Report to Congress:

First Interim Report on the Informatics for Diabetes Education and Telemedicine (IDEATel) Demonstration

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Secretary of Health and Human Services
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EXECUTIVE SUMMARY

BACKGROUND

Improving access to care and quality of care for underserved Medicare beneficiaries with diabetes is an important policy objective for the Medicare program. Among older Americans, diabetes is a leading cause of mortality, morbidity, and health care costs. Some of the serious health complications of diabetes include loss of vision, kidney failure, nerve damage, coronary artery disease, cerebrovascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections. Appropriate management and regular monitoring of persons with diabetes, however, can delay or avert many of these complications.

Medicare beneficiaries with diabetes living in medically underserved inner-city or rural areas are likely to suffer poor access to high-quality diabetes care. These areas, by definition, have an inadequate supply of health care providers. Lack of transportation, geography, and high out-of-pocket costs present additional barriers to medical care. Diabetes has disproportionate impacts on minority senior populations. Compared to White Americans, African American and Hispanic/Latino Americans have much higher rates of diabetes (Harris et al. 1998; National Institutes of Health 1997; and Carter et al. 1996), and also greater risks of severe complications and death (Karter et al. 2002; Harris et al. 2001; Resnick et al. 1999; Harris et al. 1999; Gu et al. 1998; and Carter et al. 1996).

Telemedicine, the use of telecommunications technology to deliver medical diagnostic, monitoring, and therapeutic services when health care users and providers are geographically separated, offers great promise for reducing access barriers for chronically ill Medicare beneficiaries. Home telemedicine, in particular, allows regular health monitoring from, and

delivery of care to peoples' homes. Potentially such improved access to care could even prevent the future need for the costly treatment of complications. There is, however, little hard evidence on the effectiveness and cost-effectiveness of telemedicine.

To address this knowledge gap, Congress mandated in the Balanced Budget Act of 1997 a four-year demonstration of telemedicine networks and services to improve primary care to Medicare beneficiaries with diabetes mellitus. This mandate was later amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.[1]

Some of the key demonstration objectives specified by the legislation include:

- Improving beneficiary access to and compliance with appropriate guidelines for individuals with diabetes mellitus, improving quality of life, and reducing costs
- Developing a curriculum to train health professionals in the use of telemedicine services
- Developing standards for the application of telemedicine services
- Applying the technologies to beneficiaries with limited English language skills
- Developing cost-effective delivery models of primary care services in both managed care and fee-for-service environments

Congress also mandated an evaluation of the demonstration. The evaluation must include an assessment of telemedicine's impacts on improving access to health care services, reducing costs of health care services, and improving quality of life.

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

In February 2000 the Centers for Medicare & Medicaid Services (CMS) awarded a $28 million cooperative agreement to perform the demonstration to a consortium (hereafter identified as "the Consortium"), led by Columbia University College of Physicians and Surgeons and Columbia-Presbyterian Medical Center (hereafter called "Columbia University"). The demonstration is called the Informatics for Diabetes Education and Telemedicine or "IDEATel." CMS contracted with Mathematica Policy Research, Inc. (MPR) to perform the mandated evaluation independently of the Consortium, although the Consortium is also conducting its own internal evaluation. The evaluation began 7 months after the award of the demonstration cooperative agreement and will last 46 months.

This report is the first interim report to Congress from the independent evaluation. The report focuses on the early implementation experiences of the Consortium. It describes the original design of the demonstration, the challenges its implementation has presented the Consortium, and its subsequent evolution. The report also assesses whether the demonstration implemented by the Consortium is consistent with the legislative mandate. The report is based on document review and data from site visits conducted in fall 2001 and winter 2002. Key informants included the consortium leadership and staff involved with various aspects of the demonstration. Neither participants in the treatment group nor their primary care physicians could be interviewed due to the Consortium's human subjects and confidentiality concerns, and key data on the use and delivery of the intervention were not yet available from the Consortium.

OVERVIEW OF THE DEMONSTRATION

The Consortium consists of two large academic medical centers (Columbia-Presbyterian Medical Center and the State University of New York Upstate Medical University), several smaller regional hospitals in New York State, a telecommunications provider, and several vendors.

The demonstration targets Medicare beneficiaries with diabetes mellitus who live in federally designated, medically underserved areas or primary care health professional shortage areas in New York City or upstate New York (hereafter identified as the "upstate site"). Many of the beneficiaries in the target areas are low-income, and those in the New York City site are predominantly Hispanic with limited English skills. As noted, this is a population for whom high-quality, timely care for their diabetes is not typically available. The demonstration is randomly assigning 750 participants each to a treatment and a control group, balanced between the New York City and upstate sites.

The participants randomized to the control group continue to receive their usual diabetes care from their primary care physicians. Participants randomized to the treatment group receive a home telemedicine unit (HTU), which is essentially a personal computer with several attached devices: an internal modem, a video camera with microphone, a set of speakers, a home blood glucose measuring device (a glucometer), and a blood pressure cuff. IDEATel diabetes nurse case managers work with the treatment group participants through the HTUs. The HTUs serve three main functions:

1. ***Monitoring:*** Participants measure blood sugars and blood pressures, which are stored in the HTUs. They periodically upload these data through the modem connection to the Internet into Columbia University's computerized clinical information system. The nurse case managers receive the monitoring data, and the system alerts them to out-of-range measurements.

2. ***Video Conferencing:*** Treatment group participants have regular televisits, which feature voice and visual contact, with the nurse case managers. During the televisits the nurse case managers assess participants' clinical status and progress and provide diabetes health education. The nurse case managers use case management software to track participants' progress and send reports and recommendations for care to the participants' primary care physicians.

3. ***Web-Based Education and Communication:*** The treatment group participants have access to a special Internet Web site created for the demonstration by the American Diabetes Association. They are also able to communicate with their nurse case managers through electronic messaging and to converse with other demonstration participants in special chat rooms and bulletin boards.

EARLY IMPLEMENTATION FINDINGS

The Consortium's members possess the necessary expertise for the project and appear to work well together as a team.

The Consortium's core organizations are Columbia-Presbyterian Medical Center in New York City (Division of General Medicine, Department of Medical Informatics, and Naomi Berrie Diabetes Center), the State University of New York Upstate Medical University in Syracuse (Division of Endocrinology, Metabolism, and Diabetes; the Joslin Diabetes Center; and the Department of Family Medicine) and the Hebrew Home for the Aged at Riverdale in New York City.

The Consortium also has a number of affiliated and subcontracted members. The affiliated members are primarily health care provider organizations that are helping to recruit participants– Harlem Hospital Center, Harlem Renaissance HealthCare Network, Arnot Ogden Medical Center, Olean General Hospital, Samaritan Medical Center, St. Luke's-Roosevelt Hospital Center, Bassett Healthcare, and Hudson Headwaters Health Network. The last three organizations joined the Consortium later to augment the number of potential participants. In addition, the American Diabetes Association is providing Web-based educational materials for participants.

Subcontracted members provide technical services and expertise. American TeleCare, Inc. (ATI) designed the HTU to the Consortium's specifications and is supplying the HTUs. Gentiva Health Care installs the HTUs in the homes of treatment group participants and performs the initial training of participants in their use. Crosshair Technologies, Siemens Health Services, Verizon, and Telergy are providing various hardware, software, networking, data security, and telecommunications products and services. Siemens Health Services, the provider of the case management software, joined later, because the original vendor for the case management software had changed its product by the time the demonstration was funded.

The Consortium uses regularly scheduled meetings to identify and resolve problems. Consortium members have well defined roles and the lines of authority are clear. Although a senior team member oversees each aspect of the demonstration, overall authority resides with the principal investigators.

The Consortium quickly ran into challenges early in the project, starting with the design of the HTUs.

The original device that Columbia University had in mind for the HTU was no longer on the market by the time the demonstration was funded, necessitating additional design work. A failure to hammer out clear design specifications and to align expectations between Columbia University and ATI delayed effective collaboration between the two organizations, and probably work on the HTU design as well. The two organizations were able to overcome these initial roadblocks, however, and formed a productive partnership that rapidly designed a functioning HTU with the required features, solving several difficult technical problems along the way.

Rather than mismatched expectations between Columbia University and ATI and a lack of clear design specifications, the Consortium leadership blamed the delay in fielding the HTUs on two

other factors. First, during the 18 months between the submission of their proposal and the award of the cooperative agreement, the originally proposed software vendor had gone out of business and the original subcontract between Columbia University and ATI had expired. The Consortium thus had to use project time to identify and subcontract with a new software vendor, and to renegotiate the agreement with ATI to account for interval changes in technology and prices. Second, they had based their original project timetable on the incorrect assumption of a time lag between the notification of the cooperative agreement and the actual start of the project. They had planned to use this time lag for design and pilot testing of the HTUs, but had to instead perform this work after project start.

Recruitment of physicians and participants has been unexpectedly difficult.

Obtaining approval for the project from the numerous institutional review boards proved to be a lengthy and difficult process. The recruitment of physicians was slow, compounded by lower than expected numbers of eligible patients with diabetes per physician panel. (The Consortium used a two-stage recruitment process–primary care physicians were first invited to participate in the demonstration, and then participants were recruited from within the physicians' practices.) Eligible Medicare beneficiaries have refused to participate at a high rate, and the treatment group participants have dropped-out at higher than anticipated rates.

The Consortium agreed that recruitment had been difficult, but stated that they had, in fact, fully anticipated the challenges in recruitment. The Consortium explained that recruitment took longer than scheduled, again because of the timetable in their proposal had been based on mistaken assumptions. They had planned to use the assumed time lag between cooperative

agreement award and project start for initial planning, Institutional Review Board (IRB) approval, and hiring of recruitment staff.

Faced with the slower than planned recruitment of participants, the Consortium leadership took steps to increase enrollment. They increased the pool of primary care physicians by bringing St. Luke's-Roosevelt Hospital Center, Bassett Healthcare, and Hudson Headwaters Health Network into the Consortium. They expanded the target geographic areas, relaxed non-critical exclusion criteria, and redoubled recruitment efforts. At the time of the writing of this report, the Consortium anticipated completing recruitment by the end of June 2002, approximately 10 months later than August 2001, the original projected date.

The key technical components of the IDEATel system have been designed and are in place. Deployment of the HTUs in participants' homes proved to be challenging.

In addition to the HTUs, the other technical components of the demonstration are also all in place. These include the educational Web resources, nurse case management software, telecommunications and networking capacities, and data security. The educational Web resources include the educational Web site by the American Diabetes Association, and the chat rooms and bulletin boards. The case management software alerts the case managers to out-of-range blood sugar and blood pressure readings, allows electronic messaging between participants and nurse case managers, and provides Web-based graphic displays of participants' own data. Telecommunications and networking includes a wide-area network covering users in both the New York City and upstate sites, Internet access for participants, videoconferencing between participants and case managers, and interfaces that permit data transfer between the HTUs, the case management software, and Columbia University's clinical information system. Data security consists primarily of a virtual private network allowing encrypted transmission of data

between users; a public key infrastructure, audit logs of users accessing patient data, and a firewall to prevent unauthorized access to Web applications. In addition, the demonstration's data systems were reported to comply with the data confidentiality requirements of the Health Insurance and Portability and Accountability Act (HIPAA).

There have been difficulties in installing the HTUs in participants' homes. Problems have included the following: language (difficulty scheduling delivery to Spanish-speaking participants), logistics (getting the nurse-installer, HTU, and participant all together at the same time), and electrical compatibility (the HTU requires a three-prong plug but some participants' houses only had two-prong outlets). The Consortium has successfully dealt with all of these problems.

The Consortium has indeed taken steps to include Medicare beneficiaries with limited English skills. Besides the HTUs themselves, which are configured in English or Spanish depending on the participant, both New York City nurse case managers are bilingual (Spanish and English), and ATI uses a Spanish-speaking staff person to schedule HTU installation in the homes of Spanish-speaking participants.

In dealing with the challenges of the IDEATel demonstration, the Consortium has shown itself to be adaptable and resourceful.

As described above, the Consortium has been able to devise strategies to overcome the multiple challenges that have arisen at each stage of the implementation.

The intervention is essentially a standard diabetes nurse case management model with technological enhancements, delivered through the HTUs.

Previous research has shown that diabetes "nurse case management interventions"—in which diabetologist-supervised nurse case managers enhance and supplement primary care physicians' diabetes care—can have positive impacts on both the health and health care expenditures of people with diabetes (Aubert et.al. 1998; Centers for Disease Control and Prevention 2001; and Renders et al. 2001). In these interventions, nurse case managers provide diabetes self-management education to patients, perform close monitoring of patients' clinical measurements and status, and help primary care physicians deliver diabetes care consistent with current, evidence-based guidelines. In such programs, patients usually communicate with the case management staff in person or by telephone.

IDEATel seeks instead to deliver diabetes nurse case management through electronic televisits. Besides the substitution of televisits for more conventional means of communication, IDEATel includes additional electronic enhancements—the ability of participants to upload blood sugar and blood pressure measurements over the Internet into Columbia University's clinical information system, an electronic medical record, the integration of diabetes case management software with the uploaded measurements and electronic medical record, electronic messaging between participants and nurse case managers, data security measures, and the Web-based educational resources and chat rooms for participants.

The demonstration has successfully hired qualified nurse case managers and established functioning clinical procedures.

The Consortium does appear to have staffed the intervention with qualified, empathetic nurse case managers with the requisite technical and interpersonal skills. It appears that well-functioning routines and procedures have been developed for televisits by the nurse case

managers, diabetologist supervision of the nurse case managers, and communication between the demonstration clinical staff and the participants' primary care physicians.

Informants report difficulties in getting participants comfortable with basic HTU use; participants are thus not using many of the features of the intervention.

The demonstration staff reported that it has been a slow, arduous process helping participants to overcome their fear of the HTUs and to learn even the most basic HTU functions. This learning process is far from complete. As a result, many participants may have had suboptimal exposure to the self-monitoring and televisiting aspects of the intervention, and virtually no exposure to several other of the proposed intervention components—Web site, electronic messaging, and chat rooms. In the view of the demonstration staff, in fact, some participants may never gain enough computer proficiency to fully experience the entire array of components. Since the actual frequency of televisits is not yet available, the independent evaluator has had to rely on the varied subjective estimates of informants, which are lower than the frequencies of televisits originally proposed in Columbia University's technical proposal.

Consortium leadership pointed out, however, that participants' usage of the HTUs could just as well be seen as a "glass half full" rather than one half empty. They pointed out project participants, all of whom are elderly, and the overwhelming majority of whom are poor, African American, or Hispanic/Latino American in the New York City site, are indeed on the "far side of the digital divide." Consortium leadership thus viewed the delivery of technology to such a large number of homes in underserved communities, and the usage of the HTUs by most participants, albeit to greatly varying degrees, as a tremendous step forward in bridging this digital divide.

There has been a high rate of broken appointments for televisits.

There has been a high frequency of participants not being at home at the scheduled times of televisits, especially in the New York City site. This high no-show rate has the potential to lessen participants' exposure to the intervention and to decrease the nurse case managers' productivity. As noted, no data on actual use of the intervention were available for this report, as the Consortium has not yet constructed working data files of HTU use.

The IDEATel staff are optimistic that these problems will be overcome in the near future and that the effectiveness of the intervention will increase.

Case managers are optimistic that many participants will become adept enough at HTU use in the coming months to start using the Web and chat features and to begin benefiting from the intervention. Consortium staff feel that their energies, previously devoted to recruitment and deployment issues, can now be focused on improving the intervention.

There has been no activity yet in developing a physician education program, developing telemedicine standards, or studying the intervention in a managed care setting.

Work on the Congressionally mandated objectives of physician education and development of telemedicine standards (for accreditation or licensing purposes) has been delayed due to the effort required in the design, recruitment, and deployment phases. Despite the lack of a concrete plan or schedule to develop the physician education program or telemedicine standards, some Consortium staff feel that the demonstration experience has helped to clarify their conceptual model for such efforts.

Another mandated demonstration objective was to develop a "model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment." The consortium's approach to meeting this objective is to enroll beneficiaries in the demonstration regardless of whether they are enrolled in a Medicare managed care plan or in fee-

for-service Medicare. Given the limited number of managed care plans operating in upstate New York, it probably would not have been possible for the consortium to test whether the model is equally effective in managed care and fee-for-service environments (and the mandate does not explicitly require this). The consortium's approach will demonstrate whether it is possible to implement the model among managed care enrollees.

The evaluation also faces challenges.

As mentioned earlier, the Consortium is undertaking its own internal evaluation activities of the IDEATel demonstration, separate from the independent evaluation by MPR. The Consortium is collecting evaluation data—treatment and control group participants undergo a baseline assessment and annual in-person assessments at the ends of Years 1 and 2, and quarterly telephone interviews in between the annual assessments. The demonstration evaluation design does feature the strengths of an experimental design—namely, that it will yield unbiased estimates of the net effects on all the study outcomes of adding telemedicine-based diabetes nurse case management to usual care for Medicare beneficiaries with diabetes.

The Consortium's evaluation design also possesses potential limitations, however, that seriously weaken the policy relevance of the evaluation findings. The design does not permit the assessment of the effects of the IDEATel intervention from the effects of standard case management provided by telephone calls and in-person visits, since the control group continues to receive only usual diabetes care with no case management. Since the evaluation design was specifically designed to detect treatment-control differences in blood pressure and glycosylated hemoglobin, the statistical power of the demonstration for outcomes that are not clinical tests but that are key policy outcomes—such as health care costs or quality of life—is likely to be limited. Moreover, since the participant dropout rate appears to be substantially higher than anticipated,

the statistical power of the demonstration is likely to be lower than expected, even for clinical outcomes. Although the Consortium is recruiting additional participants to compensate for the higher-than-expected dropout rate, its final effect on statistical power remains to be seen. There also will be no way to control for secular time trends, or to control for the possibility that the intervention may also affect how participating physicians treat the control group participants. The Consortium has not yet addressed these potential limitations in any detail in the documents available for this report.

Given the fixed time frame of the demonstration, the problems encountered so far in the implementation will likely lead to a less than fair test of the intervention, and thus a compromised ability of the evaluation to detect any actual impacts. First, the proposed design called for treatment group participants to receive the telemedicine intervention for two years. Because of the longer than expected recruitment period, either the intervention period will be less than the full two years for the later enrollees, or the demonstration will have to be extended for these enrollees to receive the full two years of intervention (as of this report, the Consortium has not requested an extension). Second, the reports by the demonstration staff of participants' struggles to learn basic HTU use and of the high no-show rate for appointments indicate that full implementation of the intervention will be over a lesser period of time than originally intended.

