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Final Report to Congress on the Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration, Phases I and II

Final Report

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EXECUTIVE SUMMARY

A. OVERVIEW OF THE IDEATel DEMONSTRATION AND EVALUATION

The IDEATel demonstration and evaluation tested the effects of providing home-based telemedicine services to a large number of eligible Medicare beneficiaries who had diabetes mellitus and lived in medically underserved areas in New York City and upstate New York. *Telemedicine* is the use of telecommunications technology to deliver medical diagnostic, monitoring, and therapeutic services to health care users. It may be a promising way to deliver such services to people who—because of geographic, linguistic, or cultural barriers—would otherwise be expected to have poor access to high-quality diabetes care. To date, however, there is little rigorous evidence to demonstrate the clinical or cost effectiveness of home telemedicine, particularly in the Medicare program.

To address this knowledge gap, the U.S. Congress mandated the implementation and independent evaluation of the IDEATel demonstration, assigning oversight to CMS.[1] CMS, in turn, awarded a $28 million cooperative agreement to perform the demonstration to a consortium led by Columbia University College of Physicians and Surgeons and Columbia-Presbyterian Medical Center (the Consortium). The Consortium consisted 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, and several vendors (U.S. Department of Health and Human Services 2003).

The demonstration began in February 2000 and was originally scheduled to end in February 2004. However, Congress extended the demonstration and the evaluation for a second four-year period and the demonstration ended in February 2008.[2,3] In its mandate, Congress added $30 million to the funding, which consisted of $29 million for the cooperative agreement and about $1 million for the evaluation. The two four-year periods of the demonstration and the evaluation are known as Phase I and Phase II.

[1] Congress included the mandate for the demonstration in the Balanced Budget Act of 1997. 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.

[2] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized the extension of the demonstration.

[3] CMS granted the Consortium a no-cost extension of the demonstration for one additional year, so the cooperative agreement between CMS and the Consortium ends in February 28, 2009. No intervention-related services will be provided to demonstration enrollees during this extension.

Key demonstration objectives specified in the original legislation include (1) improving access to care and quality of life, and reducing overall health care costs for beneficiaries with diabetes mellitus through patient-provider telecommunications and increasing their physicians' adherence to guidelines; (2) developing a curriculum to train health professionals, particularly primary health care providers, in the use of medical informatics and telemedicine services; (3) demonstrating the application of advance home-based telemedicine functions, including video-conferencing from a patient's home, remote monitoring of a patient's medical condition, and individualized automated guidelines, to assist primary care providers in providing high quality care to the target population; (4) applying the technologies to beneficiaries with limited English-language skills; (5) developing standards for the application of telemedicine services; and (6) developing cost-effective models of primary care services in both managed care and fee-for-service environments.

CMS contracted with Mathematica Policy Research, Inc., to perform the mandated independent evaluation of the Consortium. The evaluation must include an assessment of impacts of telemedicine on increasing access to health care services, reducing Medicare costs, and improving quality of life. The original legislation specified that interim and final evaluation reports be submitted to Congress and required that the final report be submitted within six months of the demonstration's conclusion. The legislation authorizing the extension did not modify any aspect of the original authorization.

This report is the third, and final, one to Congress on the mandated evaluation. It updates the first and second reports, submitted to Congress in May 2003 and December 2005, and draws overall conclusions about the impact of the demonstration during both Phase I and Phase II (U.S. Department of Health and Human Services 2003 and 2005). The first interim report examined the original design and evolution of the demonstration and initial challenges the Consortium encountered during the first 21 months of implementation (February 2000 through November 2001). The second report addressed 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 during the first phase (February 2000 through October 2003). It also updated the evolution of the demonstration during this period. Overall, this study reflects a very targeted focus that is not consistent with, or necessarily generalizable to, other telemedicine research findings.

B. KEY GOALS AND FEATURES OF THE IDEATel INTERVENTION

IDEATel had clinical and behavioral goals for participants and referring physicians. In its original proposal and subsequent design documents, the Consortium listed IDEATel's primary clinical goals for participants as control of blood sugar and reduction or control of such risk factors as obesity, physical inactivity, high blood pressure, abnormal lipid levels, and smoking. The goal for physicians was to improve the quality of care by ensuring that care was provided as consistently as possible with clinical guidelines, including regular provision of diabetes-specific preventive care. To meet its goals for participants and physicians, the Consortium developed an

intervention that allowed (1) remote monitoring and case management, (2) web-based patient education, and (3) a curriculum for physicians. However, the Consortium did not consider Medicare costs as a key demonstration outcome.

Between December 2000 and October 2002, the demonstration recruited 1,665 eligible Medicare beneficiaries (775 in New York City and 890 in upstate New York) and randomly assigned them, in equal proportions, to a treatment or control group. These enrollees are known as Cohort 1 (Table 1). Subsequently, between December 2004 and October 2005, the demonstration recruited 504 eligible Medicare beneficiaries (174 in New York City and 330 in upstate New York) and randomly assigned them to a treatment or a control group. These enrollees are known as Cohort 2.

At baseline, Cohort 1 enrollees in the two sites differed from each other in several ways. Compared with enrollees in the upstate site, enrollees in New York City were more likely to be low-income, nonwhite, and Spanish-speaking (as opposed to English-speaking). New York City enrollees had fewer years of education than upstate enrollees and were less likely to have ever used a personal computer at baseline. In each site, the treatment and control groups were similar on all characteristics, as expected with random assignment (U.S. Department of Health and Human Services 2005).

In each site, Cohort 1 and Cohort 2 enrollees differed from each other in several ways. In New York City, Cohort 2 enrollees, compared to Cohort 1 enrollees, were younger, more likely to be Hispanic, less likely to have formal education, and less likely to have had experience with personal computers before enrolling in the demonstration. In upstate New York, Cohort 2 enrollees were younger, but substantially more likely to have had prior personal computer experience than Cohort 1 enrollees. As with Cohort 1, the Cohort 2 treatment and control groups in both sites were similar on all characteristics.

During the demonstration, control group members in both sites received diabetes care as usual from their primary care physicians. Treatment group participants also continued to see their primary care physicians *and* received a home telemedicine unit (HTU).[5] For the demonstration's first phase, the HTU (Generation 1) consisted of a personal computer with audio/video communication capabilities and devices for measuring blood sugar and blood pressure. For the second phase, the Consortium redesigned the Generation 1 HTU to address several features such as its large size and difficulty of use which Cohort 1 participants are suspected to have found unappealing and therefore may have inhibited use of the device. The redesigned HTU is known as Generation 2 or Generation 3 HTU, depending on the manufacturing date. The Generation 3 HTU had several advantages over the Generation 2 HTU, such as a cast aluminum case, higher screen resolution, and a smaller desktop "footprint," that is, the table or desktop surface area occupied by the machine (Columbia University 2005a).

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

TABLE 1

DISTRIBUTION OF ENROLLEES, BY SITE, EVALUATION GROUP, AND COHORT

Evaluation Group/Cohort	Site		Total
	New York City	Upstate New York	
Cohort 1			
Treatment	397	447	844
Control	378	443	821
Total	775	890	1,665
Cohort 2			
Treatment	86	163	249
Control	88	167	255
Total	174	330	504

Source: IDEATel tracking status file (Columbia University 2007a).

Demonstration participants could use the HTU (1) to measure and monitor blood pressure and blood sugar and transmit their measurements to a nurse case manager, (2) to communicate with a nurse case manager via audio/videoconferences known as "televisits", and (3) to access web-based chat rooms and educational materials available only to participants.

There was an important difference in the way staff in the demonstration sites interacted with referring physicians to adjust participants' diabetes treatment: upstate staff requested physicians' written, advance permission to adjust participants' diabetes treatment; by contrast, New York City staff sent recommendations to physicians by fax and then asked participants whether the recommendations had been implemented. This difference could contribute to between-site differences in the demonstration's estimated effects on clinical outcomes, as noted below.

C. KEY FINDINGS

The IDEATel demonstration met requirements established by Congress for implementation. However, the intervention as delivered was neither as intensive nor as technologically sophisticated as originally designed, since the Consortium encountered unexpected challenges and deliberately departed from its plans in some areas. For example, it abandoned its intent to hold televisits every two weeks with all participants, as demonstration leadership argued that the nurse case managers should determine the appropriate frequency for each participant in their caseload. Likewise, the Consortium disavowed the premise that use of advanced HTU functions was central to the intervention, as leadership revised their hypotheses about the connection between these functions and participants' well-being and motivation to self-care. The most important unplanned departure resulted from the inability of a key subcontractor to deliver Generation 2 or 3 HTUs to most participants, which meant that only a few participants were able to experience the planned Phase II technological improvements in the newer units.

The evaluation found IDEATel to be clinically effective in only one site and to have no effects on Medicare Part A and Part B expenditures or the use of expensive services, such as hospital

care. The findings reveal mixed success with the demonstration (Table 2). For example, the use rates of HTU functions, particularly televisits, declined steadily during the demonstration period for both cohorts. It is unclear what factors drove this trend, particularly because nurse case managers, instead of participants, initiated televisits. Particularly in New York City, the frequency of televisits in both sites would have been higher if participants had broken fewer appointments. The steady reduction of the intensity of use for all functions suggests that the novelty of the HTU wore off rapidly for both cohorts, but more important, the trend implies that the intervention was less likely to have effects even over longer follow-up periods.

In its first three years of operation, IDEATel had modest to large positive impacts on Cohort 1 enrollee communication with providers, patient self-care, and clinical indicators (results not shown). However, the impacts varied by site, and were greater in upstate New York. By the fourth year, the intervention had substantial and significant impacts on communication between participants and their health care providers across sites and cohorts, and on Cohort 1 participants' satisfaction with their diabetes care.

The treatment-control difference for IDEATel's key clinical outcomes—diabetes control, lipid levels, and blood pressure control—increased (diabetes control and lipid levels, Figure 1) or remained relatively constant (blood pressure control, not shown) across the first four years of operation among Cohort 1 enrollees upstate. Among Cohort 1 participants in New York City, treatment-control differences in lipid levels reached a maximum in Year 1, after which they became smaller in Years 2 through 4 and statistically significant for total cholesterol only in Year 3, and for both total cholesterol and LDL cholesterol in Year 4 (with no statistically significant differences in either outcome in Year 2) (Figure 1). Also for Cohort 1 participants in

TABLE 2

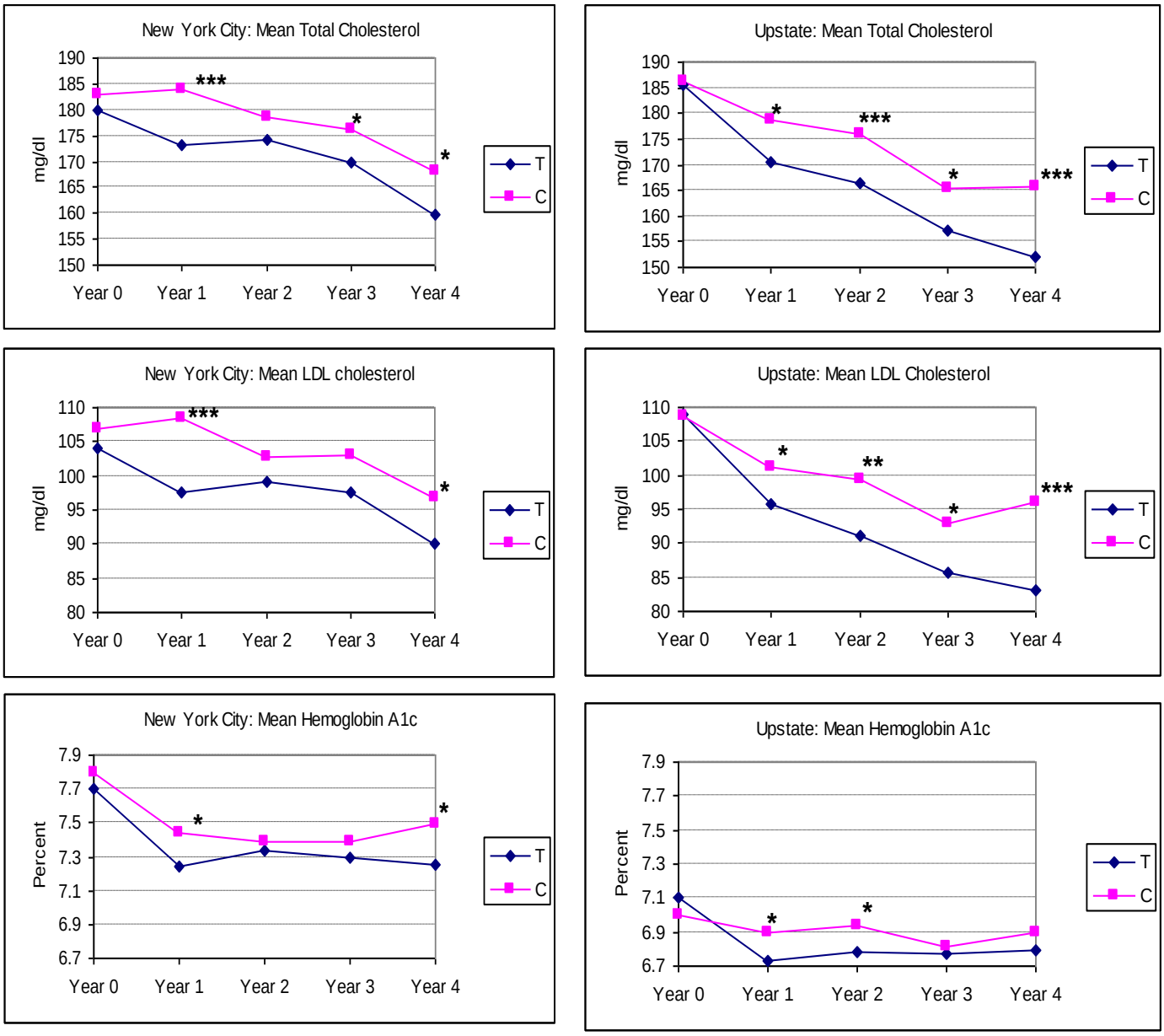
SUMMARY OF FINDINGS, BY SITE

Outcome	New York City	Upstate
Implementation Analysis		
HTU Use	Cohort 1: Declined rapidly over time Cohort 2: Declined rapidly over time	Cohort 1: Constant through 2003, but declined thereafter Cohort 2: Declined rapidly over time
Impact Analysis		
Communication with Providers and Patient Self-Care	Cohort 1: Large positive impacts[a] Cohort 2: Large positive impacts in year 1	Cohort 1: Large positive impacts[a] Cohort 2: Large positive impacts in year 1
Clinical Outcomes	Cohort 1: Little or no impact[a] Cohort 2: No significant impacts in year 1	Cohort 1: Large and sustained impacts[a] Cohort 2: No significant impacts in year 1
Service Use and Expenditures	Cohort 1: No Medicare savings in any year except year 3 No effects on hospitalizations or service use, for either cohort	Cohort 1: No Medicare savings in any year No effects on hospitalizations or service use, for either cohort
Total Medicare Costs	The demonstration's high costs ($8,662 per participant per year for Cohort 1 and $8,437 per participant per year for Cohort 2) were not offset by any savings in Medicare Part A or Part B expenditures	

[a] Findings are for all four years for which follow-up survey data were available.

FIGURE 1

IMPACTS OF IDEATel ON COHORT 1 ENROLLEES' SELECTED KEY CLINICAL AND LABORATORY OUTCOMES, BASELINE TO YEAR 4



Source: IDEATel annual in-person interviews, conducted from December 2000 through October 2006 (Columbia University 2007c).

*,**,*** Indicate treatment-control difference is statistically significant at the .05, .01, or .001 level, respectively.

New York City, there were statistically significant treatment-control differences in hemoglobin A1c in the first and fourth year of follow-up (Figure 1), but no significant effects on blood pressure control in any of the four years (not shown). There were no impacts on Cohort 2 participants in either site.

The high attrition rate in both sites, especially among treatment group members upstate (which was about 64 percent between baseline and year 4 for Cohort 1), reduces the evaluation's statistical power and raises the possibility of bias of unknown magnitude in the estimated impacts on these quality-of-care indicators. Therefore, the amount of confidence that can be placed in the results is limited.

Finally, Cohort 1 enrollees showed no sign of a trend toward cost savings in either site, and Cohort 2 showed no statistically significant treatment-control differences in Medicare expenditures during the first year of the intervention. Because the treatment and control groups had generally similar patterns of Medicare service use, there were no savings in Medicare service use to offset the demonstration's high costs (Table 3). Furthermore, the costs of the demonstration were much higher than those of comparable, clinically effective, home-based telemedicine programs that served patients with diabetes and used televisits with nurse case managers, in addition to in-home visits (Dansky et al. 2001; Johnston et al. 2000).

TABLE 3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, DEMONSTRATION SERVICE COSTS, AND TOTAL COSTS

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Cohort 1 (Both Phases)						
Total Expenditures for Medicare-Covered Services	$13,845	$12,961	$884 (.476)	$9,566	$8,450	$1,116 (.094)
Total Intervention-Related Costs[a]	$8,662	0	n.a.	$8,662	0	n.a.
Total Costs	$22,507	$12,961	$9,546 (.001)	$18,228	$8,450	$9,778 (.000)
Cohort 2 (Only Phase II)						
Total Expenditures for Medicare-Covered Services	$11,906	$11,661	$245 (.931)	$6,450	$8,694	–$2,244 (.132)
Total Intervention-Related Costs	$8,437	0	n.a.	$8,437	0	n.a.
Total Costs	$20,343	$11,661	$8,682 (.000)	$14,877	$8,694	$ 6,183 (.000)
Cohort 1 Sample Size	**379**	**358**	**-**	**446**	**442**	**-**
Cohort 2 Sample Size	**82**	**84**	**-**	**161**	**164**	**-**

[a] Total demonstration service costs for Cohort 1 are based on the arithmetic average of demonstration costs for Phase I and Phase II (from Table VII.2), weighted by the average length of time that Phase I participants were enrolled during each phase.
n.a. = not applicable.

D. CONCLUSION

The IDEATel demonstration met Congressional implementation requirements, although the Consortium's response to several implementation challenges weakened the ability of the demonstration to achieve its intended effects. IDEATel was clinically effective over the medium term in only one of two sites, which made it difficult to determine why it was more effective among participants upstate than in New York City or whether some demonstration features are essential for long-term impacts. The expectation that the demonstration could generate offsetting savings for Medicare services did not materialize, in spite of the six-year followup. The main driver of these costs was the size of the cooperative agreement allocated to the demonstration's operations, compounded with the use of very expensive HTUs. While an ongoing program similar to IDEATel could potentially have lower costs, it would be virtually impossible for such a program to generate cost savings, particularly because the intervention-related costs of the demonstration were excessive by any standard. Given the absence of effects on costs or services, however, even a less expensive version of this demonstration would not produce sufficient Medicare savings to offset demonstration costs. Furthermore, while IDEATel had similar clinical impacts as other interventions for individuals with diabetes, it cost far more.

PART 1: BACKGROUND

This report presents findings from the congressionally mandated Evaluation of the Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration, funded by the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (DHHS). IDEATel targeted Medicare beneficiaries who had diabetes mellitus and lived in New York City or upstate New York, in areas federally designated as medically underserved or as having a shortage of primary care health professionals. The evaluation focused on the two sites where IDEATel was implemented between February 2000 and February 2008. The evaluation drew on case studies of the demonstration. In addition, the study relied on in-person survey data (including clinical and laboratory outcomes) collected annually of all active demonstration enrollees. The study also used data collected from the interactions of demonstration enrollees with the technology used to deliver the intervention. Finally, the study used Medicare enrollment and claims data on all enrollees over the life of the study.

Mathematica Policy Research, Inc. (MPR) conducted the independent evaluation under contract to CMS. This is the third and final report submitted to Congress. The first two interim reports to Congress were submitted in May 2003 and December 2005.

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I. OVERVIEW OF THE IDEATel DEMONSTRATION AND EVALUATION

The IDEATel demonstration and evaluation tested for effects of providing home-based telemedicine services to a large number of eligible Medicare beneficiaries who had diabetes mellitus and lived in New York City and upstate New York medically underserved areas. Telemedicine is the use of telecommunications technology to deliver medical diagnostic, monitoring, and therapeutic services to health care users. It may be a promising way to deliver such services to people who—because of geographic, linguistic, or cultural barriers—would otherwise be expected to have poor access to high-quality diabetes care. To date, however, there is little rigorous evidence to demonstrate either the clinical or the cost effectiveness of home telemedicine, particularly in the Medicare program.

To address this knowledge gap, the U.S. Congress mandated the implementation and independent evaluation of the IDEATel demonstration, assigning oversight to CMS.[1] CMS in turn awarded a $28 million cooperative agreement to perform the demonstration to a consortium led by Columbia University College of Physicians and Surgeons and Columbia-Presbyterian Medical Center (the Consortium). The Consortium consisted 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 (U.S. Department of Health and Human Services 2003).

The demonstration began in February 2000 and originally was to end in February 2004. However, Congress extended the demonstration and the evaluation for a second four-year period and the demonstration ended in February 2008.[2,3] In its mandate, Congress added $30 million to the funding, which consisted of $29 million for the cooperative agreement and about $1 million for the evaluation. The two four-year periods of the demonstration and the evaluation are known as Phase I and Phase II.

[1] Congress included the mandate in the Balanced Budget Act of 1997. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 amended the mandate by clarifying that the target population should reside in medically underserved areas and by prohibiting cost sharing for demonstration services. Appendix A contains copies of both laws.

[2] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 authorized the extension of the demonstration.

[3] CMS granted the Consortium a no-cost extension of the demonstration for one additional year, so the cooperative agreement between CMS and the Consortium ends in February 28, 2009. No intervention-related services will be provided to demonstration enrollees during this extension.

Key demonstration objectives specified by the original legislation include:

- Improving the access to care and quality of life, and reducing overall health care costs, for beneficiaries with diabetes mellitus through patient-provider telecommunications, and increasing their physicians' adherence to guidelines
- Developing a curriculum to train health professionals, particularly primary health care providers, in the use of medical informatics and telemedicine services
- Demonstrating the application of advance home-based telemedicine functions, including video-conferencing from a patient's home, remote monitoring of a patient's medical condition, and individualized, automated guidelines, to assist primary care providers in providing high quality care to the target population
- Applying the technologies to beneficiaries with limited English-language skills
- Developing standards for the application of telemedicine services and medical informatics
- Developing cost-effective delivery models of primary care services in both managed care and fee-for-service environments

As noted, Congress also mandated an evaluation of the demonstration, and CMS contracted with MPR to perform this evaluation independently of the Consortium. The evaluation must include an assessment of the impacts of telemedicine on improving access to health care services, reducing Medicare costs, and improving quality of life.

The original legislation specified that interim and final evaluation reports be submitted to Congress. Specifically Congress specified the final report to be submitted within six months of the conclusion of the demonstration. The legislation authorizing the extension of the demonstration did not modify any aspect of the original authorization.

This report is the third and final one to Congress on the mandated evaluation. It updates the first and second reports, submitted to Congress in May 2003 and December 2005, and draws overall conclusions about the impact of the demonstration during both Phase I and Phase II (U.S. Department of Health and Human Services 2003 and 2005). The first interim report examined the original design of the demonstration, the evolution of the demonstration, and the challenges the Consortium encountered during the first 21 months after implementation (February 2000 through November 2001). The second report drew conclusions from Phase I on three major issues laid out in the legislative mandate: (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 during the first phase (February 2000 through October 2003).

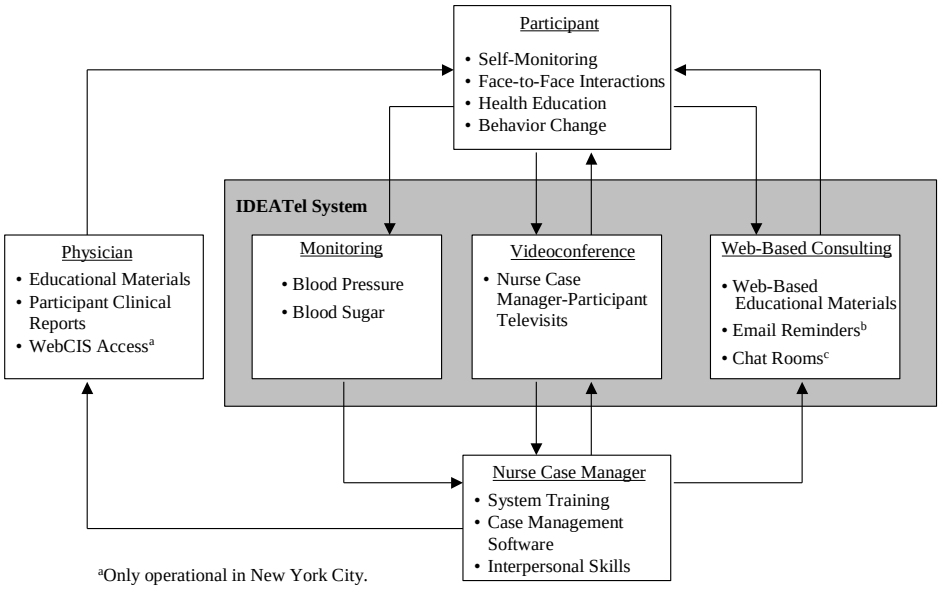
II. KEY GOALS AND FEATURES OF THE IDEATel INTERVENTION

IDEATel had clinical and behavioral goals for participants and referring physicians (Shea et al. 2006). The primary clinical goals for participants were (1) control of blood sugar; and (2) reduction or control of such risk factors as obesity, physical inactivity, high blood pressure, abnormal lipid levels, and smoking. The demonstration's goal for physicians was to improve care quality by ensuring that care was provided as consistently as possible with clinical guidelines, including regular provision of diabetes-specific preventive care. To meet its goals for participants and physicians, the Consortium developed an intervention that allowed remote monitoring and case management, web-based patient education, and a curriculum for physicians (Figure II.1). However, the Consortium did not considered Medicare costs as a key demonstration outcome.

Between December 2000 and October 2002, the demonstration recruited 1,665 eligible Medicare beneficiaries (775 in New York City and 890 in upstate New York) and randomly assigned them, in equal proportions, to a treatment or control group. These enrollees are known as Cohort 1 (Table II.1). Subsequently, between December 2004 and October 2005, the demonstration recruited 504 eligible Medicare beneficiaries (174 in New York City and 330 in upstate New York) and randomly assigned them to a treatment or a control group. These enrollees are known as Cohort 2.

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.

TABLE II.1

DISTRIBUTION OF ENROLLEES, BY SITE, EVALUATION GROUP, AND COHORT

Evaluation Group/Cohort	Site		Total
	New York City	Upstate New York	
Cohort 1			
Treatment	397	447	844
Control	378	443	821
Total	775	890	1,665
Cohort 2			
Treatment	86	163	249
Control	88	167	255
Total	174	330	504

Source: IDEATel tracking status file (Columbia University 2007a).

At baseline, Cohort 1 enrollees in the two sites differed from each other in several ways. Compared with enrollees in the upstate site, enrollees in New York City were more likely to be low-income, nonwhite, and Spanish-speaking (as opposed to English-speaking). New York City enrollees had fewer years of education than upstate enrollees and were less likely to have ever used a personal computer at baseline. In each site, the treatment and control groups were similar on all characteristics, as expected with random assignment (U.S. Department of Health and Human Services 2005).

In each site, Cohort 1 and Cohort 2 enrollees differed from each other in several ways. In New York City, Cohort 2 enrollees, compared to Cohort 1 enrollees, were younger, more likely to be Hispanic, less likely to have formal education, and less likely to have had experience with personal computers before enrolling in the demonstration. In upstate New York, Cohort 2 enrollees were younger, but more substantially more likely to have had prior personal computer experience than Cohort 1 enrollees. In each site, however, the Cohort 2 treatment and control groups were similar on all characteristics (Moreno et al. 2007).

During the demonstration, control group members in both sites received diabetes care as usual from their primary care physicians. Treatment group participants also continued to see their primary care physicians, *and* they received a home telemedicine unit (HTU).[2] For the demonstration's first phase, the HTU (Generation 1) consisted of a personal computer with audio/video communication capabilities and devices for measuring blood sugar and blood pressure (Figure II.2, right panel). For Phase II, the Consortium redesigned the Generation 1 HTU to address several features such as its large size and difficulty of use that Cohort 1 participants had found unappealing (Figure II.2, left panel). The redesigned HTU is known as

[2] 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.

Generation 2 or Generation 3, depending on the manufacturing date. The Generation 3 HTU had several advantages, such as a cast aluminum case, higher screen resolution, and a smaller desktop "footprint," that is, the table or desktop surface area occupied by the machine. (Columbia University 2005a).

Demonstration participants could use the HTU:

- To measure and monitor blood pressure and blood sugar and transmit their measurements to a nurse case manager
- To communicate with a nurse case manager through audio/videoconferences known as "televisits"
- To access web-based chat rooms and educational materials available only to participants[3]

FIGURE II.2

THE GENERATION 2 HTU AND ITS PREDECESSOR

Generation 2 Generation 1

Source: Foster et al. (2006).

[3] However, email reminders were not systematically implemented in the upstate site. Chat rooms were implemented in both sites, but only one participant ever used them. WebCIS access was operational only in New York City (U.S. Department of Health and Human Services 2005).

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III. DATA AND METHODS

MPR collected information through case studies of the IDEATel demonstration, including Consortium leadership and staff, participating physicians, and demonstration enrollees assigned to the treatment group. The evaluation also drew on (1) annual, in-person surveys of treatment and control group enrollees; (2) log-use data of the interactions of participants with their HTUs; and (3) Medicare enrollment and claims data, all of which were collected by the Consortium. Table III.1 summarizes the major features of the analysis.

TABLE III.1

ANALYTIC APPROACH SUMMARY

Comparison	Key Measures Used	Primary Data Sources
Implementation analysis	Whether IDEATel was implemented as Congress intended	Periodic site visits and telephone discussions with Consortium leadership and staff, participating physicians, and participants[a] Demonstration documentation
Analysis of HTU	Frequency of use of specific HTU functions and patterns of use over time across cohorts	HTU-use log data[b]
Impacts on behavioral, physiologic, and other health-related outcomes	Enrollees' self-reported communication with providers Enrollees' self-reported behavior Selected clinical and laboratory outcomes Enrollees' health-related quality of life Enrollees' satisfaction with diabetes care	Annual, in-person survey data[b]
Impacts on use of Medicare-covered services and costs	Medicare-covered service use Medicare expenditures Costs of implementing the demonstration	Medicare claims data[b] Demonstration documentation

Source: Columbia University (2007a-d).

[a] MPR selected the samples of participating physicians and participants who had given consent to be interviewed from lists prepared by the Consortium, following their IRBs' guidelines.

[b] To ensure confidentiality, the Consortium collected these data and shared them with MPR *without* individual-level identifiers.

The analyses were conducted separately for the New York City site and the upstate site because a) some aspects of the intervention implementation at the sites were quite different, and b) enrollees from each site differed markedly on many major characteristics.

To assess implementation of the demonstration, the analysis synthesized information from site visits, telephone calls, and demonstration documentation. Site visits and telephone discussions with Consortium leadership and staff took place during fall/winter 2001, fall 2002, fall 2003,

winter 2005, and winter 2007 (U.S. Department of Health and Human Services 2003 and 2005). The interviews with participating physicians and treatment group enrollees took place in winter 2007 (Foster et al. 2008).

