continuously enrolled in a health maintenance organization between randomization and the end of the follow-up period. For enrollees who were enrolled in a health maintenance organization for a fraction of the study period, the independent evaluator subtracted the number of months of enrollment from the length of the interval between randomization and the end of study period (that is, *m*) when annualizing expenditures per enrollee.

managed care (that is, the intervention cannot affect the Medicare expenditures for demonstration enrollees in a health maintenance organization). Thus, the adjustment ensures that only the expenditures that IDEATel could affect are included in the analysis.

In addition to total Medicare expenditures, the independent evaluator calculated expenditures for Part-A–covered services only and for Part-B–covered services only. It also calculated Medicare expenditures for a number of specific services that the demonstration was expected to affect, as discussed in Chapter IV. (The services examined are hospitalization, emergency room use, skilled nursing facility care, home health care, durable medical equipment, outpatient hospital services, physician visits, laboratory services, and Other Part B services) (See Appendix B, Section C).

C. METHODS FOR ESTIMATING IMPACTS ON MEDICARE EXPENDITURES AND COSTS

The independent evaluator fitted a weighted linear regression model to each measure of Medicare expenditures, controlling for enrollees' characteristics at the time of randomization, using STATA (StataCorp 2003).[118] It also fitted this type of model separately, for each site.

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[118]The demographic characteristics included are age, race/ethnicity, sex, education, living arrangements, employment status, household income, previous knowledge of computers, length of Medicare enrollment, whether dually eligible for Medicare and Medicaid, whether enrolled in a health maintenance organization in the month before randomization, and Medicare expenditures during the year before randomization. The health characteristics are reason for Medicare entitlement and years since diabetes was diagnosed. Finally, the model included a binary indicator for the intervention group. As noted in Appendix B, Section C.4, a few categorical variables were constructed differently for the New York City and upstate regression models. For example, race/ethnicity was constructed as black/Hispanic/white for New York City, and as minority/nonminority for upstate New York, to reflect the degree of heterogeneity in the respective sites. In addition, models used in the analysis of the upstate site did not control for enrollment in a health maintenance organization, because very few enrollees were enrolled in managed care plans.

Weights were equal to the length of the period between randomization and the end of the study period (for instance, December 31, 2003, for the intention-to-treat sample). The independent evaluator predicted outcomes for treatment and control group enrollees, using the method described in Appendix B, Section C.4.

D. SENSITIVITY ANALYSIS OF THE IMPACTS OF THE DEMONSTRATION ON MEDICARE EXPENDITURES

In addition to examining differences in the demonstration's impacts on Medicare expenditures, by site, the independent evaluator assessed whether these impacts varied with (1) different specifications of the study sample, (2) expenditures greater than the 98th percentile, and (3) different subgroups defined by the intensity of use of the intervention. This analysis aims at assessing the robustness of the findings discussed in Chapter V.

1. Variations in the Definition of the Study Sample

The findings discussed in Chapter V correspond to an *intention-to-treat* analysis for all beneficiaries enrolled in the demonstration. This analysis is feasible because Medicare enrollment and claims records were available for the full sample of 1,665 enrollees, regardless of whether or not the enrollees still were enrolled in the demonstration by the end of the study period (December 31, 2003).[119] Alternative samples correspond to scenarios defined by data availability and enrollment status in the demonstration. The independent evaluator constructed

[119]The actual sample size was 1,616 enrollees. The independent evaluator excluded from the impact analysis on costs all enrollees who were continuously enrolled in a health maintenance organization between randomization and December 2003 (n = 48; see Section B). The independent evaluator also excluded one enrollee whose dropout date preceded her randomization date.

six additional samples: (1) all enrollees, but excluding Medicare expenditures between the time of dropout, when applicable, and December 31, 2003 (n = 1,613); (2) enrollees who remained continuously enrolled in the demonstration for 6 months after randomization (n = 1,427); (3) enrollees who remained continuously enrolled in the demonstration for 12 months after randomization (n = 1,125); (4) enrollees who remained continuously enrolled in the demonstration for 24 months after randomization (n = 1,010); (5) enrollees who remained continuously enrolled in the demonstration through the time of the Year 1 in-person interview (n = 1,262); and (6) enrollees who responded to a Year 1 interview, regardless of enrollment status at interview (n = 1,324). In each of these samples, Medicare expenditures were counted only between randomization and the event that defines the sample.[120]

The impact analysis with alternative samples found that, in most instances, the treatment–control difference in Medicare costs was substantially smaller than the difference estimated for the intention-to-treat, full sample. For example, for the sample of enrollees who remained continuously enrolled in the demonstration through the Year 1 in-person interview, the treatment–control difference was two-thirds of the difference for the intention-to-treat sample ($647 versus $994; Table F.3).