The demonstration has apparently been successfully collecting data from participants and their primary care physicians, and reportedly in compliance with the data privacy requirements of HIPAA. Unfortunately, only limited enrollment data were available for the preparation of this report. In order for the independent evaluation contractor to fully assess the impacts of the demonstration, the Consortium will have to make demonstration data available to the contractor in the future.

CONCLUSIONS

The Consortium appears to have made substantial progress and overcome difficult barriers in implementing the IDEATel demonstration. Considerable challenges remain, however. The intervention is still evolving and is anticipated by Consortium staff to strengthen over time. Hopefully, neither the prolongation of the recruitment phase nor the steep "learning curve" among participants and Consortium staff will compromise the implementation and evaluation of the intervention.

These interim findings have limitations, since they are based solely upon Columbia University's technical proposal, demonstration documents provided by the Consortium, articles published by the Consortium, and site visit interviews with Consortium staff. Data on several crucial aspects of the demonstration—including the number and characteristics of referring physicians, the number of people participating in or leaving the demonstration, and the actual usage of HTUs—were not yet available. The databases needed to capture these data were not yet fully developed, and the Consortium staff reported that the data that have been collected required additional verification and cleaning. Moreover, data are not yet available on the cost of designing and implementing the demonstration in its first 21 months.

FUTURE IMPLEMENTATION ANALYSIS ACTIVITIES BY THE INDEPENDENT EVALUATOR

The implementation analysis will continue in Years 2 and 3. In Year 2, followup telephone interviews will be conducted with a subset of the informants identified in the Year 1 site visits.

In Year 3, another round of site visit interviews will be conducted with the same Consortium staff members as were interviewed in Year 1. Efforts will be made to gain approval from the relevant IRBs to interview participants and their primary care physicians in the Year 3 site visits. The Year 2 and Year 3 contacts will focus on how the demonstration is functioning, problems encountered, challenges to implementing the demonstration, and changes in the demonstration design. Another goal of the implementation analysis will be to identify additional information that will help in the measurement of the costs of the demonstration. The results of these analyses will be presented in a second interim report and in the final report to Congress.

I. BACKGROUND

This is the first report to Congress on an independent evaluation of a large and complex demonstration of home-based telemedicine services in the United States. The report focuses on the early implementation experiences of the demonstration consortium. The demonstration, as mandated by Congress, is targeted to Medicare beneficiaries with diabetes residing in medically underserved areas. This population is particularly vulnerable to having substantial barriers to appropriate and timely care for this chronic condition. Telemedicine services offer great promise to reduce these barriers and deliver cost-effective diabetes care for the demonstration's target population.

A. IMPORTANCE OF REDUCING BARRIERS TO CARE FOR MEDICARE BENEFICIARIES WITH DIABETES

Diabetes mellitus is common and costly among Medicare beneficiaries: approximately half of all diabetes cases occur in people older than 55 years of age, and the cost of treating this group accounts for two-thirds of all diabetes costs (ADA 2002a). If not managed appropriately and monitored regularly, diabetes can have serious health complications, including loss of vision, kidney failure, nerve damage, coronary artery disease, cerebrovascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections. The high prevalence of diabetes, coupled with increasing numbers of newly diagnosed cases, particularly among senior minority populations (Harris et al. 1998; National Institutes of Health 1997; and Carter et al. 1996), pose a challenge to the delivery and financing of effective diabetes care by the Medicare program.

Although the treatment of diabetes continues to evolve rapidly, traditional methods of health care delivery can hamper diabetes management for the populations with the greatest need. Medicare beneficiaries with diabetes living in inner-city or rural areas are particularly vulnerable to poor access to high-quality, in-person care, for three main reasons (ADA 2002b). First, living in a medically underserved area greatly limits the availability of and choices among health care providers that Medicare beneficiaries have for taking care of their conditions. Second, the lack of affordable and readily available transportation in rural and inner-city areas constrains residents' access to medical care. Third, the high personal and monetary costs of managing chronic conditions—including periodic in-person examinations, monitoring materials, and prescription drugs—are important barriers to care. As a result, receiving frequent, in-person medical attention to monitor and care for diabetes is challenging for Medicare beneficiaries living in poor and isolated areas.

B. POTENTIAL OF TELEMEDICINE TO IMPROVE CARE

Advances in telecommunications technology and the emphasis of the federal government on delivering cost-effective care have put telemedicine at the forefront of the efforts to reduce access barriers for Medicare beneficiaries. Telemedicine has the potential to deliver appropriate and timely care, as well as provide regular monitoring of chronic diseases, directly in the homes of those in greatest need. Moreover, telemedicine offers the possibility of reducing the costs of this care.

Telemedicine is the use of telecommunications technology for medical diagnostic, monitoring, and therapeutic purposes when distance separates the users (AHRQ 2002). Telemedicine services have been part of the U.S. health care system for several decades. Initially, telemedicine

was confined to links between physicians and academic medical centers. More recently, boosted by advances in technology and lowered costs of telecommunication and computer equipment, telemedicine is being used in nonclinical settings, such as home health care (Dansky et al. 2002).

Home-based telemedicine applications rely on personal computers and video equipment to transmit data over ordinary telephone lines. Home-based telemedicine applications focus on three functions: (1) self-monitoring and transmittal of disease-specific measurements from patients to providers; (2) education, monitoring, and motivation of patients via videoconference; and (3) messaging and access to education materials via the World Wide Web (AHRQ 2002; Lewis 1999; Starren et al. 2002). As a result, home-based telemedicine offers great promise to those with substantial barriers to care, such as limited personal mobility, or residence in a remote or medically underserved area. However, there is scant evidence to date on the effectiveness of telemedicine services, in general, and home-based telemedicine, in particular (Hersh et al. 2002).

Recognizing the potential of telemedicine services for delivering cost-effective care for the Medicare population, Congress authorized the U.S. Secretary of Health and Human Services to cover telehealth services (that is, professional consultations, office visits, and office psychiatry services) provided by physicians in a clinical setting in select rural areas (P.L.106-554). However, whether home-based telemedicine services can realize their potential of reducing barriers to care for Medicare beneficiaries with chronic conditions, while controlling costs, remains largely unknown.

C. CONGRESSIONAL MANDATES TO DEMONSTRATE AND EVALUATE TELEMEDICINE

To address a dearth of rigorous evidence about the effectiveness of telemedicine services for Medicare beneficiaries, Congress included in the Balanced Budget Act of 1997 a mandate for a demonstration project to use telemedicine networks and services to improve primary care to Medicare beneficiaries with diabetes mellitus. This mandate was later amended by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.[2] The law required that the demonstration be completed in four years.

Congress specified the following key aspects of the demonstration:

- ***Objectives of the Demonstration:*** The Congressional mandate emphasizes that the demonstration should improve beneficiary access to and compliance with appropriate guidelines for individuals with diabetes mellitus, improve their quality of life, and reduce costs. It also emphasizes
  - The development of a curriculum to train health professionals in the use of telemedicine services
  - The development of standards in the application of telemedicine services
  - The utilization of advanced telecommunication technologies in providing primary care services
  - The English language skills of the target population of eligible beneficiaries
  - The development of cost-effective delivery models of primary care services in both managed care and fee-for-service environments

- ***Type of Organization to Conduct the Demonstration:*** Congress also specified the nature of the organization to implement the demonstration, its location relative to medical schools and tertiary care facilities, and the responsibilities of that organization in conducting the demonstration.

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

- ***Services Covered by the Demonstration:*** The Congressional mandate specifies the allowable and unallowable costs of Medicare services to be provided under the demonstration.
- ***Budget for the Demonstration:*** Congress also indicates that $30 million will be available for this demonstration and its evaluation.
- ***Evaluation of the Demonstration:*** Congress requires an evaluation of the demonstration, which should include an assessment of the impact of the use of telemedicine on improving access to Medicare beneficiaries to health care services, on reducing costs of such services, and on improving the quality of life of such beneficiaries. The legislation also specifies that there be interim and final evaluation reports to Congress. Although Congress did not specify a schedule for the interim reports, it required that the final report should be submitted within six months of the demonstration's conclusion.

D. PURPOSE OF THIS REPORT ON EARLY IMPLEMENTATION

This is the first interim report to Congress from the mandated evaluation. As determined by the U.S. Secretary of Health and Human Services, this evaluation is being conducted independently of the consortium leading the demonstration. The independent evaluation, to be completed in 46 months, began 7 months after award of the demonstration grant in February 2000. The consortium awarded the demonstration also is conducting its own evaluation.

This report focuses on the implementation of the demonstration. It examines the original design of the demonstration, its evolution, and the challenges the consortium encountered in implementing it. The report assesses whether the consortium is implementing a demonstration that is consistent with the legislative mandate and that can successfully provide home-based telemedicine services for Medicare beneficiaries with diabetes who reside in medically underserved areas. It uses data collected during visits to the demonstration consortium in fall 2001 and winter 2002; key informants included the consortium leadership and staff involved

with various aspects of the demonstration.[3] Subsequent reports will rely primarily on data that are being collected by the demonstration consortium (including Medicare enrollment and claims data), supplemented with data collected by the independent evaluator in a second round of site visits.

The report is organized in nine chapters. The first two chapters describe the basic structure of the demonstration, starting with an overview of the entire demonstration (Chapter II) and a description of the consortium that is implementing the demonstration (Chapter III). The following four chapters describe key operational elements of the demonstration, including success in recruiting physicians and Medicare beneficiaries (Chapter IV), the demonstration's technological components (Chapter V), the design and implementation of the clinical intervention (Chapter VI), and the analytical approach that the consortium will follow in measuring the intervention's effectiveness (Chapter VII). The final two chapters present the independent evaluation's findings on the implementation of the demonstration (Chapter VIII) and the contents and schedule of future reports from the independent evaluation (Chapter IX).

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

II. OVERVIEW OF THE DEMONSTRATION

The goal of the demonstration is to evaluate the ability of telemedicine services to increase quality of care, while simultaneously reducing the costs of care, for Medicare beneficiaries with diabetes in underserved urban and rural settings. In addition, the demonstration aims to:

- Demonstrate the feasibility of a large-scale, Web-based telemedicine system that complies with Health Insurance Portability and Accountability Act (HIPAA) requirements
- Assess the acceptability and desirability of telemedicine to patients and physicians
- Determine the impact of the demonstration on access to care; patient knowledge, attitudes, and beliefs about diabetes; processes of care; clinical outcomes of care; quality of life; costs of care; and overall cost-effectiveness
- Develop curricula to train health providers in the use of telemedicine, and, at the completion of the demonstration, develop standards for the credentialing and licensure of health professionals in the use of telemedicine and medical informatics

Overall, the demonstration is designed to meet these specific aims and the objectives of the Congressional mandate. However, in contrast to the mandated goals, the demonstration does not specifically target Medicare managed care beneficiaries. In addition, while the demonstration will collect a variety of process and outcome measures, its design will allow detection of meaningful impacts only on two clinical outcomes. Impacts on broader outcomes—such as access, quality of care, and costs—will not be detected unless they are very large (see Chapter VII).

On February 28, 2000, the Centers for Medicare & Medicaid Services (CMS) awarded a $28 million cooperative agreement to Columbia University to conduct the demonstration, referred to as Informatics for Diabetes Education and Telemedicine (IDEATel). To implement the

demonstration, Columbia University assembled a consortium (hereafter identified as the "Consortium") that includes two academic medical centers and smaller regional hospitals, a telecommunications provider, and several vendors. The demonstration is targeted to Medicare beneficiaries with diabetes mellitus who live in federally designated, medically underserved areas (MUAs) or health professional shortage areas (HPSAs), either in New York City or in upstate New York (hereafter identified as the "upstate site").[4] The demonstration will randomly assign 750 participants each to a treatment and a control group, balanced between New York City and upstate sites.

Broadly speaking, the demonstration's intervention seeks to overcome the challenges all people with diabetes face in managing their conditions, challenges that are especially daunting for the Medicare beneficiaries targeted by the demonstration—all of whom reside in medically underserved areas, and many of whom have limited English skills. The primary clinical goals of the intervention are: (1) sustained control of blood sugar levels at levels as close to normal as possible; (2) elimination or control of concomitant risk factors of smoking, obesity, physical inactivity, high blood pressure, and abnormal lipid levels; and (3) regular performance of clinical preventive interventions, such as eye examinations, urinalysis, examination of the feet, and vaccinations against pneumococcal pneumonia and influenza (see Chapter VI). Reaching these clinical goals requires that people with diabetes make and maintain extensive changes in lifestyle and behavior, that providers prescribe regimens of diabetes medications proven to be effective,

[4]As described in an amendment to the Public Health Service Act (42 CFR Chapter 1, part 5) there are three types of HPSAs: primary care, dental, and mental health. It is assumed that the Consortium recruits participants from primary care HPSAs only.

and that patients or their providers keep track of when the various clinical preventive interventions are due and make sure they get done.

The demonstration's interventions contain elements of three telemedicine models: monitoring, videoconferencing, and Web-based consulting, which includes monitored chat rooms (Starren et al. 2002). Figure II.1 illustrates the structure and interactions among the demonstration's interventions. Participants randomized to the treatment group receive a home telemedicine unit (HTU). The HTU is the basis of the IDEATel system and has several components, including a personal computer with a monitor, speakers, keyboard, and internal modem; video camera with microphone; and a glucometer and blood pressure cuff connected to the HTU through medical device data ports. Demonstration participants, nurse case managers, and physicians use the IDEATel system to communicate among themselves and to conduct the demonstration's three primary interventions:

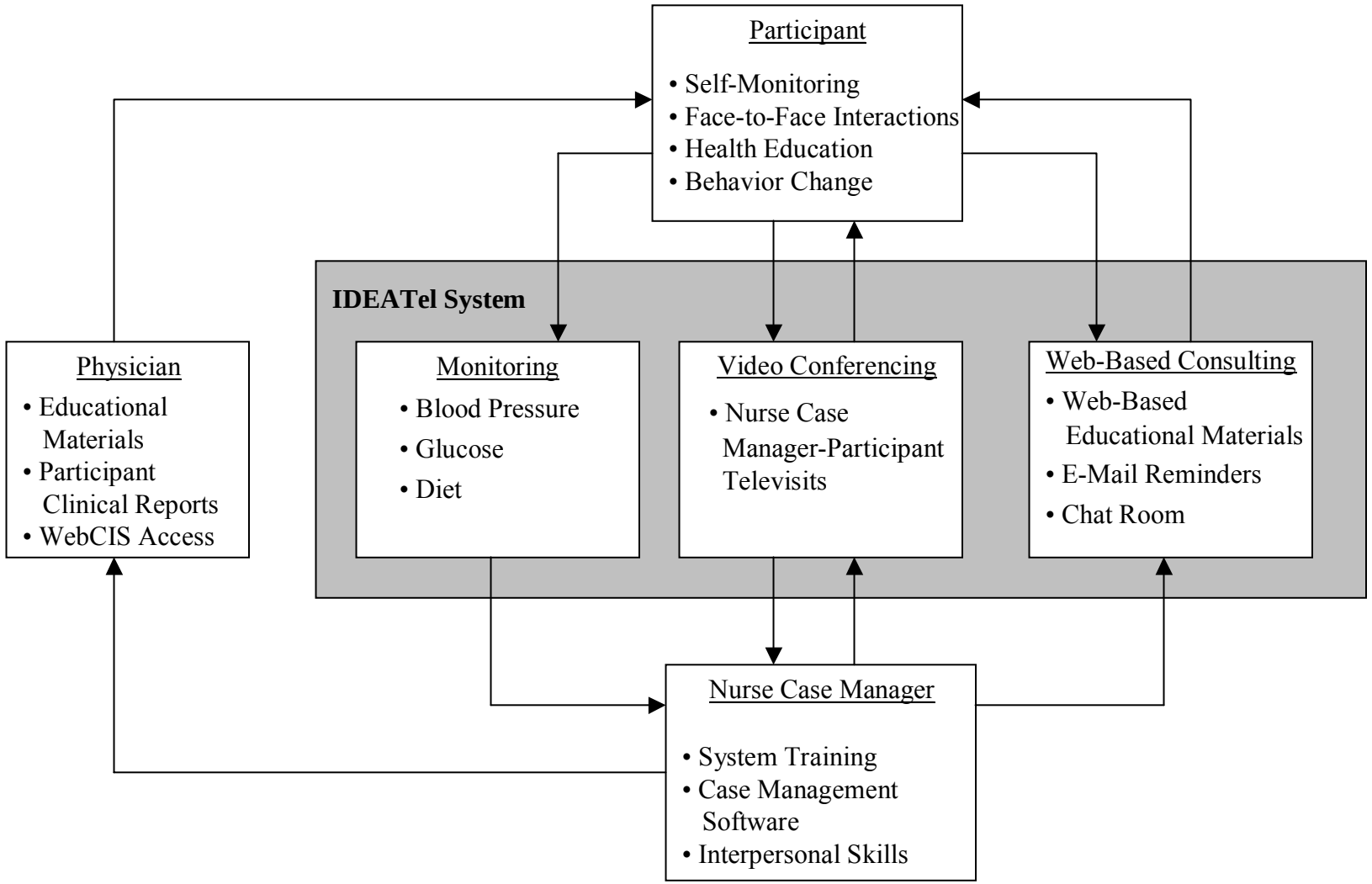
1. ***Monitoring:*** Treatment group participants use the HTU to monitor their blood sugar and blood pressure. They upload these data from the HTU into a central clinical database that can be accessed by the participants' themselves, the nurse case managers, or the participant's own primary care physician (PCP). Nurse case managers receive monitoring data and alerts regarding out-of-range measurements.

2. ***Video Conferencing:*** Treatment group participants have regular televisits with the nurse case managers in which the nurse case managers both promote desired behavioral changes and build participants' skills in using the HTU's hardware and software components. The nurse case managers use case management software to track participant progress and send reports and recommendations for care to the participants' PCPs after every televisit.

3. ***Web-Based Consulting:*** Treatment group participants use the HTU to access a special internet Web page created for the demonstration by the American Diabetes Association. They also are able to visit chat rooms with other demonstration participants and send E-mail to their nurse case managers.

FIGURE II.1

THE IDEATel SYSTEM INTERVENTION



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

In contrast to the treatment group participants, the participants randomized to the control group receive usual diabetes care from their PCPs without the HTU or nurse case manager televisits.