To assess how participants interacted with the HTU, the analysis examined the time between installation of the HTU in the home and its first use, frequency of use, and the patterns of use over time from log-use data. It also compared the experience of Cohort 1 and Cohort 2 participants during the first two years after the start of HTU installation for each phase, controlling for a standard set of baseline characteristics. This analysis relied on HTU-use data for December 2000 through February 2007 for Cohort 1 and for December 2004 through February 2007 for Cohort 2.

To assess impacts of the intervention on behavioral, physiologic, and other health-related outcomes, the analysis compared outcomes of treatment and control group enrollees using regression models that controlled for the baseline characteristics noted above and baseline values for the outcomes in question (Moreno et al. 2007).[4] This analysis used the longitudinal survey data collected at baseline and at up to four follow-up annual interviews conducted for Cohort 1 through February 2007, the end of demonstration operations. Likewise, the analysis used the baseline and first annual interviews conducted through February 2007 for Cohort 2.[5]

To also assess impacts of the intervention on the use of Medicare-covered services and costs, the analysis compared outcomes of treatment and control group enrollees using regression models similar to those described above. This analysis used Medicare enrollment and claims data from 1999 through 2006.

Finally, to assess the costs of the demonstration implementation, the analysis synthesized information from demonstration documents and market prices of products and services used in the demonstration, according to a methodology developed for the Phase I analysis (U.S. Department of Health and Human Services 2005).

[4] 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, the evaluation cannot determine whether the clinical impacts of the demonstration resulted from the telemedicine intervention, the intensive nurse-case management, or both (U.S. Department of Health and Human Services 2005).

[5] For Cohort 1, data on the fifth and sixth follow-up annual interviews were not available for enrollees whose annual interview data had not come up by the end of the study period (that is, February 27, 2007). Therefore, the analysis did not include these data. For Cohort 2, data on the second follow-up interview were available only for a small number of enrollees. As a result, the analysis did not use data from this round of in-person interviews.

PART 2: FINDINGS

Findings from the independent evaluation are presented in Part 2. Chapter IV describes (1) the design and implementation of the demonstration's two phases, including recruitment of physicians and Medicare beneficiaries; (2) the challenges the Consortium encountered with the technical design of the HTU; (3) the implementation of the intervention (that is, intensive nurse case management delivered through the HTU). Chapter V describes the HTU use patterns by Cohort 1 and Cohort 2 treatment group enrollees. The subsequent chapters, VI and VII, highlight the findings from the impact analysis. Chapter VI describes the impacts of the intervention on behavioral, physiologic, and other health-related outcomes. Chapter VII describes the impacts on use of Medicare-covered services and expenditures and summarizes the demonstration's implementation costs.

The Congressionally mandated evaluation found that the IDEATel demonstration met Congressional implementation requirements, despite numerous challenges that arose during implementation, but not its cost-saving goals. The Consortium's responses to several of these challenges may have affected the ability of the demonstration to achieve its intended effects. In addition, the evaluation found IDEATel to be clinically effective in only one site and not cost-saving. The findings suggest mixed success. For example, rates of HTU use steadily declined during the demonstration period for both cohorts, but the intervention had substantial and significant impacts on communication between participants and their health care providers across sites and cohorts, and on Cohort 1 participants' satisfaction with their diabetes care. The treatment-control difference for diabetes control, lipid levels, and blood pressure control increased or remained constant across the first four years of the demonstration among Cohort 1 enrollees in the upstate site. However, treatment-control differences in these outcomes for Cohort 1 participants in New York City over the four years were of small magnitude and often did not reach statistical significance. There were no impacts on Cohort 2 participants in either site. Effects on service use and costs were unambiguous, however, with no trend toward cost savings in either site for Cohort 1 enrollees and, for Cohort 2, no statistically significant treatment-control group differences in Medicare expenditures during the first year of the intervention. The treatment and control groups generally had similar patterns of Medicare service use. As a result, there were no savings in Medicare service use to offset the demonstration's high costs.

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IV. IDEATel IMPLEMENTATION

This chapter (1) confirms that the IDEATel demonstration met Congressional implementation requirements; (2) describes major challenges that arose during implementation; and (3) discusses how the challenges, and in some cases the Consortium's responses, may have affected the demonstration's ability to achieve its intended effects.

The chapter draws information from qualitative sources (semistructured interviews). It refers to other chapters that present quantitative evidence to corroborate (or refute) the qualitative findings. The chapter proceeds chronologically from Phase I to Phase II.

PHASE I

Phase I implementation of the IDEATel demonstration was successful by several measures. The Consortium met its enrollment target, installed HTUs in homes of participants in treatment groups, and conducted periodic televisits with most of those participants.[6]

These achievements came despite major challenges. One instance is the enrollment of beneficiaries which took about a year longer than planned, because physicians and beneficiaries were less willing to participate than the Consortium expected. Moreover, the HTU that participants received was not the all-in-one device the Consortium had planned to install, but an alternative model made up of various off-the-shelf components. Televisits did not occur nearly as frequently as prescribed by the Consortium and were often marred by technical difficulties. Finally, disenrollment among participants was quite high. Anecdotal evidence suggested that the size and the complexity of the HTU were sources of participant dissatisfaction.

Physicians and Beneficiaries Were Less Willing to Participate than Expected

The Consortium recruited Medicare beneficiaries through referrals from primary care physicians in selected practices in New York City and upstate New York. The New York City site (led by Columbia University) enrolled beneficiaries from northern Manhattan and the Bronx. The upstate New York site (led by SUNY Upstate Medical University) enrolled beneficiaries from a 30,000-square-mile area in upstate New York. As congressionally required, the demonstration was open to beneficiaries in the fee-for-service Medicare program and Medicare managed care

[6] The Consortium that Columbia University assembled to implement the demonstration met Congressional requirements for organizational membership and was stable throughout both phases of the demonstration; therefore, it is not discussed further.

plans.[7] Physicians who agreed to participate identified potentially eligible beneficiaries from among their patient rosters and told them about the demonstration.

The Consortium then screened beneficiaries for eligibility by telephone, adding inclusion and exclusion criteria to Congress's specifications for the target population. Medicare beneficiaries in designated areas were eligible for the demonstration if they (1) were aged 55 or older, (2) spoke English or Spanish, and (3) were being treated for diabetes by diet and oral medications and/or insulin. Beneficiaries with moderate or severe cognitive, visual, or physical impairment or with severe comorbid disease were not eligible. Neither literacy nor prior computer experience, however, was a criterion for or against eligibility.

The original enrollment target for the demonstration was 1,500 beneficiaries in total. However, persuading physicians to participate was more difficult than the Consortium expected and eligible beneficiaries refused more often than expected. Among beneficiaries who did enroll, an unexpectedly large proportion dropped out during their first year. Concerned about the loss of sample, the Consortium increased the enrollment target by 10 percent. Enrollment in New York City was completed in April 2002; enrollment upstate took until October 2002, about 14 months after the original target date. As noted in Part I, Chapter II, 1,665 beneficiaries enrolled (Figure IV.1).

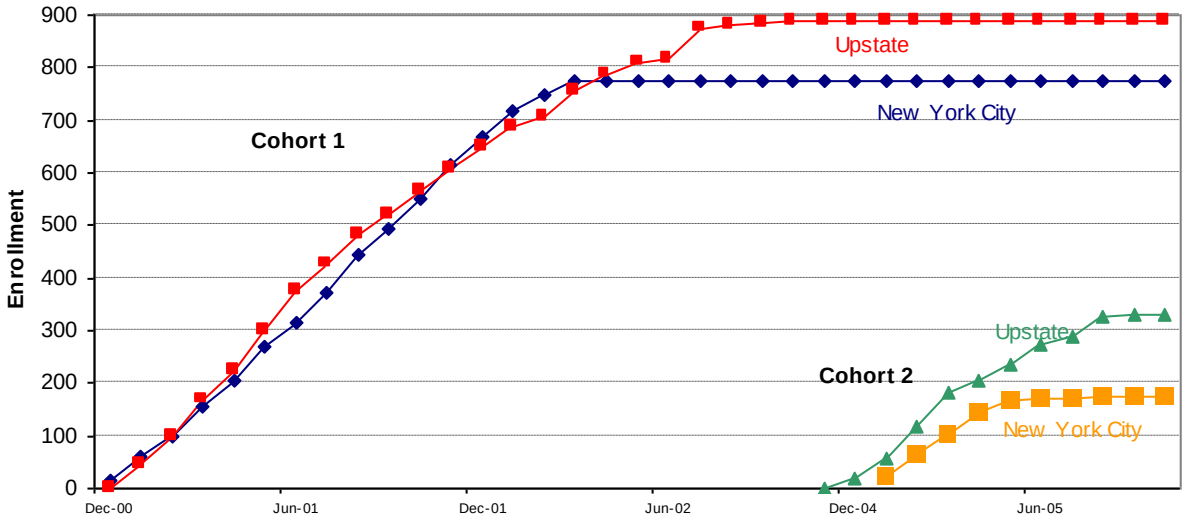
The Technical Design of the HTU Changed Dramatically Early in Phase I

The HTU that the Consortium originally planned to use for the IDEATel intervention was an all-in-one device available from its subcontractor, American TeleCare, Inc. (ATI). But by the time the intervention started in February 2000, ATI had stopped supplying that device. No close substitute existed, so the Consortium and ATI configured a new HTU—which became known as the Generation 1 HTU—from off-the-shelf components. Designing and assembling the new HTUs, and addressing compatibility issues with another contractor's case management software, took 10 months (until December 2000) to resolve.

[7] At baseline, nine percent of Phase I enrollees in New York City and one percent of enrollees in upstate New York were enrolled in a health maintenance organization (HMO) in the month before randomization. For Phase II, eight percent of enrollees in New York City and two percent of enrollees in the upstate site were enrolled in an HMO (Moreno et al. 2007). As discussed in Appendix D, Section B, the analysis excluded HMO enrollees from our estimates of Medicare expenditures because IDEATel could not affect their expenditures.

FIGURE IV.1

CUMULATIVE ENROLLMENT IN THE IDEATel DEMONSTRATION, COHORTS 1 AND 2, BY SITE



Source: IDEATel tracking status file (Columbia University 2007a).

The redesign of the HTU had consequences for participants. The HTU was very large because of all the components (personal computer with internal modem, keyboard, mouse, video camera, speakers, microphone, glucose meter, and blood pressure meter). A computer cart was required to hold all the equipment and conceal wires that participants might trip on. Moreover, the HTU could be difficult to use for some participants because the new HTU was based on a personal computer. Therefore, the Consortium designed a "launch pad" that let participants perform four basic functions at the press of a button, without typing commands or using the mouse to manipulate a cursor. The launch pad made the HTU easier to use, but also enlarged its "footprint."

The Intervention Was Delivered as Mandated, but Engaging Participants and Physicians Was Challenging

Phase I of the IDEATel intervention had four components: (1) participants using the HTU to have televisits with nurse case managers; (2) participants using other HTU functions for self-monitoring and education; (3) communications between IDEATel staff and referring physicians; and (4) education of primary care physicians in telemedicine.

Televisits. Televisits were a major component of the IDEATel intervention. By providing regular interaction between participants and nurse case managers (who were positioned at

workstations in New York City or Syracuse), televisits were expected to help participants become more knowledgeable about diabetes and self-care, improve their attitude toward their disease, and motivate behavioral change.[8] Consortium staff reported that protocols for the televisits and case management supervision worked well. The nurse case managers hired for the project were well qualified and exhibited little turnover.

Televisits were to occur every two weeks, be scheduled in advance, and last about 30 minutes each. In reality, IDEATel nurse case managers found that many participants did not want to schedule such frequent televisits, a preference nurses attributed to participants' busy lives. In New York City, many participants were said to skip televisits even though they had been scheduled. As a result, televisits actually occurred an average of every four to eight weeks, rather than every two weeks.[9]

Many participants had difficulty connecting to televisits. To connect with the Generation 1 HTU, participants had to answer a regular telephone call from a nurse, hang up, activate the HTU, and then answer a second call from the nurse using the HTU launch pad. This process confused many participants and could be interrupted by incoming calls from other sources. Nurses and participants were frustrated that part of many televisits was devoted to connecting and other technical issues, rather than to the participants' clinical and behavioral progress. By the end of Phase I, staff said most participants who were still taking part in the intervention were able to connect to televisits.

Other HTU Functions. Between televisits, IDEATel participants were supposed to measure their blood sugar and blood pressure levels and share the information with their nurse case manager. With the Generation 1 HTUs, participants shared their measurements by uploading the data themselves. According to the nurse case managers interviewed late in Phase I, most participants were able to upload their blood pressure and blood glucose measurements, and many were able to monitor their clinical data. Sometimes, however, participants forgot to perform the upload or inadvertently uploaded the same data multiple times—the HTU gave no indication as to when transmission had succeeded.

Participants could also use the HTU to exchange email with nurse case managers and visit the web pages of the American Diabetes Association (ADA). According to nurse case managers, only about half the participants knew how to access email late in Phase I. Although the nurses thought about half the participants also knew how to access the ADA web pages, they believed few actually had done so. In addition, Consortium staff reported that few participants had used

[8] In the upstate site only, some participants had televisits with a dietitian as well as a nurse case manager. However, it is unclear whether this staff combination resulted in the higher frequency of televisits or fewer broken appointments than in New York City in the absence of a suitable control group.

[9] Chapter V presents an analysis of the frequency and duration of televisits based on HTU log records.

their HTUs to enter behavioral goals (such as for exercise), record their exercise activity, or send email to nurse case managers.[10]

The Consortium tried to increase participants' proficiency with the HTUs. It developed a video tutorial that was believed to gradually increase participants' facility, and expected that participants would become more willing to use the HTUs as their skills grew. However, by the third year of the demonstration, staff realized that HTU use was still not increasing. To understand participants' difficulties, an expert on human-machine interactions from Columbia University's Department of BioInformatics analyzed HTU use among a subset of participants who enrolled during the second year (Kaufman et al. 2003a and 2003b).

Based on the expert's findings, Consortium staff made several changes. 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. Between July 2002 and January 2003, staff were able to train 203 of 359 participants in New York City (57 percent) and 350 of 379 in upstate New York (92 percent).[11] This effort required the hiring of a new staff member to train some Spanish-speaking participants in New York City, and the rehiring of the two nurses who originally installed the HTUs in upstate New York.

Communication Between IDEATel Staff and Referring Physicians. Referring physicians received periodic recommendations from IDEATel nurse case managers about prescribing medications or modifying dosages to bring participants in line with blood sugar, blood pressure, and cholesterol guidelines. IDEATel endocrinologists reviewed and approved these recommendations before they were sent to physicians. In Phase I, Consortium staff said physicians seemed receptive to the recommendations for their patients.

There was an important difference in the way staff in the demonstration sites interacted with referring physicians. Upstate staff requested physicians' written, advance permission to adjust participants' diabetes treatment. By contrast, New York City staff sent recommendations to physicians by fax, then asked participants whether the recommendations had been implemented. Because the upstate site was geographically vast, referring physicians were unlikely to worry about losing patients to the Joslin Diabetes Center in Syracuse and thus may not have been concerned about direct intervention by the demonstration. The New York City intervention, however, occurred in a relatively small area, and the Consortium did not want to be viewed as competing for physician's patients. This difference in the sites' ability to adjust participants'

[10] Consortium staff said that chat rooms (mentioned in Chapter II, Figure II.1) were never used, with one exception (U.S. Department of Health and Human Services 2005).

[11] These numbers refer to participants with HTUs as of July 1, 2002. The retraining effort required the hiring of a new staff member to train some participants in New York City in Spanish, and the rehiring of two nurse installers who originally installed the HTUs in upstate New York. In New York City, many participants reportedly broke their retraining appointments or were unavailable for this training (U.S. Department of Health and Human Services 2005).

diabetes treatment could have contributed to the somewhat larger and more sustained treatment-control differences on some of the clinical outcomes (such as lipid levels and blood pressure control) seen in Upstate New York compared to New York City.[12]

Education of Primary Care Physicians. The Consortium began work on the Congressionally mandated objectives of physician education and development of telemedicine standards in 2002 (Columbia University 2003b). It developed a physician's syllabus about telemedicine and posted it 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 in April 2003 held a webcast that offered participating physicians credit for continuing medical education. The online syllabus is still available at [www.ideatel.org/syllabus/index.html].

Participant Disenrollment Was Unexpectedly Common in Phase I

According to its technical proposal to CMS, the Consortium expected 15 percent of the treatment group and 20 percent of the control group to disenroll from the demonstration by the end of its second year. In fact, 15 percent of the treatment group dropped out (12 percent) or died (3 percent) within only one year of enrollment.[13] As noted, the Consortium compensated by enrolling about 10 percent more than the 1,500 it had originally targeted. In addition, one of the study investigators personally telephoned participants who planned to drop out and also asked their physicians to urge the participants to reconsider. Finally, the ultimate goal of the retraining effort described above was to make participants feel more positive and confident about using the HTU. (Figure IV.2 shows the number of active participants over time, including dropouts and new enrollees.)

THE TRANSITION FROM PHASE I TO PHASE II

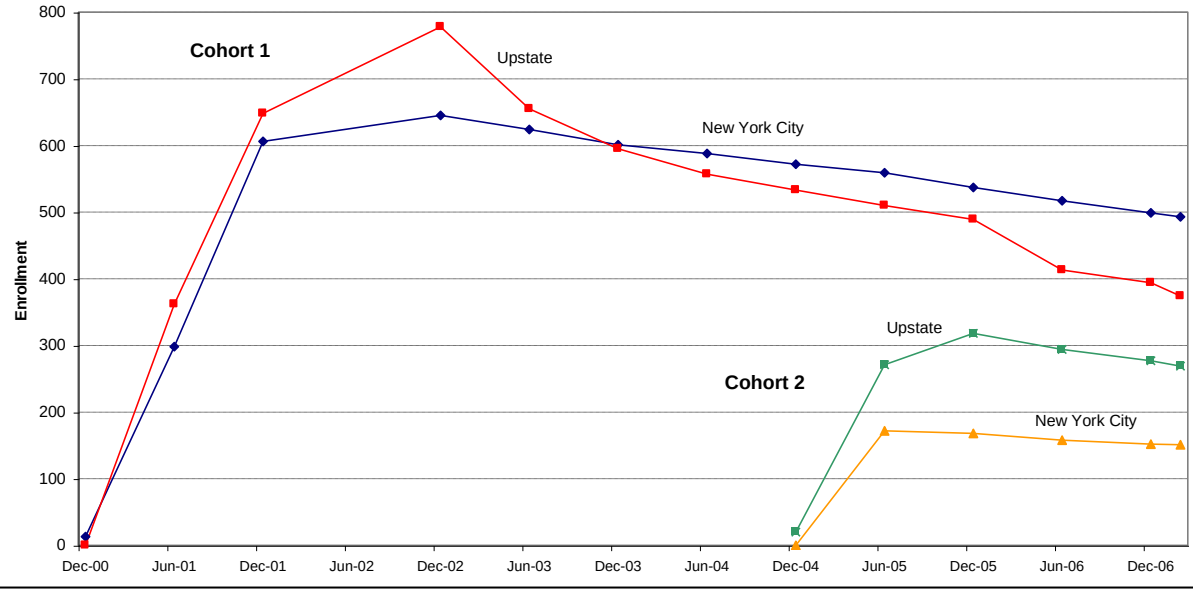
Phase II of IDEATel, which began February 28, 2004, was an opportunity for the Consortium to follow participants for a longer time and improve the intervention based on lessons from Phase I. The improvements that the Consortium hoped to realize included making the HTU more physically acceptable to participants; making it easier for participants to connect to televisits and transmit health data; increasing participation in scheduled televisits; simplifying the HTU user interface; and increasing the effectiveness of technical support to participants. All these improvements were to hinge on a redesigned HTU for participants—known as the Generation 2 HTU—and a more effective workstation for nurse case managers. The major Phase I lessons and the responses the Consortium had planned for Phase II appear in Table IV.1.

[12] Data were unavailable on (1) the number of upstate physicians who granted permission to IDEATel staff, and (2) the frequency with which New York City physicians implemented changes recommended by IDEATel staff. Staff *estimated* that half the upstate physicians would preauthorize recommended changes to dosages in Phase II. They said New York City physicians seemed more amenable to changes in Phase II than in Phase I.

[13] Chapter VI presents the distribution of reasons for disenrollment by period.

FIGURE IV. 2

ACTIVE ENROLLEES IN THE IDEATel DEMONSTRATION, COHORTS 1 AND 2, BY SITE



Source: IDEATel tracking status file (Columbia University 2007a).

TABLE IV.1

PHASE II RESPONSES TO PHASE I LESSONS

Phase I Lesson	Phase II Response
Voluntary sample attrition was higher than expected	Recruit a new cohort (Cohort 2) of about 200 demonstration enrollees in each site
Participants found the HTU large and cumbersome	Design a new HTU—smaller and with fewer components
Participants often missed scheduled televisits (in part because of the intrusiveness of televisits)	Make televisits less intrusive; nurse case manager will not see participants without their permission
Participants had difficulty connecting to televisits	Introduce automatic "call conversion" so that connection requires only the pressing of a single button
Participants had difficulty uploading and transmitting data and had no way of knowing whether transmission had succeeded	Introduce automatic data transmission
Participants found the HTUs difficult to use. Few used advanced HTU functions, such as consulting educational websites	Simplify and improve user interface; provide remote technical assistance to participant from nurse workstation

Sources: Foster and Moreno 2005; Foster et al. 2006.

PHASE II

As with Phase I, the implementation of Phase II of the IDEATel demonstration was successful by several measures. The Consortium recruited a new cohort of demonstration enrollees and achieved most of its intended improvements with respect to the HTU. Unfortunately, most Cohort 1 participants never experienced the improvements. Owing to the dire fiscal straits of a key subcontractor, those participants had to use Generation 1 HTUs for the duration of their participation in the project.[14] Participant disenrollment remained common.

Physician and Beneficiary Recruitment Was Smoother in Phase II

The Consortium implemented an effective recruitment strategy for referring primary care physicians and participants in Phase II. Most physicians were recruited from large practices that had been fruitful recruitment sources in Phase I. Not only did these physicians have substantial numbers of Medicare patients to refer to the demonstration, but they were also favorably impressed with their Phase I experiences and thus particularly willing to refer patients. Both sites met their participant recruitment goals for Phase II (Figure IV.1).

Most, but Not All, of the Technological Advances Planned for Phase II Were Implemented

The Generation 2 and 3 HTUs. Phase II of the demonstration featured a redesigned HTU—the Generation 2—that was much smaller and less cumbersome than its predecessor. The tabletop unit (pictured in Part I, Chapter II) consisted of a small flat screen, a large green answer button, a top-mounted camera, a pliable and "indestructible" keyboard, and a blood pressure cuff and glucose monitor. The unit featured built-in speakers and touch screen technology rather than a stand-alone launch pad.

In addition to being physically compact, the Generation 2 HTU was meant to be less technically demanding of participants. For example, participants connected to televisits simply by pressing the green answer button, and automatic data transmission ("data pulling") relieved participants of having to upload glucose and blood pressure readings. Finally, the Generation 2 HTUs were supposed to be programmed to turn on automatically at a time of the participant's choosing and ask the participant clinical questions in text format. Installation of Generation 2 HTUs began in January 2005 and was expected to be completed in a few months.

[14] In late 2005, near the end of the second year of Phase II operations, the subcontractor informed the Consortium that it was not in a position to purchase and deliver approximately 254 Generation 3 HTUs that were part of the original contract because of cost overruns during the development of and purchasing of the Generation 2 HTUs (Columbia University 2006a). With the recruitment of Cohort 2 enrollees nearly complete by that date, the Consortium decided to rely on Generation 1 HTUs as the substitute for the Generation 3 HTUs that the subcontractor could not supply.

In spring 2005, however, the Consortium confronted a major technical challenge. The company manufacturing the customized computer boards that ATI used in the Generation 2 HTUs experienced severe supply shortages. Moreover, the cost of designing the new HTUs and securing the parts had been, as from the beginning, much greater than ATI had anticipated. Because of the supply shortages, newly enrolled Cohort 2 participants were not receiving HTUs—or any form of intervention—as quickly as they had been told they would. Cohort 1 participants had no choice but to continue using their Generation 1 HTUs. Rather than wait out the supply shortage, the Consortium and ATI embarked on the design of another model, the Generation 3 HTU. From the user's viewpoint, the Generation 3 HTU featured the same technical improvements as its immediate predecessor: connecting to televisits was to be simple, clinical data uploads automatic, and the user interface easy to navigate.

Nurse Workstations. The nurse case managers' workstations were redesigned for Phase II. Whereas the Phase I workstations consisted of two computer systems, one for communicating with participants during televisits, the other for managing case notes, the Phase II workstations were more streamlined. Nurses still used two monitors, but in Phase II they used a single keyboard and a single mouse to perform all computer functions. The new workstations were expected to facilitate nurses' interactions with participants. For example, they let nurse case managers give participants remote-access technical support instead of helping by telephone.

IDEATel nurse case managers were mostly satisfied with the technology they used to do their jobs. They were especially pleased to be able to provide remote technical support to participants during televisits. The nurses said they commonly adjusted the volume on participants' HTUs, moved cursors around the screen to help participants navigate pages, and reset the date and time on the HTUs so that information on blood sugar and blood pressure levels would be recorded accurately. However, other technological changes were not for the best. For example, nurses said they had much less control over the quality of the images they presented to participants with the newer model HTUs, and an annoying echo in a new audio system interfered with communication during televisits.

Another Unexpected Challenge – Unrealized Technical Improvements. In September 2005, ATI revealed to the Consortium that it was in severe financial distress and would not be able to replace all the Generation 1 HTUs with the newer units. Ultimately, only 27 percent of Cohort 1 participants received a Generation 2 or 3 HTU. Another result of ATI's difficulties was that several technological advances planned for Phase II were not realized. These included switching the intervention from telephone-based to wireless technology, programming the HTUs to turn on automatically each day, and equipping the nurse case manager workstations with internet faxing and decision-support software.

The Intervention Was Delivered in About the Same Way as in Phase I, Except That Some Participants Had New Models of HTUs[15]

Televisits. Despite problems with HTU inventory, televisits continued to be the main component of the IDEATel intervention during Phase II. Unlike in Phase I, in which intervention teams initially sought to have televisits with participants every two weeks, there was no standard frequency for televisits during Phase II, according to Consortium staff. Instead, the nurse case managers determined an appropriate frequency for each participant in their caseload. In both demonstration sites, televisits every four to six weeks was said to be average.

Much of the difficulty with connecting to televisits resolved in Phase II. The large green button on the Generation 2 HTU (or on the screen of the Generation 3 HTU) seemed an effective solution for most participants with these models, according to nurse case managers. However, some participants who had to keep their Generation 1 HTUs, and even a few with the newer models, never overcame their uncertainty about how to connect. Nurses reported that 10 to 15 percent of televisits were affected by poor transmission of audio or video data or by disconnections. Nurse case managers attributed this problem to aging telephone lines. When audio or video was inordinately poor, nurses opted to interact with participants by telephone rather than through the HTU.

Missed televisits, which had been a concern for the Consortium during Phase I, were not troublingly high during Phase II, according to nurse case managers. Except for a small number of participants the nurses described as "chronic missers," others participated in visits unless they were on a trip or in the hospital. If participants were less likely to miss visits in Phase II than in Phase I, it may simply have been because, as noted, fewer visits were scheduled.

Other HTU Functions. As noted, participants with Generation 1 HTUs had to upload data themselves from their blood sugar and blood pressure readings. The Generation 2 and 3 HTUs, however, were programmed to transmit such readings automatically each day with no action required of the participant. Nurse case managers said the newer procedure worked well, but not perfectly. If participants turned off or unplugged their HTUs between televisits, data were not transmitted.

By the time Phase II began, Consortium staff had drastically lowered their expectations about participants' use of advanced HTU functions, such as visiting the web pages of the ADA and exchanging email with nurse case managers.[16] By that time, staff also tended to downplay the importance of these functions to participants' well-being and motivation for self-care. Nonetheless, the user interfaces of the Generation 2 and 3 HTUs were designed to be much

[15] Two aspects of the delivery of the intervention—communication between staff and referring physicians, and physician education—did not change much from Phase I to Phase II. The topics are therefore not discussed further.

[16] Access to ADA web pages that had been developed specifically for IDEATel was discontinued in November 2003. Thereafter, participants could access only ADA pages available to the general public, but the Consortium did not track those visits.

easier to navigate than the interface of the Generation 1 HTU, which should have facilitated the use of advanced functions. According to interviews conducted in 2007, use of advanced functions was as rare in Phase II as it had been in Phase I, except for a few participants with prior internet experience.

Participants Who Stayed with the Intervention Seemed to Find It Educational; Physicians Seemed to Agree

The consensus among IDEATel staff was that on average, participants who remained enrolled were highly satisfied with the intervention. One principal investigator explained, "The project has made a lot of patients better in ways that won't show up in the laboratory data. They are better informed about nutrition and diabetes management." Staff said that many participants liked the attention they received from nurse case managers, and some seemed to count on IDEATel as a connection to the "outside world." However, within four years of enrolling in the demonstration, 32 percent of Cohort 1 participants in New York City, and fully 64 percent of their upstate counterparts, had dropped out. Among Cohort 2 participants, 13 percent in New York City and 20 percent upstate dropped out during their first year of enrollment.

There was only one opportunity in March 2007, to speak directly with a small number of Cohort 2 participants (seven) and physicians (six) about their experience with the intervention. The participants, randomly selected from those who at enrollment had consented to be contacted by MPR, said they understood more about using diet and exercise to control their diabetes, and they learned about the importance of diabetes in relation to their overall health. The seven participants all said they would recommend IDEATel to others. The six physician respondents, selected in the same manner as participants, were quite detached from the project. When they received recommendations about their patients from the demonstration, they said they neither minded the interaction nor particularly welcomed it. The physicians believed their patients benefited from having regular contact with IDEATel nurse case managers.

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V. USE OF THE HOME TELEMEDICINE UNIT (HTU)

Demonstration participants' use of the HTU was key for the success of the intervention.[17] Because the intervention hinged entirely on the use of the HTU, participants who took a long time to learn to use the device, or used it infrequently, received correspondingly less intervention. To examine the intensity of the intervention and how it varied with length of time in the demonstration and across cohorts, the analysis examined use data recorded by participants during their interactions with the HTU. Appendix B summarizes the analytic methods used in this chapter.

HTU Use Declined Steadily for Cohort 1 Participants

Cohort 1 participants' HTU use varied substantially over the 75-month period between December 2000 and February 2007. After an initial peak immediately after intervention startup, the use rate of all functions remained more or less flat in both sites through the end of 2002 (Figure V.1).[18] Thereafter, the use pattern diverges by site. In New York City, use of most functions sharply increased during early 2003—this corresponds to the period during which the Consortium retrained participants in HTU use in both sites. Use rates then declined sharply to nearly zero during the second part of 2003, as Phase I operations ended in this site on October 2003. The use rates of most HTU functions (including televisits) increased somewhat as the Consortium resumed operations in mid-2004, but the declining trend continued through the end of the demonstration for monitoring readings while, for televisits, the use rates remained flat and low through the end of the demonstration. By mid 2006, the use rate for monitoring readings was close to zero. In contrast, for uploading clinical readings, use increased rapidly beginning in early 2005 as the result of the phasing-in of the Generation 2 HTU, with its "data-pulling" feature, among Cohort 1 participants.[19] By early 2006, the average number of uploads was higher than ever. However, the use rate for this function also showed a declining trend over the last six months of the demonstration.