These findings suggest that, as expected, enrollees who remained continuously enrolled for some period after randomization had better outcomes (and lower expenditures) than did those who dropped out of the demonstration because of poor health or for other reasons. Moreover, the findings underscore the potential for bias in the impact estimates derived from samples that

[120]However, the evaluator counted expenditures for enrollees who died through the date of death reported in the Medicare enrollment records.

TABLE F.3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, BY EVALUATION GROUP AND STUDY SAMPLE
(Mean, in Dollars)

Sample	Sample Size	Evaluation Group		Difference (*p*-Value)
		Treatment	Control	
Year Before Randomization	**1,612**	**6,461**	**6,247**	**214 (.671)**
Full Sample—No Dropouts	1,616	8,901	7,907	994 (.125)
Full Sample—Factoring Dropouts	1,613	8,585	7,864	721 (.257)
6-Month Continuous Enrollment	1,427	6,934	5,994	940 (.217)
12-Month Continuous Enrollment	1,125	6,886	6,410	476 (.497)
24-Month Continuous Enrollment	1,010	7,460	6,513	947 (.140)
Continuously Enrolled Through the Time of the Year 1 In-Person Interview	1,262	6,613	5,966	647 (.277)
All Participants with Year 1 Interview, Regardless of Enrollment Status	1,324	6,562	5,953	609 (.288)

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c).

Note: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the event that defines the sample, and weighted by the length of the interval between randomization and the event that defines the sample. Means were predicted with linear regression models and controlling for baseline characteristics and outcomes. (See Section E of this appendix, for the list of characteristics.)

depart from the intention-to-treat analysis, primarily those that include only enrollees who remained enrolled in the demonstration.[121]

2. Variation to Large Expenditures

The independent evaluator also assessed the variation of the impact estimates for the intention-to-treat sample to large Medicare expenditures (that is, those exceeding the 98th percentile of the distribution of a specific outcome). People with serious health problems typically incur large expenditures by near the end of their life. Rerunning the impact analysis with capped (or truncated) expenditures allowed the independent evaluator to assess whether the estimated impact of the intervention is due to the influence of a few beneficiaries with unusually high use of Medicare-covered services.

Overall, the impact estimates are quite insensitive to unusually large expenditures (Table F.4). For the vast majority of estimates, capping expenditures at their 98th percentile resulted in neither a change of the sign of the difference between treatment group and control group expenditures nor to the statistical significance of the test of the difference in outcomes from zero between groups relative to the unadjusted (or uncapped) estimates. Only in a handful of instances, such as the treatment-control difference of total expenditures for upstate enrollees, did capping of expenditures result in a change of the statistical significance of this estimate from

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[121] An analysis of enrollees who were continuously enrolled in the demonstration for 24 months after randomization (n = 1,010) suggests no clear trend in the impacts of the demonstration on Medicare expenditures over time. In New York City, the treatment-control difference in total Medicare expenditures declined between the first and second year of enrollment (from $720 to $99). In contrast, in the upstate site, this difference increased substantially (from $568 to $2,067). None of the differences involved in the comparison are statistically significant (see Appendix F, Section D.1)

TABLE F.4

ESTIMATED DIFFERENCE IN ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, FOR UNCAPPED AND CAPPED EXPENDITURES BY SITE