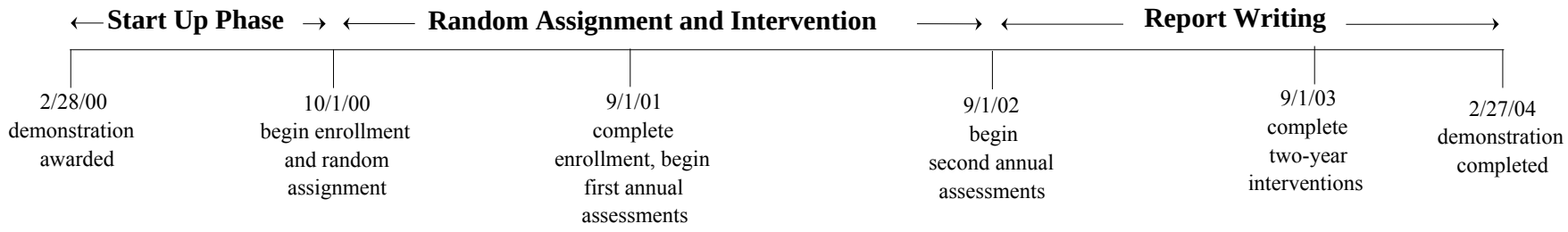
The Consortium proposed a demonstration design with a start-up phase, a randomization and intervention phase, and a data analysis and report writing phase. Figure II.2 shows the deviation of the actual demonstration implementation from the proposed timeline.[5] The seven-month start-up phase was to be followed by 11 months of participant recruitment and randomization. However, enrollment of participants did not begin until December 2000, 9 months after award. Similarly, participant recruitment was slower than expected and had not been completed at the time this report was written. These delays will be fully described in Chapters IV and V. The proposed design called for treatment group participants to receive the telemedicine intervention for two years. Both treatment and control group participants are to have an in-person, baseline assessment and in-person assessments at the end of Years 1 and 2 (see Chapter VII). In the last phase of the demonstration, the demonstration staff will conduct data analysis and write reports. Because of the longer than planned recruitment period, either the demonstration will have to be extended for the last enrollees to receive two years of the intervention, or the intervention period will have to be shortened to less than two years.

[5]The proposed timeline for the demonstration was taken from Columbia University's OMB supporting statement (HCFA 2000). Attachment D.6-B to this document contains a more current timeline than that in Columbia University's original proposal to CMS (Columbia University 1998). Note that the attachment lists the end date of the project as February 27, 2003; this is a typographical error and should be February 27, 2004.

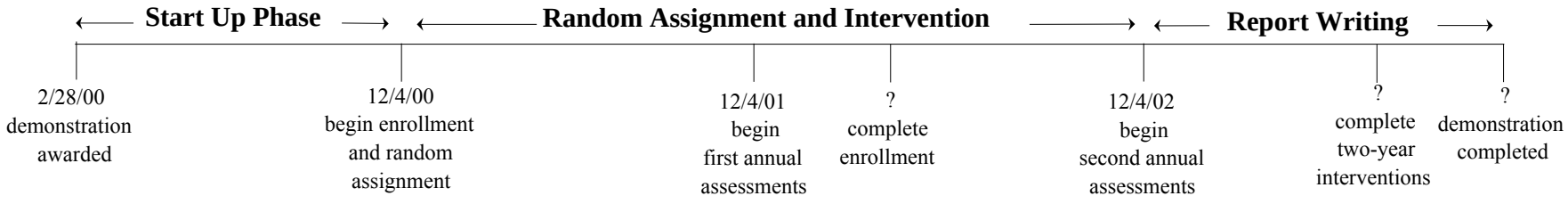
FIGURE II.2

IDEATel DEMONSTRATION TIMELINE

Proposed Design



Actual Implementation



SOURCE: Columbia University (1998); HCFA (2000); interviews with Consortium informants.

III. THE COLUMBIA UNIVERSITY CONSORTIUM

As required by the Congressional mandate, the organization to implement the IDEATel demonstration needed to be a consortium that included at least one tertiary care hospital (but no more than two such hospitals), at least one medical school, no more than four facilities in rural or urban areas, and at least one regional telecommunications provider (see Appendix A). Moreover, the legislation specifies the location of the consortium in relation to medical schools and tertiary care facilities, and the responsibilities of the organization in conducting the demonstration. Columbia University successfully assembled a consortium that, in addition to fulfilling the legislative requirement, combines a wide range of skills and expertise in implementing a complex clinical trial, as required by the IDEATel demonstration. This chapter assesses the consortium's expertise, use of external consultants to fill gaps in knowledge and expertise, and ability to manage the activities involved in the start-up phase of the demonstration. This assessment draws from several data sources, including Columbia University's Response to the CMS Request for Proposals (Columbia University 1998); reports to CMS on the progress of the demonstration (Columbia University 2000b and 2001); interviews with the Consortium's leadership and staff; and other materials provided by the Consortium.

A. EXPERTISE OF CONSORTIUM MEMBERS

The Consortium requires many types of skills to implement the demonstration. These include expertise in the treatment of diabetes among Medicare beneficiaries, the ability to deliver telemedicine services to Medicare beneficiaries living in medically underserved urban and rural communities, and the ability to implement a large-scale clinical demonstration. This last area of expertise itself requires experience in hiring support staff, coordinating the collection of multiple

sources of data, and managing the different members of a research team. More important, it requires that the Consortium have the capacity to recruit participants for the demonstration on schedule.

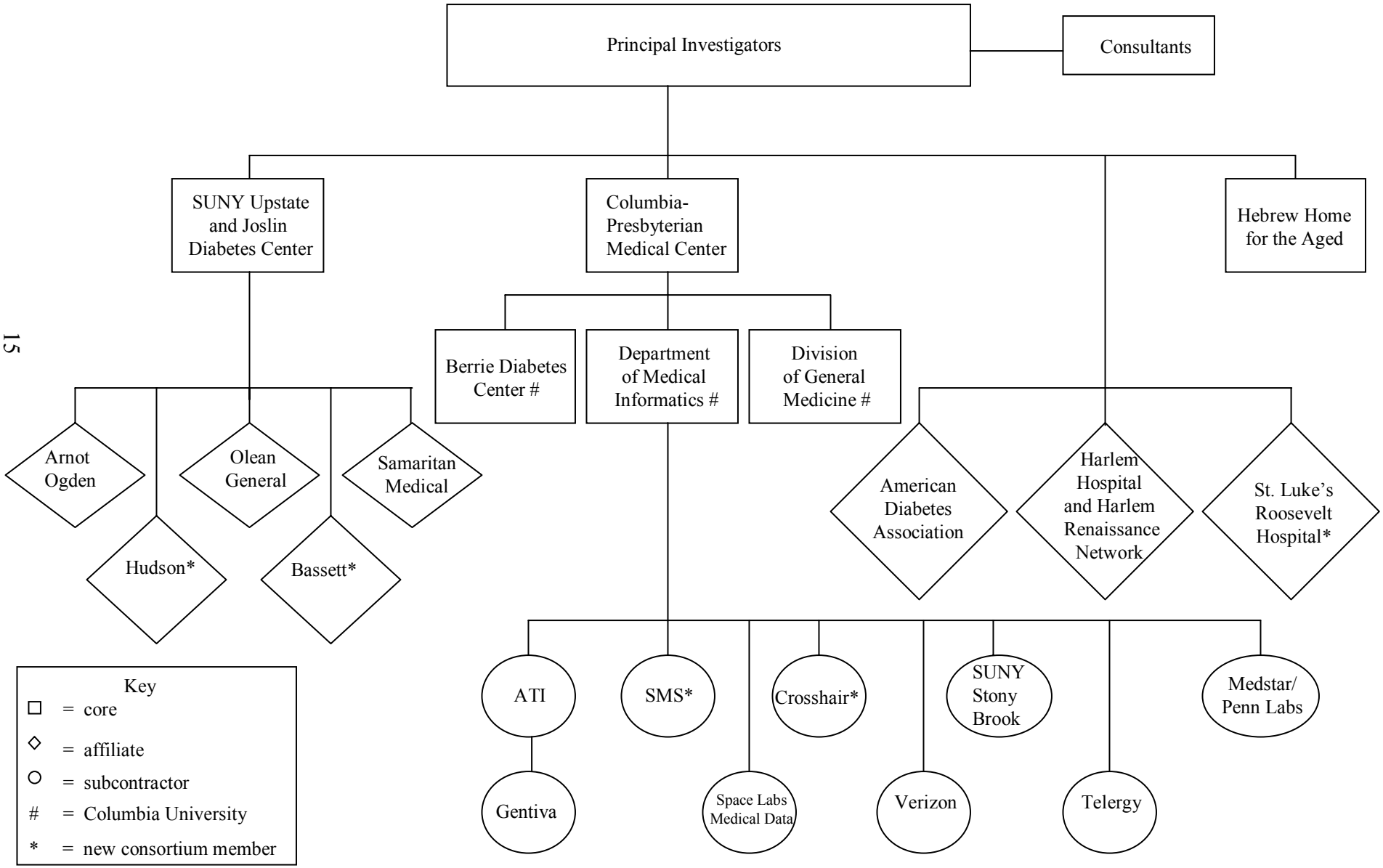
The Consortium includes core organizations that are responsible for the demonstration's design and implementation; affiliated members who offer additional technical expertise or are a source of potential participants; and subcontractors who provide hardware, software, and other services for the demonstration (see Figure III.1).

The core organizations include:

- ***Columbia University's Division of General Medicine,*** which manages the implementation of the demonstration under the directorship of the principal investigator. Other responsibilities include participant recruitment in the New York City site and management of the logistics of handling demonstration participants during the baseline and annual, in-person examinations.
- ***Columbia University's Department of Medical Informatics,*** which oversees the IDEATel system architecture, including hardware and software components, directs three programmers on the project (including systems and network analysts), and oversees the installation of the home telemedicine units (HTUs) by a subcontractor under the direction of a co-principal investigator.
- ***The Naomi Berrie Diabetes Center,*** which oversees the case management component of the demonstration intervention in New York City.
- ***The SUNY Upstate Medical University,*** which is responsible for participant recruitment in the upstate New York site under the direction of a co-principal investigator. SUNY is also responsible, jointly with the ***Joslin Diabetes Center***, for coordinating case management training in both sites and, under the direction of two physician project leaders, deals with clinical issues related to participant care.

FIGURE III.1

THE IDEATel DEMONSTRATION CONSORTIUM



SOURCE: Columbia University (1998); interviews with Consortium informants.

- ***The Hebrew Home for the Aged at Riverdale,*** which is the research data coordinating center for the demonstration. Demonstration staff are responsible for a number of research-related activities—including survey instrument development, randomization, data monitoring and tracking, data quality assurance, and data analysis. These activities are conducted by more than a dozen full- and part-time research staff under the direction of two co-directors, who have appointments at Columbia University.

Affiliated members of the Consortium include non-core health service organizations— recruited as sources of demonstration participants—and the American Diabetes Association (ADA), which is responsible for providing Web-based educational materials for participants about self-care for diabetes. As of February 2002, non-core health services organizations in the New York City site include: Harlem Hospital Center, a community hospital; Harlem Renaissance HealthCare Network, which operates a network of community-based primary care practice sites; and St. Luke's-Roosevelt Hospital Center, affiliated with the Columbia-Presbyterian Medical Center. The non-core health services organizations in the upstate New York site include: Arnot Ogden Medical Center, Olean General Hospital, and Samaritan Medical Center, all rural hospitals; Bassett Healthcare, a network of rural hospitals and community health centers; and Hudson Headwaters Health Network, a network of rural community health centers (Figure III.1).

The Consortium contracted with a number of subcontractors to provide the hardware and software components for the telemedicine system, as well as assist in participant training in the use of HTUs, HTU configuration and installation, and technical support. As of February 2002, nine subcontractors are providing the following services:

- ***American TeleCare, Inc. (ATI)*** provides the HTUs, carts on which the HTUs sit, and data encryption software for ensuring security of clinical readings transferred from participant homes to a demonstration data repository (see Chapter V).
- ***Gentiva Health Care, Inc.***, under a subcontract from ATI, installs HTUs and provides initial participant training on HTU use.

- ***Crosshair Technologies, Inc.*** provides the software components to validate system user identities.
- ***Shared Medical Systems (SMS)***, a unit of Siemens Health Services, developed the case management software licensed to the Consortium.[6]
- ***Verizon, Inc.*** provides telephone services in the New York City site, as well as providing a 1-500 number that converts calls from up to 50 different long-distance carriers in the upstate New York site into a local phone call.
- ***Telergy*** provides telecommunications services to connect nurse case managers in the upstate New York site to a clinical information system (WebCIS) database at Columbia University.[7]
- ***SUNY Stony Brook*** is responsible for database management and statistical analysis of 24-hour blood pressure data.
- ***Space Labs Medical Data*** leases 24-hour blood pressure monitoring equipment for annual examinations and provides initial data reduction.
- ***MedStar/Penn Labs*** is responsible for analyzing laboratory specimens from annual examinations.

The membership of the Consortium, and the roles of some members, changed in response to challenges encountered during the start-up phase of the demonstration. The changes that the Consortium implemented fall into two categories. First, the Consortium recently added non-core health services organizations (see Table III.1). As discussed in Chapter IV, these members were added to address a shortfall of eligible Medicare beneficiaries. Second, the Consortium changed subcontractors in response to changes in the technology marketplace. As discussed in Chapter

[6]SMS has recently changed its name to Siemens Medical Solutions Health Services Corporation.

[7]Telergy ceased to provide services to its customers beginning October 26, 2001. It is unclear what alternative arrangements the Consortium made to connect the upstate New York site server to the Columbia-Presbyterian Medical Center servers (Starren et al. 2002).

TABLE III.1

CHANGES IN CONSORTIUM MEMBERSHIP BETWEEN THE START OF THE DEMONSTRATION AND FEBRUARY 2002

Organization and Changes	Reason for Change
St. Luke's-Roosevelt Hospital, in the New York City site, and Bassett Healthcare and Hudson Headwaters Health Network, in the upstate New York site, joined the Consortium	Address a shortfall of potentially eligible Medicare beneficiaries willing to participate in the demonstration
SMS replaced CareSoft, Inc. as the subcontractor responsible for providing the case management software	SMS offered a product superior to that of CareSoft, Inc.
Crosshair Technologies, Inc. was added as a subcontractor to develop the data security features	Develop data security features of the IDEATel system with the same personnel from the Bell Atlantic division that the Consortium had originally planned to work with. Crosshair is a spin off company created after Verizon split off from Bell Atlantic
ATI assumed responsibility for activities conducted by Gentiva Health Care, Inc.	Lower the per diem for HTU installation and training of demonstration participants on HTU use. ATI had originally subcontracted with Gentiva for all installation of the HTUs. However, ATI agreed to be responsible for HTU installation because Gentiva's per diem rate was too expensive for the Consortium

SOURCE: Columbia University (2000a); interviews with Consortium informants.

ATI = American TeleCare, Inc.; HTU = home telemedicine unit; SMS = Shared Medical Systems.

V, the Consortium changed the subcontractor responsible for supplying the case management software. In addition, it added a subcontractor to provide data security. Finally, the Consortium changed the role of ATI, which assumed direct responsibility for some roles originally planned for Gentiva, its subcontractor, primarily for financial reasons. These changes in membership, or in the roles of some consortium members, did not affect the balance of skills and expertise that the Consortium brings to the demonstration.

No single member of the Consortium had experience in all three needed competencies for a successful demonstration team: (1) treatment of diabetes mellitus among Medicare beneficiaries; (2) delivery of telemedicine services to Medicare beneficiaries in medically underserved areas; and (3) implementation of a large-scale clinical trial. However, the combined experience and expertise of Consortium members appears to have been successful in designing and implementing the demonstration. First, staff from the Joslin Diabetes Center and the Naomi Berrie Diabetes Center provide expertise in diabetes case management for demonstration participants. Their expertise also has been tapped in designing the informational pages for the demonstration Web site supplied by the American Diabetes Association and in designing the case management "screens" in Columbia University's Clinical Information System (WebCIS) (see Chapter VI). Second, under the leadership of the co-principal investigator from Columbia University's Department of Medical Informatics, a team of experts designed the telemedicine system and oversees its deployment. Third, staff in Columbia University's Division of General Medicine, and the co-principal investigator and staff at SUNY Upstate Medical University, have extensive experience recruiting organizations and individuals for research projects. Fourth, the principal investigator and staff from Columbia University's Division of General Medicine, along

with staff from the Hebrew Home, have extensive experience in designing and managing large clinical trials.

B. USE OF EXTERNAL CONSULTANTS

In its technical proposal, the Consortium planned to use four consultants with expertise in developing telemedicine systems, implementing and evaluating telemedicine demonstrations, and developing and evaluating health education programs. Consortium staff reported that they had used the services of only one of the consultants. When Columbia University prepared its technical proposal for the demonstration and, subsequently, during the demonstration design phase, one consultant provided critical guidance for identifying organizations with software and hardware products that would be required for developing the telemedicine system. As one informant stated, "the consultant knew all the players in the field."

C. CONSORTIUM MANAGEMENT

Given the multi-organizational and multi-site nature of the Consortium, an effective management structure was needed to coordinate the various groups. The management structure needed to ensure communication among the various groups and to have a mechanism for identifying issues and resolving them. Consortium members also needed to have clearly defined roles. In addition, the Consortium needed to be able to adapt to challenges arising during the demonstration.

The Consortium put into place a series of three regularly scheduled meetings to identify and resolve problems during implementation. A weekly Steering Committee meeting is the forum in which all high-level technical and implementation issues are discussed. Composed of the principal investigators and staff from core and subcontractor members of the Consortium, the

Steering Committee meeting is the primary point of communication for all Consortium members. A weekly Systems Implementation meeting, chaired by the systems implementation manager, and including representatives from both sites and subcontractors, deals with issues related to the installation of the HTU, technical problem-solving, and system design and operational issues. A third meeting, dealing with case management issues, includes representatives from the Naomi Berrie Diabetes Center and the Joslin Diabetes Center.

Despite the use of these regular meetings and other ad hoc contacts, there is some evidence of communication problems early on. For example, an informant reported that early in the project Columbia University and ATI had different expectations about the HTU design, and that design specifications for the HTUs were unclear, both of which resulted in delays. Although this miscommunication delayed the implementation of the intervention, which might have resulted in higher costs for the Consortium, the respondent felt it was a pivotal point in the demonstration, ultimately forging better communications and a better working relationship between ATI and Columbia University.