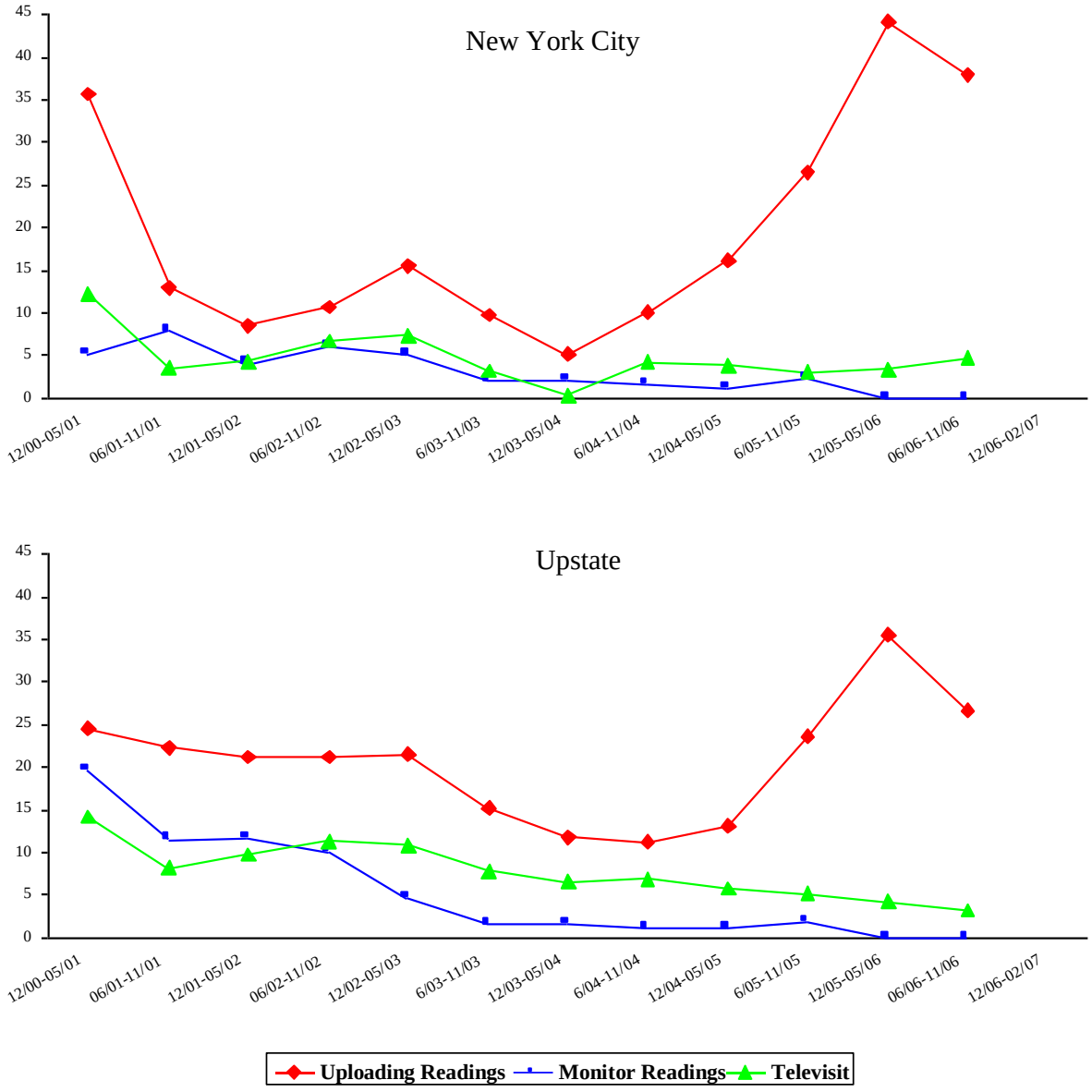
[17] Appendix B, Table B.1, shows the steps a participant must take to use each HTU function and Figure B.2 shows the screenshot for monitoring blood pressure readings.

[18] "User rate" is defined as instances of use per person-year of enrollment. Participants who drop out of the study are excluded from the denominator in the months following their disenrollment.

[19] Unlike users of Generation 1 HTUs, users of Generation 2 or 3 HTUs did not have to upload their measurements, because this was done automatically (this is called "data pulling") in the upgraded HTUs, thus relieving participants of having to upload their readings between televisits (see Appendix B).

FIGURE V.1

MEAN ANNUAL NUMBER OF TIMES HTU FUNCTION WAS USED BY COHORT 1 PARTICIPANTS, BY PERIOD AND SITE



Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and the baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2007c).

Notes: 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.

Upload readings = upload blood pressure and blood sugar readings; monitor readings = monitor blood pressure and blood sugar readings; televisits = participate in televisits.

In upstate New York, the use rates for monitoring readings and televisits declined steadily between mid-2003 and the end of the demonstration, even though operations were never interrupted in this site.[20] As in New York City, the use rate for uploading clinical readings also began rising in early 2005 with the replacement of the Generation 1 HTU with its redesigned counterpart but, after peaking in early 2006, declined over the last six months of the demonstration.

HTU Also Decreased for Cohort 2 Participants

Cohort 2 participants' HTU use also varied substantially over the 27-month period from December 2004 to February 2007 (Figure V.2).[21] As with Cohort 1 participants in New York City, after an initial peak immediately after Phase II startup, the use rate of most HTU functions, such as monitoring readings and televisits, declined rapidly through the end of 2005. Thereafter, the use rate for televisits remained low and flat through the end of the demonstration. Furthermore, as with Cohort 1 participants, the HTU use rate for monitoring readings was close to zero by mid-2006. In upstate New York, use rates throughout the 27 months followed a trend similar to that in New York City.

Cohort 1 Participants Had Steeper Learning Curves than Their Cohort 2 Counterparts

Since some HTU functions were more complex than others, comparing the *learning curves* in the early and later cohorts may suggest whether the redesign of the Generation 1 HTU resulted in a more user-friendly device for Cohort 2 participants using Generation 2 HTUs. For several HTU functions, Cohort 1 participants took longer than their Cohort 2 counterparts to use their HTUs for the first time. For example, the median time to monitoring clinical readings, as well as the time to uploading them, was substantially higher for Cohort 1: 284 versus 179 days after installation for monitoring, and 19 versus 3 days for uploading (Moreno et al. 2007). In contrast, the median time to first measurement of blood sugar or blood pressure was the same for both cohorts (1 day), as was the time from HTU installation to the first televisit (23 and 21 days, respectively).[22] For complex functions, 12 months after installation, between 6 and 23 percent of Cohort 1 participants had learned how to use these functions. For Cohort 2, these percentages ranged from 2 to 7 percent.

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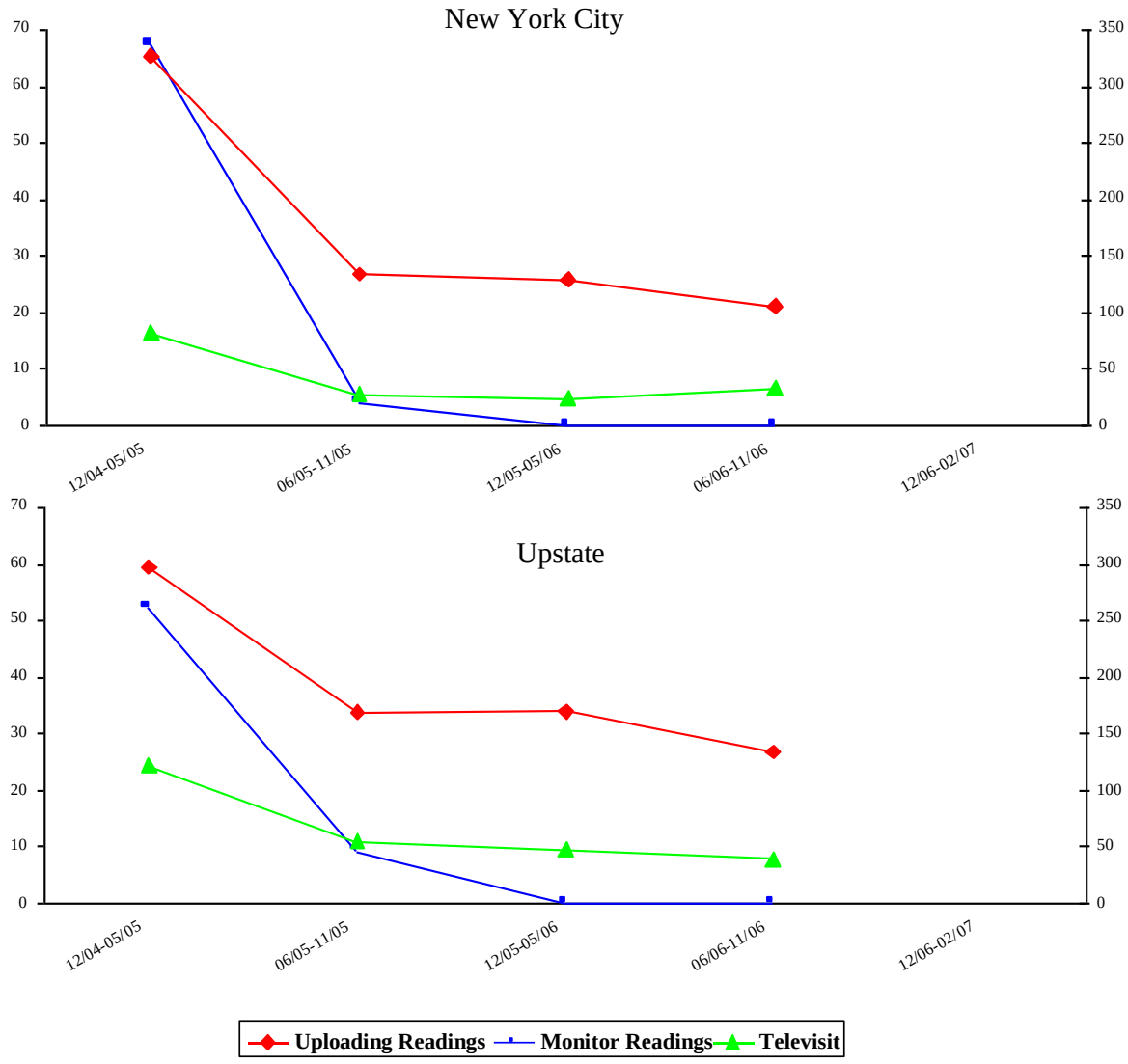
[20] An analysis of the proportion of participants who used an HTU function at least once during a six-month period, as specified in Figure V.1, confirms the declining trend in the HTU use rates. For instance, during the last six months of 2006, only 31 percent of participants in upstate New York participated in a televisit at least once, compared with its peak (that is, 88 percent of participants during the last six months of 2002; data not shown).

[21] All Cohort 2 participants used a Generation 2 or 3 HTU, with the exception of four participants in upstate New York who initially had a Generation 1 HTU installed and asked not to have it upgraded.

[22] Taking blood pressure and blood sugar measurements did not require logging in on the HTU, and most participants had been taking them before the demonstration began.

FIGURE V.2

MEAN ANNUAL NUMBER OF TIMES HTU FUNCTION WAS USED BY COHORT 2 PARTICIPANTS, BY PERIOD AND SITE



Source: IDEATel database on HTU use linked to both the IDEATel tracking status file and the baseline in-person interview, conducted between December 2000 and October 2002 (Columbia University 2007c).

Notes: 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.

The right vertical axis corresponds to the use rate for uploading readings.

Upload readings = upload blood pressure and blood sugar readings; monitor readings = monitor blood pressure and blood sugar readings; televisits = participate in televisits.

Cohort 1 Participants Were as Likely as Cohort 2 Participants to Use the Basic HTU Functions

During roughly the first 27 months after the start of HTU installation for each of the demonstration's phases (December 2000 and December 2004), Cohort 1 participants were as likely as their Cohort 2 counterparts to use the basic HTU functions (Table V.1). For example, in New York City, virtually all Cohort 1 participants (99 percent) participated in a televisit at least once during the follow-up period, compared with 97 percent among Cohort 2 participants—a difference that is not statistically significant. Likewise, in upstate New York, all Cohort 1 and 2 participants attended a televisit at least once during the follow-up period. In contrast, use of the complex HTU functions was rare for participants in both phases, although Cohort 1 participants in both sites were significantly more likely than their Cohort 2 counterparts to monitor clinical readings. Furthermore, Cohort 1 participants were also significantly more likely to read and send electronic messages in both sites and to enter behavioral goals in upstate New York. These differences are partly explained by the Consortium's decision to de-emphasize the use of complex HTU functions during Phase II, a result of the difficulties participants experienced during Phase I (U.S. Department of Health and Human Services 2005).

Frequency of HTU Use Was Higher for Cohort 2 than for Cohort 1 Participants

The intensity of HTU use was higher for Cohort 2 than for Cohort 1 participants for five of the eight functions examined, although differences were statistically significant for only four (Table V.2). For example, in New York City, Cohort 2 participants used the televisit function significantly more often than their Cohort 1 counterparts—about every 8 and 12 weeks, respectively.[23] Likewise, in upstate New York, Cohort 2 participants attended televisits significantly more often than their Cohort 1 counterparts—about every five weeks versus every seven, respectively. Furthermore, in both sites, Cohort 2 participants measured their blood sugar and blood pressure significantly more often than Cohort 1 participants. Because of the data-pulling feature of the Generation 2 and 3 HTUs, Cohort 2 participants in both sites uploaded their blood pressure and blood sugar readings between seven and nine times more often, on average, than their Cohort 1 counterparts. For the complex functions, such as monitoring clinical readings, the between-cohort differences in the average frequency of use of HTU functions were small and not statistically significant.

[23] Participants were asked to attend televisits every two weeks (about 24 times a year), and more often if necessary (Columbia University 1998). The frequency of self-monitoring recommended to each participant depended on the clinical circumstances and was determined by the nurse case managers, with support from the clinical guidelines and supervising diabetologists (U.S. Department of Health and Human Services 2003).

TABLE V.1

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

HTU Function	Cohort 1	Cohort 2	Difference (*p*-Value[a])
Upload Blood Pressure or Blood Sugar Readings			
New York City	99.6	99.3	– 0.3 (.614)
Upstate New York	100.0	99.9	– 0.1 (.580)
Measure Blood Pressure			
New York City	99.4	99.3	– 0.1 (.725)
Upstate New York	100.0	99.9	– 0.1 (.992)
Measure Blood Sugar			
New York City	98.5	99.3	0.8 (.751)
Upstate New York	99.6	99.8	0.2 (.945)
Participate in Televisits			
New York City	99.0	97.3	– 1.7 (.253)
Upstate New York	99.5	99.5	0.0 (.588)
Monitor Clinical Readings			
New York City	83.6	38.8	– 44.8 (.000)
Upstate New York	82.6	58.0	– 24.6 (.000)
Read Electronic Messages			
New York City	64.4	2.8	– 61.6 (.000)
Upstate New York	52.2	7.0	– 45.2 (.000)
Send Electronic Messages			
New York City	54.3	4.1	– 50.2 (.000)
Upstate New York	52.1	7.8	– 44.3 (.000)
Enter Behavioral Goals			
New York City	5.2	1.2	– 4.0 (.338)
Upstate New York	15.4	2.4	–13.0 (.000)
Sample Size[b]	**753**	**230**	–

Source: IDEATel database on HTU use linked to the IDEATel tracking status file (Columbia University 2007a, 2007b).

TABLE V.1 *(continued)*

Notes: Estimates are weighted based on the duration of enrollment between HTU installation and either the dropout date or the cutoff date, which is February 15, 2003, for Cohort 1 participants and February 27, 2007, for Cohort 2 participants. Most Cohort 1 participants used only Generation 1 HTUs, and 226 Cohort 2 participants used Generation 2 HTUs, with the remaining 4 using Generation 1 HTUs.

Results for the following functions are not presented, because no Cohort 2 participants used them: consult American Diabetes Association web pages, enter medications, and enter exercise activities.

[a] Controlling for participants' characteristics at baseline (see Appendix B).

[b] The sample size varies by site.

HTU = home telemedicine unit.

TABLE V.2

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

HTU Function	Cohort 1	Cohort 2	Difference (*p*-Value[a])
Measure Blood Sugar			
New York City	161.1	208.6	47.5 (.048)
Upstate New York	237.0	386.2	149.2 (.000)
Measure Blood Pressure			
New York City	147.4	199.1	51.7 (.013)
Upstate New York	163.8	245.6	81.8 (.000)
Upload Blood Pressure or Blood Sugar Readings			
New York City	9.3	128.5	119.2 (.000)
Upstate New York	14.7	169.4	154.7 (.000)
Monitor Clinical Readings			
New York City	5.5	6.8	1.3 (.697)
Upstate New York	8.7	6.7	– 2.0 (.737)
Participate in Televisits			
New York City	4.5	6.4	1.9 (.000)
Upstate New York	7.0	10.5	3.5 (.000)
Read Electronic Messages			
New York City	2.1	0.5	– 1.6 (.869)
Upstate New York	4.8	3.1	– 1.7 (.878)
Send Electronic Messages			
New York City	1.1	0.5	– 0.6 (.897)
Upstate New York	1.5	1.3	– 0.2 (.893)
Enter Behavioral Goals			
New York City	3.0	0.6	– 2.4 (.806)
Upstate New York	1.6	1.5	– 0.1 (.503)
Sample Size[b]	**753**	**230**	–

Source: IDEATel database on HTU use linked to the IDEATel tracking status file (Columbia University 2007a, 2007b).

TABLE V.2 *(continued)*

Notes: Estimates are weighted based on the duration of enrollment between HTU installation and either the dropout date or the cutoff date, which is February 15, 2003, for Cohort 1 participants and February 27, 2007, for Cohort 2 participants. Most Cohort 1 participants used only Generation 1 HTUs, and 226 Cohort 2 participants used Generation 2 HTUs, with the remaining 4 using Generation 1 HTUs.

Results for the following functions are not presented, because no Cohort 2 participants used them: consult American Diabetes Association web pages, enter medications, and enter exercise activities.

[a]Controlling for participants' characteristics at baseline (see Appendix B).

[b]The sample size varies by site and function.

HTU = home telemedicine unit.

Cohort 2 Participants Had Longer Televisits, on Average, than Their Cohort 1 Counterparts

Cohort 2 participants in both sites had longer televisits, on average, than their Cohort 1 counterparts. In New York City, the average duration of a Cohort 2 televisit (29 minutes) was significantly higher, by about 5 minutes on average, relative to the Cohort 1 estimate (Table V.3). In the upstate site, the difference in the average duration of a televisit was shorter (about 2 minutes), but still significantly (statistically) longer for Cohort 2 participants relative to their Cohort 1 counterparts (33 and 31 minutes, respectively).

Cohort 1 Participants Used More Functions than Cohort 2 Participants

In both sites, Cohort 1 participants used more HTU functions than Cohort 2 participants (Table V.3). For example, in New York City, Cohort 1 participants used 4.3 HTU functions, on average, compared with 2.5 functions for Cohort 2. For upstate New York, the estimates are very similar to those in New York City (4.5 and 2.7, respectively). As noted, these differences are partly explained by the Consortium's decision to de-emphasize the use of complex HTU functions during Phase II as the result of the difficulties experienced during Phase I. Furthermore, by the end of the follow-up period, none of the Cohort 2 participants in both sites had used all the functions, though between 2 and 6 percent of Cohort 1 participants (New York City and upstate, respectively) had used all of them.

TABLE V.3

PATTERNS OF HTU USE DURING THE INTERVENTION, BY COHORT AND SITE

HTU Function	Cohort 1	Cohort 2	Difference (*p*-Value[a])
Any Function (Percentage)[b]			
New York City	99.6	99.3	– 0.3 (.602)
Upstate New York	100.0	99.9	– 0.1 (.580)
All HTU Functions (Percentage)[b]			
New York City	2.4	0.0	– 2.4 (.233)
Upstate New York	5.7	0.0	– 5.7 (.017)
Number of Functions Used[b]			
New York City	4.3	2.5	– 1.8 (.000)
Upstate New York	4.5	2.7	– 1.8 (.000)
Average Duration of Televisits (Minutes)[c]			
New York City	24.3	29.4	5.1 (.000)
Upstate New York	31.2	33.0	1.8 (.004)
Sample Size[d]	**753**	**230**	–

Source: IDEATel database on HTU use linked to the IDEATel tracking status file (Columbia University 2007a, 2007b).

Notes: Estimates are weighted based on the duration of enrollment between HTU installation and either the dropout date or the cutoff date, which is February 15, 2003, for Cohort 1 participants and February 27, 2007, for Cohort 2 participants. Most Cohort 1 participants used only Generation 1 HTUs, and 226 Cohort 2 participants used Generation 2 HTUs, with the remaining 4 using Generation 1 HTUs.

[a] Controlling for participants' characteristics at baseline (see Appendix B).

[b] Excludes measurement of blood pressure and measurement of blood sugar, as neither function required system log-in. Also excludes consultations of American Diabetes Association web pages, because the Consortium did not collect data on these consultations after November 13, 2003.

[c] The number of participants participating in televisits varies by the function.

[d] The sample size varies by site.

HTU = home telemedicine unit.

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

The IDEATel intervention was expected to affect several types of outcomes for both participants and their physicians. For participants, IDEATel was expected to improve the frequency and quality of communications with health care professionals, as well as self-care knowledge, attitudes, behaviors, use of health services, physiologic outcomes, health-related quality of life, and satisfaction with diabetes care. For physicians, the intervention's continual provision of feedback and recommendations was expected to lead to prescribing of better medical regimens as well as faster and more accurate adjustment of those regimens. These changes would then lead to improvement in enrollees' physiologic outcomes, health-related quality of life, and satisfaction with care, which in turn would reduce use of acute care services and provide cost savings to Medicare, though the timing of these different effects might vary. Figure VI.1 shows the anticipated mechanisms of intervention impacts and the categories of outcomes.

This chapter presents year 4 estimates of the impacts of the intervention on selected measures of health outcomes for Cohort 1 participants and year 1 estimates for Cohort 2. Data were drawn from in-person assessments that demonstration staff conducted of enrollees (physiologic and survey data from baseline and years 1, 2, 3, and 4).[24] First, the discussion focuses on the substantial attrition rate among enrollees, particularly in Cohort 1; its implications for power to detect impacts; and the potential for biased impact estimates on these health outcomes. Then, to provide a sense of how impacts changed over time, the discussion examines the year 4 impacts for Cohort 1 participants and presents selected baseline mean values and regression-adjusted outcomes for years 1, 2, 3, and 4. Finally, the discussion examines the early effects of the intervention on selected measures of health outcomes in the first follow-up year for Cohort 2 participants and compare this experience with that of Cohort 1 participants in their first follow-up year. Because of the small sample sizes and the limited duration of followup, the analyses of Cohort 2 outcomes were limited. Appendix C summarizes the data and analytic methods.

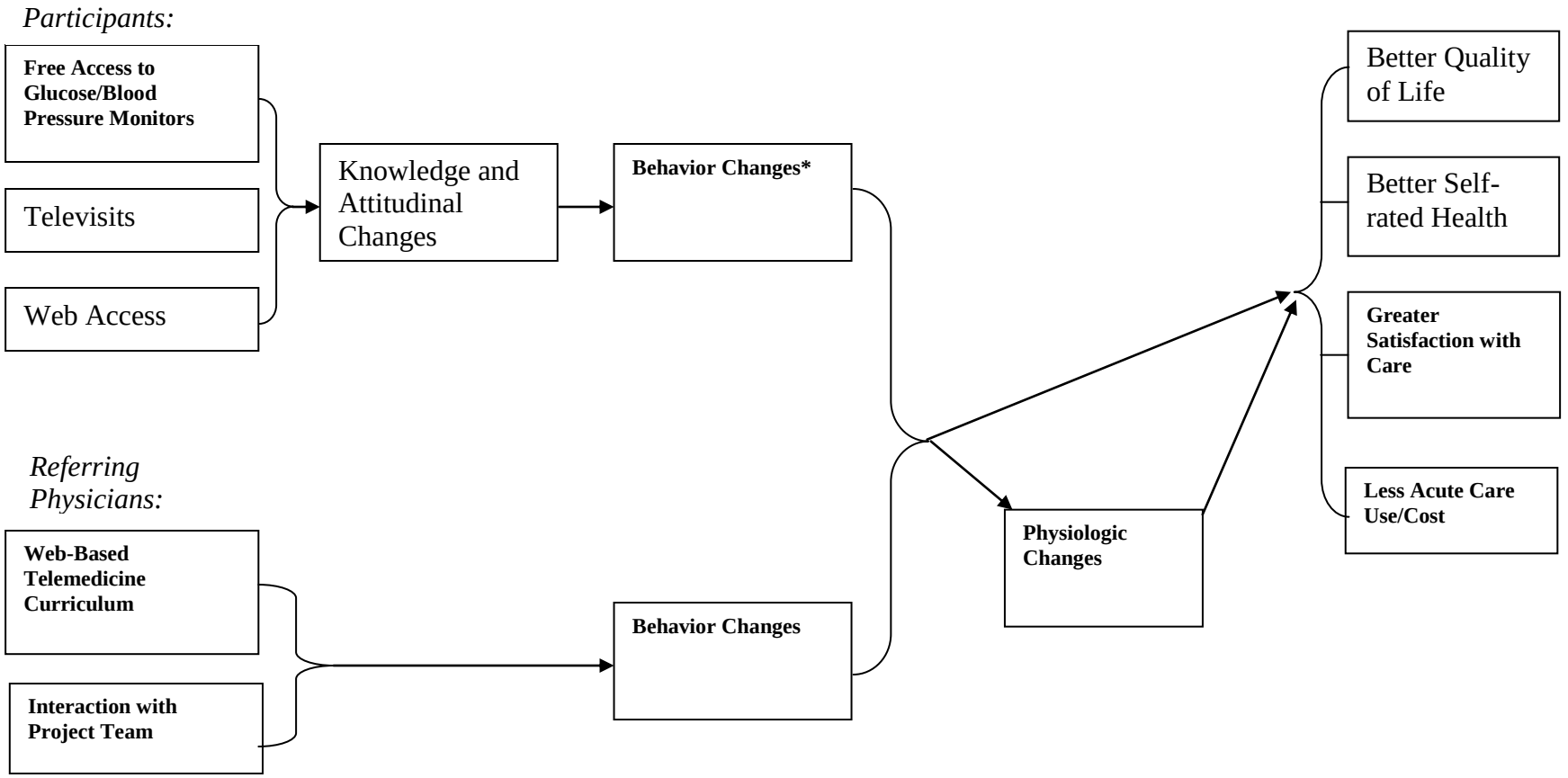
The Demonstration Experienced Substantial Attrition Among Enrollees

By the fourth year of follow-up interviews, there was a substantial reduction in sample sizes for health outcomes analyses in Cohort 1, both in New York City and upstate. The overall dropout rates in Cohort 1 were 30 percent in New York City and 58 percent upstate. Although reductions in statistical power due to attrition were not formally calculated, the loss of these proportions of the original samples substantially decreased the ability of the evaluation to detect impacts. Loss of sample size also compromised the statistical power of the Cohort 2 analyses. In Cohort 2,

[24] As mentioned in Chapter III, data on years 5 and 6 were not available for Cohort 1 and data on year 2 were not available for Cohort 2.

FIGURE VI.1

EXPECTED EFFECTS OF THE IDEATel INTERVENTION



*Includes changes that result from provider feedback on monitored blood sugar, blood pressure, cholesterol, diet, exercise, and examination of feet.

after one year of follow-up interviews, the attrition rate was 13 percent in New York City and 19 percent upstate (Appendix C, Table C.2). As with Cohort 1, however, numbers relative to the original sample were small, and there were no great differences between treatment and control dropouts in baseline characteristics.

Reasons for dropping out differed between treatment and control groups. There was a somewhat higher dropout rate among the treatment groups (33 percent in New York City, 64 percent in upstate New York) than the control groups (28 and 52 percent, respectively) (Table VI.1). In the New York City site, the rates of dropout in the treatment group because of death and "no reason recorded" were lower than in the control group, whereas the rates for "other reason" and, of course, HTU problems, were higher than in the control group. Although bias in the estimated impacts due to differences between treatment and control group enrollees who dropped out is unknowable, the potential for bias may be mitigated by the small numbers in any given category of reason for dropping out relative to the original sample size. Treatment and control group members also dropped out for different reasons in upstate New York. As in New York City, the rate of dropout in the treatment group because of death was lower than in the control group, while the rates of dropout for enrollee refusal and "too sick" were higher. But again, the numbers for individual reasons are small relative to the original sample.[25]

To assess further the possible effects of attrition on the estimates of program effects on health outcomes, the analysis compared the baseline characteristics of those who dropped out in Cohort 1 and those who remained. The analysis also assessed the sensitivity of a selected set of the calculated year 4 impacts to a range of favorable and unfavorable imputed outcome values for Cohort 1 enrollees who dropped out of the treatment or control groups. These comparisons and sensitivity analyses did not reveal major differences between treatment and control group members who dropped out, or indicate that results were sensitive to even extreme assumptions about the missing outcome values.

IDEATel Had a Large Positive Impact on Cohort 1 Participant Contact with and Receipt of Education from Diabetes Nurse Educators in Both Sites and the Dietitian in Upstate New York

Not surprisingly, Cohort 1 treatment group members in both sites were much more likely than their control group counterparts to report having seen a diabetes nurse educator at least once in the year before the year 4 interview. In New York City, 62 percent of treatment group members and 15 percent of control group members reported having seen a nurse educator in year 4 (Table VI.2). In upstate New York, 86 percent of treatment group and 6 percent of control group

[25] The intention-to-treat impact estimates based on Medicare claims data, presented in Chapter VII, are not affected by differential dropout, since claims data are available for all enrollees whether they remained in the demonstration or not.