	No Adjustment						Capped at 98th Percentile of Outcome					
	Total		New York City		Upstate		Total		New York City		Upstate	
	Difference	p-value	Difference	p-value	Difference	p-value	Difference	p-value	Difference	p-value	Difference	p-value
Total Medicare	993.92	0.125	799.98	0.474	1,136.78	0.127	753.23	0.159	359.46	0.689	1,139.52	0.077
Medicare Part A	721.68	0.175	803.33	0.392	663.22	0.261	564.60	0.196	531.57	0.480	656.28	0.174
Medicare Part B	272.24	0.161	-3.34	0.992	473.56	0.047	228.16	0.154	-88.17	0.737	471.14	0.019
Hospitalization	673.45	0.165	696.23	0.421	679.16	0.200	553.45	0.151	521.14	0.450	652.00	0.121
Skilled Nursing Facility Care	47.48	0.528	89.46	0.436	-15.67	0.874	27.30	0.578	68.88	0.313	-22.37	0.751
Emergency Room	8.50	0.387	7.58	0.482	9.99	0.525	13.05	0.071	7.41	0.428	17.98	0.096
Outpatient Hospital	88.53	0.291	-33.74	0.820	176.58	0.064	43.16	0.328	-53.85	0.469	113.22	0.035
Home Health Care[a]	25.32	0.699	45.56	0.698	6.64	0.926	8.26	0.869	-3.58	0.968	22.22	0.680
Durable Medical Equipment	81.73	0.061	18.80	0.774	130.28	0.026	57.05	0.111	-4.96	0.918	102.31	0.046
Physician Visits	-5.27	0.731	-26.18	0.336	17.00	0.292	-1.93	0.089	-21.24	0.388	17.73	0.258
Laboratory Services	-3.30	0.570	-7.06	0.397	4.06	0.620	-3.90	0.352	-4.55	0.468	0.37	0.949
Other Part B	82.44	0.440	9.32	0.951	140.30	0.356	94.67	0.254	31.87	0.804	149.84	0.175

Source: Table V.3 and IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003 a and 2003c)

[a]Includes both Part A and Part B expenditures.

non-significance to marginal significance (that is, from p-value equal to 0.127 to 0.077). Likewise, only in New York City, the treatment-control difference reversed sign for home health care and durable medical equipment expenditures between the uncapped and capped estimates (but the statistical significance of these differences did not change substantively).

3. Variation by Intensity of Use of the Intervention

As noted in Chapters II and IV, IDEATel was not designed to answer the question of whether the impacts of the demonstration resulted from the telemedicine intervention, from the intensive nurse management, or from both the intervention and the intensive management. Nevertheless, given the substantial variability in HTU use among treatment group enrollees , it might be informative to exploit this variability to examine whether participants who received more intervention had better outcomes (and lower Medicare expenditures) relative to those who received less of it.

Because televisits are one of the key HTU functions through which the intervention is delivered, the independent evaluator examined impact variation across subgroups defined by the frequency of use of this function. The independent evaluator examined impact variability across two subgroups: (1) whether participants participated in more than or fewer than the median annual number of televisits (that is, 9.3 visits per year) and (2) whether the participants participated in more than or few than one televisit per month. Enrollees in the treatment and control groups were then matched on their likelihood of being a *frequent* or *infrequent* user of televisits, given the baseline characteristics of each of them.[122] Under the assumption that the regression model

[122]The independent evaluator used a *propensity score* model to assign treatment group enrollees to one of the two categories of HTU use (see, for example, Agodini and Dynarski 2004). The

correctly identified comparison group members who were similar, on average, to treatment group enrollees with regard to their HTU use, the independent evaluator estimated impacts on Medicare expenditures for frequent and infrequent users, controlling for demographic and health characteristics at randomization.

The analysis suggests that the demonstration's impact on Medicare expenditures did not differ for frequent televisit users and for infrequent televisit users. Although enrollees in the treatment group in New York City who were frequent televisit users had lower Medicare expenditures than did their control group counterparts, the difference was not statistically significant.[123] These findings underscore the importance of an evaluation design that would have allowed for an assessment of whether the demonstration's outcomes were more influenced by the participants' interactions with their nurse case managers or by the participants' use of their HTUs. However, these findings must be interpreted with caution because treatment–control differences in each of the groups defined by use of televisits might be biased if treatment and control group members

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(continued)

model (logit) was fitted to data on televisit use *among treatment group members,* controlling for demographic and health characteristics at randomization. The propensity score model explained between 27 and 31 percent of the variance of the binary indicator of whether a participant participated in a number of televisits greater than the threshold frequency—a high percentage. The model then was used to predict the propensity of being a high or low user for *both* treatment and control group members. Enrollees whose propensity scores were higher than the median predicted score were assigned to the *frequent* category, and those whose scores were lower than the median score were assigned to the *infrequent* category. The model correctly assigned 77 percent of treatment group members who actually participated in televisits frequently (that is, high model *sensitivity*), and 75 percent of participants who participated in televisits infrequently (that is, high model *specificity*).