Rather than communication problems between Columbia University and ATI, the Consortium leadership blamed the delay in HTU design on the timing of the award relative to the submission of the technical proposal and the start date of the project. First, 18 months had passed between the submission of the technical proposal and the award of the cooperative agreement, and some of the proposed subcontracting arrangements no longer applied. During the first few months of project the Consortium had to identify new vendors and renegotiate previous agreements. Second, the Consortium had based their original project timetable on the incorrect assumption of a time lag between the notification of the cooperative agreement and the actual start of the

project. They had planned to use this time lag for the design and pilot testing of the HTUs, but instead had to perform this work after the project start date.

Consortium members have clearly defined roles, and the demonstration is structured with clear lines of authority. Although a senior team member oversees each aspect of the demonstration, ultimate authority resides with the principal investigator. Overall, informants reported that there is mutual respect among Consortium members. It appears that Consortium members work extremely well together as a team.

D. SUMMARY

The Consortium appears to possess the expertise in the wide variety of areas necessary to carry out the IDEATel demonstration. The Consortium added and changed members to overcome implementation barriers, such as a shortfall of eligible Medicare beneficiaries and changes in the technology marketplace. Despite some initial communication problems, the Consortium members were able to work together to design and implement the demonstration intervention.

IV. PHYSICIAN AND PARTICIPANT RECRUITMENT

The Consortium recruits eligible Medicare beneficiaries to take part in the demonstration by seeking referrals from primary care physicians (PCPs), rather than by approaching potential participants directly. This strategy allows the demonstration to build a relationship with the PCPs, making it more likely that the PCPs will follow the patient care recommendations generated by the case managers. In addition, this strategy was expected to be more acceptable to potential participants who are more likely to act on their PCP's recommendation to enroll in the demonstration than to respond to a recruitment letter or telephone call from someone they have never had contact with before. Thus, to recruit participants, it was important for the demonstration to first recruit physicians, and then for those physicians to refer suitable patients to the demonstration. This chapter will describe the demonstration's approaches to recruiting both physicians and participants and will assess the success of these approaches.

A. PHYSICIAN RECRUITMENT

Physician recruitment began with, and was heavily dependent upon, physicians and physician groups with whom the Consortium leaders had existing relationships. In New York City, physician recruitment was facilitated by existing ties between the Columbia-Presbyterian Hospital system, Harlem Hospital Center, and the Harlem Renaissance Healthcare Network. In upstate New York, physician recruitment was facilitated by the longstanding relationship between community PCPs and SUNY Upstate through its Rural Medical Education program, which places medical students in rural, community-based physician practices.

Despite these preexisting relationships, physician recruitment still required significant effort. Early in the demonstration, the Consortium staff decided that physicians would be more likely to participate if a physician approached them. Therefore, in New York City, one physician member of the demonstration staff was assigned the task of physician recruitment, while, in upstate New York, two physicians filled this role. These "recruiter" physicians used many strategies to recruit physicians. They visited physician offices, sometimes multiple times; gave presentations on the demonstration, telemedicine, or diabetes in general; and provided information on the demonstration or any other information or materials the physician(s) requested. The physician recruiters considered it very important to form one-on-one relationships with the PCPs to secure their participation.

Early in the recruitment process, it became clear to the Consortium leaders that, in addition to their existing physician contact base, they would need to recruit other physicians to reach their patient recruitment targets. In New York City, the Consortium extended recruitment to physicians affiliated with St. Luke's-Roosevelt Hospital Center and to community-based PCPs without ties to any of the medical centers participating in the demonstration. In upstate New York, the Consortium added Bassett Healthcare—a network of hospitals and clinics based in Cooperstown, New York—and the Hudson Headwaters Health Network—a network of community health centers based in Warrensburg, New York that includes Glens Falls and Ticonderoga.

The demonstration staff described physician recruitment as being slow and reported that the physician reaction to recruitment efforts was "neutral." There are no financial incentives for physicians to refer their patients to the demonstration. While some physicians are willing to participate, believing it could improve their patients' quality of care, most of them require

considerable convincing. The demonstration staff report that they must spend a great deal of time addressing physicians' concerns.

Physicians have two primary concerns about participating in the demonstration. First, they worry about the amount of their time it will take. The physicians were reported as stating that they are already overburdened with work and have very little time to devote to participating in research projects. They worry about the amount of time that is needed to identify potential participants and review/followup on the televisit summaries sent by the nurse case manager. Second, they are concerned that their participation may increase their liability. The physicians are concerned that if the televisit summaries make a recommendation for care or highlight an issue for clinical concern, and if they fail to act on this information (because they are overburdened with other work), they could be held legally responsible for any negative patient outcome occurring as a result of their inaction. While the demonstration staff acknowledged that these concerns were understandable, they have also sought to reassure physicians that participation in the demonstration will place only a minimal burden on them. For example, demonstration staff assist physicians in identifying patients with diabetes potentially eligible to participate in the demonstration. In addition, the nurse case managers do not contact physicians unnecessarily, the televisit notes are well structured and easy to read, and recommendations for care are based on nationally recognized, evidence-based clinical practice guidelines. Indeed, it appears that the demonstration has not placed an unreasonable burden on physicians. The demonstration staff reported that none have withdrawn from the demonstration or stopped referring patients.

At the time of the independent evaluation's site visits, one year after the demonstration began, the demonstration staff estimated that approximately 350 physicians had referred potential

participants to the demonstration.[8] Although the demonstration staff collect information on the demographic characteristics of referring physicians, they were unable to provide these data for inclusion in this report. They believe that most physicians who have referred patients to the study are general internists or family practitioners and that few are endocrinologists or other specialists. They do not believe that there are significant differences between the characteristics of physicians in New York City and upstate New York. However, some staff members thought that the upstate physicians may be slightly older. No data were provided to substantiate these opinions.

B. PARTICIPANT RECRUITMENT

As mandated, the demonstration targets Medicare beneficiaries with diabetes mellitus residing in medically underserved rural and inner-city areas. The Consortium described the original eligibility criteria in its technical proposal (Columbia University 1998). Since the demonstration began, the criteria have changed. Table IV.1 lists the demonstration's current participant inclusion and exclusion criteria. These criteria identify potential participants who have diabetes, who live in a medically underserved area of New York City or upstate New York, and who are physically and cognitively able to participate in the demonstration's telemedicine interventions.

[8]Site visits occurred in December 2001 and January 2002 (see Appendix B). At the writing of this report, the Consortium indicated that more than 600 physicians had referred patients to the demonstration.

TABLE IV.1

CURRENT DEMONSTRATION INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria	**Exclusion Criteria**[a]
Age ≥ 55 years	Unable to communicate verbally
Medicare Part A enrollment	Difficulty understanding verbal communication
Resides in target medically underserved area	Visual impairment preventing use of HTU
Meets ADA criteria for diabetes mellitus (being treated with insulin or oral agents or being treated with diet/exercise alone and having random glucose ≥200 mg/dl or fasting glucose ≥126 mg/dl on more than one occasion)	Hearing impairment preventing telephone communication
	Comorbid condition or pain preventing use of HTU
	Life-threatening comorbid condition
	Requires dialysis
	Previous organ transplant
	Severe functional limitation preventing use of HTU
	Cognitively impaired
	Participation in other research studies
	Subject spends three or more months a year not in primary residence (traveling or staying with relatives)

SOURCE: Columbia University (2002).

HTU = Home Telemedicine Unit; ADA = American Diabetes Association.

[a] The exclusion criteria are not absolute, in that the recruitment supervisors may use their discretion to determine whether a potential participant with one of the exclusion criteria may still be capable of participating.

There have been five changes in the inclusion and exclusion criteria since the start of the demonstration. A minor change was that the demonstration staff chose to exclude people from the demonstration who were participating in other research studies, to prevent contamination of study results.[9] The remaining four changes are more substantial and were made to increase the number of people eligible to participate. First, the age criterion was decreased from age 65 years and above, to age 55 years and above.[10] Second, people with milder forms of diabetes, treated with diet or exercise alone, were now eligible to participate in the demonstration. Third, the scoring of the inclusion- and exclusion-screening instrument was changed. At the start of the demonstration, a potential participant would have been determined ineligible if he or she met even one of the exclusion criteria on the screening instrument. This rule was relaxed to say that, if an individual had one of the exclusions, it was up to the site's recruitment supervisor to determine whether he or she was capable of participating. For example, potential participants may be visually impaired or physically unable to use the HTU, but if they have a caregiver who would be present during all televisits, then they would be able to participate. Fourth, the area of New York City targeted for recruitment changed. The Consortium's response to CMS's Request for Proposals called for participants in Manhattan to reside north of 100th Street west of Central Park or 110th Street east of Central Park. At the time of the site visits, demonstration staff

[9]However, participants could have joined another research study after enrolling in the IDEATel demonstration.

[10]Although Medicare eligibility is still required, this change may have important programmatic implications. Almost all demonstration participants under age 65 with Medicare coverage will have collected Social Security Disability Insurance benefits for at least two years. Thus, these participants will have had a substantial history of disability at the time they enroll in the demonstration. These participants are likely to have much higher levels of impairment than many (or even most) of the participants over age 65.

indicated that the target area had changed to north of 90th Street west and 96th Street east in Manhattan and included an area of the southwest Bronx. The former change is at odds with the definition used in the Consortium's telephone-screening tool (that is, 96th Street and above, both east and west) (Columbia University 2002). Although the area north of 96th Street east is a medically underserved area, not all the area north of 96th west is designated as such area (HRSA 2002).[11] Consortium staff did not elaborate on the reason for these two changes.

The demonstration staff used different processes to recruit participants in New York City and upstate New York. In upstate New York, the study staff went directly to PCPs associated with the Consortium's upstate hospitals to ask them to participate in the demonstration and provide a list of their patients with diabetes.[12] In New York City, demonstration staff used the centralized patient information systems in the Consortium hospitals to obtain lists of patients treated for diabetes in these hospitals. Then they contacted the PCPs of these patients to request that they participate in the demonstration and to recommend the demonstration to their patients. However, when the staff in New York City extended recruitment to non-academic, community-based physicians, their process for recruiting patients was the same as in upstate New York—they contacted physicians directly. In addition, the demonstration is advertised directly to potential participants on one of the Spanish-language television stations in New York City (channel 47). Staff have also made presentations about the demonstration at community centers and churches

[11]Census tracts 189.00, 191.00, 193.00, and 195.00 form a medically underserved area that spans between 100th Street and 110th Street west. However, census tracts 177.00, 179.00, 181.00, 183.00, 185.00, 187.00, 197.00, 201.01, 203.00, and 205.00 (all north of 90th Street west) are not included in a medically underserved area (HRSA 2002).

[12]Patients were identified by searching physician records for a diabetes diagnosis, International Classification of Diseases (ICD-9) code 250.

in New York City. However, the staff stated that these activities were more focused on creating awareness of the demonstration than actually recruiting patients.

After a hospital or a physician's office generates a list of patients with diabetes, demonstration staff ask the physician to review the list and cross off any person he or she thinks would be unsuitable for the demonstration. The list of patients is then turned over to the demonstration staff, who use a geocoding software program to verify that potential participants live in a medically underserved area. They also verify with CMS that potential participants are enrolled in Medicare. After this initial eligibility check, they send a letter to the patient describing the demonstration and asking him or her to participate.[13] The letter invites those interested to call a toll-free number where a research assistant conducts the telephone screen to apply the criteria shown in Table IV.1.[14] If the potential participant passes the telephone screening for inclusion and exclusion criteria, he or she is invited to have a baseline assessment.[15] Informed consent is obtained before the start of the baseline assessment. In New York City, the research assistants at the demonstration offices at Columbia-Presbyterian Medical Center conduct the baseline

[13]The letter is sent to the patient on their physician's own letterhead. The content of the letter is standardized and has been agreed upon by the physician and, wherever appropriate, the institutional review board of the hospital with which the physician is affiliated.

[14]In New York City, the research assistants are physicians who are foreign medical graduates and are bilingual in English and Spanish. In upstate New York, the research assistants are nurses or the demonstration's dietitian.

[15]The in-person baseline assessment consists of a survey of health conditions and medical history, medication use, diabetes self-management skills, functional ability, psychosocial status, satisfaction, quality of life, and sociodemographic characteristics. The baseline assessment also includes resting blood pressure, measurement of height, weight, and waist and hip girths, urine collection for measurement of microalbuminuria, blood drawing for measurement of glycosylated hemoglobin and lipid levels, and a 24-hour blood pressure recording. The assessment takes a little over three hours (see Chapter VII).

assessment. The demonstration arranges for a transportation service to pick up individuals at their homes, bring them in for the baseline assessment, and return them home. In the upstate site, study nurses conduct the baseline assessments at the Clinical Research Unit at SUNY Upstate Medical University, Bassett Healthcare, Olean General Hospital, Samaritan Medical Center, Arnot Ogden Medical Center and, occasionally, at regional rural health centers or at the offices of participants' primary care providers. The visits are conducted at the homes of demonstration participants only when they cannot travel to one of the regional demonstration clinics. After the baseline assessment, the participant is randomized to either the treatment or control groups.

For several reasons, the process of recruiting physicians and participants took longer than the demonstration staff had expected. First, the demonstration needed approvals from the Harlem Hospital institutional review board (IRB), New York City Health and Hospitals IRB, and Columbia University's IRB, and had to have Single Project Assurances from the upstate hospitals. The IRB approval process was time-consuming and difficult. At the request of one of the IRBs, the Consortium leaders placed an HTU in the room at Columbia University used for the baseline assessments.[16] This was done to help potential participants understand the size of the equipment that would be placed in their homes. Second, the number of potentially eligible patients per physician was smaller than expected; thus, to attain enrollment targets, the demonstration staff had to recruit more physicians. Third, the demonstration leaders found that the initial inclusion and exclusion criteria were eliminating potential recruits. The criteria were

[16]In upstate New York, in cases when the baseline assessments are done in the participants' homes, the nurse doing the assessment carries a picture of a person standing next to the HTU.

relaxed to increase the number of people eligible to participate. Fourth, only a relatively small percentage of eligible Medicare beneficiaries agreed to participate.

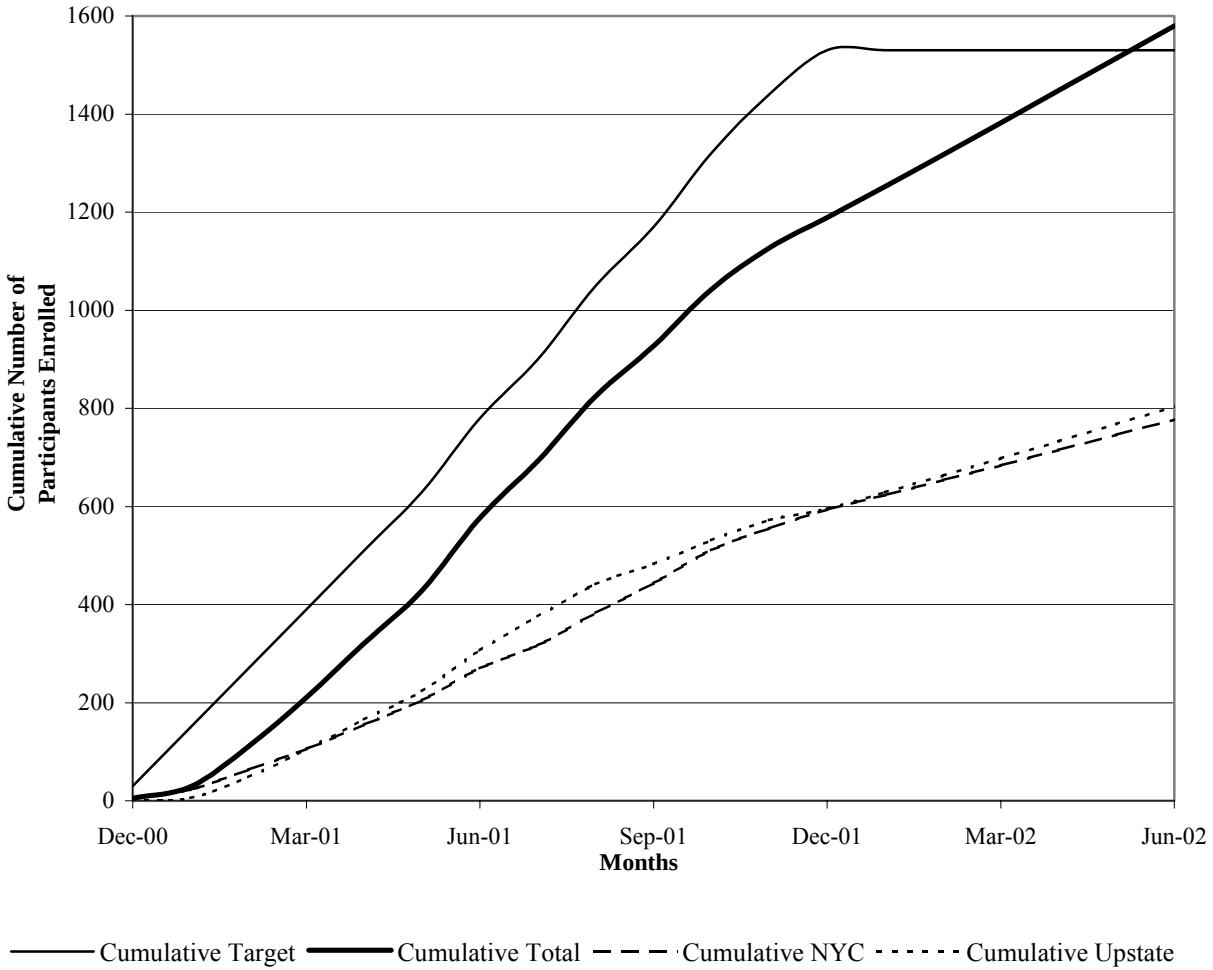
When asked to comment on the recruitment difficulties and delays, the Consortium stated that they had, in fact, fully anticipated the challenges in recruitment. The Consortium explained that recruitment took longer than originally scheduled, again because the original timetable in their proposal was based on the mistaken assumption of a time lag between project award and project start (see Section C of Chapter III). They had planned to accomplish the IRB approval process, refinement of the recruitment strategy, and hiring of recruitment staff during this time lag before the actual start of the project.