TABLE VI.1

COHORT 1 ENROLLEES DROPPING OUT OF THE STUDY AND REASONS FOR DROPOUT,
BY STUDY YEAR AND INTERVENTION GROUP[a]
(Numbers and Percentages)

New York City																
	Baseline to Year 1			**Year 1 to Year 2**			**Year 2 to Year 3**			**Year 3 to Year 4**			**Baseline to Year 4**			
	Treatment	**Control**		**Treatment**	**Control**		**Treatment**	**Control**		**Treatment**	**Control**		**Treatment**	**Control**		
Enrollee Refusal	7	6		6	2		3	3		2	2		18	13		
Percentage of starting sample	1.8	1.6		1.5	0.5		0.8	0.8		0.5	0.5		4.6	3.4		
Percentage of period's dropouts	12.3	26.1		26.1	10.0		13.6	11.1		9.1	58.8		14.0	12.5		
Family Refusal	0	0		0	0		1	0		0	0		1	0		
Percentage of starting sample	0.0	0.0		0.0	0.0		0.3	0.0		0.0	0.0		0.3	0.0		
Percentage of period's dropouts	0.0	0.0		0.0	0.0		4.5	0.0		0.0	0.0		0.8	0.0		
Physician Refusal	1	1		0	0		0	0		0	0		1	1		
Percentage of starting sample	0.3	0.3		0.0	0.0		0.0	0.0		0.0	0.0		0.3	0.3		
Percentage of period's dropouts	1.8	4.3		0.0	0.0		0.0	0.0		0.0	0.0		0.8	1.0		
Cognitive Impairment	1	0		0	0		0	0		2	0		3	0		
Percentage of starting sample	0.3	0.0		0.0	0.0		0.0	0.0		0.5	0.0		0.8	0.0		
Percentage of period's dropouts	1.8	0.0		0.0	0.0		0.0	0.0		9.1	0.0		2.3	0.0		
Too Sick	6	2		1	2		2	4		5	4		14	12		
Percentage of starting sample	1.5	0.5		0.3	0.5		0.5	1.1		1.3	1.1		3.6	3.2		
Percentage of period's dropouts	10.5	8.7		4.3	10.0		9.1	14.8		18.5	11.8		10.9	11.5		
Deceased	12	11		8	12		6	9		3	9		29	41		
Percentage of starting sample	3.0	2.9		2.0	3.2		1.5	2.4		0.8	2.4		7.3	10.9		
Percentage of period's dropouts	21.1	47.8		34.8	60.0		27.3	33.3		11.1	26.5		22.5	39.4		
HTU Problem	8	0		2	0		1	0		5	0		16	0		
Percentage of starting sample	2.0	0.0		0.5	0.0		0.3	0.0		1.3	0.0		4.1	0.0		
Percentage of period's dropouts	14.0	0.0		8.7	0.0		4.5	0.0		18.5	0.0		12.4	0.0		
Other[b]	22	3		6	4		9	10		9	13		46	30		
Percentage of starting sample	5.5	0.8		1.5	1.1		2.3	2.7		2.3	3.4		11.6	8.0		
Percentage of period's dropouts	38.6	13.0		26.1	20.0		40.9	37.0		33.3	38.2		35.7	28.8		
No Reason Recorded[c]	0	0		0	0		0	1		1	6		1	7		
Percentage of starting sample	0.0	0.0		0.0	0.0		0.0	0.3		0.3	1.6		0.3	1.9		
Percentage of period's dropouts	0.0	0.0		0.0	0.0		0.0	3.7		3.7	17.6		0.8	6.7		
Total	**57**	**23**		**23**	**20**		**22**	**27**		**27**	**34**		**129**	**104**		
Percentage of starting sample	**14.4**	**6.1**		**5.8**	**5.3**		**5.5**	**7.2**		**6.8**	**9.0**		**32.5**	**27.6**		

TABLE VI.1 (*continued*)

Upstate																
	Baseline to Year 1			**Year 1 to Year 2**			**Year 2 to Year 3**			**Year 3 to Year 4**			**Baseline to Year 4**	
	Treatment	**Control**		**Treatment**	**Control**		**Treatment**	**Control**		**Treatment**	**Control**		**Treatment**	**Control**
Enrollee Refusal	25	26		20	3		73	53		7	0		125	82
Percentage of starting sample	5.6	5.9		4.5	0.7		16.3	12.0		1.6	0.0		28.0	18.6
Percentage of period's dropouts	33.8	37.7		32.8	7.9		62.4	60.2		19.4	0.0		43.4	35.8
Family Refusal	2	0		1	0		0	0		0	0		3	0
Percentage of starting sample	0.4	0.0		0.2	0.0		0.0	0.0		0.0	0.0		0.6	0.0
Percentage of period's dropouts	2.7	0.0		1.6	0.0		0.0	0.0		0.0	0.0		1.0	0.0
Physician Refusal	0	0		0	0		0	0		0	0		0	0
Percentage of starting sample	0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
Percentage of period's dropouts	0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
Cognitive Impairment	0	0		0	0		0	0		0	0		0	0
Percentage of starting sample	0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
Percentage of period's dropouts	0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
Too Sick	16	2		6	0		4	2		2	2		28	6
Percentage of starting sample	3.6	0.5		1.3	0.0		0.9	0.5		0.4	0.5		6.2	1.5
Percentage of period's dropouts	21.6	2.9		9.8	0.0		3.4	2.3		5.6	5.9		9.7	2.6
Deceased	14	22		14	18		12	13		5	9		45	62
Percentage of starting sample	3.1	5.0		3.1	4.1		2.7	2.9		1.1	2.0		10.0	14.0
Percentage of period's dropouts	18.9	31.9		23.0	47.4		10.3	14.8		13.9	26.5		15.6	27.1
HTU Problem	11	0		7	0		3	0		1	0		22	0
Percentage of starting sample	2.5	0.0		1.6	0.0		0.7	0.0		0.2	0.0		5.0	0.0
Percentage of period's dropouts	14.9	0.0		11.5	0.0		2.6	0.0		2.8	0.0		7.6	0.0
Other[b]	6	7		8	3		11	1		7	6		32	17
Percentage of starting sample	1.3	1.6		1.8	0.7		2.5	0.2		1.6	1.4		7.2	3.9
Percentage of period's dropouts	8.1	10.1		13.1	7.9		9.4	1.1		19.4	17.6		11.1	7.4
No Reason Recorded[c]	0	12		5	14		14	19		14	17		33	62
Percentage of starting sample	0.0	2.7		1.1	3.2		3.1	4.3		3.1	3.8		7.3	14.0
Percentage of period's dropouts	0.0	17.4		8.2	36.8		12.0	21.6		38.9	50.0		11.5	27.1
Total	**74**	**69**		**61**	**38**		**117**	**88**		**36**	**34**		**288**	**229**
Percentage of period's dropouts	**16.6**	**15.6**		**13.6**	**8.6**		**26.2**	**19.9**		**8.1**	**7.7**		**64.4**	**51.7**

Source: IDEATel tracking status file (Columbia University 2007a).

Note: At each follow-up year, enrollees were categorized as having dropped out if they missed that in-person assessment and all subsequent assessments (for example, a Cohort 1 enrollee who missed the assessments in years 2 and 3 but then attended the remaining assessment in year 4 would not be categorized as having dropped out). The reasons for dropping out are those reported by the Hebrew Home for the Aged at Riverdale, the demonstration's data coordination center. HTU=home telemedicine unit.

[a]As of June 29, 2007.

[b]Includes the following reasons as specified by the Consortium: "unreachable" and "other" ("other" reasons not specified by the Consortium).

[c]Enrollees who were assumed to have dropped out because they stopped attending the in-person assessments but were not formally recorded in the Consortium's tracking status file as having dropped out.

TABLE VI.2

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' APPOINTMENTS WITH NURSE EDUCATORS AND DIETITIANS, AND ENROLLEE REPORTS OF PROVIDER PRACTICES IN YEAR 4, BY SITE

	New York City			Upstate		
Outcome	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator at Least Once (Percentage)	61.9	15.4	46.5 (.000)	86.2	6.3	79.9 (.000)
Number of consultations (mean)	4.4	1.3	3.1 (.000)	8.6	0.2	8.4 (.000)
Saw a Dietitian (Percentage)	20.7	21.8	-1.1 (.749)	82.9	12.8	70.1 (.000)
Number of consultations (mean)	0.8	1.0	-0.3 (.396)	7.9	0.4	7.5 (.000)
In the Past Year, Number of Times Health Care Professionals Discussed						
Exercise						
Four or more times	49.1	39.2	9.9 (.019)	64.5	23.7	40.9 (.000)
Not at all	30.4	41.1	-10.7 (.008)	19.6	50.3	-30.7 (.000)
Eating Habits						
Four or more times	52.5	41.2	11.2 (.007)	76.5	17.5	59.0 (.000)
Not at all	26.8	36.7	-9.9 (.012)	13.9	62.2	-48.3 (.000)
Controlling Blood Sugar						
Four or more times	25.0	17.3	7.7 (.030)	38.0	4.6	33.3 (.000)
Not at all	63.0	70.0	-7.0 (.086)	62.0	86.3	-24.4 (.000)
Sample Size	**270**	**273**	—	**169**	**224**	—

Source: IDEATel Year 4 in-person interview, conducted between December 2004 and October 2006 (Columbia University 2007c).

Notes: Means were predicted with either logit models (binary outcome) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

members said they saw a nurse educator. Likewise, a much higher proportion of treatment than control group members reported having seen a dietitian at least once in upstate New York, where a dietitian also conducted televisits.[26] In addition, treatment group members in upstate New York had many more consultations than control group members with either a diabetes nurse educator or the dietitian (8.6 and 0.2 consultations with the nurse educator, respectively; and 7.9 and 0.4 with the dietitian).

Cohort 1 treatment group members were also more likely than control group members to report that the health care professionals who cared for their diabetes discussed exercise and diet at all and that they did so frequently in the past year; however, estimated effects were much larger upstate than in New York City, both in the fourth year and across all previous years (Figure VI.2). In New York City at year 4, more treatment group than control group members reported that their health care providers had talked to them four or more times about exercise (49 and 39 percent, respectively) or eating (52 and 41 percent) (Table VI.2). Upstate treatment group members were three to four times more likely as the control group members to report four or more discussions with their health care professional about exercise and eating habits, and three to four times less likely to report no discussions at all.

Enrollees were also asked how often health care providers discussed control of blood sugar. Statistically significant differences favored the treatment group in both sites (Table VI.2). However, the number of enrollees reporting that providers did not discuss this topic at all (almost two-thirds of treatment group members and over two-thirds of control group members at both program sites) are surprisingly high and suggest misunderstanding of the somewhat complex question: "In the past 12 months, about how many times in total did any of your health care providers discuss or refer you to someone who taught you how to keep your blood sugar normal?" Some people, apparently confused by the wording, responded simply "no," so their responses might not provide valid measures of how often this key topic was discussed. However, in both the treatment and control groups, the responses to two less ambiguously worded questions on whether their physician had discussed proper eating habits and exercise suggest that many diabetics (30 to 40 percent or more) are not getting adequate information from their providers.

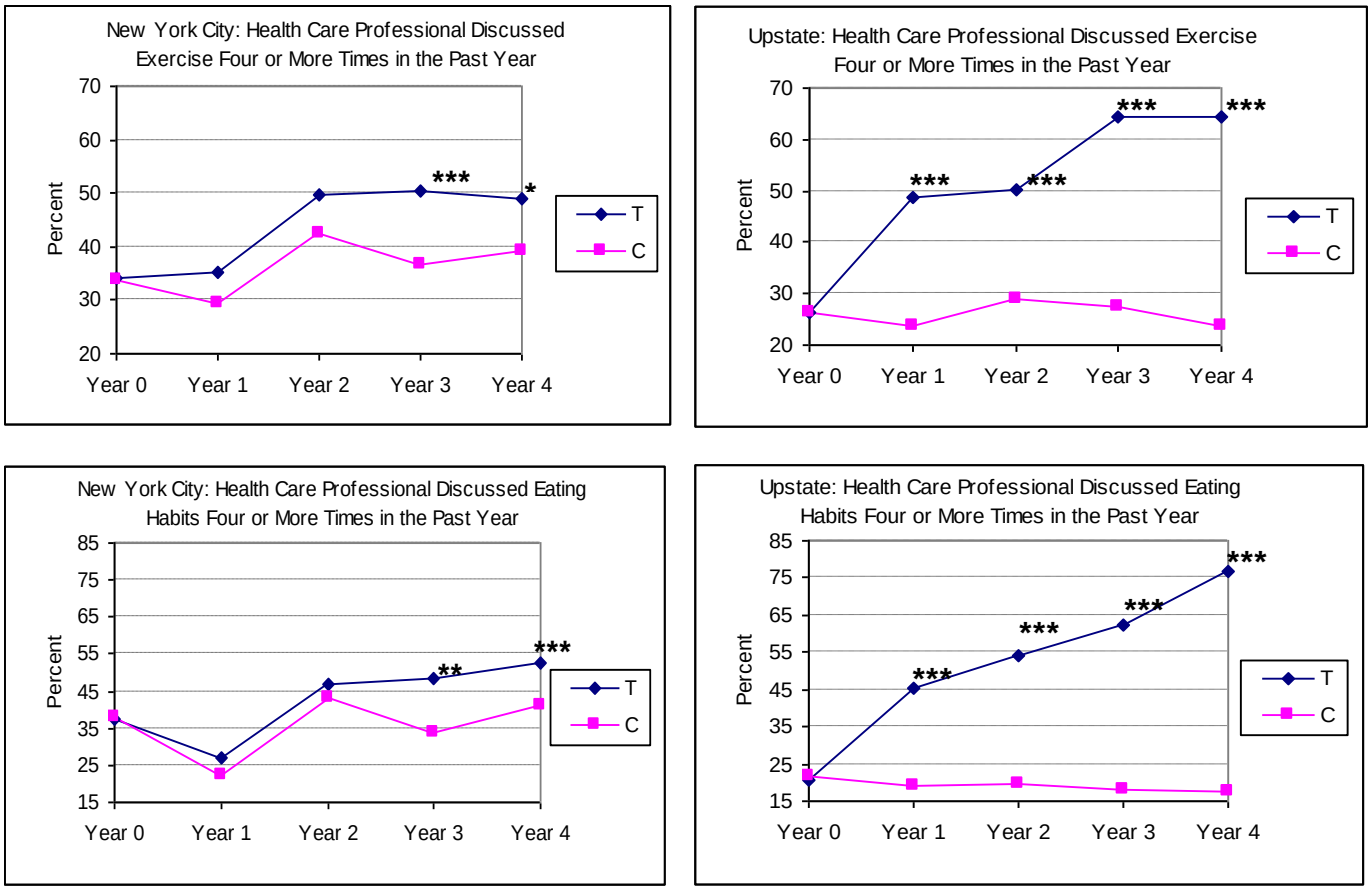
Cohort 1 Treatment Group Members Were More Satisfied than Control Group Members with Their Diabetes Health Care

In both sites, Cohort 1 treatment group members were more likely than control group members to report good experiences and satisfaction with health care professionals who cared for their

[26] During interviews, treatment group members were *not* prompted either to include or to exclude televisits as instances in which they "saw" nurse educators or dietitians, and the extent to which they did so is not known.

FIGURE VI.2

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEE REPORTS OF PROVIDER PRACTICES, BASELINE TO YEAR 4



Source: IDEATel annual in-person interviews, conducted from December 2000 through October 2006 (Columbia University 2007c).

Note: Means predicted using the "all cases available" analysis. This analysis included each of the data points (baseline, year 1, year 2, year 3, and year 4) for selected interview and laboratory outcomes for enrollees who completed that interview with demonstration staff, even if they had missed one or more of the preceding interviews (for the follow-up interviews) or dropped out after the interview being analyzed.

*,**,*** Indicate treatment-control difference is statistically significant at the .05, .01, or .001 level, respectively.

diabetes.[27] Furthermore, in both sites, treatment group members were significantly more likely than control group members to rate the quality of their diabetes care in the past year as very good or excellent in year 4 and in all years between baseline and year 4 (in New York City, 60 and 46 percent, respectively; in upstate New York, 77 and 63 percent) (Table VI.3). There were other significant positive effects that varied by site (for example, how well health care professionals gave test results when promised or explained what to expect from diabetes or its treatment), but treatment-control differences tended to be uniformly favorable to the treatment group across both sites, even for outcomes that were not statistically significant. In both the treatment and control groups, over 90 percent of sample members said they would recommend these physicians to others.

IDEATel Had Mixed Effects on Patient Self-monitoring and Self-care, Depending on Site

In New York City, IDEATel had statistically significant positive effects on the proportion of Cohort 1 treatment group enrollees who tested their blood sugar daily or examined their feet daily during the week before their fourth year interview (Table VI.4). In the fourth year, about 52 percent of treatment group members in New York City tested their blood sugar daily, compared with 43 percent in the control group; about 88 percent of treatment group members in New York City examined their feet daily, compared with 81 percent in the control group. Treatment and control group proportions for taking recommended doses of diabetes pills daily, administering recommended insulin injections daily, adhering to diet daily, and adhering to exercise several days were not significantly different. In the upstate site, there were no significant treatment-control differences in any of these self-monitoring and self-care outcomes, that is, in testing of blood sugar, examination of feet, taking recommended doses of diabetes pills or insulin injections daily, and adherence to diet and exercise (Table VI.4).

IDEATel Had Unsustained Effects on Blood Pressure but Consistently Improved Cholesterol and HbA1c Levels in Both Sites

The clinical and laboratory outcomes presented in this chapter are blood pressure control (systolic blood pressure [SBP] and diastolic blood pressure [DBP]), lipid levels (total low-density lipoprotein [LDL] and high-density lipoprotein [HDL] cholesterol levels), and diabetes control (glycosylated hemoglobin [HbA1c]).[28] The Consortium prespecified these three measures as the main study outcomes (Columbia University 1998).

[27] During interviews, treatment group members were *not* prompted either to include or to exclude IDEATel nurses as "health care professionals," and the extent to which they did so is not known.

[28] Additional outcomes analyzed for this report were body mass index (BMI), waist girth, waist-to-hip ratio, and urine microalbumin results; however, there were no significant impacts.

TABLE VI.3

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' SATISFACTION WITH DIABETES CARE IN YEAR 4, 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)
How Well Doctors and Health Care Professionals Cared for Enrollees' Diabetes[a]						
Showed Concern, Courtesy, Respect, and Sensitivity						
Very good or excellent	66.0	55.0	11.0 (.008)	84.3	77.9	6.4 (.108)
Fair or poor[b]	9.7	16.3	-6.6 (.027)	2.4	6.8	-4.4 (.049)
Disclosed All Pertinent Information						
Very good or excellent	59.7	50.2	9.5 (.023)	80.3	77.8	2.6 (.530)
Fair or poor[b]	16.5	21.9	-5.3 (.118)	6.1	9.6	-3.6 (.205)
Answered Questions About Diabetes						
Very good or excellent	52.7	49.4	3.3 (.444)	70.5	63.8	6.6 (.147)
Fair or poor[b,c]	16.2	23.4	-7.1 (.040)	7.3	11.0	-3.7 (.222)
Gave Test Results When Promised						
Very good or excellent	61.7	47.5	14.2 (.001)	76.7	66.5	10.2 (.022)
Fair or poor[c]	13.0	24.3	-11.2 (.001)	10.0	12.9	-2.9 (.369)
Reviewed and Explained Test and Laboratory Results						
Very good or excellent	51.8	45.7	6.1 (.153)	63.0	59.3	3.7 (.444)
Fair or poor	16.9	20.8	-4.0 (.234)	11.1	11.9	-0.8 (.800)
Explained and Included Enrollee in Treatment Decisions						
Very good or excellent	52.0	42.0	10.1 (.019)	62.2	59.4	2.8 (.563)
Fair or poor[b]	19.8	30.8	-11.0 (.004)	13.3	22.1	-8.9 (.027)
Explained Side Effects of Medications						
Very good or excellent	49.1	40.0	9.2 (.031)	53.2	48.1	5.1 (.302)

TABLE VI.3 *(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)
Fair or poor	27.6	37.7	-10.1 (.013)	24.4	31.7	-7.3 (.112)
Explained What to Expect from Diabetes or Its Treatment						
Very good or excellent	48.4	39.0	9.4 (.029)	60.0	43.1	16.9 (.001)
Fair or poor	27.5	37.9	-10.4 (.011)	20.8	28.0	-7.1 (.086)
Made Sure They Could Be Reached Easily in Emergencies						
Very good or excellent	52.1	42.6	9.5 (.031)	57.0	52.2	4.8 (.356)
Fair or poor	25.2	32.4	-7.2 (.074)	17.0	25.0	-8.0 (.058)
General Measures of Satisfaction						
Rating of Quality of Diabetes Care in the Past Year[a]						
Very good or excellent	59.5	45.5	14.0 (.001)	76.8	62.9	13.9 (.002)
Fair or poor[b]	10.1	20.7	-10.5 (.001)	4.2	10.5	-6.3 (.021)
Would Recommend Doctor/Health Care Professional Based on Personal Manner[b,c,d]	93.7	89.6	4.1 (.085)	92.8	91.9	0.9 (.739)
Intends to Follow Doctor's/Health Care Professional's Advice[b,c,e]	96.7	97.4	-0.8 (.602)	97.6	96.4	1.2 (.492)
Sample Size	**270**	**273**	**—**	**169**	**224**	**—**

Source: IDEATel Year 4 in-person interview, conducted between December 2004 and October 2006 (Columbia University 2007c).

Notes: Means were predicted with logit models, which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

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

[b]Because of small sample sizes, effects for the upstate sample could not be predicted with the logit model. The results presented here are the unadjusted means and treatment-control differences.

[c]Because of small sample sizes, 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.

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

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

TABLE VI.4

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' SELF-MONITORING AND ADHERENCE IN YEAR 4, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percentage)	Predicted Control Group Mean (Percentage)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percentage)	Predicted Control Group Mean (Percentage)	Estimated Effect (*p*-Value)
In the Past Week						
Tested Blood Sugar Daily[a,b]	51.7	43.0	8.8 (.048)	69.5	62.4	7.1 (.154)
Examined Feet Daily	87.5	80.9	6.5 (.037)	71.8	63.9	8.0 (.088)
Took Recommended Doses of Diabetes Pills Daily[b,c]	94.2	92.0	2.2 (.359)	97.0	94.2	2.8 (.240)
Administered Recommended Insulin Injections Daily[b,d]	96.8	99.0	-2.2 (.289)	98.3	96.3	2.0 (.492)
Adhered to Diet Daily[e]	37.4	38.3	-1.0 (.805)	39.1	42.2	-3.1 (.520)
Adhered to Exercise Plan on Three or More Days[e]	33.9	28.9	5.0 (.190)	65.1	56.9	8.2 (.098)
Sample Size	**270**	**273**	—	**169**	**224**	—

Source: IDEATel Year 4 in-person interview, conducted between December 2004 and October 2006 (Columbia University 2007c).

Notes: Means were predicted with logit models, which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

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

[b] Because of small sample sizes, 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 only by enrollees who were taking diabetes pills (New York City: 224 treatment group members, 225 control group members; upstate: 135 treatment group members, 173 control group members).

[d] This question was answered only by enrollees who were taking insulin (New York City: 93 treatment group members, 98 control group members; upstate: 50 treatment group members, 81 control group members).

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

In New York City, SBP readings were not significantly different between Cohort 1 treatment and control group members in year 4, although the DBP readings were significantly lower, by 1.7 mm Hg (Table VI.5). In the upstate site, in-person SBP and DBP readings in the fourth year were both lower for treatment group members than for control group members (5.0 mm Hg lower for SBP and 3.1 mm Hg lower for DPB).

Over time, IDEATel did not have an impact on the proportions of participants in New York City with high SBP or DBP. By year 4, treatment group members were only slightly less likely than their control group counterparts to have elevated values for either type of blood pressure (Figure VI.3). In upstate New York, there was a decrease between years 1 and 3 in the proportion of treatment group members with high SBP. However, between years 3 and 4, that proportion increased so that the treatment-control group difference narrowed from 10 to 6 percentage points. This increase between years 3 and 4 is attributable mainly to a net increase in treatment group members with high blood pressure readings (25 participants with SBP under 130 mm Hg in year 3 had SBP over 130 the following year, while 17 participants experienced the opposite transition), and partly attributable to a higher attrition level between years 3 and 4 among treatment group members with SBP under 130 mm Hg. The proportion of Cohort 1 treatment and control group members in upstate New York with high DBP remained more or less constant between years 1 and 4.

In both sites, Cohort 1 treatment group members had lower total cholesterol levels than control group members (in New York City, the figures were 160 and 168 mg/dl, respectively; in upstate New York, 152 and 166 mg/dl) (Table VI.6). In addition, treatment group members in both sites had lower LDL levels than control group members (in New York City, 90 and 97 mg/dl; in upstate New York, 83 and 96 mg/dl). The treatment-control differences expressed as a proportion of the control group mean were somewhat larger upstate than in New York City (8 and 5 percent relative decreases for total cholesterol, and 14 and 7 percent relative decreases for LDL for upstate New York and New York City, not shown). Moreover, fewer treatment than control group members had LDL levels of 100 mg/dl or more (30 versus 39 percent in New York City; 26 versus 38 percent upstate).

New York City participants initially experienced positive effects of the intervention in terms of their total and LDL cholesterol levels, but these impacts decreased in years 2 and 3 before rising to a difference that was statistically significant in year 4 (Figure VI.4). In upstate New York, however, the intervention had a sustained impact on total and LDL cholesterol levels, and the treatment-control differences for both total and LDL cholesterol levels increased between years 3 and 4 (from 8 to 13 mm Hg for total cholesterol and from 7 to 13 mm Hg for total LDL).

In New York City, treatment group members had slightly lower HbA1c levels than control group members on average (7.3 percent versus 7.5 percent) (Table VI.6), and the treatment-control difference increased between years 3 and 4 (Figure VI.4). However, treatment-control differences in the proportion of enrollees with HbA1c levels above either 7 or 8 percent were modest and not statistically significant. In upstate New York, there were no significant treatment-control differences in any of the measures of diabetes control in year 4.

TABLE VI.5

ESTIMATED EFFECTS OF IDEATeL ON COHORT 1 ENROLLEES' BLOOD PRESSURE MEASUREMENTS IN YEAR 4, BY SITE

	New York City			Upstate		
Outcome	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Systolic Blood Pressure (mm Hg)	141.4	143.1	-1.7 (.344)	134.5	139.5	-5.0 (.008)
Systolic blood pressure >130 mm Hg (percentage)	67.6	69.3	-1.7 (.670)	59.7	65.5	-5.8 (.231)
Diastolic Blood Pressure (mm Hg)	68.4	70.1	-1.7 (.042)	66.9	70.0	-3.1 (.001)
Diastolic blood pressure >80 mm Hg (percentage)[a]	14.9	17.9	-3.1 (.334)	8.9	15.1	-6.1 (.070)
Sample Size	**270**	**273**	—	**169**	**224**	—

Source: IDEATel Year 4 in-person interview and anthropometry, conducted between December 2004 and October 2006 (Columbia University 2007c).

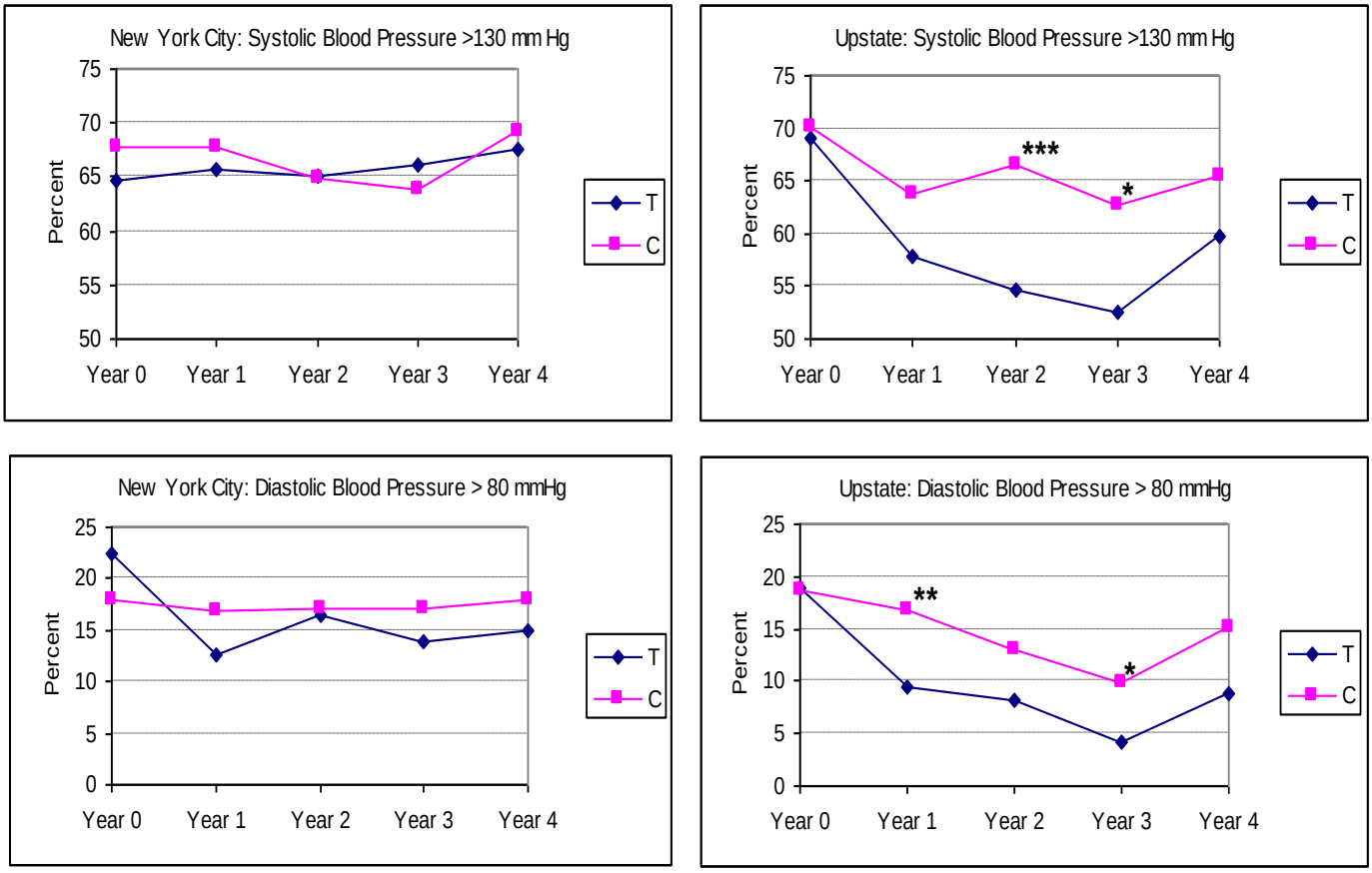
Notes: Means were predicted with either logit models (binary outcome) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

[a]Because of small sample sizes, effects could not be predicted with the logit model. The results presented here are the unadjusted means and treatment-control differences

mm Hg = millimeters of mercury.

FIGURE VI.3

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' BLOOD PRESSURE, BASELINE TO YEAR 4



Source: IDEATel annual in-person interviews, conducted from December 2000 through October 2006 (Columbia University 2007c).

Note: Means predicted using the "all cases available" analysis. This analysis included each of the data points (baseline, year 1, year 2, year 3, and year 4) for selected interview and laboratory outcomes for enrollees who completed that interview with demonstration staff, even if they had missed one or more of the preceding interviews (for the follow-up interviews) or dropped out after the interview being analyzed.

*,**,*** Indicate treatment-control difference is statistically significant at the .05(*), .01(**), or .001(***) level.