[123]For instance, the treatment–control difference in total Medicare costs is $2,232 versus $1,594 for infrequent and frequent users of televisits, respectively.

differed systematically with regard to characteristics that were not, or that could not, be included in the propensity score model that might be correlated with outcomes.

APPENDIX G

SUPPLEMENTAL TABLES
TO CHAPTER V

TABLE G.1

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, BY EVALUATION GROUP
(Mean, in Dollars)

	Evaluation Group		
Component/Services	Treatment	Control	Difference (*p*-Value)
Total Medicare	8,901	7,907	994 (.125)
Medicare Part A	4,833	4,111	722 (.175)
Medicare Part B	4,068	3,796	272 (.161)
Hospitalization	4,308	3,635	673 (.165)
Skilled Nursing Care	291	243	47 (.528)
Emergency Room	99	91	8 (.387)
Outpatient Hospital	1,031	943	88 (.291)
Home Health Care[a]	471	446	25 (.699)
Durable Medical Equipment	463	381	82 (.061)
Physician Office Visits	335	340	–5 (.731)
Laboratory Services[b]	45	49	–4 (.570)
Other Part B[c]	1,827	1,745	82 (.440)
Sample Size[d]	**818**	**797**	—

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c).

Notes: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the follow-up period (December 2003), and weighted by the length of the interval between randomization and December 2003 (see Appendix F). Means were predicted with linear regression models that controlled for baseline characteristics and outcomes. (See Appendix F, Section C, for the list of characteristics.)

The sum of Medicare costs, by type of service, is not equal to the total Medicare costs (or to the Part A or Part B components) because the list of services is not exhaustive.

[a]Includes both Part A and Part B expenditures.

[b]Refers to services rendered by a certified laboratory independent of an institution or a physician office.

[c]Refers to Part B-covered services, such as other physician services (for example, hospital visits, ophthalmology, and pathology); imaging services; laboratory services not independent of an institution or a physician office; minor procedures; medical supplies; therapy; and ambulance services.

[d]Refers to all enrollees in the study.

TABLE G.2

AVERAGE ANNUAL MEDICARE EXPENDITURES PER BENEFICIARY/PARTICIPANT IN THE UNITED STATES, NEW YORK STATE, AND IDEATel
(Dollars)

Population	Amount per Medicare Beneficiary/Participant[a]
United States	5,841
Beneficiaries with Diabetes	6,525[b]
New York State	7,483
IDEATel	17,221[c]

Source: Centers for Medicare & Medicaid Services (2004b), IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c), and Krop et al. (1999).

[a]Data correspond to 2001, except as noted.

[b]Data correspond to 1994–1996 and *have not* been adjusted by inflation for the period 1997–2001.

[c]Data correspond to 2000–2003. This estimate is equal to the sum of the average, annual Medicare expenditures for *all* 1,664 participants as randomized ($8,297) and the per-participant demonstration's costs ($8,924).

n.a. = not available.

TABLE G.3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, DEMONSTRATION SERVICES, AND TOTAL SERVICES, BY EVALUATION GROUP
(Mean, in Dollars)

	Evaluation Group		
Component/Service	Treatment	Control	Difference (*p*-Value)
Total Medicare-Covered Services	8,901	7,907	994 (.125)
Total Demonstration Services	8,924	0	n.a.
Total Services	17,825	7,907	9,918 (.000)
Sample Size[a]	**818**	**797**	—

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2003a and 2003c) and Table V.2.

Notes: Estimates have been adjusted for health maintenance organization enrollment during the period between randomization and the end of the follow-up period (December 2003), and weighted by the length of the interval between randomization and December 2003 (see Appendix F). Means were predicted with linear regression models that controlled for baseline characteristics and outcomes. (See Appendix F, Section C, for the list of characteristics.)

[a]Refers to all enrollees in the study.

n.a. = not applicable.