Despite these problems with recruitment, participant enrollment has been steady. Figure IV.1 shows cumulative participant enrollment through mid-June 2002 for the New York City and upstate sites, as well as for the demonstration as a whole. Enrollment began in December 2000 in New York City and in January 2001 in the upstate site. As of the writing of this report, enrollment is complete in New York City (777 participants enrolled) and is expected to close at the end of June in the upstate site (803 currently enrolled). The Consortium plans to enroll more participants than the 1,500 originally projected (current enrollment stands at 1,580) to replace participants who dropped out early in the study.

The participant dropout rate appears to be higher than projected. Demonstration staff originally projected a 15 percent dropout rate over the two years of the intervention in the treatment group, and a 20 percent dropout rate in the control group (Columbia University 1998). Instead, they

FIGURE IV.1

CUMULATIVE DEMONSTRATION ENROLLMENT



SOURCE: Data for December 2000 through November 2001 from Columbia University (2002) and data for December 2001 through June 2002 from a letter from Steven Shea of Columbia University to Carol Magee of the Centers for Medicare & Medicaid Services (June 14, 2002).

have experienced an estimated 12 percent dropout rate in the treatment group in the first year (13.4 percent in New York City, and 10.3 percent in upstate New York).[17] Staff at the Hebrew Home, who are responsible for tracking the demonstration's participants, categorize dropouts as two kinds: involuntary and voluntary. For example, a participant may be terminated from the demonstration involuntarily if the participant moves out of the study area. Participants may terminate voluntarily if they do not want to participate any more or if they believe they are too ill to continue participating. The study staff reported that among the 12 percent of treatment group participants who had dropped out of the demonstration as of January 2002: 5 percent dropped out because of problems with their HTUs, 3 percent refused to continue participating, 2 percent died, 2 percent became too ill to continue participating, and less than 1 percent either were too cognitively impaired to participate or were advised by their physician not to participate.

C. SUMMARY

As stated at the beginning of this chapter, the demonstration needed to recruit and retain both physicians and participants. Although slower than planned, recruitment of physicians and participants is taking place. The demonstration staff addressed their recruitment difficulties by adding new hospital members to the Consortium and expanding their pool of PCPs by reaching out to community-based physicians. They also relaxed the inclusion and exclusion criteria to increase the number of people eligible to participate in the demonstration.

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[17]The estimate of the participant dropout rate and the reasons for participant dropouts are based on information provided by the demonstration staff during the site visits. A flowchart of the enrollment process is provided in Appendix C. However, the Consortium leaders did not provide the specific number of people leaving the demonstration.

Participant enrollment should be completed in late June 2002, approximately 10 months behind schedule. Two issues bear continued observation, however. First, physicians have been neutral—neither critical of participation nor eager to participate in the demonstration and its interventions. An important component in improving participant outcomes is the willingness of physicians to act on the recommendations generated by the participant-nurse case manager televisit. As discussed in Chapter VI, for the demonstration to meet its clinical goals, physicians need to become active partners and follow up on case managers' clinical recommendations. Second, the treatment group participant drop-out rate is higher than anticipated, which could impair the demonstration's ability to estimate accurately telemedicine's net effect on participant outcomes. Consortium staff are closely monitoring the drop-out rate and attempting to dissuade people from leaving the study, and they have increased the target sample size. In addition, a careful analysis of participant attrition will be essential.

V. TECHNICAL DESIGN

The success of the demonstration depends on whether the Consortium deployed a telemedicine system that offers all the applications needed to carry out the clinical intervention. This system should also be acceptable to participants, so that they have optimal exposure to the intervention components. The Consortium modified the hardware and software of the IDEATel system in response to unexpected challenges during demonstration startup. Two years after the start of the demonstration, most of the components of the system were operating well, although, as discussed further in Chapter VI, the extent to which demonstration participants are effectively using the home telemedicine unit remains largely unknown. This chapter will describe (1) the original design of the IDEATel system proposed for the demonstration intervention and (2) the changes to the IDEATel system to make it operable in the field.

A. IDEATel SYSTEM DESIGN

The Consortium designed a telemedicine system with four primary functions: (1) remote clinical monitoring, (2) videoconferencing, (3) Web-based consulting (educational materials and chat rooms), and (4) communication in an integrated and secure environment (Starren et al. 2002). Remote monitoring, videoconferencing, and Web-based consulting have each been tested individually in earlier home telemedicine interventions, but the demonstration was innovative in combining all three approaches into a single system.

To support the system's four functions, the Consortium identified five different hardware and software components in its technical proposal (see Table V.1):

TABLE V.1

COMPONENTS AND FUNCTIONS OF THE IDEATel SYSTEM

System Component	Technical Functions			
	Remote Clinical Monitoring	Video Conferencing	Web-based Health Education	Integration and Data Security
Home Telemedicine Unit (HTU)	**X**	**X**	**X**	
Video Conferencing		X		
Web Browser			X	
Glucose Meter	X			
Automated Blood Pressure Cuff	X			
Electronic Data Port	X	X	X	
Web Resources			**X**	**X**
American Diabetes Association Web site			X	
CPMC Clinical Information System (WebCIS)				X
Nurse Case Management Software	**X**		**X**	
Alerts and Reminders	X			
Chat rooms and bulletin boards			X	
Electronic Messaging	X		X	
Web pages for self-selecting goals and self-reporting progress			X	
Data Security				**X**
Encryption				X
One-Time Password				X
Public Key Infrastructure				X
Audit Logs				X
Firewall				X
Telecommunications	**X**	**X**	**X**	**X**
Wide Area Network				X
Remote Data Upload				X
Televisits (through standard telephone line)		X		
Internet Access	X		X	
Virtual Private Networks				X

SOURCE: Columbia University (1998); Starren et al. (2002); interviews with Consortium informants.

CPMC = Columbia-Presbyterian Medical Center; WebCIS = Clinical Information System.

- ***A Home Telemedicine Unit*** (HTU) to support video teleconferencing for participant-provider interactions. The HTU is a modified IBM-compatible desktop personal computer equipped with an internal modem, video camera, speakers, a microphone, and Web-browsing software. In addition, the HTU includes two peripheral devices—a glucose meter and blood pressure cuff—for obtaining participant clinical data. Through the HTU, demonstration participants store glucose and blood pressure readings and forward these clinical data readings to a central location; nurse case managers monitor these data.

- ***Web Resources***, including educational materials from the ADA Web site accessible to participants and chat rooms and bulletin boards where participants can discuss common issues in managing their care.[18] The case management software (see below) supports Web pages where participants can view graphic trend displays of their blood pressure and blood sugar readings, enter self-selected behavior goals, and self-report progress toward those goals. Participating physicians also can use the system to access data on their patients participating in the demonstration from Columbia University-Presbyterian Medical Center's Web-based Clinical Information System (WebCIS), including both clinical readings uploaded by participants and other medical records data.[19]

- ***Nurse Case Management Software***, including alerts and reminders to the case manager about unsafe glucose and blood pressure readings based on clinical algorithms, electronic messaging with participants, and Web-based graphic trend displays of participant measurements, participants' self-selected behavior goals and self-reported progress toward those goals.

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[18]Before installation, the HTU is configured to show system prompts and displays in Spanish for Spanish-speaking participants and to access a Spanish version of the ADA educational materials. The Web browser also enables participants to access other Web educational materials, which may or may not be in Spanish.

[19]The Clinical Information System (WebCIS) of the Columbia University-Presbyterian Medical Center stores the medical records of demonstration participants (Starren et al. 2002). Participating physicians have access to WebCIS. Physicians affiliated with the Columbia University-Presbyterian Medical Center have access through authenticated network-connected terminals. The upstate and New York City physicians not affiliated with the Columbia University-Presbyterian Medical Center were given special "passcards" that allow Web access to WebCIS. For New York City participants who receive their care through Columbia University-Presbyterian Medical Center, WebCIS contains all of their medical records, which besides demonstration data, might include clinical notes from other providers, routine clinical lab data, pharmacy data, and so on. For participants who are not Columbia University-Presbyterian Medical Center patients (which includes all the upstate participants and some New York City participants), WebCIS contains only demonstration data.

- ***Data Security,*** consisting primarily of a public key infrastructure for ensuring confidentiality of all participant clinical data and authentication of all users who have access to such data.[20] Through the public key infrastructure, all clinical data are encrypted prior to transmittal to the case manager. Similarly, physicians accessing the data (for example, participating physicians using WebCIS) are authenticated as valid users. Additional data security features include audit logs of users accessing patient data (which maintains a virtual paper trail of medical record access) and a firewall (a system designed to prevent unauthorized access to and from a private network) to prevent unauthorized access to Web applications.
- ***Telecommunications*** include a wide-area network covering users in the New York City and upstate sites, a virtual private network consisting of encrypted transmission of data across users; remote data upload for physicians using WebCIS; Internet access for participants through an Internet service provider; and participant televisits with a case manager at the participant's home on an existing telephone line.

Chapter VI describes the clinical intervention—how the hardware and software components are actually used by the nurse case managers and participants in ways that hopefully will lead to improved clinical outcomes for demonstration participants.

B. CHANGES TO THE IDEATel SYSTEM

The Consortium's original system design encountered a number of challenges in the startup phase of the demonstration. Although the Consortium's original design incorporated all the components required to support the four technical functions of the IDEATel demonstration, the current IDEATel system differs from the one the Consortium originally envisioned, due to two factors:

- As mentioned in Chapter III, the Consortium was under the mistaken impression that the demonstration would include some time for design and planning activities before

[20]A public key infrastructure is a combination of hardware and software products, policies, and procedures required to provide basic information security.

the actual start of the project. The original design was thus incomplete at the time the demonstration was launched. At that time, the Consortium discovered that some components it thought were available were obsolete or unavailable. Thus, the Consortium had to rethink its design in the context of changing technology and time constraints. In addition, as discussed in Chapter III, miscommunication problems between Columbia University and American TeleCare, Inc. (ATI) delayed the implementation of the intervention.[21]

- After installing the IDEATel system in participants' homes, the Consortium had to address the difficulties that demonstration participants experienced with the HTUs. Many participants had no prior computer experience or were functionally illiterate.

As a result of these two factors, there were several changes to the hardware and software system components.

1. Changes to the System Hardware

Six major changes were made in the hardware (see Table V.2). The first change resulted from changes in the technology. The Consortium originally had anticipated obtaining an "all-in one" home telemedicine unit from ATI, with additional components to be added later; however, by the start of the demonstration, the all-in-one unit was no longer available.[22] According to a representative from ATI, this earlier design also had "some problems," and users had been

[21]Specifically, the Consortium later reported that the originally proposed case management software vendor had gone out of business, and that the previously negotiated subcontract with ATI no longer reflected technology and price changes that had occurred in the 18 months between the submission of the proposal and project award. Consortium leadership did not feel miscommunication between Columbia and ATI played a role.

[22]An "all-in-one" home telemedicine unit includes a PC in which a flat-screen monitor and CPU are combined in a single unit—the front side of the unit is a screen (a flat panel unit), as opposed to the separate cathode ray tube and box in the usual desktop personal computer.

TABLE V.2

MAJOR ADDITIONS AND MODIFICATIONS TO THE IDEATel SYSTEM

Addition or Modification	Reason for the Change
Hardware	
Larger desktop IBM-compatible personal computer using off the shelf technology replaces an "all-in-one" HTU	The "all-in-one" HTU was no longer available.
Cart added to the HTU	Provide a stable unit to hold the HTU and other peripheral devices with no external wiring; make more efficient use of space in small homes and apartments.
Restart button modified to enable participants to turn off the HTU	Addresses participant concerns about the use of electricity and background noise.
1-500 number made available to upstate participants	Avoids participants having to pay long-distance charges
Three-prong to two-prong electrical plug adapter	Several participants' homes in New York City only had two-prong outlets, whereas the HTUs require three-prong outlets
Four-button launch pad added	Added to help participants lacking computer literacy to turn on and off machine, initiate televisits, upload their clinical measurements, and launch Web browser.
Software	
SMS case management software replaced CareSoft's case management software	CareSoft no longer offered case management software as a stand-alone product. Among the other remaining vendors, SMS is considered a superior product.
Training video added	Added to address participant's poor comprehension and retention after initial training by nurse installers.

SOURCE: Starren et al. (2002); interviews with Consortium informants.

HTU = Home Telemedicine Unit.

unhappy with its performance. As a result, ATI and Columbia University redesigned the system from off-the-shelf technology to make a home telemedicine unit suitable for Medicare beneficiaries.

Second, upon the recommendation of ATI, a cart was added on which to hold the HTU. The cart is a specially designed unit intended to increase acceptability of the HTU to participants with limited space in their home by making efficient and attractive use of space. The cart also hides all system wires, with the aim of minimizing the potential for participants to accidentally unplug or disconnect devices and to then need on-site technical assistance.

Third, the Consortium addressed participants' concerns about background noise and electricity use. Although the IDEATel system was intended to be on all the time, many participants complained of a high-pitched noise (described by demonstration staff as a "submarine noise") when the system was on but not in use.[23] Consortium staff also reported that participants were concerned about the HTUs running up their electric bill. To accommodate these concerns, the Consortium redesigned the system to allow participants to reboot or turn the system off entirely.

Fourth, in the upstate site, there were problems dealing with the 40 to 50 phone companies available to residents in the area. Verizon, a subcontractor to the Consortium, provided participants with a 1-500 number that converts a long-distance call through any of the local phone companies into a local call. This addressed potential concerns among participants about long-distance charges.

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[23]This would occur whenever the participants received an ordinary incoming telephone call unrelated to a case-manager televisit.

Fifth, in New York City, several participants' homes did not include a three-prong electrical outlet, as required by the HTU. Although the Consortium considered excluding from the study those participants who did not have the appropriate electrical installation in their homes, the problem was solved after Consortium staff identified an adapter that allows converting the connection of the HTU plug into a two-prong outlet.

The sixth and most important change in the IDEATel system hardware was in response to participants' problems using the HTU. For example, Consortium informants reported that participants had problems remembering how to upload their blood pressure and blood sugar measurements. Other participants were reported to have found the HTU too difficult to use, owing to no prior experience using a computer and/or to functional illiteracy.[24] In response, the Consortium added a customized launch pad to simplify operation of the HTU. The launch pad is a device with four large buttons that allow participants to (1) answer video calls from the nurse case manager, (2) electronically transmit glucose and blood pressure readings, (3) connect to the demonstration's Web site, and (4) restart or reboot the system. Each button is color-labeled to tell them apart easily. The launch pad was suggested by ATI, which has extensive experience designing such systems for seniors with little or no computer experience. Although the launch pad allayed many of the Consortium's concerns about the acceptability of the demonstration's technology by the target population, no data are yet available to substantiate whether this design change paved the way for more frequent and effective use of the HTU.

[24]Demonstration participants were not interviewed for this study. Thus, the description of the problems they encountered using the HTU relies on reports from demonstration staff.

2. Changes to the System Software

There were two major software changes. The first was a change in the available choices for nurse case management software. The Consortium had originally intended to purchase the case management software developed by CareSoft (see Chapter III); however, by the time the demonstration was awarded, CareSoft was no longer offering software as a stand-alone product. After reviewing the alternatives available at the time of the demonstration award, the Consortium decided on a product developed by SMS. In exchange for participating in the demonstration, SMS licensed its case management software to the Consortium for a flat fee. The SMS case management software supports many of the functions desired by the Consortium, including flags to nurse case managers indicating when clinical readings are out of range, electronic messaging, chat rooms, bulletin boards, Web pages for participants to view graphic trends in clinical measurements, self-selected behavior goals, and self-reported progress toward goals.

The SMS software has two limitations. One is that the software does not flag whether or not a participant has had, or is due for, clinical preventive interventions, such as an eye exam. Another problem is that the SMS software was somewhat difficult to make compatible with WebCIS. These limitations are relatively minor, however. Though demonstration nurse case managers have to review their notes and remind participants when it is time, for example, to visit an ophthalmologist, they report that this is not a difficult task for them (see Chapter VI). Overall, nurse case managers report that all the software, including WebCIS, where they record their clinical notes, and the SMS software, is easy to use and helps them perform their job well.

The second software change was made in response to participant difficulties in using the IDEATel system. Even after initial training, many participants were having difficulty

remembering how to use the system. In response, the Consortium installed a training video in the HTUs of some participants, which participants can watch when they need instructions on how to use the system.[25]

C. SUMMARY

The IDEATel system includes remote clinical monitoring, video conferencing, and access to Web-based educational materials on diabetes management—all, reportedly, seamlessly integrated into a data-secure environment. For the most part, all the system components seem to be fully operable.

The IDEATel intervention is designed to effect changes in behavior through participant-nurse case manager interactions, health education, and close clinical monitoring. Notwithstanding the operability of the technology itself, the success of the intervention depends crucially on participant use of the IDEATel system. Several informants expressed surprise that many participants have had problems learning to use the system, owing to little computer experience and low literacy levels. Had the Consortium foreseen the potential barriers to use among demonstration participants, they could have been more proactive in designing a telemedicine system more easily operated by the demonstration's target population.[26]

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[25] An informant reported that the video was installed in 250 HTUs running an earlier version of the SMS software.

[26] As discussed in Section B of this Chapter and in Chapter III, the Consortium leadership pointed to their misunderstanding of the availability of a start-up phase as the reason these problems had not been ironed out earlier. In addition, as discussed in Chapter VI, the Consortium leadership views any HTU use by participants as a very encouraging sign given the demographic characteristics of the target population.

VI. THE INTERVENTION

This chapter discusses the IDEATel intervention itself. Information for the chapter comes entirely from the following sources: Columbia University's technical proposal to perform the demonstration (Columbia University 1998; referred to hereafter as "Columbia University's technical proposal"), a limited set of demonstration documents provided by the Consortium (HCFA 2000; Columbia University 2000a; Columbia University 2000b; Columbia University 2001), articles on the demonstration published by the Consortium (Shea et al. 2002; Starren et al. 2002), and site visit interviews with Consortium staff. As discussed in Appendix B, the Consortium felt that human research confidentiality considerations precluded interviews of participants and primary care physicians. The Consortium also stated that data on participants' usage of HTUs and on nurse case manager-participant contacts are not yet available, as the databases recording these data were still under development, and the data already collected needed to be cleaned and validated. The first and second sections of this chapter review the intervention's goals and design. The third section describes the actual implementation of the intervention, and the fourth section summarizes the chapter.

A. INTERVENTION GOALS

Broadly speaking, the intervention seeks to overcome the challenges all people with diabetes face in managing their condition, challenges that are especially daunting for the Medicare beneficiaries targeted by the demonstration—all of whom, the reader will recall, reside in medically underserved areas, and many of whom have limited English skills. A list of these challenges, followed by a description of the specific goals of the intervention, is provided below.