TABLE VI.6

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' LABORATORY RESULTS IN YEAR 4, 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	159.6	168.0	-8.4 (.011)	152.2	165.6	-13.4 (.001)
Mean LDL Cholesterol	90.1	96.9	-6.9 (.029)	83.0	96.0	-13.0 (.001)
Mean HDL Cholesterol	48.1	47.6	0.5 (.597)	43.0	42.7	0.3 (.725)
Mean Triglycerides	127.1	130.8	-3.7 (.495)	144.2	172.8	-28.6 (.008)
High LDL Cholesterol (≥100; Percentage)	29.7	39.0	-9.3 (.023)	25.5	38.4	-12.9 (.006)
Diabetes Control						
Mean HbA1c (%)	7.3	7.5	-0.2 (.022)	6.8	6.9	-0.1 (.370)
HbA1c ≥7.0% (percentage)	52.5	58.2	-5.7 (.133)	36.7	38.1	-1.4 (.768)
HbA1c >8.0% (percentage)	20.4	25.0	-4.6 (.174)	10.7	12.5	-1.8 (.587)
Sample Size	**270**	**273**	—	**169**	**224**	—

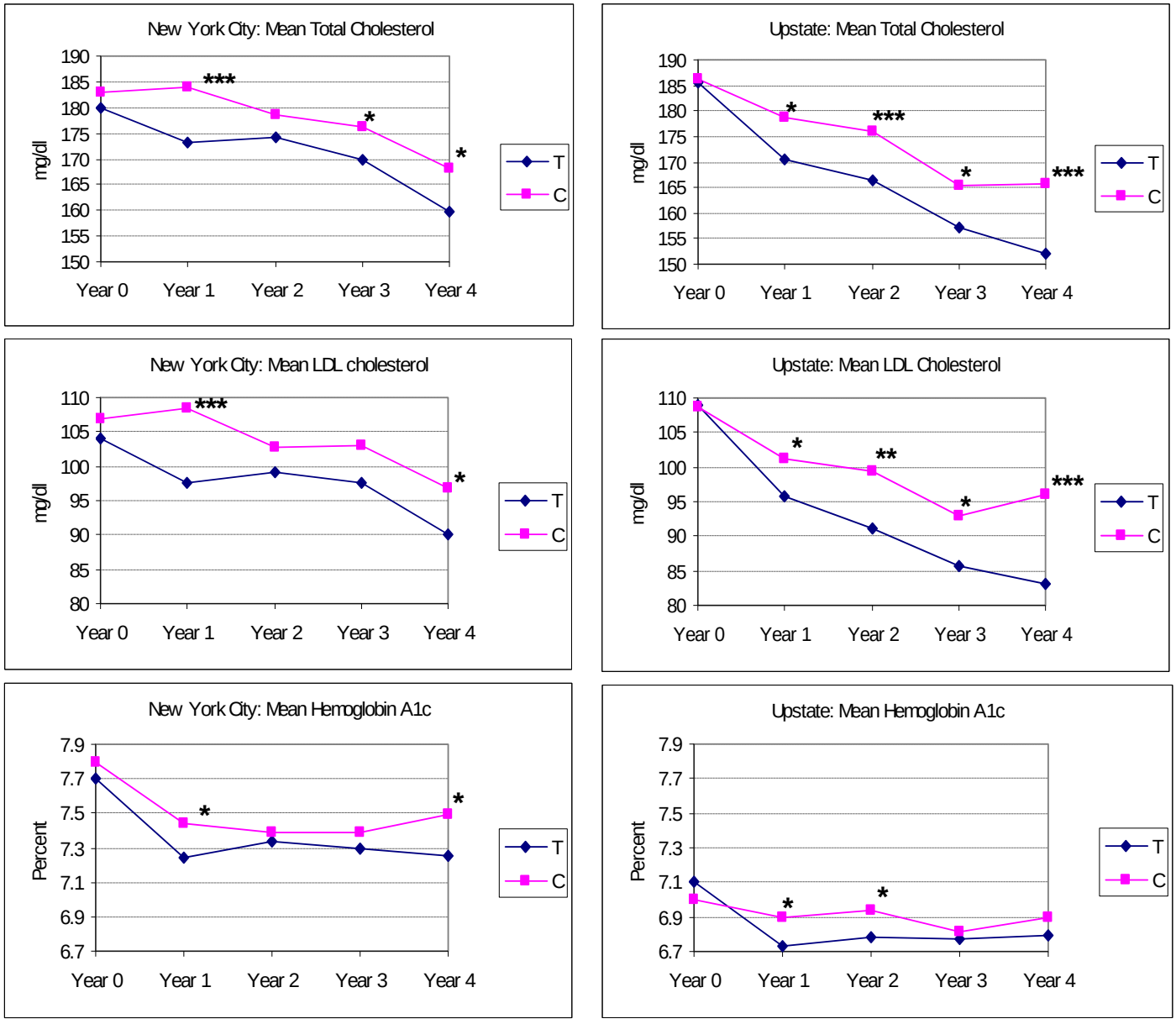
Source: IDEATel Year 4 in-person interview and anthropometry, conducted between December 2004 and October 2006 (Columbia University 2007c).

Notes: Means were predicted with either logit models (binary outcome) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

HDL = high-density lipoprotein; LDL = low-density lipoprotein; HbA1c = glycosylated hemoglobin.

FIGURE VI.4

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' TOTAL CHOLESTEROL, LDL CHOLESTEROL, AND HEMOGLOBIN A1c RESULTS, BASELINE TO YEAR 4



Source: IDEATel annual in-person interviews, conducted from December 2000 through October 2006 (Columbia University 2007c).

Note: Means predicted using the "all cases available" analysis. This analysis included each of the data points (baseline, year 1, year 2, year 3, and year 4) for selected interview and laboratory outcomes for enrollees who completed that interview with demonstration staff, even if they had missed one or more of the preceding interviews (for the follow-up interviews) or dropped out after the interview being analyzed.

*,**,*** Indicate treatment-control difference is statistically significant at the .05, .01, or .001 level, respectively.

HDL = high-density lipoprotein; LDL = low-density lipoprotein; HbA1c = glycosylated hemoglobin.

Finally, the analysis examined a composite binary outcome measure for Cohort 1 enrollees called "multiple risk factor controlled" for whether three main clinical and laboratory measurements—blood pressure, LDL cholesterol, and HbA1c—were all simultaneously well controlled.[29] At year 4, there were no statistically significant differences in either site of the proportions of treatment and control group members with multiple risk factors controlled (New York City 14 and 11 percent respectively; upstate 19 and 17 percent respectively; results shown in Appendix C, Section D).

The time course of this combined outcome in New York City resembled the time course of the component outcomes; namely, a statistically significant difference favoring the treatment group at year 1 (13 percent with multiple risk factors controlled for the treatment group versus 6 percent for the control group), but with narrowed and non-statistically significant treatment-control gaps in subsequent years. Starting in year 2, the proportion of control group members with multiple risk factors controlled improved over year 1, and at the same time the proportion of the treatment group worsened compared to year 1 (see Appendix C, Figure C.1).

In contrast, in the upstate site there was steady and marked improvement among the treatment group in the proportion with multiple risk factors controlled over years 1 through 3 (18 percent in year 1, increasing to 29 percent in year 3). The control group did not show an equivalent improvement, so that there were statistically significant differences in years 2 and 3 favoring the treatment group (in year 3, 29 percent for the treatment group and 17 percent in the control group). In year 4, however, the treatment-control difference vanished, due to a large drop in the treatment group proportion with multiple risk factors controlled (19 percent with multiple risk factors controlled in year 4), nearly down to the year 1 proportion (see Appendix C).

IDEATel Had Modest Effects on Cohort 1 Enrollees' Self-rated Health

In New York City, the treatment-control difference among Cohort 1 enrollees on their self-rated health was not statistically significant; however, treatment group members were less likely than control group members to rate their health as fair or poor (56 percent versus 64 percent) (Table VI.7). In the upstate site, treatment group members on average reported a slightly higher health rating on a scale of 0 to 100 (76 percent versus 73 percent), but there was no treatment-control difference among enrollees who rated their health as fair or poor. In contrast to previous results (Moreno et al. 2007), in year 4, the intervention appears to be affecting perceived health among upstate enrollees for the first time since IDEATel began.

[29] Specifically, this measure had the value 1 only if SBP$\leq$130 *and* DBP$\leq$80, *and* LDL cholesterol<100, *and* HbA1c<7.0; otherwise its value was 0, where DBP = diastolic blood pressure; HbA1c = glycosylated hemoglobin; LDL = low-density lipoprotein; and SBP = systolic blood pressure.

TABLE VI.7

ESTIMATED EFFECTS OF IDEATel ON COHORT 1 ENROLLEES' SELF-REPORTED QUALITY-OF-LIFE OUTCOMES IN YEAR 4, 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]	72.1	70.1	2.1 (.174)	76.0	72.8	3.2 (.038)
Health Fair or Poor	56.1	64.4	-8.3 (.034)	22.0	28.3	-6.3 (.135)
Sample Size	**270**	**273**	—	**169**	**224**	—

Source: IDEATel Year 4 in-person interview, conducted between December 2004 and October 2006 (Columbia University 2007c).

Notes: Means were predicted with either logit models (binary outcomes) or linear regression models (continuous outcomes), which controlled for enrollees' baseline characteristics. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

[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.

There Were Few Significant Effects on Cohort 2 Enrollees for Any of the Outcomes Studied in Their First Year of the Intervention

The IDEATel intervention had large, positive effects on (1) the likelihood of any consultation with diabetes nurse educators in both sites or with the dietitian in upstate New York, and (2) the number of consultations (Appendix C, Table C.3). In New York City, the intervention increased the frequency of health care providers' discussions with participants about exercise. However, it had no significant impacts on either discussions about diet and controlling blood sugar or treatment group members' adherence to medication, diet, and exercise regimens. In upstate New York, the intervention resulted in a significant increase in the number of discussions treatment group members had with health care providers about diet, exercise, and controlling their blood sugar. However, as with treatment group members in New York City, there were no significant treatment-control differences on enrollees' self-adherence and self-care of their diabetes. These impacts echo similar impacts found among Cohort 1 enrollees after one year of followup (U.S. Department of Health and Human Services 2005).

However, while there were impacts on enrollees' communications with health care providers, the intervention had no significant effects in either site on any of the key clinical measures (diabetes control, lipid levels, and blood pressure control) among Cohort 2 enrollees (Appendix C, tables C.4 and C.5).[30] This is different from the experience of Cohort 1 enrollees, for whom the intervention after one year had substantial, and statistically significant, favorable impacts on diabetes control, lipid levels, and blood pressure control in both sites (U.S. Department of Health and Human Services 2005), although the size and significance of those impacts decreased over time and varied by site. One possible reason is that the small number of enrollees in Cohort 2 limited the ability of the evaluation to detect impacts.

Since the sample sizes in Cohort 2 are extremely small, rather than looking for statistically significant results in the satisfaction with care outcomes, the estimated treatment-control differences were qualitatively assessed (Appendix C, Table C.6), with a focus on perceived quality of diabetes care as the most meaningful outcome. The other outcomes were also examined for patterns of "sizeable" treatment-control differences (10 percent of the control group mean).[31] In both sites, treatment group members had somewhat higher ratings of diabetes care quality. The ratings of specific aspects of care were mixed, however, without any clear-cut pattern favoring either treatment or control groups.

Similarly, no intervention impacts are apparent among the estimated effects on self-monitoring and adherence (Appendix C, Table C.7). The compliance for the control groups was already

[30] In fact, the estimated treatment-control differences tended to favor the control group, although none were significant at the 5 percent level.

[31] Statistical tests are reported in the Appendix C tables; however, the reader should keep in mind that, on average, 1 in 20 comparisons will result in a *p*-value of 0.05 or less, and 1 in 10 in a value of 0.10, by chance alone.

quite high (in the upper-80 to mid-90 percent) for two of the outcomes (took recommended doses of diabetes pills daily and administered recommended insulin injections daily), limiting the amount of improvement possible in the treatment groups. For the remaining outcomes, a roughly equal number of differences favor the treatment group as the control group.

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VII. THE DEMONSTRATION'S COSTS AND IMPACTS ON MEDICARE EXPENDITURES AND USE OF SERVICES

Evaluating the impact of the demonstration on Medicare costs is crucial so that CMS can compare the costs and benefits of IDEATel with those of other policy options. The second interim report to Congress estimated that the intervention-related costs of the IDEATel demonstration during Phase I were $8,924 per participant per year, and that there were no offsetting savings in total Medicare expenditures for all Part A and Part B services (U.S. Department of Health and Human Services 2005). Nonetheless, it was possible that the demonstration would begin to show offsetting savings in Medicare expenditures (exclusive of intervention-related costs) during Phase II, because prolonged control of diabetes risk factors over several years should help enrollees to avoid complications of diabetes. In turn, enrollees' use of Medicare-covered services, and consequently expenditures, might decrease.

This chapter presents estimates of the net effects of the demonstration over Phase I and Phase II. It provides estimates first of intervention-related costs during each phase, then of the impact of the demonstration on enrollees' Medicare Part A and Part B expenditures. Finally, it assesses the net costs of the demonstration by subtracting any savings in Medicare Part A and Part B expenditures from the costs of the intervention.[32]

The estimates of the demonstration's intervention-related costs are based on data provided by the Consortium and information obtained by MPR. Medicare claims data were available for December 2000 through December 31, 2006, which allowed an "intent-to-treat" analysis of 1,625 Cohort 1 and 491 Cohort 2 enrollees' expenditures from the time of randomization until nearly the end of the intervention period. The only enrollees excluded were the 30 Cohort 1 sample members and 13 Cohort 2 sample members who were continuously enrolled in an HMO and therefore lacked data on service use or expenditures.[33,34]

[32] Appendix D presents a detailed description of the methods used to estimate the demonstration's costs, impacts on Medicare-service use expenditures, and impact on total Medicare expenditures.

[33] One enrollee was excluded from the analysis because her dropout date preceded her randomization date. Three control group members in Cohort 1 in New York City are excluded from particular analyses because they are missing control variables used in the regressions.

[34] Appendix D presents a sensitivity analysis of the demonstration's impacts on Medicare expenditures to capping expenditures greater than the 98th percentile. The results of this sensitivity test suggest that our findings are not sensitive to outliers. The appendix also reports estimates for different specifications of the sample and discusses impact estimates by subgroups defined by the intensity of use of the intervention.

Estimated Phase I intervention Costs Were High—$8,924 per Participant per Year

The estimated intervention-related costs of the IDEATel demonstration during Phase I were high. About 61 percent of the $28,159,066 cooperative agreement award was spent on costs related to the intervention (Table VII.1), including costs for design (such as for developing software for the HTUs) and implementation (such as for purchasing hardware and software for the HTUs and conducting televisits).[35] The remaining 39 percent of the award was spent on research, such as randomizing enrollees and conducting data analysis, which primarily included staff salaries (see Appendix D, Section A). Using 2000-2001 as a base year, costs related only to implementation translated to an estimated $12,905,572, or $7,645 per participant per year (assuming two years of participation per treatment group member; Table VII.2). The total cost of the intervention, including implementation costs and design and closeout costs depreciated over four years, was $8,924 per person per year.

Intervention-Related Costs in Phase II Were Similar to Those Incurred in Phase I

During Phase II, about 61 percent of the $28,812,419 cooperative agreement was spent on intervention, the same percentage as in Phase I (Table VII.1). Large components of the Phase II implementation-stage costs were for purchasing and installing Generation 2 and Generation 3 HTUs, training participants to use them, and conducting televisits. Using 2004-2005 as the base year, costs solely for implementation were $14,338,429, or $7,029 per participant per year (assuming that Cohort 1 participated in Phase II for three years and Cohort 2 for two years). The figure was $8,437 if depreciated costs for designing the demonstration and closing it out were included (Table VII.2). The *annual* costs per participant for implementation-related costs during Phase II were slightly lower than during Phase I (even though the total implementation-related costs were higher during Phase II) because the costs were spread over a longer period.

Cohort 1 Treatment Group Members Had Higher Total Mean Medicare Expenditures than Control Group Members

Contrary to expectations, mean annual Medicare expenditures were higher for Cohort 1 treatment group members than for control group members in both sites, but the difference was statistically significant (at the .10 level) only in upstate New York. In New York City, the mean annual Medicare expenditures for treatment group members were $13,845 versus $12,961 for control group members (Table VII.3). Similarly, in upstate New York, mean annual Medicare expenditures for treatment group members ($9,566) significantly exceeded the expenditures for control group members ($8,540).

[35] The Phase I estimates also included closeout costs for de-installing HTUs, because it was not clear whether the demonstration would be extended.

TABLE VII.1

COSTS OF THE DEMONSTRATION BY COMPONENT AND STAGE OF THE INTERVENTION

	Phase I		Phase II	
	Estimated Cost	Percentage of Grant Award	Estimated Cost	Percentage of Grant Award
Total Award	$28,159,066	100	$28,812,419	100
Research-Related Costs	$10,935,713	39	$11,250,257	39
Intervention-Related Costs	$17,223,353	61	$17,562,162	61
Components of Intervention-Related Costs				
Design Stage				
Develop Systems Architecture	$1,989,252	7	n.a.	n.a.
Purchase of Nurse Case Managers' Workstations	$38,570	<1	$14,659	<1
Redesign of Software for HTUs	$2,076,033	7	$3,094,490	11
Recruitment of Physicians and Participants	$203,491	<1	$85,166	<1
Total Design Stage Costs	$4,307,346	15	$3,194,315	11
Implementation Stage				
Purchase of HTUs	$3,598,340	13	$2,865,349	10
Installation of HTUs and Training/Retraining of Participants	$1,512,555	5	$3,530,129	12
Lease of Case Management Software	$285,749	1	$318,226	1
Information Systems Support	$2,421,982	9	$2,228,956	8
Case Management and Televisits	$3,044,144	11	$3,395,355	12
Participant Screening and Assessment	$164,611	<1	$57,425	<1
Quality Improvement	$99,720	<1	$116,794	<1
Project Management and Other Direct Costs	$1,778,470	6	$1,826,194	6
Total Implementation Stage Costs	$12,905,572	46	$14,338,429	50
Closeout Stage				
Deinstallation of HTUs	$10,697	<1	$29,418	<1

Source: Cost data for Phase I were based primarily on data, proposals, and progress reports provided by the Consortium and on MPR's research on the market prices of the goods and services used in the demonstration, as described in U.S. Department of Health and Human Services (2005). Phase II cost estimates relied on updated versions of the same sources.

Notes: Costs for developing the systems architecture were incurred during Phase I (U.S. Department of Health and Human Services 2005).

n.a. = not applicable.

TABLE VII.2

SUMMARY OF DEMONSTRATION'S ANNUAL IMPLEMENTATION COSTS PER PARTICIPANT

	Implementation Costs Only	Implementation Costs plus Design/Closeout Costs
Annual Implementation Costs per Participant, Phase I	$7,645	$8,924
Annual Implementation Costs per Participant, Phase II	$7,029	$8,437

Source: Total implementation, design, and closeout costs were drawn from Table VII.1 and were used to calculate annual implementation costs per person.

Notes: Total implementation costs were divided by the number of participants to determine average costs per participant. The number of Phase I participants includes all 844 Cohort 1 treatment group members. The number of Phase II participants includes the 514 treatment group members from Cohort 1 who were still participating in the demonstration at the beginning of Phase II (February 2004), as well as all 249 Cohort 2 treatment group members. To calculate the annual costs per participant, the analysis assumed that Phase I lasted two years, as stated in the Consortium's original proposal, and that Phase II lasted an average of 2.67 years (three years for Cohort 1 and two years for Cohort 2 [Columbia University 1998]). Design and closeout costs were depreciated over four years for Cohort 1 and over three years for Cohort 2 (U.S. Department of Health and Human Services 2005).

TABLE VII.3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES DURING STUDY FOLLOW-UP PERIOD FOR MEDICARE-COVERED SERVICES, COHORT 1, 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	13,845	12,961	885 (.476)	9,566	8,450	1,116 (.094)
Medicare Part A	8,446	7,502	945 (.344)	5,136	4,539	597 (.247)
Medicare Part B	5,399	5,459	-59 (.870)	4,430	3,911	519 (.025)
Selected Part A Services						
Inpatient hospital	7,523	6,702	821 (.365)	4,297	3,709	588 (.192)
Skilled nursing facility	568	426	142 (.272)	562	534	28 (.787)
Emergency room	118	129	-12 (.355)	127	122	5 (.716)
Selected Part B Services						
Outpatient hospital	1,467	1,500	-33 (.837)	1,080	913	167 (.113)
Durable medical equipment	416	380	36 (.544)	691	531	159 (.009)
Physician visits	389	412	-23 (.392)	298	289	8 (.595)
Laboratory services	69	77	-7 (.446)	58	54	3 (.657)
Other Part B services[a]	2,375	2,215	160 (.326)	1,889	1,725	164 (.198)
Part A and B Services						
Home health care	818	1,014	-196 (.131)	388	384	5 (.938)
Sample Size	**379**	**358**	**-**	**446**	**442**	**-**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Estimates reflect annualized expenditures for the period from each sample member's randomization through the end of the study follow-up period (December 31, 2006), and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of the follow-up period that the enrollee was alive and not in an HMO. The reported sample size includes the full sample of enrollees (excluding only those who were continuously enrolled in an HMO). Three control group members were dropped from the analysis in New York City because they are missing control variables used in the regression analysis. Because the list of services is not exhaustive, the sum of Medicare costs, by type of service, is not equal to total Medicare costs. Total Part A costs and total Part B costs are not equal to the sum of their components, because home health expenditures are partially covered under Part A and partially covered by Part B. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

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

HMO = health maintenance organization.

For Cohort 1, There Were Few Statistically Significant Treatment-Control Differences for Expenditures on Particular Medicare Services

In both New York City and upstate New York, treatment group members had somewhat higher expenditures for Medicare Part A services than control group members, a result primarily of the sizable treatment-control differences for inpatient hospital care, but the differences were not statistically significant. In New York City, treatment-control differences in Part B expenditures were not statistically significant overall and for any particular type of Part B services. However, mean Medicare expenditures for Part B services were significantly higher for the treatment group than for the control group in upstate New York, primarily because the treatment group had higher average spending for durable medical equipment and for outpatient hospital services. Only the treatment-control difference in durable medical equipment ($159) was statistically significant.

There Does Not Appear to Be a Trend Toward Cost Savings in Either Site for Cohort 1 Enrollees

Previous cost estimates based on Medicare claims data for Cohort 1 through 2004 suggested a trend toward cost savings in New York City, as there was a sizable negative treatment-control difference in New York City during year 3 (Moreno et al. 2007). However, the apparent trend reversed over a longer follow-up period; while the treatment-control difference in New York City was *negative* $4,179 in year 3, it was close to zero during year 4 and positive and sizable (though not statistically significant) during year 5 (Table VII.4).[36] Likewise, there was no trend

[36] The results for year 3 are anomalous for several reasons. Part of the reason that the Medicare cost difference increased in year 3 for those in the upstate site, but not for those in the New York City site, could be that the treatment group in the upstate site had more frequent regular contact with nurse case managers, which prompted the upstate treatment group members to seek more service, test, or equipment. As noted in Chapter VI, Table VI.2, the demonstration's impact on the number of consultations with a nurse educator was much greater in upstate New York than in New York City, perhaps because the demonstration was interrupted for many months in New York City. This could have led to the treatment group's higher costs for durable medical equipment or other Part B Medicare services (which included, for example, some types of laboratory services, therapy, and medical supplies). However, the difference across sites in inpatient hospital costs is more puzzling. The demonstration's favorable effects on clinical outcomes such as blood pressure and total cholesterol were larger in the upstate site than in the New York City site, which theoretically, could translate to greater cost savings for inpatient hospital services in the upstate site. However, only in New York City were there cost savings for inpatient services; in the upstate site, the treatment group had statistically significant higher costs for inpatient hospital services than the control group did. The demonstration did have more favorable impacts on adherence to medication and self-reported health status in New York City than in the upstate site. It is possible that the demonstration somehow improved the treatment group's general health (in areas that would not be reflected in the clinical outcomes for diabetes), which in turn translated to a reduction in inpatient hospital costs. However, it is unclear what would account for the *positive* treatment-control difference in inpatient costs in the upstate site. The puzzling inpatient hospital cost results could also simply be a statistical fluke. Alternatively, it is possible that the greater increase in test and monitoring in the upstate site identified some patients who needed a hospital stay before their condition worsened.

See Appendix D, tables D.6 and D.7 for the demonstration's effects on expenditures for specific components of service, by site.

TABLE VII.4

TRENDS IN PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES FOR COHORT 1, BY SITE AND EVALUATION GROUP
(Means, in Dollars)

Component/Service	Year 1	Year 2	Year 3	Year 4	Year 5
New York City					
Total Medicare					
Treatment group	9,840	10,627	9,849	15,768	21,127
Control group	7,891	9,502	14,027	15,459	15,386
Difference	1,949	1,125	-4,179	309	5,741
(*p*-value)	(.132)	(.431)	(.030)	(.902)	(.113)
Medicare Part A					
Treatment group	5,669	5,790	5,052	9,563	14,371
Control group	4,056	4,566	8,491	9,587	8,959
Difference	1,613	1,224	-3439	-24	5,412
(*p*-value)	(.155)	(.294)	(.040)	(.991)	(.086)
Medicare Part B					
Treatment group	4,171	4,837	4,797	6,205	6,756
Control group	3,835	4,936	5,536	5,872	6,426
Difference	336	-99	-739	333	329
(*p*-value)	(.273)	(.837)	(.118)	(.642)	(.670)
Sample Size					
Treatment	**369**	**355**	**344**	**331**	**309**
Control	**353**	**337**	**327**	**311**	**282**
Upstate New York					
Total Medicare					
Treatment group	7,322	8,078	10,015	10,506	11,296
Control group	6,493	7,772	7,368	9,489	10,950
Difference	830	306	2,647	1,017	347
(*p*-value)	(.374)	(.772)	(.011)	(.404)	(.829)
Medicare Part A					
Treatment group	3,879	4,130	5,652	5,555	6,131
Control group	3,381	4,190	3,796	5,261	5,938
Difference	498	-60	1,856	294	194
(*p*-value)	(.518)	(.944)	(.026)	(.760)	(.885)
Medicare Part B					
Treatment group	3,443	3,948	4,363	4,951	5,165
Control group	3,112	3,582	3,572	4,228	5,012
Difference	331	366	791	723	153
(*p*-value)	(.229)	(.244)	(.019)	(.067)	(.756)
Sample Size					
Treatment	**445**	**431**	**412**	**388**	**364**
Control	**442**	**423**	**403**	**383**	**363**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Enrollees' data have been annualized, and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of each year that the enrollee was alive and not in an HMO. Reported sample sizes reflect the full sample of enrollees (excluding those that were continuously enrolled in an HMO during the year), though actual sample sizes may vary slightly because enrollees were missing data for control variables used in the regressions. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

toward cost savings in upstate New York, as the treatment-control differences were positive each year (ranging from $306 in year 2 to a high of $2,647 in year 3).

The Cohort 1 Treatment and Control Groups Generally Had Similar Patterns of Medicare Service Use

There were few statistically significant differences between treatment and control group members in the likelihood that they used particular Medicare services or in the number of services they received. Exceptions were that, in New York City, treatment group members were less likely to have an inpatient hospital stay or to use home health services[37]; among those who did use home health services, treatment group members were more likely to have a skilled nursing visit, but less likely to have a social work visit. Exceptions in upstate New York were that treatment group members were less likely to have an aide visit (among those using home health services) and more likely to use durable medical equipment. Finally, there were no significant differences in the percentage of sample members receiving various diabetes-related tests (a dilated eye exam, HbAlc test, LDL cholesterol test, or urine microalbumin test) in either site. However, compared to control group members, among those receiving a given diabetes related-test, treatment group members received more dilated eye exams but fewer HbA1c and urine microalbumin tests in New York City.

Treatment-Control Differences in Medicare Expenditures for Cohort 2 Were Not Statistically Significant

For Cohort 2, mean Medicare expenditures were similar for the treatment and control groups in New York City (Table VII.5). However, in upstate New York, the treatment group had lower total Medicare costs ($6,450) than the control group ($8,694); though the -$2,244 difference was not statistically significant. The source of the treatment-control difference in total Medicare costs in upstate New York was driven by the treatment group's significantly lower use of inpatient hospital services (29 versus 39 percent; see Appendix D, Table D.7).

For Cohort 2, the Demonstration Had Few Impacts on the Use of Specific Medicare Services or Expenditures

The treatment and control groups in Cohort 2 generally had similar use of and expenditures for particular types of Medicare services. However, there were several exceptions. Compared to the control group, the treatment group had higher costs for physician services (in New York City only; Table VII.5) and received more physician visits (in New York City only; Appendix D, Table D.11). The treatment group was also more likely to use durable medical equipment (in

[37] See Appendix D, tables D.8 and D.10 for the demonstration's effects on service use for Cohort 1.

TABLE VII.5

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES DURING STUDY FOLLOW-UP PERIOD, COHORT 2, BY SITE AND EVALUATION GROUP

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Total Medicare	11,906	11,661	245 (.931)	6,450	8,694	-2,244 (.132)
Medicare Part A	7,296	6,886	410 (.867)	2,991	4,957	-1,966 (.118)
Medicare Part B	4,610	4,775	-165 (.799)	3,458	3,736	-278 (.443)
Selected Part A Services						
Inpatient hospital	6,665	6,146	520 (.814)	2,475	4,387	-1,912 (.102)
Skilled nursing facility	452	468	-16 (.972)	294	388	-94 (.612)
Emergency room	146	174	-28 (.569)	109	111	-2 (.960)
Selected Part B Services						
Outpatient hospital	892	1,367	-475 (.115)	878	1,000	-122 (.291)
Durable medical equipment	249	279	-30 (.781)	636	603	33 (.805)
Physician visits	450	312	139 (.049)	236	267	-30 (.286)
Laboratory services	93	54	39 (.121)	41	35	6 (.600)
Other Part B services[a]	2,441	2,250	191 (.599)	1,349	1,524	176 (.383)
Part A and Part B Services						
Home health care	389	469	-80 (.687)	306	246	60 (.580)
Sample Size	**82**	**84**	**-**	**161**	**164**	**-**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Estimates reflect annualized expenditures for the period from each sample member's randomization through the end of the study follow-up period (December 31, 2006), and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of the follow-up period that the enrollee was alive and not in an HMO. Because the list of services is not exhaustive, the sum of Medicare costs, by type of service, is not equal to total Medicare costs. Total Part A costs and total Part B costs are not equal to the sum of their components because home health expenditures are partially covered under Part A and partially covered by Part B. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

TABLE VII.5 *(continued)*

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

HMO = health maintenance organization.

upstate New York only) and to receive home health services from a social worker (in New York City only) (Appendix D, Table D.9). Treatment and control members' rates of receiving diabetes-related tests were similar, although treatment group members received fewer microalbumin tests in New York City (Table D.11).

Savings in Medicare Part A or Part B Expenditures Did Not Offset the High Costs of the Intervention

The savings in total Medicare expenditures in any site or cohort were either nonexistent or far too small to offset the high costs of the intervention. The net effects of the demonstration on Medicare costs are equal to the treatment-control difference in Medicare expenditures plus the intervention-related costs of the demonstration described in this chapter. Adding the per-participant cost of the intervention to the average total expenditures for Medicare-covered services of the treatment group members results in per-person costs ($22,507 in New York City and $18,228 in upstate New York; Table VII.6) that were nearly $10,000 higher for treatment than for control group members for Cohort 1 in both sites. Similarly, the annual per-person costs for the Cohort 2 treatment group were $8,682 higher than for the control group in New York City, and $6,183 higher in upstate New York.

TABLE VII.6

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, DEMONSTRATION SERVICE COSTS, AND COSTS FOR 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)
Cohort 1 (Both Phases)						
Total Expenditures for Medicare-Covered Services	13,845	12,961	884 (.476)	9,566	8,450	1,116 (.094)
Total Intervention- Related Costs[a]	8,662	0	n.a.	8,662	0	n.a.
Total Costs	22,507	12,961	9,546 (.001)	18,228	8,450	9,778 (.000)
Cohort 2 (Only Phase II)						
Total Expenditures for Medicare-Covered Services	11,906	11,661	245 (.931)	6,450	8,694	-2,244 (.132)
Total Intervention-Related Costs	8,437	0	n.a.	8,437	0	n.a.
Total Costs	20,343	11,661	8,682 (.000)	14,877	8,694	6,183 (.000)
Sample Sizes						
Cohort 1	**379**	**358**	-	**446**	**442**	-
Cohort 2	**82**	**84**	-	**161**	**164**	-

Source: See tables VII.1 and VII.2 for details on the data sources for and construction of intervention-related cost estimates, and tables VII.3 and VII.5 for the details on the data sources for and estimation of expenditures for Medicare-covered services.