1. Challenges and Strategies in the Treatment of Diabetes Mellitus

Medical research has identified important clinical goals in the long-term management of diabetes. The primary ones are: (1) sustained control of blood sugar levels at levels as close to normal as possible; (2) elimination or control of the concomitant risk factors of smoking, obesity, physical inactivity, high blood pressure, and abnormal blood lipid levels; and (3) regular performance of clinical preventive interventions, such as eye examinations, urinalysis, examination of the feet, and vaccinations against pneumococcal pneumonia and influenza. Achievement of these goals can greatly reduce suffering, death, and health care costs resulting from the complications of diabetes: loss of vision, kidney failure, nerve damage, coronary artery disease, cerebrovascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections.

These clinical goals are difficult to achieve. They require people with diabetes to make and maintain extensive changes in lifestyle and behavior—stopping smoking, following recommended diets, exercising, losing weight, monitoring blood sugar levels, faithfully taking oral medications or insulin injections, and getting regular checkups. Ideally, patients would receive help in undertaking such major changes from health care providers who have the time and special skills needed to educate, motivate, and guide them to make these lifestyle changes (diabetes self-management education) and to routinely review with them the results of blood sugar monitoring and adjust treatment appropriately. Reaching the clinical goals also requires that providers prescribe regimens of diabetes medications proven to be effective. Finally, patients or their providers need a way to keep track of when the various clinical preventive interventions, such as eye examinations or blood tests, are due and to make sure they get done.

A number of respected clinical practice guidelines comprehensively summarize and organize all of this knowledge. These guidelines cast the clinical goals, the necessary patient behavioral changes, effective methods of diabetes self-management education, types and frequency of clinical preventive interventions, and effective medication regimens in the form of recommendations for best practice (American Diabetes Association 2001; Veterans Health Administration/Department of Defense 1997). The Consortium chose as the demonstration's guidelines the *Clinical Practice Guidelines for the Management of Diabetes Mellitus in the Primary Care Setting*, developed by the Veterans Health Administration and Department of Defense (Veterans Health Administration/Department of Defense 1997). These guidelines incorporate the respected, evidence-based recommendations of the American Diabetes Association, reflect the input of numerous federal health agencies and professional organizations, and are in an easy-to-use algorithmic format.

Numerous studies show that, unfortunately, the current health care system, including traditional Medicare, provides poor-quality diabetes care that falls far short of the recommendations in practice guidelines (National Committee for Quality Assurance 2001; Centers for Disease Control and Prevention 1999; Jencks et al. 2000; Asch et al. 2000). There are too few trained diabetes educators, diabetologists (physicians specializing in the care of diabetes), and specialized diabetes treatment centers for most Medicare beneficiaries with diabetes to have access to them. Primary care physicians and their staff typically lack the time, office systems, and expertise to provide the care outlined above that people with diabetes need. The Medicare beneficiaries targeted by the demonstration face an especially hard time achieving optimal diabetes care, given the socioeconomic, educational, ethnic, cultural, and geographic barriers to

care that confront them (Harris et al. 1999; Centers for Disease Control and Prevention 1999; Asch et al. 2000).

There is good evidence, however, that "nurse case management interventions"—in which diabetologist-supervised nurse case managers enhance and supplement primary care physicians' diabetes care—can have a positive impact on the quality of diabetes care. Such programs have had positive effects on both the health and health care expenditures of people with diabetes (Aubert et al. 1998; Centers for Disease Control and Prevention 2001; Renders et al. 2001). In these interventions, nurse case managers provide diabetes self-management education to patients, perform close monitoring of patients' clinical measurements and status, and help primary care physicians deliver diabetes care consistent with current, evidence-based guidelines. In previous trials of such interventions, however, contacts between patients and nurse case managers and diabetes educators have either been in person or by telephone.

2. IDEATel Goals

IDEATel basically seeks to deliver diabetes nurse case management through electronic televisits, instead of through in-person or telephone contacts. As detailed in Chapter V, besides the substitution of televisits for more conventional means of communications, IDEATel adds other electronic enhancements beyond a standard diabetes nurse case management program. These enhancements include a system for participants to upload blood sugar and blood pressure measurements over the Internet into Columbia-Presbyterian Medical Center's Web-based clinical information system (WebCIS), the use of WebCIS for medical record keeping, the integration of diabetes case management software with the uploaded measurements and WebCIS,

data security measures, and the introduction of Web-based educational resources and chat rooms for participants.

a. Goals for Participants

IDEATel's goals for participants are no different from those for most diabetes self-management education efforts; there are both psychological and behavioral goals for participants. For most people with diabetes, attempts at behavior and lifestyle change often have the best chances for long-term success when preceded or accompanied by certain psychological and cognitive changes, such as increased motivation, knowledge, and skills for diabetes self-care; and strengthened feelings of self-reliance, confidence, and empowerment (Glasgow et al. 2001). Included in the behavioral goals are: smoking cessation; weight loss; dietary improvement; greater exercise levels; and increased adherence to glucose and blood pressure monitoring, medications, and medical appointments. Attaining the behavioral goals should ultimately lead to the health outcome goals of improved control of blood sugar, blood pressure, and lipids; and reduction of morbidity and mortality.

IDEATel does have a unique goal for participants, described in the Columbia University's technical proposal that is not included in standard diabetes self-education management. This is the goal of making "*the HTU a part of [participants'] daily life just as a telephone is for most people*" (emphasis added). Because, for participants, the intervention consists of performing and uploading blood pressure and blood sugar measurements, videoconferencing and electronic messaging, and Web access, participants should obviously be as proficient as possible in the technology to receive the full benefit of the intervention.

b. Goals for Physicians

IDEATel's goals for primary care physicians' diabetes care are also the same as in other diabetes case management programs—that is to improve the quality of primary physicians' care of participants, and make care as consistent with clinical practice guideline recommendations as possible. The location of the nurse case managers in the two specialized diabetes centers (the Naomi Berrie Diabetes Center and the Joslin Diabetes Center at SUNY Upstate) with supervision by senior center diabetologists, allows the provision of expert recommendations to primary care physicians on participants' treatment regimens.

The authorizing legislation mandated two additional general goals for physicians. One is that the demonstration develop a training curriculum for health professionals in medical informatics and telecommunications. The second is that the demonstration develop telemedicine and medical informatics standards.

c. Additional Demonstration Goals

Columbia University's technical proposal listed as a demonstration goal the preservation of the established relationships and patterns of care between participants and their primary care physicians. Primary care physicians are thus supposed to retain full responsibility and control of their patients' care. Maintenance of these relationships ensures continuity of care for treatment group participants after the end of the project, and as discussed in Chapter IV, makes the intervention acceptable to both physicians and potential participants in the recruitment process.

Finally, the legislation mandated that the demonstration address different types of Medicare health plans. The demonstration is to develop a telemedicine model of care applicable to both traditional (fee-for-service) Medicare and Medicare managed care environments.

B. THE DESIGN OF THE INTERVENTION

Columbia University's technical proposal and other demonstration documents discussed four major components of the intervention. The first three make up the direct clinical care part of the intervention: (1) nurse case manager-participant interactions through televisits, (2) participant interactions with the system through self-monitoring, Web browsing, and chat rooms, and (3) nurse case manager communications with primary care physicians. The fourth component, separate from the first three, is the educational program to train primary care physicians in telemedicine. A description of the design of each of these components is presented below.

1. Plans for Nurse Case Manager-Participant Interactions Through Televisits

As discussed above, televisits are an electronic version of in-person visits with nurse case managers. They are a means of providing diabetes self-management education and a way for the nurse case managers to routinely stay current on participants' clinical status and treatment regimens.

Nurse case managers use tried-and-true diabetes self-management education strategies. As one informant noted, "We are not re-inventing the clinical encounter." Indeed, to describe IDEATel's anticipated effects, both Columbia University's technical proposal and the site visit informants cited established theories and methods of health behavior modification (the Stages of Change Model [Prochaska et al. 1992] and the Self-Efficacy Model [Bandura 1997]) and health

education (the collaborative setting of goals [Von Korff et al. 1997] and the Precede-Proceed model [Green and Kreuter 1999])—all developed well before telemedicine services were available. As with other types of diabetes self-management education, success depends on having diabetes educators who are skilled in listening, who show empathy and personal interest in participants, negotiate individualized goals, deliver tailored education messages, and help participants solve problems (Glasgow et al. 2001).

The clinical content of televisits, as in standard diabetes case management interventions, is guided by clinical practice guidelines and protocols—in this case, the VHA/DoD diabetes guidelines. In the initial visit, the nurse case managers perform a comprehensive assessment that gathers all the data recommended by the guidelines: diet, exercise level, diabetes related hospitalizations, medications, diabetes complications, diabetes preventive care, and diabetes safety. The nurse case manager assesses the degree of control of the participant's diabetes, identifies problems, and starts to negotiate specific learning and behavioral goals with the participant, such as exercise frequency or dietary changes. In follow-up visits, the nurse case manager updates such key information as the participant's general well-being, general medical events, diabetes-related events (episodes of high or low blood sugar, for example), changes in diabetes or blood pressure medications made by the primary care physician, and progress toward the participant's goals. She reviews uploaded blood sugar and blood pressure readings with the participant, evaluates progress toward goals, and following guideline protocols, provides diabetes self-management education, and makes any necessary suggestions to primary care physicians. The nurse case managers enter all data into WebCIS. As mentioned, they may also refer participants to educational resources on the IDEATel Web site or to appropriate chat rooms.

Columbia University's technical proposal highlighted the video capability of televisits as an important design feature. Visible contact with an empathetic provider, it was felt, would encourage participants to initiate and maintain positive behavior changes, and enhance their adherence to treatment. The video camera would also allow nurse case managers to monitor wound care, an important aspect of diabetes care. In the illustrative scenario in Columbia University's technical proposal, a patient undergoing antibiotic treatment for an infected foot wound shows her foot to the video camera so that the nurse case manager can capture a still image for future comparisons.

Though not explicitly discussed in Columbia University's technical proposal, the frequency of televisits for each participant would presumably depend on individual clinical and educational needs. Determinations of frequency would be made by the nurse case managers with help from the clinical guidelines and supervision from the project's diabetologists. Based on the assumption of one contact every two weeks, with more frequent contacts as needed, Columbia University's technical proposal projected one full-time equivalent nurse case manager for every 200 participants.

2. Plans for Participant Self-Monitoring, Web Site, and Bulletin Boards and Chat Rooms

In between televisits, participants would regularly perform blood pressure and blood sugar measurements, which are stored in the glucometer and blood pressure apparatus, and periodically upload these results to WebCIS. The diabetes case management software would provide automated decision support to the nurse case managers by alerting them to out-of-range blood pressure or blood sugar values that require attention, and by applying computerized versions of the algorithms from the VHA/DoD guidelines. The frequency of self-monitoring recommended

to each participant would presumably also depend on clinical circumstances, and would be determined by the nurse case managers, with support from the clinical guidelines and supervising diabetologists.

The demonstration Web site proposed in Columbia University's technical proposal had both straightforward informational pages and pages that were more elaborate. There would be a collection of articles on basic topics, such as explanations of diabetes, diabetes treatment, diabetes nutrition, and answers to frequently asked questions. These articles would be carefully written for people with low levels of literacy. More interactive Web pages would allow participants to select their own self-management goals and track progress toward attainment of the goals. Finally, sophisticated Web pages for learning would feature quizzes, games, and "streaming" audio and video presentations (streaming is a technology that allows participants to hear and watch audio and video media without having to wait for entire files to download). These pages would tell participants how they scored on the quizzes, send them links to articles on answers they had missed, and record their scores and progress in a database. The videos would demonstrate such topics as how insulin works, how to give insulin injections properly, or how to exercise. Finally, these Web pages would have smart "info buttons" that would provide highly individualized information. For example, pressing an info button on medication side effects would cause the system to scan the database for the participant's current medications and display information on those particular medications.

The design included Web-based chat rooms and bulletin boards for discussions between participants. These could constitute a form of "virtual" community, and participation in support groups has been shown to have beneficial psychological and physical health effects for chronically ill people (Ford et al. 1998; Brennan et al. 1994). Electronic bulletin boards, like real

bulletin boards, allow participants to read and post messages to members of the participant community and then return later to read the responses. Contributors to a discussion do not have to be online at the same time. Chat rooms, on the other hand, are live, and conversations occur in real-time between participants who happen to be online at the time and wish to join in. The nurse case managers would moderate these discussions, to ensure the accuracy of any information shared.

3. Plans for Communications with Primary Care Physicians

Columbia University's technical proposal envisioned communications between the nurse case managers and primary care physicians as resembling those from a home health care agency or visiting nurse service, except that home visits would be "virtual." In other words, communications would be one-way, since most communications from visiting nurses to physicians generally receive no specific replies, beyond the physicians signing and returning any forms that require their signatures. After each televisit, demonstration nurse case managers would E-mail or fax the primary care physicians a clinical note documenting the visit and communicating any routine recommendations for treatment changes. As mentioned, decisions to implement any recommendations for treatment changes ultimately would be the primary care physicians' to make.[27]

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[27]Unlike standard home health care, in which the primary care physician is viewed as supervising the care of the home health care staff, in the demonstration, the project diabetologists are supervising the nurse case managers. Furthermore, IDEATel merely makes recommendations. There are thus no orders or treatment plans as in home health care; nor are there any requirements for primary care physicians to co-sign any paperwork.

4. Plans for Training of Primary Care Physicians in Telemedicine and Development of Telemedicine Standards

Columbia University proposed developing instructional materials and curriculum for the participating primary care physicians in the first year of the demonstration. These materials would have general educational goals of increasing provider competence and comfort with the demonstration technologies, as well as specific learning goals of: understanding data security and confidentiality concerns; knowing how to access online clinical information resources; and appreciating the effects of the new technology on interpersonal relations between patients, nurse case managers, and primary care physicians.

In discussing the legislatively mandated objective of developing telemedicine standards, Columbia University's technical proposal pointed out that the necessity for a separate credentialing procedure was controversial. Columbia University thus proposed working closely together with the New York State Board of Medicine and Department of Education, starting in Month 12 of the demonstration, to study the issue. Columbia University's technical proposal did not address the other mandated objective of demonstrating the intervention in a managed care setting.

C. IMPLEMENTATION OF THE INTERVENTION

At roughly 21 months into the demonstration, the Consortium appears to have overcome a number of difficult challenges and successfully implemented some elements of the intervention (Chapter V described the technical design of the demonstration). Other challenges appear to have been more problematic, however, and there are elements that have yet to be fully implemented. A description of the elements that appear to be working successfully, those that appear to still be under development, and prospects for the remainder of the demonstration is

provided below. This is followed by discussion of whether the intervention, as implemented so far, will provide a fair test of its effectiveness.

1. Elements Apparently Successfully Implemented

Some important intervention elements now in place are the nurse case managers, the process for conducting televisits, and the process for communicating with primary care physicians.

a. Case Management Staff

Both sites have filled their positions with nurse case managers who appear to possess the crucial interpersonal and counseling skills mentioned earlier.[28] In fact, having interpersonal and problem-solving skills seemed for the Consortium to outweigh any prior experience in diabetes care. Two of the current four nurse case managers had no experience in diabetes before the project; yet, after three months of training in diabetes, they appear to be performing effectively. Both of the New York City nurse case managers also have the necessary Spanish and English bilingual skills.

The Consortium diabetologists talked about the importance of the nurse case managers having strong counseling and interpersonal skills. The diabetologists explained, for example, why nurse case managers need to be adept at helping each participant select initial behavior goals that are

[28]Actually, in addition to its two registered nurses (RNs), the upstate site has a registered dietitian (RD) serving in a role similar to that of a case manager. The New York City site has two RNs, one of whom is also a RD. In this report, the term "nurse case manager" refers generically to all the clinical case management personnel because they have very similar roles, even though, technically, the dietitian is not a nurse. See Appendix D for a description of the case management staff.

realistic and attainable. Realistic goals increase participants' likelihood of success, which then empowers them to tackle new goals. Nurse case managers themselves related how they helped participants choose behavior goals that were feasible, acceptable, and culturally compatible. Two site visit informants described the rapport that the nurse case managers were building with their participants; one of them even related anecdotes of how participants and nurse case managers who had seen each other only in televisits greeted each other like long-lost friends when meeting by chance in person for the first time at the diabetes center. In fact, two former nurse case managers who lacked the necessary "problem-solving skills" to help participants change behavior decided to resign after being counseled on the need for improvement.

b. Process of Performing Televisits

The two sites have also established a work routine, medical records system, and supervisory structure for the televisits that appear to be functioning smoothly. Nurse case managers at both sites described similar work schedules for a typical day. They start the day by reviewing blood pressure and blood sugar results uploaded by participants overnight and making phone calls for any out-of-range values that need immediate attention, after which they return phone and electronic messages from participants. Televisits then occupy most of the rest of the day. The nurse case managers initiate televisits through a phone call that participants answer by pressing the video button on their HTUs. Supervising diabetologists are available throughout the day for questions. Using structured WebCIS computer forms developed by one of the diabetologists, the nurse case managers complete a note with recommendations for the primary care physician after each televisit. The supervising diabetologists review all notes, make any changes they feel

appropriate, countersign them, and return them to the nurse case managers, who finalize the notes in WebCIS and send hard-copy versions to participants' primary care physicians.

The content of the televisits appears to have followed the original design and to be working well. The structured WebCIS computer forms have served to standardize the content of the televisits.[29] Besides gathering data in the initial televisits, the nurse case managers go through an overview of diabetes with the participants, and go over such essential safety issues as recognition and management of hypoglycemia (low blood sugar). In the second televisit, they start to discuss nutrition and begin collaborative goal setting; then, in subsequent visits, they review participants' medications, uploaded readings, and progress toward goals. The nurse case managers assess participants' learning by asking simple questions—asking them, for example, to name foods with carbohydrates or to recall their dietary intake over the past few days. The nurse case managers report that initial assessments take 45 to 60 minutes, follow-up televisits for education 30 to 40 minutes, and follow-up televisits for routine care 15 to 30 minutes; and that they are performing six to eight televisits per day.

c. Function of the Video Cameras in Practice

The site visit informants believed that the intervention's video camera feature was indeed providing some of the advantages hypothesized in Columbia University's technical proposal. Informants felt that the video capability allowed development of closer rapport with participants than would have been possible with regular telephone calls. One of the nurse case managers also

[29]See Appendix E for copies of the WebCIS computer forms.

cited the value of being able to see a participant's reactions and mood, which helped the nurse case manager gauge whether she was perhaps "pushing" the participant too much. The nurse case managers have also used the still-photo feature of the video camera to document participant learning. For example, they can ask a participant to fill an insulin syringe with a certain dose of insulin and hold it up to the camera to make a photo record of the properly filled syringe.

The video capability has also come to play important roles in participant education in ways not explicitly anticipated in Columbia University's technical proposal. For example, one of the New York City nurse case managers described how she convinced a reluctant participant to start blood sugar monitoring by pricking her own finger in front of the camera. The nurse case managers have document cameras that transmit sharp images of documents or small objects to participants. The case managers in the upstate New York site appear to be taking much greater advantage of these than the New York City nurses. While instructing participants, the upstate New York case managers have shown pictures from printed patient education materials, used slides or overheads (for example, drawings of how participants' insulin or food intake affects their blood sugar levels over the course of a day), and displayed small plastic models of proper food portions. Copies of the slides or printed materials are then mailed to participants. The upstate New York dietitian has developed a large mock nutrition label—by showing it on the document camera, she can help participants read nutritional information from the labels on their own food containers at home (the resolution of the HTU video cameras is not sharp enough for the nurse case managers to read nutrition labels held up by participants).

d. Process of Communicating with Primary Care Physicians

Communications with primary care physicians also appear to be functioning as originally planned. The intervention has developed a series of strategies and protocols for communicating with the primary care physicians. When primary care physicians agree to participate in the demonstration, the nurse case managers ask them when and how they wish to receive communications: by fax, E-mail, telephone, or by being paged. The nurse case managers and diabetologists try to word recommendations very carefully and "softly." For example, the primary care physician of a participant with a contraindication to a prescribed medication might receive a recommendation to "consider discontinuing [the medication] because of known problems from [the contraindication]."

Consortium informants report that primary care physicians often wait for a participant's next scheduled office visit to implement any treatment changes. Occasionally, a primary care physician or the physician's office staff will call a participant to come in for an extra office visit to make a change. Less commonly, the physician or the physician's office staff will instruct the participant over the phone to make the change. Nurse case managers generally learn whether primary care physicians have implemented recommended treatment changes only by asking participants during follow-up televisits.

The nurse case managers and diabetologists followed a series of steps if recommendations that they felt were clinically important for participants' care were not being followed. They first repeated the recommendation to the primary care physician in the subsequent note. The next step was a "directed note," which is a form letter with a space for the specific recommendation. The step after that was a tactful, direct doctor-to-doctor telephone call from one of the

diabetologists to the primary care physician—did the primary care physician perhaps know additional information about the participant that the IDEATel staff did not, information that would alter the recommendation? In their relations with the primary care physicians, the IDEATel staff tried to be persistent, yet low-key and flexible, because, as they pointed out, the primary care physicians knew their patients the best and retained ultimate responsibility for their care.

Informants reported primary care physician reactions to IDEATel as generally positive. One of the informants pointed out that since most of the physicians in the New York City site were academic physicians, perhaps they were more accustomed to getting advice from consultants and specialists than physicians in a non-academic setting.

There were occasional complaints from among the participating physicians. A few of the participating physicians had complained about the volume of communications and had asked not to be contacted about every visit with one of their patients, but only when there were recommendations for treatment changes. The informants also mentioned one or a few physicians who initially had misgivings about the potential legal liability of receiving additional information and clinical recommendations that required further followup or action; but, apparently, they had overcome their reservations and continued in the project.

2. Apparent Difficulties and Unimplemented Elements

The informants described IDEATel elements whose implementations have not proceeded smoothly, such as participants learning to use the HTUs, and participants not being present at scheduled visits. Other elements have not been implemented at all yet, such as the physician education program. Some of these elements, such as participants being able to use the HTUs,

seem critical to the intervention. The Consortium is working to resolve these difficulties, although it is unclear when it will have corrected them all.

a. Participants and Basic HTU Use

Several informants talked about the difficulties that participants, particularly those in New York City, were having with learning to use the HTUs. They reported that many participants feared making a mistake and damaging the HTUs. They also noted that participants tended to have limited capacity for new information on any one occasion, and to have limited retention of new information over time. Beyond the initial training by the Gentiva nurse-installers, participants often required several additional, repetitive sessions of instruction to learn the basic HTU functions, such as turning the power on and off, receiving televisits, performing blood pressure and blood sugar measurements, and uploading data. Participants were thus still some distance away from the ambitious goal set by Columbia University's technical proposal, of being as comfortable with the HTUs as they were with their telephones. (These reported learning difficulties are similar to those described by Gold and Stevens [2001] for Medicare beneficiaries in the context of understanding information about Medicare + Choice plans.) Obviously, since the intervention is delivered entirely through the HTUs, participants who take a long time learning to use them (or who never learn to use them) receive correspondingly less of the intervention.[30]

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[30]The Consortium calls participants' ability to use the HTUs "acceptability." According to the OMB supporting statement, "Acceptability is assessed by whether participants can use the devices effectively, like the devices and the electronic service delivery model of care, and are satisfied with their care." (HCFA 2000).

The nurse case managers appeared to be expending a great deal of effort helping participants with the HTUs. One of the nurse case managers, for example, did not start televisiting new participants right away after the Gentiva nurse-installer had installed the HTU and performed the initial instruction. Instead, she made an initial voice call, both to introduce herself and to calm participants down from their high anxiety about the HTUs. Some of the nurse case managers mentioned the value of patience in dealing with the participants. A non-nurse case manager informant observed that the nurse case managers were spending up to the first 20 minutes of each session dealing with participants' technical questions. Another informant described problems getting participants to remember to push the televisit button to receive televisit calls, instead of picking up the phone (picking up the phone necessitated rebooting the machine, which was a laborious job to talk participants through). One informant did comment, however, that once the participants learned something, they rarely forgot it. The large amounts of time and energy expended by the nurse case managers on helping participants through basic HTU use could potentially reduce the amount of time and energy available to help participants with their diabetes.

b. Participant Use of Electronic Messaging, Web Site, and Chat Rooms

Not surprisingly, given participants' reported difficulty with basic HTU use, informants said that use of the electronic messaging, Web, and chat room features was low. Use of these features requires basic keyboard and mouse skills, which many of the participants lack. Apparently, a number of participants were even having difficulty typing in their two-letter, two-number passwords. Thus, typing messages and clicking on links was currently beyond the level of many

participants; some case managers thought that some participants would never learn to reach that level.

Some participants, however, were apparently using electronic messaging. The original design envisioned the nurse case managers sending participants electronic messages with Uniform Resource Locators (URLs, or Web page addresses) linked to relevant, educational Web pages. Informants were uncertain, however, about participants' ability to learn how to click on links or to bookmark Web pages.

The informants noted that almost no one was using the Web site, bulletin boards, or chat rooms. Very few participants had entered self-management goals, medications, diet, or activity levels by themselves, since doing so required visiting the appropriate Web page. One informant noted that, besides problems with keyboard and mouse use, another barrier to bulletin board and chat room use by the New York City participants was that Spanish-language bulletin boards and chat rooms had yet to be developed. One of the case managers did remember a single participant who had ventured into the chat area and typed "is anyone here?" with no reply. (Although only a hypothetical issue due to the inactivity of the bulletin boards and chat rooms, it is not clear how the nurse case managers would schedule their time to moderate these discussions, especially the chat rooms, which take place in real time.)

c. Participants and Broken Appointments

Informants, particularly those at the New York City site, described another factor with the potential to reduce full implementation of the intervention—an unexpectedly high rate of participant "no-shows"; that is, participants not being at home at the time of scheduled televisits. Some of the informants felt that the high no-show rate was causing nurse case managers to

average fewer than the full 16 televisits a day that they said they could handle. The recent addition of an administrative assistant in New York City to call and remind participants of appointments has helped but not eliminated the problem. No-shows seem to be fewer in the upstate New York site, but they still present a problem. An upstate New York case manager did mention sometimes not seeing all of her scheduled participants because of their not being home. The upstate New York site also has an assistant to call participants the day before to confirm appointments. A high-rate of no-shows could weaken the intervention, both through participants not being seen at appropriate intervals, and through nurse case managers' time being used unproductively.

d. Lack of Data on Reported Problems

Without data on HTU use—such as frequency of participant uploads, quantity of data uploaded; frequency, duration, and content of televisits; Web visits; bulletin board and chat room use—the true magnitude and potential significance of these reported stumbling blocks, as well as the overall implementation of the intervention to date, are difficult to assess. Certainly some participants are performing uploads; one of the diabetologists even described the amount of data as "tremendous," but the actual volume and distribution of self-measurement use are unknown.

It is also hard to tell how well televisiting is going. Informants indicated that routine televisits were occurring approximately monthly (rather than semi-monthly, as proposed). Given participants' difficulties learning HTU use and/or their presumably heavy needs for diabetes self-management education, it is unclear whether monthly visits are sufficient to improve either their computer skills or their diabetes self-management skills. The case managers also stated that they had the flexibility to see participants as often as necessary, even weekly, depending on clinical or

learning needs; but the proportion of participants receiving more intense attention is unknown. Also unclear is whether, and how, no-shows are included in the reported monthly visit frequency.

The range of televisit frequencies set forth in Columbia University's technical proposal and reported by informants is very wide. As described in Section B.1 of this chapter, Columbia University's technical proposal projected one full-time equivalent nurse case manager per 200 participants, based on the assumption that each participant would be televisited every two weeks (with more frequent contacts as needed). This assumption means that each televisit would last 24 minutes, if the nurse case managers spent no time on any other activities.[31] In Section C.1.b, the nurse case managers state that they were actually performing 6 to 8 televisits per day (or 80 televisits every 2 weeks), with initial assessments lasting 45 to 60 minutes and follow-up routine televisits lasting 15 to 30 minutes. In the paragraph before this one, the nurse case managers report that routine visits are occurring monthly, with higher frequency as needed. Finally, in Section C.2.c, some informants reported that the nurse case managers were capable of performing a maximum of 16 televisits per day (which translates into 160 televisits every two weeks). The informants seem to be relying on their own perceptions; but, without data, it is hard to know what the true frequency of televisiting is. Informants seemed agreed that usage of the Web site and chat rooms was low. "Low usage" remains unquantified at this point, however.

[31]Two weeks is 80 hours; 80 hours divided by 200 televisits every 2 weeks is 24 minutes per televisit.

e. Physician Education Program

Informants reported that little or no work has yet been done on the formal physician education program, originally scheduled in Columbia University's technical proposal to be developed during the project's first year. Some Consortium members were uncertain whether the originally proposed subject matter—to teach physicians about telemedicine—was still the most appropriate topic. Certainly, the participating physicians are learning informally about telemedicine through their involvement with the demonstration, and the Consortium members did feel that they had a much clearer idea than when the demonstration first started of how the intervention affects primary care physicians and what their learning needs are. Thus, they feel that they will have a stronger conceptual model on which to base the physician education program when they do start work on it.

f. Other Deviations from Columbia University's Technical Proposal and from the Authorizing Legislation

Although the case management software was alerting the nurse case managers about out-of-range values for blood sugar and blood pressure measurements as planned, the software seemed to provide somewhat less computerized decision support to the nurse case managers than might be expected from Columbia University's technical proposal. Implementation of the guidelines appears to be occurring primarily through the memory, expertise, and experience of the nurse case managers and diabetologists, rather than through any computer support. One informant explained that the nurse case managers had became very familiar with the guidelines simply through constant exposure to them—for example, the nurse case managers had all come to learn the recommended target hemoglobin A_{1c} and blood pressure levels by heart (although the nurse case managers did have electronic and paper versions of the VHA/DoD guidelines they could

refer to). The nurse case managers said they knew when a participant was due for an eye exam, for example, because they knew to check for this, and the structured WebCIS medical records allowed them to easily look up the last eye exam. The software did not incorporate the VHA/DoD diabetes guidelines, and there did not appear to be any automated reminder or algorithm system to assist the case managers, unlike in other interventions (Peters and Davidson 1998; Meneghini et al. 1998).

Informants did not recall any instances where video cameras had been used to monitor wound healing, as originally proposed. This may have been because there had not yet been any instances of wounds. However, informants were also unsure whether the current HTU video cameras had enough resolution to take acceptable photos of wounds.

Another task described in Columbia University's technical proposal was to work with the New York State Board of Medicine and Department of Education in Months 12 through 36 of the demonstration to study the issue of developing telemedicine standards. Apparently, work has not yet started on this task, either.

Another mandated demonstration objective was to develop a "model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment." The consortium's approach to meeting this objective is to enroll beneficiaries in the demonstration regardless of whether they are enrolled in a Medicare managed care plan or in fee-for-service Medicare. Given the limited number of managed care plans operating in upstate New York, it probably would not have been possible for the consortium to test whether the model is equally effective in managed care and fee-for-service environments (and the mandate does not

explicitly require this). The consortium's approach will demonstrate whether it is possible to implement the model among managed care enrollees.[32]

3. Informants Anticipate Increasing Intervention Strength in Year Three of the Demonstration

Despite the challenges described above, several of the informants were optimistic that the intervention would strengthen in the upcoming several months. One informant admitted that demonstration staff had been so preoccupied with recruitment and deployment that they had not paid as much attention to the intervention itself (for example, by getting participants to do more uploading, electronic messaging, or visiting of the Web site); but now, with the recruitment and deployment tasks nearly completed, they would be devoting much more energy to improving it. Some of the case managers commented that the longer participants used the system, the more comfortable they became, and the more enjoyable they found it. Some felt that their more motivated participants could possibly be ready to start using the Web to learn and enter information in the next several months. One of the case managers also remarked that the nurse case managers themselves have become increasingly skilled at teaching participants how to use the HTUs and how to get them on the Web.

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[32]IDEATel does not specifically target Medicare managed care beneficiaries. While several managed care plans are available in New York City, this is not true of upstate New York. Thus, it would not be possible to balance enrollment of Medicare managed care and fee-for-service participants between the New York City and upstate sites.

D. SUMMARY

The implementation of the intervention during the first 21 months of the demonstration appears to have been uneven, as assessed from the available documents and articles, and the site visit interviews. Hiring of nurse case managers with the requisite skills, and establishment of a workflow, supervisory structure, and communication process with primary care physicians appear to be notable accomplishments of the intervention itself (the recruitment, system design, and HTU deployment phases were described in the preceding two chapters).

On the other hand, problems have been reported. Informants report difficulties in getting participants comfortable with basic HTU use. The Web site, the bulletin boards and chat rooms, and, to a lesser extent, electronic messaging, are thus said to be essentially inactive at this time. There is a wide range of estimates of televisit frequency reported by various informants, and these are not consistent with what was originally proposed. Another apparent problem is getting participants to keep their appointments. Without data, the magnitude and potential significance of these reported problems cannot be assessed, nor can the actual frequency of televisits ascertained. There also has been no activity yet in developing a physician education program, developing telemedicine standards, and studying the intervention in a managed care setting.

When asked about the low HTU usage, however, the Consortium leadership replied that participants' usage of the HTUs could just as well be seen as a "glass half full" rather than one half empty. They pointed out project participants, all of whom are elderly, and the overwhelming majority of whom are poor, African American, or Hispanic/Latino American in the New York City site, are indeed on the "far side of the digital divide." Consortium leadership thus saw the delivery of technology to such a large number of homes in underserved communities, and the usage of the HTUs by most participants, albeit to greatly varying degrees, as actually a tremendous step forward in bridging this digital divide. The informants are

optimistic that the intervention will become much more active in the coming months, and thus, hopefully, increasingly effective.

Most complex health interventions entail a "learning curve" for both providers and participants, and IDEATel appears to be no exception. Clearly, implementation of the intervention described in this chapter, as well as recruitment, system design, and HTU deployment phases described in Chapters IV and V, have all exhibited learning curves. Ideally, a formal evaluation of a complex health intervention makes the learning curve phase explicit, either through a period of intensive and iterative development and pilot testing *before* fielding the intervention in the definitive evaluation, or through some type of "run-in" period for potential participants prior to formal recruitment (Campbell et al. 2000; Bradley et al. 1999).

In the case of the IDEATel demonstration design, however, the learning curve period has been embedded in the implementation.[33] In the analysis of the demonstration, impact estimates can either implicitly incorporate any learning curve effects, or attempts may be made to "tease out" learning curve effects by including indicator variables for time period or by defining a later "start" to the intervention. The first approach may make the intervention seem less effective than it might truly be when fully implemented. The latter approaches may be constrained by the post hoc nature of defining the start date retrospectively, the limited follow-up period of the demonstration, or limitations in sample sizes. If implementation of the intervention still remains incomplete by the end of the demonstration, it will indeed be difficult to ascertain whether the demonstration provided a fair test of the intervention, and thus to reach firm conclusions about program impacts (Basch et al. 1985).

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[33]Again, as mentioned earlier the Consortium mistakenly expected a time period for start-up activities between demonstration award and project start.

VII. THE CONSORTIUM'S INTERNAL EVALUATION

The Consortium is conducting an assessment of the feasibility, acceptability, effectiveness, and cost-effectiveness of the IDEATel demonstration. This internal evaluation is a distinct and separate effort from the external, independent evaluation that Mathematica Policy Research, Inc. (MPR) is conducting for CMS, which will be described elsewhere. Because both studies will rely on the same demonstration data, it is expected that the assessments from these studies will greatly overlap. However, because these evaluations have different objectives, it is also possible that the Consortium and MPR may differ on the emphasis and interpretation they provide to these findings. A summary of the Consortium's evaluation design and data collection efforts is provided below.

A. EVALUATION DESIGN

The IDEATel demonstration is designed as a randomized, controlled clinical trial. Half of the expected 1,500 participants are randomized to the telemedicine intervention and half to a control group that receives "usual care," which includes physician care and self-care for diabetes without the case management or telemedicine components. In addition, half of the participants come from New York City and half from upstate New York. The original study design intended to freeze the technical component of the intervention at the start of the demonstration and allow the clinical component to vary because of ethical and practical considerations (Shea et al. 2002). Thus, the standards of medical care for diabetes in both treatment and comparison groups were allowed to vary and reflect new knowledge. However, as discussed in the two previous chapters, the technical component has evolved somewhat in response to the difficulties participants have had in basic HTU use. Each study participant is enrolled in the demonstration for two years,

either receiving the intervention or usual care during this period of time. Each study participant has a primary care physician and randomization is within physicians' patient panels. Randomization procedures remain basically unchanged since the beginning of the demonstration (HCFA 2000).