[a]Total demonstration service costs for Cohort 1 are based on the arithmetic average of demonstration costs for Phase I and Phase II (from Table VII.2), weighted by the average length of time that Phase I participants were enrolled during each phase.

n.a. = not applicable.

PART 3: SUMMARY, IMPLICATIONS, AND CONCLUSION

The Congressionally mandated evaluation found that the IDEATel demonstration met Congressional implementation requirements despite numerous challenges that arose. The Consortium's responses to several of these challenges may have affected the ability of the demonstration to achieve its intended effects. The evaluation found IDEATel to have been clinically effective in only one site and to have had no effects on Medicare Part A and Part B expenditures or the use of expensive services, such as hospital care. The findings reveal mixed success with the demonstration. For example, the HTU use rates declined steadily during the demonstration period for both cohorts, although the intervention had substantial and significant impacts on communication between participants and their health care providers across sites and cohorts. Furthermore, the treatment-control difference for diabetes control, lipid levels, and blood pressure control increased (diabetes control and lipid levels) or remained relatively constant (blood pressure control) across the first four years of the demonstration only for Cohort 1 enrollees in the upstate site. Finally, there does not appear to be a trend toward cost savings in either site for Cohort 1 enrollees, and for Cohort 2, there were no statistically significant treatment-control group differences in Medicare expenditures during the first year of the intervention. The implications of these findings are discussed in the rest of this section.

The IDEATel Demonstration Met Congressional Implementation Requirements. As Delivered, However, the Intervention Was Neither as Intensive Nor as Technologically Sophisticated as the Consortium Had Originally Planned

The Consortium's implementation of the IDEATel demonstration met Congressional mandates. In both phases, however, the Consortium made some deliberate departures from its original plans and confronted unexpected challenges. The Consortium abandoned its intention to hold televisits every two weeks with all participants, as demonstration leadership argued that the nurse case managers were to determine the appropriate frequency for each participant in their caseload. Likewise, the Consortium disavowed the premise that use of advanced HTU functions was central to the intervention, as demonstration leadership revised their hypotheses about the connection between these functions and participants' well-being and motivation to self-care. The most important unplanned departure was a key subcontractor's inability to deliver Generation 2 or 3 HTUs to most participants, who thus had no opportunity to experience the planned Phase II technological improvements in the newer units.

Qualitative data collected for this analysis suggest that, as implemented, IDEATel had limited success leading participants down the paths toward significant impacts on physiologic and long-term outcomes. Consortium staff, referring physicians, and Cohort 2 participants all said that IDEATel helped participants become more knowledgeable about diabetes and the importance of diet and exercise. No respondents, however, described people who had substantially changed their behavior, in terms of diet and exercise, while participating. While some behavioral changes probably occurred, they were not foremost in the minds of people closest to the project. It is

possible that the planned and unplanned departures from the Consortium's plans weakened the intensity of the intervention and undermined its potential to affect participants' behavior.

HTU Use Was Uneven Across Sites and Cohorts and Over Time, Which Suggests Limited Acceptability of the Intervention to Participants

The comparison of HTU use confirms that Cohort 1 participants faced considerably more hurdles using the Generation 1 HTU during the early stages of the demonstration than Cohort 2 participants using the Generation 2 or 3 HTU during a comparable period. For instance, Cohort 2 participants began using the HTU faster. In addition, the higher intensity of use of the basic HTU functions by Cohort 2 participants relative to their Cohort 1 counterparts during the first 27 months after the start of HTU installation suggests that, as reported by Consortium staff, the redesigned Generation 2 HTU was simpler to use than the Generation 1 HTU.

Furthermore, in both sites, intensity of use declined for Cohort 1 participants over the 75-month period from December 2000 to February 2007. HTU use patterns closely followed (1) the retraining of participants on HTU use between late 2002 and early 2003 (increasing trend), (2) the end of operations for Phase I in New York City in 2003 (decreasing trend), (3) the resumption of operations in mid-2004 (increasing trend), and (4) the upgrade of Generation 1 HTUs with Generation 2 or 3 HTUs (increasing or decreasing trend, depending on the function). Surprisingly, the use rates of key HTU functions were low (televisits) or nearly zero (monitoring clinical readings) near the end of the demonstration. It is unclear what factors drove this declining trend, particularly because nurse case managers, instead of participants, initiated televisits. Although one could interpret this reduction as an indication that participants' health remained stable or improved, it could also reflect technical problems with the redesigned HTU or loss of interest in the intervention among the remaining participants. The interruption of operations in New York City might also have contributed to this trend, but it is unclear what effects this hiatus had on the confidence of participants to use their HTU when televisits resumed. More puzzling is the declining trend in HTU use in upstate New York, where demonstration operations continued uninterrupted between phases, although reportedly there was a reduction in the number of nurse case managers available to conduct televisits during the last six months of the intervention.

Unfortunately, the shorter follow-up period (27 months) for Cohort 2 participants, all of whom used Generation 2 or Generation 3 HTUs, does not help clarify whether the use patterns observed among Cohort 1 participants would have differed for Cohort 2 participants had the follow-up period for this cohort lasted an additional four years. Nevertheless, the available evidence suggests that HTU use also dropped by the end of the demonstration for Cohort 2 participants. Since Cohort 2 participants neither experienced an interruption of operations nor had their HTUs upgraded, as Cohort 1 participants did, the decline in use rates may well be due simply to diminished interest in the demonstration.

While the steady reduction of the intensity of use for all functions suggests that the novelty of the HTU declined rapidly for both cohorts, the trend, more significantly, implies that the intervention was less likely to have effects even over longer follow-up periods.

The Intervention's Positive Impacts on Participants' Contact with Their Health Care Providers Contributed to the Sustained Positive Effects on Clinical and Laboratory Outcomes in Upstate New York

Impacts on participants' contact with their health care providers were seen across cohorts and sites. The intervention also had favorable impacts on Cohort 1 participants' satisfaction with their diabetes care. The impacts on enrollee-provider communication were greater in the upstate site than in New York City for both cohorts. Among Cohort 1 participants upstate, the higher frequency of contact might have contributed to the sustained positive effect across the first four years of the demonstration on their discussions with their providers on exercise and nutrition, as well as on their adherence to self-care.

IDEATel had a sustained effect on most clinical and laboratory outcomes in upstate New York. Among Cohort 1 enrollees upstate, the treatment-control differences for the main clinical outcomes (diabetes control, lipid levels, and blood pressure control) increased, or remained relatively constant, across the first four years of the demonstration. There were sustained positive impacts between years 1 and 4 on systolic and diastolic blood pressure in upstate New York, and lipid levels (total and LDL cholesterol) for treatment group members continued to decrease across the first four years of the demonstration, which led to a substantial and increased effect by the fourth year. However, impacts on these outcomes for Cohort 1 participants in New York City were isolated and smaller, and there were no impacts on Cohort 2 participants in either site. The smaller impacts among Cohort 1 participants in New York City might be partially attributable to the interruption of operations in that site (operations in New York City were interrupted between phases for about six months).

It Is Unclear Why IDEATel Was More Effective in the Upstate Site

Because the demonstration was implemented in only the two sites, it is difficult to determine (1) why it was more effective among participants upstate than in New York City, and (2) whether some demonstration features are essential for long-term impacts. Whether IDEATel's greater effectiveness upstate was due to the ability of the upstate intervention team to adjust participants' diabetes treatment (an option not available to the New York City team), to the socioeconomic and cultural differences between the participants in New York City (mostly Latino) and those in upstate New York (mostly white), or to the continuity of operations in upstate New York cannot be determined.

Although the Results on Health Outcomes from the Upstate Site Appear Promising, Demonstration Findings Are Limited by Substantial Attrition

IDEATel, at least as implemented upstate, may have the potential to exert substantial and lasting effects on the intermediate outcomes measures (such as blood pressure and lipid levels). Sustained improvement in these intermediate clinical outcomes are the first step toward avoiding the long-term complications of diabetes—strokes, heart attacks, blindness, kidney failure, and limb loss (although no significant impacts on hospital use or Medicare expenditures emerged in either site in Cohort 1).

However, any conclusions from the survey and in-person data are limited by the high attrition rate in both sites. The Cohort 1 treatment group in the upstate site lost 64 percent of its members between baseline and year 4, which raises the possibility of bias of unknown magnitude and direction in the estimated impacts.[38] The loss of sample in the New York City site (33 percent) also greatly reduced the evaluation's statistical power to detect impacts there.

The Intervention-Related Costs of the Demonstration Were Excessive by Any Standard

The intervention-related costs of the demonstration were too high—more than $8,000 per participant per year.[39] The main driver of these costs was the size of the cooperative agreement allocated to the demonstration's operations (see Table VII.1), compounded with the use of very expensive HTUs (see Appendix D, section A). To put this into perspective, the annual costs of the intervention for Cohort 1 were similar to the control group's average annual expenditures for all Medicare Part A and Part B services in upstate New York and about two-thirds of the corresponding expenditures for the control group in New York City. The costs of the demonstration were also too high relative to the costs of comparable home-based telemedicine programs (which ranged from $415 to $1,830 per participant per year) that served patients with diabetes and used televisits with nurse case managers in addition to in-home visits, and that were reported as having the "potential to effect cost savings" (Dansky et al. 2001; Johnston et al. 2000).

[38] Somewhat surprisingly, the percentage of enrollees that died during the follow-up period was similar for the treatment and control groups within each site and cohort (see Appendix D, footnote 4).

[39] The intervention-related costs exclude Medicare Part A and Part B expenditures (see Table VII.1).

There Were No Offsetting Savings for Medicare Services in Spite of the Long Follow-up Period

During Phase I, the treatment group might have had higher use of, and expenditures for, Medicare-covered services, because IDEATel met the latent demand for health services among medically underserved beneficiaries. If this was the case, favorable treatment-control differences in Medicare expenditures might appear over a longer follow-up period. Moreover, over a longer follow-up period, the demonstration was expected to prevent diabetes-related complications; in turn, participants' costs for hospitalizations and other Medicare services should fall. However, there was no trend toward cost-savings even after the six-year follow-up period observed for Cohort 1.

While an Ongoing Program Similar to IDEATel Could Improve Health Outcomes, It Would Almost Surely Increase Net Costs Substantially

There were several reasons that the demonstration might have had higher costs than a similar telemedicine program in another area or with a different population. For example, the demonstration was implemented in New York State, where the costs of living are higher than in most parts of the United States. Also, training costs for IDEATel may have been high because the population served was not familiar with computers. Finally, the demonstration did not include enough beneficiaries to benefit from economy of scale. However, even if the intervention-related costs were substantially reduced, it would be impossible for the demonstration to meet the legislative goal of "reducing overall health care costs," since there were no savings in Medicare service-costs in any site or cohort. (In fact, for Cohort 1, the treatment group had significantly higher expenditures than the control group for Medicare-covered services in upstate New York.)

It Is Unlikely That IDEATel Would Be Cost-effective Relative to Other Interventions Intended to Improve Care for People with Diabetes

Caution must be exercised when comparing findings from IDEATel to those from other interventions, since other studies typically use different methods for assessing impacts and serve different populations. Nonetheless, it seems unlikely that IDEATel would be more cost-effective than other interventions intended to improve care for people with diabetes, since IDEATel cost more than $8,000 per participant per year. For example, the cost of an intervention that consisted of automated telephone disease management with telephone followup by nurses was about $400 per patient annually, including the costs for the extra time each nurse devoted to followup (3.8 hours per patient per year).[40] According to randomized trials, patients receiving this low-cost intervention significantly improved their glycosylated hemoglobin (HbA1c) levels (Piette et al. 2000 and 2001). The intervention's costs would be more than fully offset if the improved glycemic control had any effect on patients' health service use.

[40] An overview of best practices in coordinated care and disease management is provided by Chen et al. (2000).

Other interventions have been cost-effective, even if not cost-saving, as the costs of the program are outweighed by the fact that they save lives or improve health.[41] For example, *Project Dulce* (a diabetes case-management and self-management training program *without telemedicine*) had clinical impacts (derived from a comparison of program participants to a matched control group) similar in size to those produced by IDEATel. The program was cost-effective according to commonly accepted standards, costing $10,141 to $69,587 per quality-adjusted life year (QALY), depending on the insurance status of the cohort of comparison (Gilmer et al. 2007).[42] However, Project Dulce cost an estimated $662 to $1,537 per participant per year to implement, about an eighth the cost of IDEATel. While the cost-effectiveness of IDEATel was not formally assessed (because of the numerous assumptions required to estimate QALYs, which are difficult to verify), it is unlikely that it would be cost-effective relative to a program like Project Dulce. In short, for IDEATel to be cost-effective, the intervention-related costs would have to be substantially reduced (perhaps through cheaper technology), while maintaining clinical impacts.

Conclusion

The IDEATel demonstration met Congressional implementation requirements, though the Consortium's response to several implementation challenges diluted the ability of the demonstration to achieve its intended effects. IDEATel was clinically effective over the medium term in only one of two sites, which made it difficult to determine (1) why the demonstration was more effective among participants upstate than in New York City, and (2) whether some demonstration features are essential for long-term impacts. The expectation that the demonstration could generate offsetting savings for Medicare services did not materialize, in spite of the six-year followup. Furthermore, Medicare expenditures were never a key demonstration outcome. While an ongoing program similar to IDEATel might have lower Medicare costs, it would be virtually impossible for it to generate cost-savings, particularly because the intervention-related costs of the demonstration were excessive by any standard. Given the absence of effects on costs or services, however, even a less expensive version of this demonstration would not produce sufficient Medicare savings to offset demonstration costs. Furthermore, while IDEATel had similar clinical impacts as other interventions for individuals with diabetes, it cost far more.

[41] A comprehensive overview of the peer-reviewed literature for telemedicine services that substitute for face-to-face medical diagnosis and treatment that may apply to the Medicare population is provided by Hersh et al. (2006). A discussion of the potential long-term effects of IDEATel on the clinical complications for diabetes is provided in Chapter IV, Section C.10 of the second interim report to Congress on the IDEATel demonstration (U.S. Department of Health and Human Services 2005).

[42] As expected, the largest improvements in life expectancy were predicted for the groups that had the largest improvements in clinical indicators, including HbA1c, total cholesterol, and triglycerides.

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APPENDIX A

ENABLING LEGISLATION FOR THE DEMONSTRATION AND THE EVALUATION

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

42 USC 1395b–1 note.

(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.

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 "60,000,00

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APPENDIX B

SUPPLEMENTAL MATERIALS TO CHAPTER V

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A. DATA SOURCES

Data for this report are drawn from HTU use logs collected by the Consortium (Columbia University 2007b). The data represent participants' experiences with the technology through the end of the study follow-period (February 27, 2007), when the demonstration's operations ceased.

For this report, the analysis examined the experience of 753 Cohort 1 participants (out of 844 in the group) and 230 Cohort 2 participants (out of 249 in the group).[43]

B. ANALYTIC METHODS

The analysis focuses on the participants' HTU use *on their own*, after they had received initial training by a nurse installer. It 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 do 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 are the key features of a telemedicine system, participants must log in. All functions are self-initiated, with two exceptions: televisits and, for users of Generation 2 HTUs, upload of blood pressure and blood sugar readings, which can be done automatically (this is called "data pulling"), thus relieving participants of having to upload their readings between televisits (Foster et al. 2006). Because it is not possible to distinguish between HTU use guided by nurse installers and use without such assistance, the analysis excludes participants' HTU use on the day the device was installed. That exclusion avoids counting instances in which it was very likely that use was guided by the nurse installer. Because some aspects of the intervention in New York City and upstate New York were quite different, and because demonstration enrollees in both sites differed so markedly from each other on so many major characteristics, the analyses were conducted separately for each site.

For the analysis of time to first use of HTU functions, the independent evaluator used life table methods, which overcome the censoring of the experience of participants either by the date they dropped out of the demonstration or the end of the study follow-up period (December 19, 2001, for Cohort 1 participants and December 31, 2005, for Cohort 2 participants), whichever came first. Unless censoring is adequately factored in, any estimates of the mean duration to first use of an HTU function will be biased downward. The median time to first use and the "tri-mean," a robust measure of central tendency based on the time-to-first-use life table distributions are

[43] For Cohort 1, the analysis excluded 50 participants because their records had a missing installation date, 6 because they dropped out before their HTUs were installed, 29 because their records did not specify the type of HTU they had received, and 6 because their records did not indicate when their HTU was upgraded from a Generation 1 to a Generation 2. For Cohort 2, the analysis excluded 17 participants because the installation date was missing and 2 because their records did not specify the type of HTU they had received.

reported (Moreno et al. 2007).[44] Finally, the analysis used the log-rank test to test whether the distribution of time to first use varied across cohorts.[45]

Finally, for the analysis of frequency of use by Cohort 1 participants, the analysis presents weighted means, with weights equal to the length of the period between HTU installation and dropout or February 27, 2007, whichever came first. The independent evaluator conducted similar analyses for the duration of the session devoted to consulting the American Diabetes Association web pages (available only through November 2003 because the Consortium discontinued collecting data on the use of this function) and the duration of the televisit. A *t*-test was used to ascertain differences between sites, controlling for baseline characteristics. For Cohort 2 participants, the independent evaluator had data from December 27, 2004 (the date when the HTU for the first Cohort 2 participant was installed) through February 27, 2007, which is a 792-day follow-up period. Therefore, Phase I data were restricted to a 792-day follow-up period when comparing the two cohorts.[46] The analysis also presents weighted means for Cohort 2 participants. To assess differences across cohorts, the analysis used a weighted linear regression model (that is, an analysis of variance) controlling for participants' characteristics at baseline. The *p*-value for the coefficient of the cohort binary indicator is reported.

C. LIMITATIONS TO THE ANALYSIS

The analysis of HTU use for Cohort 1 and Cohort 2 participants has four limitations. First, without a suitable control group to account for secular trends against which to compare changes in use in both cohorts, it is not possible to determine whether the redesign of the HTU is the sole factor behind the higher use by Cohort 2 participants of the array of HTU functions. Second, because communications between participants and providers are confidential, the independent evaluator was 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. Furthermore, the use of the data-pulling feature in Generation 2 HTUs could have changed Cohort 2 participants' use of other functions by relieving them of the need to upload their glucose and blood pressure readings between televisits. Thus, it is unclear how much effort

[44] This measure is defined as: $T = \frac{P_{25} + 2P_{50} + P_{75}}{4}$, where P_{25}, P_{50}, and P_{75} denote the 25th, 50th, and 75th percentiles of the cumulative survival distribution, respectively.

[45] The sample size for the life table calculations varies by the duration of the interval between HTU installation and the end of the study follow-up period. On the day after installation, the sample size is equal to the total number of participants in the study sample. As participants use their HTUs for the first time, the sample size decreases. A decrease in the sample in this way implies that, for long intervals since installation, the sample size might become too small to permit robust estimates of the rate at which participants use an HTU function.

[46] The HTU for the first Cohort 1 participant was installed on December 15, 2000, so the analysis used data from this date through February 15, 2003 (that is, 792 days later) when comparing the two cohorts.

was required of Consortium staff to generate the levels of use observed and how this varied by HTU type and cohort. Third, the sample size for Cohort 2 participants was small. Thus, it is likely that the estimates from this group are less robust than the estimates for the Cohort 1 sample. Finally, the Consortium stopped collecting data on use of the American Diabetes Association web pages—an important intervention component—in November 2003. Therefore, it is not possible to assess the extent to which participants in both phases used these educational materials, particularly after Cohort 1 participants were retrained on HTU use during the third year of the demonstration.

D. SUPPLEMENTAL TABLE AND FIGURES

TABLE B.1

STEPS INVOLVED IN USING SPECIFIC HTU FUNCTIONS OF THE GENERATION 1 HTU

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.

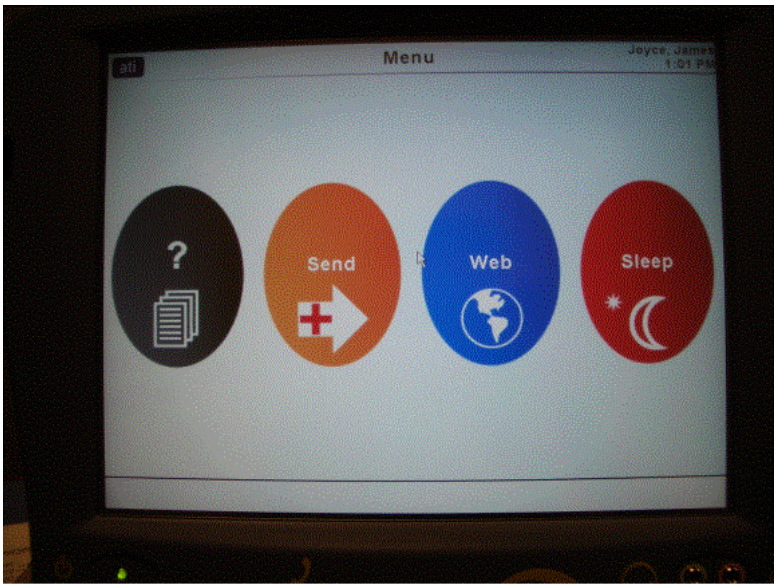
[c]See Figure B.1. In the Generation 2 and 3 HTUs, the launch pad was activated in the flat touch screen.

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

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

FIGURE B.1

HTU LAUNCH PAD FOR THE GENERATION 1 AND 2 HTUs

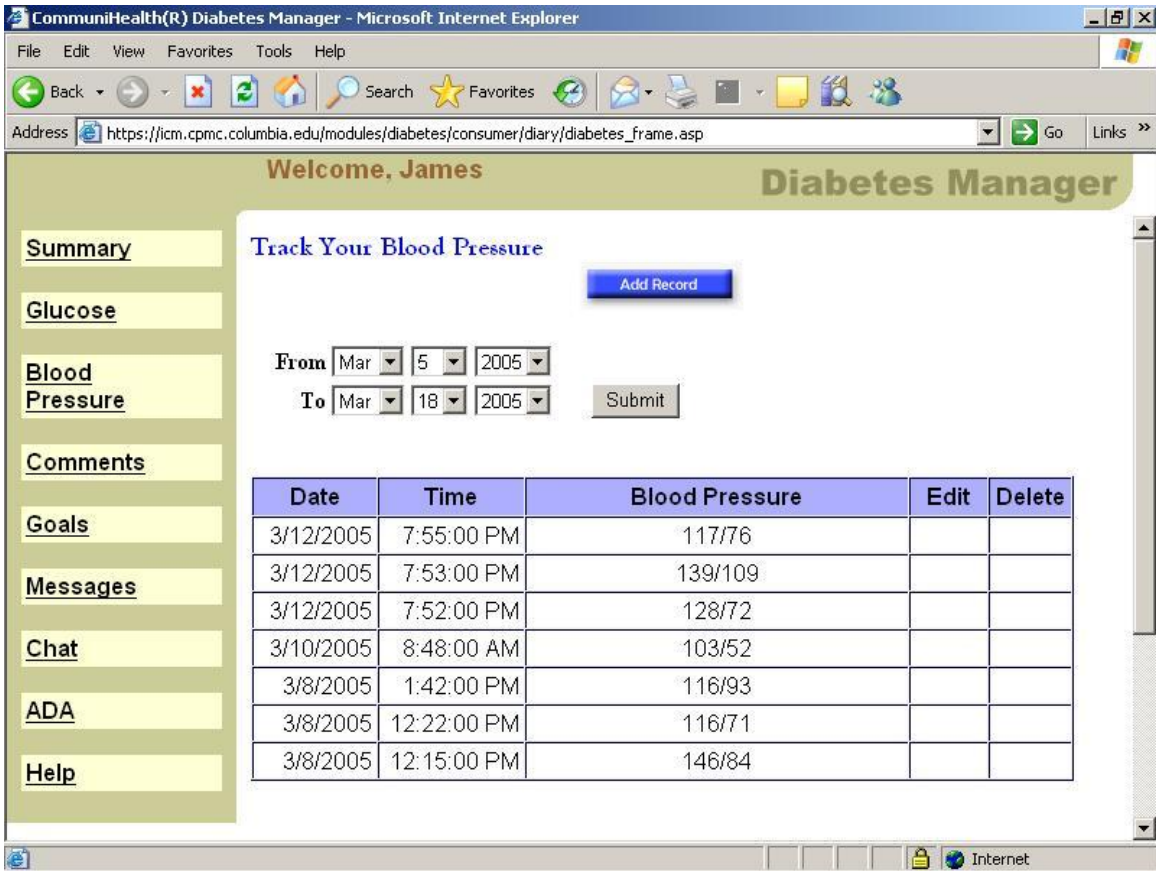


Source: Starren et al. (2003) and Columbia University (2005c).

HTU = home telemedicine unit.

FIGURE B.2

SCREENSHOT FOR MONITORING BLOOD PRESSURE
WITH A GENERATION 2 HTU



Source: Columbia University (2005c).

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APPENDIX C

SUPPLEMENTAL MATERIALS TO CHAPTER VI

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A. DATA SOURCES

Data for this report were drawn from in-person assessments of enrollees (physiologic and survey data from baseline and years 1, 2, 3, and 4) and Medicare claims data for all program months through December 2006. Demonstration staff conducted assessments at baseline (immediately before randomization) and annually thereafter. Each assessment consisted of a detailed structured interview; measurements of body dimensions, weight, and blood pressure; and blood and urine tests.[47] The interview instruments asked enrollees to rate and report on their general health, comorbidities, severity of diabetes, self-care behavior, prescribed medications, physical activities, use of alcohol and tobacco, access to care, and satisfaction with care. The instruments also included a number of scales for measuring subjective symptoms, attitudes, emotions, and functional capacities; for some scales, the independent evaluator summed responses to individual questions to create continuous scores.

B. ANALYTIC METHODS

This demonstration had an experimental design with longitudinal followup. Because some aspects of the intervention in the New York City site and the upstate site were quite different, and because demonstration enrollees in both sites differed so markedly from each other on so many major characteristics, the analyses were conducted separately for each site.

The independent evaluator used regression models to estimate the fourth-year impacts of Cohort 1, and a *t*-test and paired *t*-test to estimate the first-year impacts of Cohort 2. The regression models used for Cohort 1 controlled for treatment and control group differences that might have occurred despite random assignment, and improved the precision of the estimated program effects.[48] The models included a standard set of baseline control variables (Moreno et al. 2007), as well as baseline values of the outcomes in question. The analysis used ordinary least squares regression models for continuous outcome variables and logit models for binary outcomes. The values reported in Chapter VI and Section C of this appendix are predicted treatment and control group means calculated from coefficients of the estimated models. The independent evaluator determined the statistical significance of the impact estimate from the *p*-value for the coefficient of the treatment-control indicator variable. The instances in which logit models could not be estimated because of small cell sizes or collinearity are indicated in the tables in this chapter, and unadjusted means are presented and compared using *t*-tests.

[47] Collection of ambulatory blood pressure data was discontinued in early 2004, before completion of the second follow-up visit.

[48] The independent evaluator set the level of statistical significance at 0.05.

Any case with a missing value for a dependent variable was dropped from the analysis of that variable. Cases with missing values for an independent variable were dropped from the analysis if fewer than 3 percent of cases were missing that variable. If 3 percent or more of cases were missing values for an independent variable, those cases were included with a dummy variable to indicate that the value was missing.[49]

To examine the sensitivity of results to handling the attrition in different ways, the independent evaluator conducted three types of longitudinal analyses of time trends for a limited number of study outcomes. In the first approach, called "quadruple endpoint all cases available analysis," selected interview and laboratory outcomes were analyzed for enrollees who completed any of the baseline, year 1, year 2, year 3, and year 4 interviews with demonstration staff, even if they dropped out after that interview, and four cross-sectional analyses were produced for these selected outcomes.[50] In the second approach, "quadruple endpoint complete cases analysis," selected interview and laboratory outcomes were analyzed for the 850 Cohort 1 enrollees who completed *all* assessments (baseline, year 1, year 2, year 3, and year 4 interviews with demonstration staff). Appendix Table C.1 presents sample sizes, by type of outcome, at baseline, year 1, year 2, year 3, and year 4 interviews).[51] The annual impact estimates for the "all cases available" and "complete cases only" analyses were regression adjusted, using the same model as in the fourth-year endpoint analyses.

Quadruple endpoint analysis tests only the significance of the yearly estimated treatment-control differences; it does not directly assess the significance of time. Thus, the third approach consisted of models for longitudinal data that included year, the interaction between year and treatment status, and the other standard covariates. The independent evaluator analyzed the continuous outcomes using generalized least squares (GLS) models, and the binary outcomes using generalized estimating equations (GEE); the results with this approach generally agreed with the main analysis presented in Chapter VI—using the quadruple endpoint all cases available analysis—but the results using the longitudinal methods were less often statistically significant when yearly means were tested for significant treatment and control differences.[52]

[49] About 5 percent of the baseline sample from the New York City site and 6 percent of the baseline sample for upstate New York were dropped for missing values for any of the independent variables for which less than 3 percent of the entire sample were missing values. About 17 percent of the New York City site and 30 percent of the upstate baseline samples had missing values for any independent variables for which 3 percent or more of the entire sample were missing values; these observations were retained with a dummy variable indicating the missing value.

[50] Enrollees could have missing observations—for example, they could miss the year 2 assessment and reappear in year 3 or year 4. Dropouts were "permanent" only if they dropped out after an annual assessment and did not return for the year 4 followup.

[51] Sample sizes were 1,664 at baseline; 1,415 at year 1; 1,266 at year 2; 1,004 at year 3; and 934 at year 4.

[52] For normally distributed continuous outcomes, modeling with GLS is equivalent to so-called random effects or mixed models.

TABLE C.1

SAMPLE SIZES BY TYPE OF OUTCOME AT DIFFERENT FOLLOW-UP POINTS IN THE DEMONSTRATION

Type of Outcome	New York City		Upstate	
	Treatment	Control	Treatment	Control
Interview Data[a]				
Cohort 1 Enrollees				
Baseline	397	377	447	443
Year 1	335	348	365	367
Year 2	311	305	315	335
Year 3	277	288	192	247
Year 4	270	273	169	222
Cohort 2 Enrollees				
Baseline	86	88	163	166
Year 1	73	78	128	144
Cholesterol and Hemoglobin A1c				
Cohort 1 Enrollees				
Baseline	396	375	446	439
Year 1	334	348	355	364
Year 2	311	305	312	334
Year 3	277	288	192	246
Year 4	270	273	167	221
Cohort 2 Enrollees				
Baseline	86	88	163	166
Year 1	73	78	126	141
Utilization Outcomes-Medicare Claims Data[b]				
Cohort 1 Enrollees	395	377	447	443
Cohort 2 Enrollees	86	88	163	166

Sources: IDEATel Cohort 1 in-person interviews in years 1, 2, 3, and 4, anthropometrics, and laboratory data collected between December 2001 and October 2006; IDEATel Cohort 2 in-person interviews in year 1, anthropometrics, and laboratory data collected between November 2004 and February 2007; and Medicare claims data (Columbia University 2007c, 2007d).

Notes: Because treatment-control comparisons are based on analyses of covariance, sample sizes for year 2 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.

[a]Includes interview data, in-person blood pressure, and anthropometry. Sample sizes may vary from specific outcome to outcome because, at the time of the interview, not all questions were answered, and not all enrollees had their blood pressure checked or anthropometric measurements taken.

TABLE C.1 *(continued)*

[b]Sample sizes correspond to the intent-to-treat sample. Complete Medicare claims data were available on these enrollees through December 31, 2006, 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.

As described in Section C of this Appendix, however, no analytic approach can overcome bias from dropouts that are related to *unobserved* or *unmeasured* outcomes or associated factors (that is, dropouts among either treatment or control group members who exit the demonstration between assessments because, unknown and unrecorded by study research staff, they are experiencing favorable or unfavorable outcomes).

In all three of these longitudinal approaches, the analysis treated missing values in the same manner as in the main fourth-year *endpoint* analysis (that is, cases with missing dependent variable values were dropped, and cases with missing values for independent variables were dropped or kept with a dummy variable, depending on the percentage of cases missing that variable).

C. LIMITATIONS TO THE ANALYSIS

The substantial attrition rate among enrollees poses two serious problems. First, the reduction in sample size limits the power to detect impacts.[53] For example, for a single comparison of treatment and control group means, the 30 percent loss of sample in the New York City site would result in minimum detectable differences (MDDs) roughly 25 percent greater than for the full sample, while the 58 percent loss of sample in the upstate site would increase the MDDs by about one-third.[54]

Second, and perhaps more important, depending on the mechanism for attrition, impacts calculated only on enrollees who remain in the study could be biased. Bias can occur if the dropout rate of enrollees with unmeasured characteristics that predict outcomes (for example, motivation or psychological distress) is greater in one intervention group than the other. Such differential dropout threatens the benefits of random assignment. Differential dropout cannot be directly ascertained. However, examining the recorded reasons for enrollee dropout and the characteristics of enrollees who dropped out, as well as conducting sensitivity tests by imputing possible values of outcome variables for those who dropped out, may provide evidence for the likelihood of bias.

[53] In New York City, the dropout rate was 10 percent between baseline and year 1, 6 percent between years 1 and 2, 8 percent between years 2 and 3, and 11 percent between years 3 and 4. In upstate New York, the dropout rate was 16 percent between baseline and year 1, 14 percent between years 1 and 2, 32 percent between years 2 and 3, and 16 percent between years 3 and 4.

[54] The precise effects of sample loss on the power of the GEE and GLS regression models for longitudinal responses are difficult to predict (Evans et al. 2001).

1. Mechanisms of Dropout in Longitudinal Studies with Random Assignment

Little and Rubin (1987) described three major mechanisms for dropout from longitudinal randomized studies. In the first, called "missing completely at random" (MCAR), dropout is unrelated to treatment group assignment or any enrollee characteristics correlated with study outcomes. MCAR dropout does not bias results.

In the second dropout mechanism, called "missing at random" (MAR), dropout is related to *observable* enrollee characteristics. These characteristics may be (1) fixed baseline characteristics (such as gender, age at enrollment, or educational status), or (2) follow-up measurements on the outcome variables made before dropout. Thus, in MAR, an enrollee's dropping out can be predicted by baseline characteristics or by outcome values at follow-up assessments before the time of dropout (in other words, how well the enrollee is doing before dropping out).

The third dropout mechanism is called "missing not at random" (MNAR).[55] For example, suppose that, between annual assessments and unobserved by the demonstration evaluators, the members of either the treatment or control group begin experiencing much better (or much worse) outcomes and, as a result, decide to drop out of the study. Or suppose that participants who greatly disliked the HTU were more likely to drop out and also more likely to experience either good or bad outcomes. In these instances, dropout cannot be predicted by observed data, and measured impacts on those remaining in the study will be misleading.

2. Analytic Approaches to Analyzing Repeated Measures Data with Dropout

Curran et al. (1998) describe three approaches for analysis of incomplete repeated measures data in randomized studies in which the dependent variables are continuous and normally distributed. In the first approach (quadruple endpoint complete cases analysis), enrollees with any missing data for the outcome measure are removed from the analysis, which can ultimately lead to a loss in power. In the second approach (quadruple endpoint all cases available analysis), all enrollees are included in the analysis, even if they are missing data for one or more of the measurement occasions, and a treatment difference is calculated at each individual time point. These first two approaches are valid only if the dropout mechanism is MCAR; they could produce biased results if the missing data are not MCAR. The third approach, the GEE model, uses generalized linear models to measure the response and separately estimate the correlation structure (for normally distributed responses, this approach reduces to a GLS approach). GEE is the most common approach to analyzing longitudinal or repeated measures discrete outcomes with incomplete data, although it assumes that missingness is MCAR (Diggle et al. 1999).

[55] Some authors also call MNAR "non-ignorable missingness" and MAR "ignorable missingness" (Curran et al. 1998; Fairclough et al. 1998).

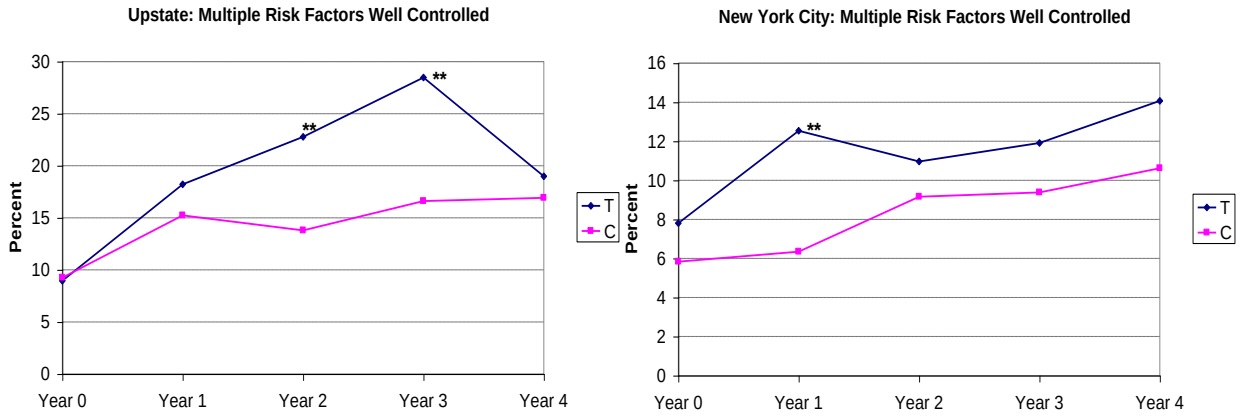
No analytic techniques satisfactorily address bias from MNAR dropouts. Unfortunately, by definition, enrollees who have dropped out have no data. The Consortium verbally informed us that it had no additional information on why people dropped out beyond the data available in the tracking status file, which lacks information on (1) reasons enrollees refused participation, (2) the details of the "other reasons," and (3) any reasons for some dropouts (Table VI.1). It is therefore impossible for us to determine directly whether dropout is or is not MNAR.

D. SUPPLEMENTAL FIGURES

The figures in this section show the time course for Cohort 1 enrollees of the "multiple risk factors well controlled" binary outcome with the value of 1 if SBP<130 *and* DBP<80, *and* LDL cholesterol<100, *and* HbA1c<7.0; and the value of 0 otherwise.[56]

FIGURE C.1

ESTIMATED EFFECTS OF IDEATel ON PROPORTIONS OF COHORT 1 ENROLLEES' WITH MULTIPLE RISK FACTORS CONTROLLED



Source: IDEATel annual in-person interviews conducted from December 2000 through October 2006 (Columbia University 2007c).

Note: The multiple-risk-factors-well-controlled binary variable had a value of 1 if SBP<130 *and* DBP<80, *and* LDL cholesterol<100, *and* HbA1c<7.0; and the value of 0 otherwise. Means predicted using the "all cases available" analysis. This analysis included each of the data points (baseline, year 1, year 2, year 3, and year 4) for selected interview and laboratory outcomes for enrollees who completed that interview with demonstration staff, even if they had missed one or more of the preceding interviews (for the follow-up interviews) or dropped out after the interview being analyzed.

** Indicates treatment-control difference is statistically significant at the .01 level.

DBP = diastolic blood pressure; HbA1c = glycosylated hemoglobin; LDL = low-density lipoprotein; SBP = systolic blood pressure.

[56] DBP = diastolic blood pressure; HbA1c = glycosylated hemoglobin; LDL = low-density lipoprotein; SBP = systolic blood pressure.

E. SUPPLEMENTAL TABLES

TABLE C.2

COHORT 2 ENROLLEES DROPPING OUT OF THE STUDY AND REASONS FOR DROPOUT, BY SITE AND INTERVENTION GROUP, BASELINE TO YEAR 1[a]
(Numbers and Percentages)

	New York City		Upstate	
	Treatment	**Control**	**Treatment**	**Control**
Enrollee Refusal	6	2	17	3
Percentage of starting sample	7.0	2.3	10.4	1.8
Percentage of period's dropouts	46.2	20.0	45.9	12.0
Family Refusal	0	0	0	0
Percentage of starting sample	0.0	0.0	0.0	0.0
Percentage of period's dropouts	0.0	0.0	0.0	0.0
Physician Refusal	0	0	0	0
Percentage of starting sample	0.0	0.0	0.0	0.0
Percentage of period's dropouts	0.0	0.0	0.0	0.0
Cognitive Impairment	0	0	0	0
Percentage of starting sample	0.0	0.0	0.0	0.0
Percentage of period's dropouts		0.0	0.0	0.0
Too Sick	1	1	1	2
Percentage of starting sample	1.2	1.1	0.6	1.2
Percentage of period's dropouts	7.7	10.0	2.7	8.0
Deceased	2	1	0	5
Percentage of starting sample	2.3	1.1	0.0	3.0
Percentage of period's dropouts	15.4	10.0	0.0	5.0
HTU Problem	0	0	4	0
Percentage of starting sample	0.0	0.0	2.5	0.0
Percentage of period's dropouts	0.0	0.0	10.8	
Other[b]	3	4	3	2
Percentage of starting sample	3.5	4.5	1.8	1.2
Percentage of period's dropouts	23.1	40.0	8.1	8.0
No Reason Recorded[c]	1	2	12	13
Percentage of starting sample	1.2	2.3	7.4	7.8
Percentage of period's dropouts	7.7	20.0	32.4	52.0
Total	**13**	**10**	**37**	**25**
Percentage of period's dropouts	**5.1**	**11.4**	**22.7**	**15.1**

Source: IDEATel tracking status file (Columbia University 2007a).

Note: At each follow-up year, enrollees were categorized as having dropped out if they missed that in-person assessment and all subsequent assessments (for example, a Cohort 1 enrollee who missed the assessments in years 2 and 3 but then attended the remaining assessment in year 4 would not be categorized as having dropped out). The reasons for dropping out are those reported by the Hebrew Home for the Aged at Riverdale, the demonstration's data coordination center.

HTU = home telemedicine unit.

[a]As of June 29, 2007.

[b]Includes the following reasons as specified by the Consortium: "unreachable" and "other" ("other" reasons not specified by the Consortium).

[c]Enrollees who were assumed to have dropped out because they stopped attending the in-person assessments but were not formally recorded in the Consortium's tracking status file as having dropped out.

TABLE C.3

ESTIMATED EFFECTS OF IDEATel ON COHORT 2 ENROLLEES' APPOINTMENTS WITH NURSE EDUCATORS AND DIETITIANS, AND ENROLLEE REPORTS OF PROVIDER PRACTICES IN YEAR 1, BY SITE

	New York City			Upstate		
Outcome	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Appointments with Nurse Educators and Dietitians						
Saw a Diabetes Nurse Educator at Least Once (Percentage)	95.8	15.4	80.5 (.000)	93.0	4.2	88.8 (.000)
Number of consultations (mean)	6.5	1.2	5.3 (.000)	8.9	0.1	8.8 (.000)
Saw a Dietitian (Percentage)	23.3	28.2	-4.9 (.491)	78.9	11.1	67.8 (.000)
Number of consultations (mean)	0.9	0.7	0.2 (.681)	6.0	0.2	5.8 (.000)
In the Past Year, Number of Times Health Care Professionals Discussed						
Exercise						
Four or more times	63.9	46.8	17.1 (.037)	64.1	25.7	38.4 (.000)
Not at all	16.7	24.7	-8.0 (.231)	18.0	39.6	-21.6 (.000)
Eating Habits						
Four or more times	55.6	50.7	4.9 (.550)	64.8	25.7	39.2 (.000)
Not at all	15.3	24.7	-9.4 (.155)	13.3	43.1	-29.8 (.000)
Controlling Blood Sugar						
Four or more times	23.3	26.9	-3.6 (.608)	31.3	4.2	27.1 (.000)
Not at all	52.1	52.6	-0.1 (.950)	54.7	82.6	-28.0 (.000)
Sample Size	**73**	**78**	—	**128**	**144**	—

Source: IDEATel Year 1 in-person interview, conducted between November 2005 and February 2007 (Columbia University 2007c).

Note: Results presented here are the unadjusted means and treatment-control differences. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

TABLE C.4

ESTIMATED EFFECTS OF IDEATel ON COHORT 2 ENROLLEES' BLOOD PRESSURE MEASUREMENTS IN YEAR 1, BY SITE

	New York City			Upstate		
Outcome	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean	Predicted Control Group Mean	Estimated Effect (*p*-Value)
Systolic Blood Pressure (mm Hg)	142.4	140.0	2.5 (.506)	138.3	135.5	2.8 (.240)
Systolic blood pressure >130 mm Hg (percentage)	68.5	66.7	1.8 (.811)	68.0	61.4	6.5 (.265)
Diastolic Blood Pressure (mm Hg)	74.4	71.7	2.7 (.151)	69.7	69.4	0.3 (.802)
Diastolic blood pressure >80 mm Hg (percentage)	31.5	18.0	13.6 (.055)	15.6	16.4	-0.8 (.858)
Sample Size	**73**	**78**	—	**128**	**144**	—

Source: IDEATel Year 1 in-person interview and anthropometry, conducted between November 2005 and February 2007 (Columbia University 2007c).

Notes: Results presented here are the unadjusted means and treatment-control differences. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

mm Hg = millimeters of mercury.

TABLE C.5

ESTIMATED EFFECTS OF IDEATel ON COHORT 2 ENROLLEES' LABORATORY RESULTS IN YEAR 1, 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	179.1	175.6	3.5 (.678)	159.0	160.9	-1.9 (.680)
Mean LDL Cholesterol	106.7	109.8	-3.1 (.695)	91.4	94.6	-3.2 (.433)
Mean HDL Cholesterol	48.2	45.1	3.1 (.233)	42.8	42.3	0.5 (.726)
Mean Triglycerides	138.8	137.6	1.2 (.937)	161.5	158.7	2.8 (.831)
High LDL Cholesterol (≥100; Percentage)	54.0	51.6	2.4 (.792)	34.9	36.8	-1.8 (.756)
Diabetes Control						
Mean HbA1c (%)	7.2	7.4	-0.2 (.486)	7.0	7.0	0.0 (.939)
HbA1c ≥7.0% (percentage)	43.8	44.9	-1.0 (.898)	42.1	37.6	4.5 (.456)
HbA1c >8.0% (percentage)	19.2	24.4	-5.2 (.443)	11.9	16.3	-4.4 (.304)
Sample Size	**73**	**78**	—	**128**	**144**	—

Source: IDEATel Year 1 in-person interview and anthropometry, conducted between November 2005 and February 2007 (Columbia University 2007c).

Notes: Results presented here are the unadjusted means and treatment-control differences. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

HDL = high-density lipoprotein; LDL = low-density lipoprotein; HbAlc = glycosylated hemoglobin.

TABLE C.6

ESTIMATED EFFECTS OF IDEATel ON COHORT 2 ENROLLEES' SATISFACTION WITH DIABETES CARE IN YEAR 1, 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)
How Well Doctors and Health Care Professionals Cared for Enrollees' Diabetes[a]						
Showed Concern, Courtesy, Respect, and Sensitivity						
Very good or excellent	53.4	52.6	0.9 (.916)	76.6	79.0	-2.5 (.627)
Fair or poor	16.4	18.0	-1.5 (.806)	3.1	2.8	0.3 (.874)
Disclosed All Pertinent Information						
Very good or excellent	45.2	59.0	-13.8 (.093)	81.8	84.6	-2.9 (.530)
Fair or poor	21.9	20.5	1.4 (.833)	7.1	4.9	2.3 (.437)
Answered Questions About Diabetes						
Very good or excellent	44.4	42.9	1.6 (.845)	65.9	68.5	-2.7 (.643)
Fair or poor	22.2	29.9	-7.7 (.290)	5.6	7.0	-1.4 (.629)
Gave Test Results When Promised						
Very good or excellent	43.8	53.9	-10.0 (.221)	71.1	74.1	-3.0 (.576)
Fair or poor	20.6	15.4	5.2 (.409)	10.9	10.5	0.5 (.905)
Reviewed and Explained Test and Laboratory Results						
Very good or excellent	50.7	44.9	5.8 (.476)	63.3	69.2	-6.0 (.301)
Fair or poor	19.2	19.2	-0.1 (.993)	10.9	7.7	3.3 (.385)
Explained and Included Enrollee in Treatment Decisions						
Very good or excellent	43.1	39.7	3.3 (.681)	58.3	63.6	-5.4 (.367)
Fair or poor	27.8	30.8	-3.0 (.688)	21.3	9.1	12.2 (.005)
Explained Side Effects of Medications						
Very good or excellent	38.4	44.9	-6.5 (.418)	44.9	45.4	-0.5 (.934)
Fair or poor	28.8	33.3	-4.6 (.546)	29.1	24.1	5.0 (.353)

TABLE C.6 *(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)
Explained What to Expect from Diabetes or Its Treatment						
Very good or excellent	44.4	30.8	13.7 (.086)	54.3	49.3	5.0 (.410)
Fair or poor	37.5	47.4	-9.9 (.221)	19.7	19.0	0.7 (.889)
Made Sure They Could Be Reached Easily in Emergencies						
Very good or excellent	50.7	45.3	5.4 (.519)	61.3	52.4	8.9 (.173)
Fair or poor	27.5	28.0	-0.5 (.951)	17.0	20.6	-3.7 (.480)
General Measures of Satisfaction						
Rating of Quality of Diabetes Care in the Past Year[a]						
Very good or excellent	60.3	52.6	7.7 (.341)	81.3	69.2	12.0 (.023)
Fair or poor	13.7	16.7	-3.0 (.613)	0.0	4.9	-4.9 (.012)
Would Recommend Doctor/Health Care Professional Based on Personal Manner[b]	91.8	89.7	2.0 (.667)	95.3	92.3	3.0 (.317)
Intends to Follow Doctor's/Health Care Professional's Advice[c]	97.3	98.7	-1.4 (.530)	95.3	92.4	3.0 (.316)
Sample Size	**73**	**78**	—	**128**	**144**	—

Source: IDEATel Year 1 in-person interview, conducted between November 2005 and February 2007 (Columbia University 2007c).

Notes: Results presented here are the unadjusted means and treatment-control differences. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

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

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

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

TABLE C.7

ESTIMATED EFFECTS OF IDEATel ON COHORT 2 ENROLLEES' SELF-MONITORING AND ADHERENCE IN YEAR 1, BY SITE

Outcome	New York City			Upstate		
	Predicted Treatment Group Mean (Percentage)	Predicted Control Group Mean (Percentage)	Estimated Effect (*p*-Value)	Predicted Treatment Group Mean (Percentage)	Predicted Control Group Mean (Percentage)	Estimated Effect (*p*-Value)
In the Past Week						
Tested Blood Sugar Daily[a]	49.3	48.6	0.7 (.935)	70.3	65.9	4.4 (.449)
Examined Feet Daily	86.3	87.2	-0.9 (.874)	64.1	68.8	-4.7 (.414)
Took Recommended Doses of Diabetes Pills Daily[b]	94.0	92.9	1.2 (.782)	95.4	96.6	-1.2 (.644)
Administered Recommended Insulin Injections Daily[c]	88.2	88.2	0.0 (.999)	87.1	97.4	-10.3 (.106)
Adhered to Diet Daily[d]	37.0	43.6	-6.6 (.410)	44.5	41.6	3.0 (.622)
Adhered to Exercise Plan on Three or More Days[d]	35.6	26.9	8.7 (.251)	67.2	62.5	4.7 (.420)
Sample Size	**73**	**78**	**—**	**128**	**144**	**—**

Source: IDEATel Year 1 in-person interview, conducted between November 2005 and February 2007 (Columbia University 2007c).

Notes: Results presented here are the unadjusted means and treatment-control differences. Sample sizes vary slightly because of item nonresponse. Because of rounding, the estimated effect may not exactly equal the treatment group mean minus the control group mean.

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

[b] This question was answered only by enrollees who were taking diabetes pills (New York City: 67 treatment group members, 70 control group members; upstate: 108 treatment group members, 117 control group members).

[c] This question was answered only by enrollees who were taking insulin (New York City: 17 treatment group members, 17 control group members; upstate: 31 treatment group members, 38 control group members).

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

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APPENDIX D

METHODOLOGY FOR ESTIMATING DEMONSTRATION COSTS AND MEDICARE EXPENDITURES AND SUPPLEMENTAL MATERIALS TO CHAPTER VII

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This appendix describes the study methodology that MPR used to estimate the impact of the demonstration on Medicare expenditures and costs. The first section focuses on the methodology used to estimate the demonstration's costs during Phase II, the second summarizes the methods used to estimate Medicare expenditures, and the third describes the approach for estimating impacts on Medicare costs. The fourth section presents sensitivity analyses of the demonstration's impacts on costs (1) if expenditures are truncated at the 98th percentile, (2) under different specifications of the study sample, and (3) on subgroups defined by intensity of use of the intervention. Finally, the independent evaluator include supplementary tables to those reported in Chapter VII.

A. CALCULATION OF THE DEMONSTRATION'S COSTS

The independent evaluator estimated the demonstration's costs based on information obtained from six sources: (1) the budget data provided by the Consortium in 2004 and 2007, (2) the Consortium's technical proposals for Phase I and Phase II and progress reports to CMS (Columbia University 1998, 2002b, 2003b, 2004a, 2004b, 2005a, 2005b, 2006a, 2006b, 2007e, 2007g), (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 2003a), and (6) the independent evaluator's research on market prices of the goods and services used in the demonstration. During Phase I, the independent evaluator also relied on information provided by a consultant on telemedicine. The independent evaluator developed cost estimates for Phase II using the same framework as during Phase I (as described in U.S. Department of Health and Human Services 2005). The estimates were built from the bottom up, by identifying and then pricing out every aspect of the demonstration.

1. Intervention Costs Versus Research Costs

The first step in developing the cost estimates was to define the demonstration's *intervention-related* and *research-related* activities. The independent evaluator used the Consortium's progress reports to CMS, as well as notes taken during site visits to and telephone calls with Consortium staff, to identify all the activities occurring in the demonstration. From these sources, the independent evaluator was able to determine 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 structure of the Consortium's own internal evaluation. Some activities, though research-related in the context of the demonstration, would still be necessary 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.

2. Intervention-Related Costs

The 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 deinstallation). *Design* costs are defined as one-time costs associated with setting up the intervention. During Phase II, these costs were for redesign of HTU software, purchase of new nurse case manager workstations, and recruitment of physicians and patients to participate in the second phase. *Implementation* costs include ongoing costs incurred for leasing of case management software, purchase of HTUs, installation of devices in participants' homes, and training of participants in how to use the HTUs. *Closeout* costs are those associated with removal of HTUs from participants' homes (which happened only during Phase II for both Cohort 1 and Cohort 2 participants).

3. Classifying Costs into Components

The third step in developing the cost estimates was to classify the demonstration's intervention-related activities into broad categories within each stage. The independent evaluator grouped design activities into three components: (1) purchase of new case manager workstations, (2) redesign of software for the HTUs, and (3) recruitment of physicians and enrollees for Phase II.[57] Likewise, the independent evaluator grouped the implementation activities into eight broad components (1) purchase of Generation 2 and Generation 3 HTUs, (2) installation of HTUs and training of participants on their use, (3) lease of case management software, (4) information systems support, (5) case management and televisits, (6) screening and assessment of enrollees, (7) internal evaluation/quality improvement, and (8) project management and other direct costs.

4. Specific Assumptions

The independent evaluator estimated the cost of each demonstration component from the Consortium's budget data, as well as the costs of specific goods and services. This section describes, for each component, specific assumptions related to the salaries of demonstration staff and the costs of goods and services. The percentage of each component that was allocated to intervention and the percentage allocated to research are described in Section 6.

a. Salaries of Demonstration Staff Members

Columbia University and SUNY Upstate Medical University provided data for the first three years of Phase II on the level of effort and salary data for each staff member working on the

[57] The Phase I cost framework also contained a category for development of systems architecture, which included the costs for the servers and routers required to store and transfer data and the costs for creation of security measures, among others. This category is not included here, as these costs were already incurred during Phase I.

project. During site visits and telephone calls, the independent evaluator asked about the responsibilities of staff employed by the demonstration, so that staff members could be allocated to appropriate tasks. For the fourth year of the project, the independent evaluator assumed that staff with research responsibilities would continue to work on the project at the same level of effort as they had during the third year, and would receive a salary increase of about 3 percent. For staff at Columbia University, fringe benefits were added to the base salary at a rate of 26.4 percent for Year 1 and were increased by about 0.2 percentage points per year (Columbia University 2007f). For staff at SUNY, fringe benefits were added to the base salary at a rate of 33 percent per year during year 1, and increased by 1 to 2 percentage points each year (SUNY Upstate Medical University 2003). 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. The independent evaluator assumed that this board met once each year and that each member received a flat fee for participating.

b. Costs of Goods and Services

Purchasing case manager workstations. The independent evaluator estimated the costs of purchasing 5 new case manager workstations and 10 flat-screen monitors that were used during Phase II.

Development of new software for the HTUs. A portion of the American Tableware, Inc. (ATI) subcontract was included here for ATI's development of the touch screen (which included an electronic launch pad), and remote training software. The salaries for Columbia's IT staff that worked on redesigning software were also included here, as were the costs of the subcontract to iSolutions for developing the enhanced help desk system, and the costs of the subcontract to CUBES for developing the new patient portal.

Physician and enrollee recruiting. This includes primarily the salaries for physician and project managers who spent the majority of their time on this task.

Purchasing HTUs. The Consortium provided the average cost for the Generation 2 and 3 HTUs ($4,398 per unit). Based on information provided in the progress reports, about 500 HTUs were purchased, which includes the HTUs provided for Cohort 2 as well as for the Cohort 1 HTU users who upgraded to Generation 2 or Generation 3. The cost of the mail client license was also included here.

HTU installation and participant training. This included a large fraction of the ATI contract, which was used to configure HTUs, install HTUs, and train and re-train participants on their use.

Leasing case management software. This includes the estimated cost of leasing case management software (PATCIS2).

Information systems support. This includes the salaries for Columbia University's BioInformatics staff who were members of the demonstration's implementation team. It also includes technical support provided by ATI for the nurse case managers.

Case management and televisits. This task includes the salaries of the nurse case managers, the salaries of support staff at the Berrie Center and the Joslin Diabetes Center, and the time of the diabetologists to oversee the nurse case managers. It also includes the telecommunications fees for accessing the internet and using the data-transfer lines.

Collecting enrollee's assessment data. This component includes salaries for research assistants (in New York City) and nurses (in upstate New York) who performed the in-person assessments for Cohort 2 enrollees at baseline, in their first and second years after enrollment, and for Cohort 1 enrollees in their third, fourth, fifth, and sixth years after enrollment. It includes the costs incurred during Phase II for both cohorts for the equipment and supplies necessary to collect the assessment data and for enrollees' laboratory tests. It also includes reimbursement of enrollees' travel expenses (in New York City) and reimbursement of nurses' travel expenses incurred while traveling to an estimated 25 percent of enrollees in upstate New York who could not travel to the clinics for the assessments. Finally, it includes the costs of providing breakfast or lunch to participants on the day of their assessment.

Internal evaluation/quality improvement. This includes the costs devoted to the internal evaluation during the active part of Phase II (years 1 through 3) for collecting and analyzing enrollee's clinical outcomes. (As described in Section 6, some of the costs for the internal evaluation would presumably be spent on quality improvement in an ongoing program.) The costs for the internal evaluation included the salaries and benefits of staff performing research activities at SUNY Upstate and Columbia University and the fees charged by contractors performing research on Medicare expenditures.

Project management. This component includes a portion of the salaries of the demonstration's principal investigators and their support staff. Also included are fees for the three consultants on the Data Safety and Monitoring Board. This component includes the cost of computer time (based on number of staff hours), as well as other direct costs incurred by Columbia University and SUNY Upstate (such as for travel and supplies).

Closeout activities. Closeout activities include the HTU deinstallation that was conducted at the end of the demonstration's operations. The independent evaluator did not assume that the demonstration's closeout phase would include costs for referring enrollees to other disease management programs or social services agencies.

Other costs. Indirect costs charged to the demonstration by Columbia University (63.5 percent) and SUNY Upstate (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 for less than $2,000 were also included in the calculation, as were all supplies purchased by SUNY Upstate (Columbia University 2003a). Subcontract and equipment costs (that is, items Columbia University purchased for a unit cost of at least $2,000) 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. While several activities were related primarily to research, the independent evaluator assumed that a small portion of such activities (10 percent) would be conducted in an ongoing program. For example, some form of assessment would presumably be done in an ongoing program, and the analysis of clinical data would be part of an ongoing program's quality control process. Likewise, some form of recruiting or marketing to participants would likely be part of an ongoing program. Table D.1 shows the allocation of each component to research and to the intervention during Phase I and Phase II.

By summing the cost of each component, the independent evaluator estimated the Phase II total costs of the demonstration to be $28,793,287. Because the estimated demonstration cost and the actual amount of the cooperative agreement differed slightly, the independent evaluator apportioned the award amount ($28,812,419), using the estimated percentages of the total cost for each component, as shown in Table D.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 observed costs.

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.[58] The second included design-stage and closeout-stage activities, but depreciated those costs over three years. Costs per participant for implementation-only (as reported in Table VII.2) were calculated by dividing the implementation-stage activities by the 514 Cohort 1 treatment group members who were still participating in the demonstration at the beginning of Phase II and the 249 treatment group members in Cohort 2.

The *annual* cost per participant assumed that the average length of participation during Phase II was three years for Cohort 1 participants and two years for Cohort 2 participants (since randomization for Cohort 2 did not occur until the end of the first year of Phase II). Costs per participant for design, implementation, and closeout simply added the depreciated design and closeout costs per participant to the estimate of annual costs per participant for implementation-only. Finally, for Cohort 1, the average annual cost per participant (as reported in Table VII.6) over the two phases of the project was calculated by averaging the annual costs per participant during Phase I and the annual costs per participant during Phase II; this average was weighted by the average length of time that Cohort 1 participants were enrolled during each phase.

[58] This calculation is comparable to the one used to estimate the demonstration costs during Phase I. At that time, it was unclear whether the demonstration would be extended for another four years or not.

TABLE D.1

ALLOCATION OF DEMONSTRATION COMPONENTS AS
INTERVENTION RELATED OR RESEARCH RELATED FOR PHASE I AND PHASE II COSTS
(Percentages)

Demonstration Component	Cost Allocation	
	Intervention-Related	Research-Related
Design Stage		
Development of systems architecture[a]	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
Internal evaluation/quality improvement[b]	10	90
Project management and other direct costs	50	50
Closeout Stage (HTU De-installation)	10	90

Sources: Cost components were constructed during Phase 1 based on proposals and progress reports provided by the Consortium, a paper published by the demonstration team (Starren et al. 2002), information collected during site visits and telephone calls, and the input of a consultant in telemedicine (as described in U.S. Department of Health and Human Services 2005).

[a] This category is relevant only for Phase I.
[b] Assumed that 10 percent of activities related to the internal evaluation (such as collecting data) would occur in an ongoing program for the purposes of quality control and reporting.

HTU = home telemedicine unit.

TABLE D.2

ALLOCATION OF ESTIMATED PHASE II DEMONSTRATION COSTS TO ACTUAL COOPERATIVE AGREEMENT AMOUNT FOR PHASE II

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	$11,242,787	39	$11,250,257
Intervention-Related Costs	$17,550,500	61	$17,562,162
Design Stage			
Purchase of case managers' workstations	$14,649	<1	$14,659
Development of software for HTUs	$3,092,435	7	$3,094,490
Recruitment of physicians and enrollees	$85,109	<1	$85,166
Implementation Stage			
Purchase of HTUs	$2,863,446	13	$2,865,349
Installation of HTUs and training of participants	$3,527,785	5	$3,530,129
Lease of case management software	$318,015	1	$318,226
Information systems support	$2,227,476	9	$2,228,956
Case management and televisits	$3,393,100	11	$3,395,355
Screening and assessment of enrollees	$57,387	<1	$57,425
Quality improvement	$116,717	<1	$116,794
Project management and other direct costs	$1,824,981	6	$1,826,194
Closeout Stage (HTU De-installation)	$29,398	<1	$29,418
Total Demonstration Costs	**$28,793,287**		**$28,812,419**

Sources: MPR's estimates based on information obtained from the Consortium's technical proposal and progress reports; a paper published by the demonstration team; information collected during site visits by the independent evaluator; the website of the Office of Grants and Contracts for Columbia University's Health Sciences Division; 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] Based on dividing column 1 estimates by the total estimated demonstration costs.

HTU = home telemedicine unit.

B. CALCULATION OF MEDICARE EXPENDITURES

The independent evaluator calculated Medicare Part A and Part B expenditures for each enrollee from claims data for the period 1999-2006,[59] adding expenditures for all episodes of care between randomization and the end of the study follow-up period (December 31, 2006). This *intent-to-treat analysis* includes 1,625 Cohort 1 sample members and 491 Cohort 2 sample members, excluding only the 30 Cohort 1 sample members and the 13 Cohort 2 sample members who were continuously enrolled in a health maintenance organization (HMO). (Three Cohort 1 sample members in New York City who were missing data for one or more regression control variables are excluded from particular analyses.) Because Medicare claims data are not available for those in managed care, IDEATel would not be expected to have an effect on the capitation payment that Medicare pays the HMOs for providing health services to demonstration enrollees in managed care (that is, the intervention cannot affect the Medicare expenditures for demonstration enrollees in an HMO). Thus, excluding those in an HMO ensures that only the expenditures that IDEATel could affect are included in the analysis.

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 in Medicare (but not in an HMO) from randomization through the end of the event that defined the study period for each sample (for instance, December 31, 2006) or death (if the beneficiary died before the end of the event that defined the study period).[60] For binary outcomes (such as the percentage of sample members using inpatient hospital services), observations that were truncated were weighted by the fraction of the interval study period (that is, between randomization and December 31, 2006) that a person was alive and not in an HMO.

C. METHODS FOR ESTIMATING IMPACTS ON MEDICARE EXPENDITURES

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 2005).[61] The independent evaluator estimated this type of model

[59] The independent evaluator also calculated expenditures per enrollee for the year before randomization; as an indicator of recent use of health services, that amount is also 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, categorized by quartile of the distribution of expenditures in each site.

[60] The percentage of sample members that died during the follow-up period (between randomization and December 31, 2006) was about 16 percent for Cohort 1 in New York City, 22 percent for Cohort 1 in upstate New York, 4 percent for Cohort 2 in New York City, and 3 percent for Cohort 2 in upstate New York. The mortality rates were similar for the treatment and control groups within each site and cohort, so excluding expenditures after death should not bias our estimates.

[61] 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 an HMO in the month before randomization, and Medicare expenditures during the year before randomization. The health characteristics are reason for Medicare

separately for each site and cohort. Weights were equal to the length of the period between randomization and the end of the study follow-up period (for instance, December 31, 2006). The independent evaluator then calculated predicted outcomes for treatment and control group enrollees by using coefficients from each of the estimated models.

D. SENSITIVITY TESTS

In addition to examining differences in the demonstration's impacts on Medicare expenditures by site, the analysis assessed whether these impacts varied for (1) expenditures greater than the 98th percentile, (2) different specifications of the study sample, 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 VII.

1. Sensitivity of Results to Large Medicare Expenditures

The independent evaluator assessed the variation of the impact estimates for the intent-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 near the end of their life. Rerunning the impact analysis with capped (or truncated) expenditures allowed us to assess whether the estimated impact of the intervention was due to the influence of a few beneficiaries with unusually high use of Medicare-covered services.

Overall, the impact estimates are insensitive to unusually large expenditures (Table D.3). For Cohort 1, capping expenditures at their 98th percentile resulted in no change to the sign of the difference between treatment group and control group expenditures relative to the unadjusted (or uncapped) estimates. Likewise, there was no change in the statistical significance of the test of the difference in outcomes from zero between groups. For cohort 2, impacts based on both capped and uncapped data were generally small and statistically insignificant in New York City. For Cohort 2 in upstate New York, the demonstration's impact on total Medicare expenditures (-$2,244) using uncapped expenditures was similar in size to the impact based on capped expenditures (-$2,033), though only the capped estimate was statistically significant at the .10 level. Likewise, the demonstration's impact on Medicare Part A expenditures using uncapped expenditures (-$1,966) was similar in size to the impact using capped expenditures (-$1,684); again, only the uncapped estimate was statistically significant.

(continued)

entitlement and years since diabetes was diagnosed. Finally, the model included a binary indicator for the treatment group.

TABLE D.3

ESTIMATED ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES, FOR UNCAPPED AND CAPPED EXPENDITURES BY SITE AND COHORT

	No Adjustment to Expenditures						Expenditures Capped at the 98th Percentile					
	New York City			Upstate New York			New York City			Upstate New York		
	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Cohort 1												
Total Medicare	13,845	12,961	885 (.476)	9,566	8,450	1,116 (.094)	13,582	12,689	893 (.434)	9,386	8,328	1,057 (.075)
Medicare Part A	8,446	7,502	945 (.344)	5,136	4,539	597 (.247)	8,146	7,320	826 (.359)	4,988	4,419	570 (.199)
Medicare Part B	5,399	5,459	-60 (.870)	4,430	3,911	519 (.025)	5,254	5,400	-145 (.656)	4,352	3,844	508 (.012)
Sample Size	**379**	**358**		**446**	**442**		**379**	**358**		**446**	**442**	
Cohort 2												
Total Medicare	11,906	11,661	245 (.931)	6,450	8,694	-2,244 (.132)	11,344	11,599	-255 (.922)	6,098	8,131	-2,033 (.081)
Medicare Part A	7,296	6,886	410 (.867)	2,991	4,957	-1,966 (.118)	6,779	6,829	-51 (.982)	2,712	4,396	-1,684 (.070)
Medicare Part B	4,610	4,775	-165 (.799)	3,458	3,736	-278 (.443)	4,519	4,724	-205 (.731)	3,414	3,715	-300 (.388)
Sample Size	**82**	**84**		**161**	**164**		**82**	**84**		**161**	**164**	

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Estimates reflect annualized expenditures for the period from each sample member's randomization through the end of the study follow-up period (December 31, 2006), and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of the follow-up period that the enrollee was alive and not in an HMO. The reported sample size includes the full sample of enrollees (excluding those who were continuously enrolled in an HMO). Three control group members are dropped from the analysis in New York City in Cohort 1 because they were missing control variables in the regression analysis. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization.

2. Comparison of Intent-to-Treat Sample to Sample Used for Behavioral, Physiologic, and Other Health-Related Outcomes

The findings in Chapter VII correspond to an intent-to-treat analysis, where all enrollees in the demonstration are included, except for the few who were continuously enrolled in an HMO throughout the study period and the few who were missing control variables for the regression analyses. However, the primary findings reported in Chapter VI reflect only those beneficiaries who responded to the year 4 follow-up interview for Cohort 1, and to the year 1 follow-up interview for Cohort 2. To assess whether bias is introduced from using the restricted respondent sample, the analysis compared the demonstration's impacts on Medicare expenditures using the intent-to-treat sample to those using the respondent sample.

For Cohort 1, in New York City, the treatment-control difference in total Medicare expenditures for the intent-to-treat sample ($885) was smaller than for the respondent sample ($1,438), though neither difference was statistically significant (Table D.4). In upstate New York for this cohort, the treatment-control difference in the intent-to-treat sample was $1,116, whereas the treatment-control difference in the respondent sample was smaller ($327) and not statistically significant. In both sites, the demonstration's impacts on Medicare Part A expenditures followed the same pattern as the impacts on total Medicare expenditures, with the impacts being smaller in the intent-to-treat sample than in the respondent sample in New York City, but larger in the intent-to-treat sample than in the respondent sample in upstate New York. Within each site, the treatment-control differences for Part B expenditures were similar across samples.

For Cohort 2, in New York City, the treatment-control difference in total Medicare expenditures was larger within the respondent sample ($1,914) than in the intent-to-treat sample ($245), though neither difference was statistically significant. Similarly, impacts on Medicare Part A expenditures were larger for the respondent sample than for the intent-to-treat sample in New York City, though impacts on Medicare Part B expenditures were similar across samples. The treatment-control differences in total Medicare expenditures (and in Medicare Part A and Medicare Part B expenditures) were similar across samples in upstate New York for Cohort 2.

Overall, the differences in the demonstration's impacts on expenditures across samples underscore the need to interpret cautiously impacts that depart from the intent-to-treat analysis, although the actual magnitude and direction of bias in the respondent sample is difficult to ascertain.

3. Results for Frequent and Infrequent HTU Users

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. Nevertheless, given the substantial variability in HTU use among treatment group enrollees, the analysis explored whether participants who received more intervention had better outcomes (and lower Medicare expenditures) relative to those who received less of it.

TABLE D.4

COMPARISON OF ANNUAL PER-PERSON EXPENDITURES FOR MEDICARE EXPENDITURES AMONG INTENT-TO-TREAT SAMPLE AND AMONG RESPONDENT SAMPLE

	Intent-to-Treat Sample						Respondent Sample					
	New York City			Upstate New York			New York City			Upstate New York		
	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Cohort 1												
Total Medicare	13,845	12,961	885 (.476)	9,566	8,450	1,116 (.094)	11,951	10,513	1,438 (.241)	7,360	7,033	327 (.663)
Medicare Part A	8,446	7,502	945 (.344)	5,136	4,539	597 (.247)	6,937	5,502	1,435 (.147)	3,343	3,532	-189 (.717)
Medicare Part B	5,399	5,459	-60 (.870)	4,430	3,911	519 (.025)	5,014	5,011	3 (.993)	4,017	3,500	517 (.101)
Sample Size	**379**	**358**		**446**	**452**		**257**	**261**		**169**	**224**	
Cohort 2												
Total Medicare	11,906	11,661	245 (.931)	6,460	8,694	-2,244 (.132)	11,476	9,562	1,914 (.485)	5,710	7,671	-1,961 (.188)
Medicare Part A	7,296	6,886	410 (.867)	2,991	4,957	-1,966 (.118)	6,837	5,039	1,798 (.442)	2,445	4,166	-1,720 (.178)
Medicare Part B	4,610	4,775	-165 (.799)	3,458	3,736	-278 (.443)	4,638	4,523	116 (.864)	3,264	3,505	-241 (.502)
Sample Size	**82**	**84**		**161**	**164**		**71**	**74**		**126**	**142**	

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Year 4 respondents are included in the respondent sample for Cohort 1, and year 1 respondents are included in the respondent sample for Cohort 2. Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Estimates reflect annualized expenditures for the period from each sample member's randomization through the end of the study follow-up period (December 31, 2006), and reflect only months during which the enrollee was alive and not in an HMO. Because the analyses based on Medicare claims data exclude those continuously enrolled in an HMO, sample sizes reported in this table do not exactly match the sample sizes reported in the tables in Chapter VI. Also, reported sample sizes reflect the full sample of enrollees (excluding those that were continuously enrolled in an HMO during the year), though actual sample sizes may vary slightly because enrollees were missing data for control variables used in the regressions. Observations are weighted by the fraction of the follow-up period that the enrollee was alive and not in an HMO. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization.

Because televisits are among the key HTU functions through which the intervention is delivered, and because televisits were initiated by the nurse case manager and not the participant, the independent evaluator examined impact variation across subgroups defined by the frequency of use of this function, as defined by whether participants were likely to participate in more than or fewer than the median annual number of televisits in their site and cohort. Enrollees in the treatment and control groups were then sorted into two groups according to their likelihood of being a *frequent* or *infrequent* user of televisits, given the baseline characteristics of each of them.[62] Under the assumption that the regression model correctly identified comparison group members who were similar, on average, to treatment group enrollees with regard to their HTU use, impacts were estimated on Medicare expenditures for frequent and infrequent users, controlling for demographic and health characteristics at randomization.

In general, the analysis suggests that the demonstration's impact on Medicare expenditures did not differ for those who were predicted to be frequent televisit users and for those who were predicted to be infrequent televisit users. While the treatment-control difference in total Medicare expenditures (-$3,542) was statistically significant among those who were predicted to be infrequent HTU users in upstate New York in Cohort 2, this impact was not significantly different from the treatment-control difference (-$1,173) for those who were predicted to be frequent HTU users within the same site and cohort (Table D.5). 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 differed systematically with regard to characteristics that were not, or could not, be included in the propensity score model that might be correlated with outcomes.

E. ADDITIONAL TABLES

In addition to estimating the demonstration's impact on Medicare expenditures, the independent evaluator estimated its impacts on Medicare service use. Tables D.6 and D.7 show the percentage of enrollees that used particular services during the entire follow-up period (that is, from randomization through December 31, 2006). Tables D.8 and D.9 show the mean number of times that sample enrollees used a given service each year among those who used that service during the study follow-up period. The demonstration had few statistically significant effects on enrollees' use of particular Medicare services.

[62] The independent evaluator used a *propensity score* model to assign treatment group enrollees one of the two categories of HTU use (see, for example, Agodini and Dynarski 2004). The model (logit) was fitted to data (separately for each site and cohort) on whether the participant had greater than the median number of televisits *among treatment group members*, controlling for demographic and health characteristics at randomization. The model was then 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 between 62 and 75 percent (depending on the site and cohort) of treatment group members who actually participated in televisits frequently (that is, high model *sensitivity*), and between 60 and 78 percent of participants who participated in televisits infrequently (that is, high model *specificity*).

TABLE D.5

ESTIMATED ANNUAL PER-PERSON EXPENDITURES DURING STUDY FOLLOW-UP PERIOD FOR MEDICARE-COVERED SERVICES, BY SITE, EVALUATION GROUP AND FREQUENCY OF HTU USE
(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)
Cohort 1						
Frequent HTU User	12,955	13,092	-137 (.936)	9,372	8,591	781 (.415)
Infrequent HTU User	14,881	12,820	2,060 (.254)	9,742	8,308	1,434 (.125)
p-Value for Interaction Term Between Treatment Status and Frequent HTU Use	-	-	.377	-	-	.626
Sample Size	**379**	358	-	**446**	**442**	-
Cohort 2						
Frequent HTU User	13,225	11,559	1,666 (.682)	8,432	9,605	-1,173 (.584)
Infrequent HTU User	10,453	11,896	-1,443 (.727)	4,366	7,908	-3,542 (.094)
p-Value for Interaction Term Between Treatment Status and Frequent HTU Use	-	-	.596	-	-	.434
Sample Size	**82**	**84**	-	**161**	**164**	-

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: A propensity score model used enrollees' baseline characteristics to predict whether they were likely to be frequent HTU users (that is, to participate in more than the median annual number of televisits). Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure, as well as a variable indicating the interaction of the enrollees' treatment group status and whether they were predicted to be a frequent HTU user. Estimates reflect annualized expenditures for the period from each sample member's randomization through the end of the study follow-up period (December 31, 2006), and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of the follow-up period that the enrollee was alive and not in an HMO. The reported sample size includes the full sample of enrollees (excluding only those who were continuously enrolled in an HMO). Three control group members were dropped from the analysis in Cohort 1 in New York City because they are missing control variables used in the regression analysis. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization.

TABLE D.6

TRENDS IN PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES FOR COHORT 1, BY SITE AND EVALUATION GROUP, NEW YORK CITY
(Means, in Dollars)

	Year Since Randomization				
Component/Service	Year 1	Year 2	Year 3	Year 4	Year 5
Selected Part A Services					
Inpatient Hospital					
Treatment group	5,260	5,131	4,615	8,239	12,767
Control group	3,811	4,277	7,348	8,642	7,791
Difference	1,449	853	-2,733	-404	4,976
(*p*-value)	(.173)	(.426)	(.070)	(.826)	(.095)
Skilled Nursing Facility					
Treatment group	167	409	189	883	1,067
Control group	34	103	752	485	672
Difference	133	306	-564	398	395
(*p*-value)	(.146)	(.121)	(.040)	(.230)	(.353)
Emergency Room					
Treatment group	71	94	154	134	153
Control group	62	93	155	173	158
Difference	9	1	-1	-39	-5
(*p*-value)	(.493)	(.969)	(.970)	(.153)	(.835)
Selected Part B Services					
Outpatient Hospital					
Treatment group	1,099	1,400	1,305	1,692	1,828
Control group	1,034	1,522	1,405	1,432	1,775
Difference	65	-122	-100	261	53
(*p*-value)	(.519)	(.627)	(.591)	(.369)	(.888)
Durable Medical Equipment					
Treatment group	307	339	433	490	418
Control group	294	249	404	437	403
Difference	13	90	29	53	15
(*p*-value)	(.855)	(.204)	(.799)	(.634)	(.861)
Physician Visits					
Treatment group	362	427	412	375	376
Control group	387	459	439	382	394
Difference	-25	-31	-27	-7	-17
(*p*-value)	(.410)	(.342)	(.436)	(.854)	(.686)
Laboratory Services					
Treatment group	43	54	61	78	107
Control group	51	56	73	92	112
Difference	-8	-2	-12	-14	-5
(*p*-value)	(.410)	(.829)	(.326)	(.397)	(.810)

TABLE D.6 *(continued)*

Component/Service	Year Since Randomization				
	Year 1	Year 2	Year 3	Year 4	Year 5
Other Part B Services[a]					
Treatment group	1,750	2,091	1,884	2,832	3,231
Control group	1,595	2,066	2,310	2,385	2,480
Difference	155	26	-427	446	751
(*p*-value)	(.302)	(.906)	(.071)	(.213)	(.062)
Part A and B Services					
Home Health Care					
Treatment group	731	640	693	913	1,038
Control group	573	619	1,046	1,285	1,420
Difference	158	22	-353	-372	-381
(*p*-value)	(.339)	(.886)	(.068)	(.183)	(.148)
Sample Size					
Treatment	**369**	**355**	**344**	**331**	**309**
Control	**353**	**337**	**327**	**311**	**282**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and preenrollment value of the outcome measure. Enrollees' data have been annualized, and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of each year that the enrollees was alive and not in an HMO. Reported sample sizes reflect the full sample of enrollees (excluding those that were continuously enrolled in an HMO during the year), though actual sample sizes may vary slightly because enrollees were missing data for control variables used in the regressions. The treatment-control difference may not exactly equal the treatment group mean minus the control group mean due to rounding.

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

HMO = health maintenance organization.

TABLE D.7

TRENDS IN PER-PERSON EXPENDITURES FOR MEDICARE-COVERED SERVICES FOR COHORT 1, BY SITE AND EVALUATION GROUP, UPSTATE NEW YORK
(Means, in Dollars)

Component/Service	Year Since Randomization				
	Year 1	Year 2	Year 3	Year 4	Year 5
Selected Part A Services					
Inpatient Hospital					
Treatment group	3,319	3,638	4,706	4,328	5,253
Control group	3,021	3,433	3,089	4,410	4,555
Difference	298	205	1,618	-82	698
(*p*-value)	(.670)	(.790)	(.026)	(.920)	(.562)
Skilled Nursing Facility					
Treatment group	354	260	574	979	651
Control group	220	386	462	529	924
Difference	134	-126	112	449	-279
(*p*-value)	(.294)	(.373)	(.549)	(.062)	(.258)
Emergency Room					
Treatment group	91	116	132	141	134
Control group	88	131	102	102	165
Difference	3	-15	31	39	-31
(*p*-value)	(.851)	(.587)	(.142)	(.111)	(.323)
Selected Part B Services					
Outpatient Hospital					
Treatment group	822	1,013	1,061	1,144	1,294
Control group	648	799	809	1,004	1,359
Difference	175	214	252	140	-66
(*p*-value)	(.094)	(.194)	(.075)	(.371)	(.777)
Durable Medical Equipment					
Treatment group	562	583	675	815	805
Control group	411	469	533	549	653
Difference	150	114	143	266	152
(*p*-value)	(.032)	(.096)	(.110)	(.024)	(.193)
Physician Visits Cohort					
Treatment group	265	281	296	316	317
Control group	255	272	278	317	317
Difference	10	10	18	-1	0
(*p*-value)	(.559)	(.608)	(.339)	(.953)	(.984)
Laboratory Services					
Treatment group	42	49	55	61	77
Control group	42	41	47	68	70
Difference	-1	8	8	-7	7
(*p*-value)	(.948)	(.503)	(.474)	(.542)	(.565)

TABLE D.7 *(continued)*

Component/Service	Year Since Randomization				
	Year 1	Year 2	Year 3	Year 4	Year 5
Other Part B Services[a]					
Treatment group	1,447	1,663	1,897	2,110	2,205
Control group	1,488	1,600	1,500	1,946	2,065
Difference	-40	64	398	164	140
(*p*-value)	(.822)	(.710)	(.049)	(.468)	(.605)
Part A and B Services					
Home Health Care					
Treatment group	281	282	451	467	395
Control group	234	426	366	349	574
Difference	46	-144	85	118	-179
(*p*-value)	(.567)	(.119)	(.434)	(.274)	(.140)
Sample Size					
Treatment	**445**	**431**	**412**	**388**	**364**
Control	**442**	**423**	**403**	**383**	**363**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and preenrollment value of the outcome measure. Enrollees' data have been annualized, and reflect only months during which the enrollee was alive and not in an HMO. Observations are weighted by the fraction of each year that the enrollees was alive and not in an HMO. Reported sample sizes reflect the full sample of enrollees (excluding those that were continuously enrolled in an HMO during the year), though actual sample sizes may vary slightly because enrollees were missing data for control variables used in the regressions. The treatment-control difference may not exactly equal the treatment group mean minus the control group mean due to rounding.

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

HMO = health maintenance organization.

TABLE D.8

PERCENTAGE USING MEDICARE-COVERED SERVICES DURING STUDY FOLLOW-UP PERIOD, COHORT 1, BY SITE

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Inpatient Hospital	62.7	69.3	-6.7 (.069)	70.9	69.8	1.1 (.726)
Skilled Nursing Facility	13.0	11.9	1.2 (.766)	19.8	21.6	-1.7 (.505)
Emergency Room	78.7	76.7	2.0 (.249)	73.7	74.9	-1.2 (.663)
Home Health Services	46.4	54.0	-7.6 (.055)	41.0	39.6	1.4 (.660)
Among Those Using Home Health Services, Percentage Having						
Skilled nursing visit	99.6	96.8	2.8 (.095)	98.2	95.6	2.6 (.192)
Aide visit	59.6	66.3	-6.6 (.148)	44.5	53.7	-9.2 (.092)
Therapy visit	73.3	79.7	-6.5 (.201)	67.8	69.8	-2.0 (.700)
Social worker visit	23.0	34.2	-11.2 (.007)	15.0	10.8	4.2 (.260)
Percentage Using Service						
Durable medical equipment	88.8	86.2	2.6 (.227)	95.5	92.9	2.6 (.090)
Physician visits	96.2	97.5	-1.3 (.366)	96.7	97.3	-0.6 (.580)
Laboratory services	64.6	69.7	-5.1 (.553)	58.5	60.4	-1.9 (.543)
Dilated eye exam	96.6	94.8	1.8 (.194)	87.7	87.2	0.4 (.833)
HbA1c test	97.9	98.2	-0.3 (.809)	98.2	97.6	0.6 (.501)
LDL cholesterol test	95.4	96.2	-0.8 (.764)	97.2	95.2	2.0 (.123)
Urine microalbumin test	93.2	93.4	-0.2 (.724)	93.0	91.4	1.6 (.369)
Sample Size	**379**	**358**	**-**	**446**	**442**	**-**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Observations that are truncated are weighted by the fraction of the interval study period (that is, between randomization and December 31, 2006) that a person was alive and not in an HMO. The reported sample size includes the full sample of enrollees (excluding those who were continuously enrolled in an HMO). Three control group members were dropped from the analysis in New York City because they were missing

control variables used in the regression analysis. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization; HbA1c = glycosylated hemoglobin.

TABLE D.9

PERCENTAGE USING MEDICARE-COVERED SERVICES DURING STUDY FOLLOW-UP PERIOD, COHORT 2

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Inpatient Hospital	35.4	38.7	-3.3 (.288)	29.1	39.3	-10.2 (.048)
Skilled Nursing Facility	5.2	2.7	2.5 (.114)	6.4	7.2	-0.8 (.783)
Emergency Room	48.4	52.4	-4.1 (.488)	35.5	32.1	3.3 (.537)
Home Health Services	16.2	19.2	-3.0 (.342)	12.1	13.9	-1.7 (.631)
Among Those Using Home Health Services, Percentage Having						
Skilled nursing visit	99.8	93.1	6.7 (.960)	94.5	95.2	-0.7 (.935)
Aide visit	66.3	52.9	13.4 (.774)	20.5	23.0	-2.5 (.923)
Therapy visit	75.0	44.5	30.5 (.219)	93.1	44.9	48.2 (.069)
Social worker visit	16.8	6.9	9.8 (.031)	23.1	7.0	16.1 (.416)
Percentage Using Service						
Durable medical equipment	60.8	59.7	1.0 (.740)	84.5	75.9	8.6 (.042)
Physician visits	85.9	83.4	2.5 (.299)	81.7	83.3	-1.7 (.658)
Laboratory services	53.8	40.8	13.0 (.108)	34.2	42.0	-7.8 (.123)
Dilated eye exam	87.5	80.7	6.9 (.197)	75.2	69.0	6.2 (.199)
Hemoglobin A1c test	95.7	92.4	3.3 (.817)	91.4	92.0	-0.6 (.825)
LDL cholesterol test	90.6	90.0	0.6 (.942)	89.4	89.0	0.4 (.915)
Urine microalbumin test	83.5	80.6	2.9 (.409)	81.9	77.2	4.7 (.312)
Sample Size	**82**	**84**	**-**	**161**	**164**	**-**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Observations that are truncated are weighted by the fraction of the interval study period (that is, between randomization and December 31, 2006) that a person was alive and not in an HMO. Means were predicted with ordinary least squares regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization.

TABLE D.10

AMONG THOSE USING A SERVICE, MEAN ANNUAL NUMBER OF SERVICES USED DURING STUDY FOLLOW-UP PERIOD, COHORT 1, BY SITE

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Inpatient Hospital	0.90	0.83	.07 (.306)	0.85	0.82	.03 (.774)
Skilled Nursing Facility	0.50	0.38	.12 (.393)	0.45	0.49	-.03 (.376)
Home Health Visits	19.84	22.13	-2.30 (.438)	11.93	11.17	.76 (.866)
Physician Visits	7.16	7.94	-.78 (.729)	7.82	7.64	.18 (.511)
Laboratory Services	2.25	2.31	-.06 (.599)	2.26	2.26	.00 (.387)
Dilated Eye Exam	3.49	3.15	.34 (.065)	1.52	1.48	.04 (.559)
HbA1c Test	1.86	2.07	-.21 (.021)	2.29	2.30	-.01 (.661)
LDL Cholesterol Test	1.47	1.54	-.07 (.668)	1.62	1.58	.04 (.149)
Urine Microalbumin Test	1.24	1.59	-.35 (.036)	1.48	1.49	-.01 (.895)
Sample Size	**379**	**358**	-	**446**	**442**	-

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Those who used a given service at any time during the follow-up period (from randomization through December 31, 2006) are defined as a user of that service. The sample size reported is for the full sample of enrollees (excluding those who were continuously enrolled in an HMO); however, the sample size varies for each row depending on the number of users of each service. The mean number of services used was annualized. Estimates are weighted by the fraction of the interval between randomization and the end of the follow-up period that an enrollee was alive and not in an HMO. Means were predicted with linear regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

HMO = health maintenance organization; HbA1c = glycosylated hemoglobin.

TABLE D.11

AMONG THOSE USING A SERVICE, MEAN ANNUAL NUMBER OF SERVICES USED DURING FOLLOW-UP PERIOD, COHORT 2, BY SITE

	New York City			Upstate New York		
Component/Service	Treatment Group	Control Group	Difference (*p*-Value)	Treatment Group	Control Group	Difference (*p*-Value)
Inpatient Hospital	1.29	1.10	.20 (.946)	1.17	1.20	-.03 (.732)
Skilled Nursing Facility[a]	0.05	0.04	.01 (.536)	0.43	0.13	.30 (.969)
Home Health Services	27.35	21.03	6.32 (.736)	21.26	28.59	-7.33 (.969)
Physician Visits	9.09	6.55	2.54 (.029)	6.63	7.94	-1.32 (.503)
Laboratory Services	2.25	2.70	-.45 (.994)	1.87	2.21	-.34 (.149)
Dilated Eye Exam	3.45	3.73	-.29 (.25)	1.80	1.64	.16 (.358)
HbA1c Test	2.05	2.05	.01 (.627)	2.44	2.34	.11 (.105)
LDL Cholesterol Test	1.96	1.84	.12 (.364)	1.99	1.97	.02 (.387)
Urine Microalbumin Test	1.45	1.97	-.52 (.001)	1.60	1.62	-.01 (.882)
Sample Size	**82**	**84**	**-**	**161**	**164**	**-**

Source: IDEATel tracking status file and Medicare claims and enrollment records (Columbia University 2007a, 2007d).

Notes: Those who used a given service at any time during the study follow-up period (from randomization through December 31, 2006) are defined as a user of that service. The sample size reported is for the full sample of enrollees (excluding those who were continuously enrolled in an HMO); however, the sample size varies for each row depending on the number of users of each service. The mean number of services used was annualized. Estimates are weighted by the fraction of the interval between randomization and the end of the study follow-up period that an enrollee was alive and not in an HMO. Means were predicted with linear regression models, which controlled for enrollees' baseline characteristics and the pre-enrollment value of the outcome measure. Because of rounding, the treatment-control difference may not exactly equal the treatment group mean minus the control group mean.

[a]Because of the small number of service users, unadjusted means and a *t*-test are reported for this set of estimates.

HMO = health maintenance organization; HbA1c = glycosylated hemoglobin.