The Consortium's evaluation will assess feasibility by whether the implementation of the demonstration is successful. Acceptability will be assessed by whether the participants in the treatment group can use the HTU effectively and are satisfied with their care. Effectiveness will be evaluated by comparing mean and adjusted mean levels of outcomes in the treatment and control groups. The main outcomes are glycosylated hemoglobin level, blood pressure level, and cost of care. Cost-effectiveness will be assessed by considering the effectiveness of the demonstration, measures of health care use, and cost of the demonstration. The study will also consider secondary outcomes (such as smoking and diabetes-related quality of care) and secondary process-of-care outcomes (such as compliance with care guidelines and self-monitoring of weight and diet) (Shea et al. 2002).

Consortium staff reported that the demonstration has adequate statistical power to detect treatment-control differences in systolic pressure of 3 mm Hg and of glycosylated hemoglobin of 0.6 percentage points, differences they consider clinically meaningful (Shea et al. 2002; Shea 2002).[34] They also indicated that the demonstration is likely to have adequate statistical power to

[34]The statistical analysis is based on intention to treat. Power calculations adjust for clustering of participants within physician panels and account for the planned attrition rates at two years (15 percent in the treatment group and 20 percent in the control group). The calculations assume two-sided tests of significance with 95 percent confidence and power of 80 percent (HCFA 2000). The reported minimum detectable differences are conservative estimates

detect differences in subgroups defined by race and ethnicity or by site (New York City and upstate New York). However, it is unclear whether the demonstration will have adequate power to detect meaningful differences in costs, since costs are considerably more variable than the other two outcomes.[35] For instance, based on estimates of Medicare costs per beneficiary from a clinical trial that provided therapeutic shoes to Medicare beneficiaries with diabetes, IDEATel's expected sample sizes would allow detecting treatment-control group differences in costs as large as 22 percent.[36] Whether such a large effect in costs can result from the expected effects of the demonstration on clinical outcomes remains to be seen. In addition, this potential design limitation is a cause for concern, since the Congressional mandate requires that the effectiveness of the demonstration be assessed in terms of its effect on costs, among other outcomes.

The demonstration has four additional limitations that pose challenges to the evaluation. First, because the control group receives usual care, it is infeasible to ascertain to which intervention component (that is, use of the HTU or case management) the impacts of the demonstration, if any, should be attributed. Second, because the focus of the Consortium's evaluation is on clinical tests—rather than measures of morbidity, quality of life, or mortality—the policy relevance and generalizability to other chronic conditions or populations of the demonstration's

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(continued)

of available power (relative to calculations assuming one-sided tests of significance at the same levels or to estimates that can control for some of the underlying population variation).

[35]No illustration of the statistical power to detect differences in costs is provided in the OMB supporting document (see Appendix D.6-I; HCFA 2000) or in the summary of the demonstration's design (Shea et al. 2002).

[36]Average Medicare payments per beneficiary in the year prior to randomization were $10,800 in 1989 dollars; the coefficient of variation was 1.4 (Wooldridge and Moreno 1994).

effectiveness are limited. Third, because the control group receives usual care, secular trends in the knowledge or treatment of diabetes might result in convergence between the treatment and control groups, particularly if other case management efforts emerge in the demonstration's target areas. Fourth, because participants are randomized within a physician panel, there is the potential that physicians might change their behavior toward control group participants (that is, contamination of the control group) as a result of the recommendations and data that physicians receive from the nurse case managers on their patients enrolled in the treatment group. The Consortium has not reported any plans to overcome these four limitations, which are central to enhance the policy relevance of the evaluation findings. However, it has responded to peer criticisms on the first and second limitations listed above in journal articles (Hersh et al. 2002; Shea 2002).

B. DATA COLLECTION AND SECURITY

Several data collection activities will support the Consortium's evaluation of the IDEATel demonstration. These include data collected from demonstration participants and from primary care physicians participating in the study. Table VII.1 provides an overview of the data collection activities, their periodicity, and contents.

Data on demonstration participants are collected in person from all demonstration participants on three occasions: baseline, one-year followup, and two-year followup visits. In New York City,

TABLE VII.1

DEMONSTRATION DATA COLLECTION ACTIVITIES,
THEIR PERIODICITY AND CONTENTS

Data Collection Activity	Periodicity	Content
Demonstration Participants		
Screening (telephone) interview	At recruitment	Eligibility assessment and nonrespondent followup.
In-person visit	Baseline, one- and two-year followup	Clinical assessment (anthropometrics, ambulatory blood pressure monitoring, and blood samples), health care service use, quality of life, process of care, demographic characteristics, functional status, vision impairment, health status, severity of disease, and social support.
Telephone interview	Every quarter between in-person visits	Health care service use, assessment of family support, smoking status, and quality of life.
Interactions with HTU and nurse case manager	Every interaction with system	Contacts with nurse case manager, the project Web page, and the clinical database in which participants view their clinical data.
Medicare claims	Not specified	Medicare claims data for demonstration participants for pre- and post-randomization periods to be determined.
Physicians		
Enrollment form	At recruitment	Physician contact information, preferred method for receiving data on demonstration participants (when applicable), provider location, type of practice, whether in an academic medical center, and practice size.
Survey[a]	Once in 2002	Experience and satisfaction with the demonstration.

SOURCE: Columbia University (2002); Shea et al. (2002); interviews with Consortium informants.

[a]The survey of participating primary care physicians is being administered by mail in New York City and by telephone in the upstate site. The telephone interviews are being conducted by two family physicians affiliated with SUNY Upstate Medical University (who are not involved in the demonstration).

these visits are conducted at the Columbia-Presbyterian Medical Center.[37] In upstate New York, the visits are conducted at the Clinical Research Unit at SUNY Upstate Medical University, Bassett Healthcare, Olean General Hospital, Samaritan Medical Center, Arnot Ogden Medical Center and, occasionally, at regional rural health centers or at the offices of participants' primary care physicians. The visits are conducted at the homes of demonstration participants only when they cannot travel to one of the regional demonstration clinics. The baseline interview precedes randomization to either the treatment or control groups. Additional data are collected from all participants by telephone at baseline (eligibility assessment and followup for nonrespondents) and at three-month intervals between the in-person visits. Staff from the Hebrew Home collect telephone data using computer-assisted telephone interviewing. The quarterly interviews focus on health care use, as well as an assessment of family support, smoking status, and quality of life. For both in-person and telephone data collection, Consortium staff reported that interviewers are blind to the treatment or control status of the participants.[38] Finally, all interactions of treatment group participants with the HTU are logged. These include contacts with the nurse case manager, the project Web page, and the clinical database in which participants view their own clinical data.[39] Columbia University is currently constructing a

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[37]In New York City, the demonstration arranges for a transportation service to pick up individuals at their homes, bring them in for the in-person assessment, and return them home (see Chapter IV). These activities would presumably minimize attrition from the demonstration.

[38]However, demonstration staff also mentioned that interviewers could figure out whether a respondent is in the treatment group from his or her responses to the questions on service use in the quarterly, telephone interview. It is unclear whether this knowledge would bias the interviews.

[39]There are also plans to collect data on use of the chat room. However, participants have not used the chat room so far, with one exception (see Chapter VI).

database to consolidate data on these interactions into a single analysis file. Finally, Medicare claims data will be extracted for all demonstration participants. The Consortium has provided neither a schedule for acquisition of these claims data nor the periods that they will cover.

Data on physicians are collected at the time of recruitment. These data include contact information, preferred method for receiving communications on treatment-group participants (when applicable), provider location, type of practice, whether in an academic medical center, and practice size. The Consortium is conducting a survey of participating physicians to ascertain their experience with the demonstration and their level of satisfaction with it. The survey is being administered by mail in New York City and by telephone in the upstate site. The telephone interviews are being conducted by two family physicians affiliated with SUNY Upstate Medical University (who are not involved in the demonstration). The Hebrew Home maintains the physician database, as well as the physician survey data.

The Hebrew Home, as the research data coordinating center for the demonstration, is responsible for the evaluation's database development and maintenance.[40] The evaluation database is located in a dedicated server to which only researchers at the Hebrew Home, Columbia University, and SUNY Upstate have access (Starren et al. 2002). Consortium staff reported that data accessibility and transmission are compliant with the data privacy requirements of the

[40]Columbia University's Department of Medical Informatics is responsible for the maintenance of the IDEATel system, including the demonstration's clinical data residing in the Clinical Information System (WebCIS) of the Columbia-Presbyterian Medical Center (Starren et al. 2002).

Health Insurance Portability and Accountability Act (HIPAA) of 1996.[41] In addition, one informant reported that Columbia-Presbyterian Medical Center is one of the first hospital systems in the United States that has appointed a computer security officer to ensure that its data systems reside in a secure environment.

C. SUMMARY

The design of the IDEATel demonstration is strong, as it will permit unbiased estimates of the effects of the demonstration on clinical outcomes, costs, and secondary outcomes. However, there are potential limitations—including the infeasibility of separating the effect of the HTU from the effect of standard case management; the limited statistical power to detect effects on costs or other nonclinical outcomes; the vulnerability of the design to secular trends in the knowledge or treatment of diabetes; the limited policy relevance and generalizability of the demonstration clinical outcomes; and the potential contamination of the control group as a result of information physicians receive from the nurse case managers on their patients enrolled in the treatment group. Development by the Consortium of a plan for addressing or mitigating these limitations, wherever feasible, would enhance the policy relevance of the evaluation findings.

The IDEATel demonstration is collecting a large volume of data from demonstration participants and from primary care physicians without apparent problems and, as reported by demonstration staff, in compliance with the data privacy requirements of HIPAA. The Consortium is developing several analysis databases, although an updated analysis plan was not available to the

[41]User authentication is established through user ID/password; transport security is attained through a password protected virtual private network (Hebrew Home and SUNY), dedicated land line (SUNY), and an intranet (Columbia University) (Starren et al. 2002).

evaluation team. Moreover, basic data on enrollment of physicians and Medicare beneficiaries in the demonstration were not yet available at the time of this report (see Chapter IV and Appendix C).

VIII. CONCLUSIONS

This chapter summarizes the preceding chapters and draws preliminary conclusions on the first 21 months of the implementation of this Congressionally mandated demonstration. These interim findings have limitations, since they are based solely upon Columbia University's technical proposal, demonstration documents provided by the Consortium, articles published by the Consortium, and site visit interviews with Consortium staff. Neither participants in the treatment group nor their primary care physicians could be interviewed due to the Consortium's human subjects and confidentiality concerns. Data on several crucial aspects of the demonstration—including the number and characteristics of referring physicians, the number of people participating in or leaving the demonstration, and the actual usage of HTUs—were not yet available. The databases needed to capture these data were not yet fully developed, and the data that have been collected required additional verification and cleaning. Moreover, data are not yet available on the cost of designing and implementing the demonstration in its first 21 months.

In dealing with substantial challenges at each stage of the implementation of the IDEATel demonstration, the Consortium has shown itself to be an effective, well managed, and adaptable organization. Its members possess the necessary expertise for the project and appear to work well together as a team.

The Consortium quickly ran into challenges in the start-up first phase of the project, especially in the design of the HTUs. The original device that Columbia University had in mind was no longer on the market by the time the demonstration was funded, necessitating a great deal of additional design work. An apparent failure to hammer out clear design specifications and to

align expectations between Columbia University and ATI delayed effective collaboration between the two organizations, and perhaps work on the HTU design as well (although Consortium leadership ascribed the delays to the need to renegotiate subcontracts and a mistaken assumption about there being a start-up period, and not to miscommunication). After overcoming these initial roadblocks, the two organizations did form a productive partnership that rapidly designed a functioning HTU with the required Web and security features, resolved compatibility issues with WebCIS, and developed the HTU launch pad and the HTU on-off capability. They also devised an HTU-cart configuration that was acceptable to demonstration participants with limited space in their homes.

Recruiting participants has presented several challenges as well. Obtaining approval from numerous IRBs was a lengthy and difficult process. Recruitment of physicians has been slow, compounded by lower than expected numbers of eligible patients with diabetes per physician panel. Eligible Medicare beneficiaries have refused to participate at a high rate, and they have dropped out at a higher than projected rate. The Consortium states that they fully anticipated these challenges and that the delays in recruitment were due to their original timetable being mistakenly based on a start-up period. The Consortium, however, has addressed these recruitment hurdles by expanding itself and its target geographic area, relaxing eligibility criteria, and redoubling recruitment efforts. The Consortium anticipates completing recruitment by the end of June 2002, approximately 10 months later than August 2001, the original projected date.[42]

[42]The Consortium has not requested any extension, however.

The Consortium next confronted the complex issues of getting the HTUs installed in participants' homes. Difficulties have included language (Spanish-speaking participants), logistics (getting installer, HTU, and participant together), and electrical (three-prong/two-prong issue) barriers. The Consortium has successfully dealt with all of these.

In particular, the Consortium has taken steps to include Medicare beneficiaries with limited English skills. Besides the HTUs themselves, which are configured in English or Spanish depending on the participant, both New York City nurse case managers are bilingual (Spanish and English), and ATI uses a Spanish-speaking staff person to arrange for HTU installation over the phone with Spanish-speaking participants.

The preceding steps are only prerequisites to the actual implementation of the intervention itself, which has not been entirely smooth. The Consortium does appear to have staffed the intervention with qualified, empathetic nurse case managers, and to have developed well-functioning routines for televisits, case management supervision, and primary care physician communication.

The Consortium has reportedly encountered difficulties with HTU use by participants, however. First, getting participants to overcome their fear of the HTUs and to learn even the most basic HTU functions has been a slow, arduous process that is far from complete. As a result, participants may have had suboptimal exposure to the self-monitoring and televisiting aspects of the intervention, and virtually no exposure to several other proposed intervention components—Web site, electronic messaging, and chat room. It also seems that some participants may never gain enough computer proficiency to fully experience the entire array of HTU functions. The actual frequency of televisits is not yet available, so the independent evaluator has had to depend

on the varied subjective estimates of informants, which differ from televisit frequencies proposed in Columbia University's technical proposal.

Second, there has been a high rate of broken appointments for televisits, especially in the New York City site. This high no-show rate has the potential to lessen participants' exposure to the intervention and to decrease the nurse case managers' productivity. As noted, no data on actual use of the intervention were available for this report, as the Consortium has not yet constructed working data files of HTU use.

Case managers are optimistic that many participants will become adept enough at HTU use in the coming months to start using the Web and chat features and to begin benefiting from the intervention. Consortium staff feel that their energies, previously devoted to recruitment and deployment issues, can now be focused on improving the intervention. Consortium leadership also pointed out that participants' usage of the HTUs could be seen as a "glass half full" rather than half empty. Many participants are "on the far side of the digital divide," and thus the large scale deployment of the HTUs and at least some usage of the HTUs is a major accomplishment.

Nonetheless, the reports by the demonstration staff of participants' struggles to learn basic HTU use and of the high no-show rate for appointments do raise the concern that the full implementation of the intervention will occur over a shorter period than originally intended. Given the fixed time frame of the demonstration, such a delay may lead to a less than fair test of the intervention, and a compromised ability of the evaluation to detect any actual impacts.

Work on the Congressionally mandated objectives of physician education and development of telemedicine standards has been delayed due to the effort required in the design, recruitment, and deployment phases. Despite the lack of a concrete plan or schedule to develop the physician

education program, some Consortium staff feel that the demonstration experience has helped to clarify their conceptual model for such a program.

Another mandated demonstration objective was to develop a "model for the cost-effective delivery of primary and related care both in a managed care and fee-for-service environment." The consortium's approach to meeting this objective is to enroll beneficiaries in the demonstration regardless of whether they are enrolled in a Medicare managed care plan or in fee-for-service Medicare. Given the limited number of managed care plans operating in upstate New York, it probably would not have been possible for the consortium to test whether the model is equally effective in managed care and fee-for-service environments (and the mandate does not explicitly require this). The consortium's approach will demonstrate whether it is possible to implement the model among managed care enrollees.

Finally, the Consortium is undertaking its own internal evaluation of the IDEATel demonstration, separate from the independent evaluation by MPR. The Consortium's evaluation design has the strengths of an experimental design—namely, that it will yield unbiased estimates of the net effects on all the study outcomes of adding telemedicine-based diabetes nurse case management to usual care for Medicare beneficiaries with diabetes.

The Consortium's evaluation design also possesses potential limitations, however, that seriously weaken the policy relevance of the evaluation findings. The design does not permit the separation of the effects of the HTU from the effects of standard case management provided by telephone calls and in-person visits, since the control group continues to receive only usual diabetes care with no demonstration-provided case management. Since the evaluation design was specifically designed to detect treatment-control differences in blood pressure and

glycosylated hemoglobin, the statistical power of the demonstration for outcomes that are not clinical tests but that are key policy outcomes—such as health care costs or quality of life—is likely to be limited. Moreover, since the participant dropout rate appears to be substantially higher than anticipated, the statistical power of the demonstration is likely to be lower than expected, even for clinical outcomes. Although the Consortium is recruiting additional participants to compensate for the higher-than-expected dropout rate, its final effect on statistical power remains to be seen. There also will be no way to control for secular time trends, or to control for the possibility that the intervention may also affect how participating physicians treat the control group participants. The Consortium has not yet addressed these potential limitations in any detail in the documents available for this report.

The demonstration has apparently been successfully collecting data from participants and their primary care physicians, and in compliance with the data privacy requirements of HIPAA. Unfortunately, only limited enrollment data were available for the preparation of this report. In order for the independent evaluation contractor to prepare reports for CMS, and for CMS to submit the Congressionally mandated reports, the Consortium will have to make demonstration data available to the contractor in the future.

In conclusion, the Consortium reportedly has made substantial progress and overcome difficult barriers in implementing the IDEATel demonstration. Considerable challenges remain, however. The intervention is still evolving and is anticipated by Consortium staff to strengthen over time. Hopefully there will not be an unduly long "learning curve" phenomenon among participants and Consortium staff that could compromise the implementation and evaluation of the intervention. The next and final chapter will describe the future reports that will document the progress and impacts of the demonstration.

IX. FUTURE REPORTS

Two additional reports will be prepared for Congress as part of the independent evaluation of IDEATel: a second interim report to Congress, and the final evaluation report specified by Congress. Table IX.1 lists the reports to be completed by the end of the study, the dates when they will be submitted to Congress, and contents.

TABLE IX.1

INDEPENDENT EVALUATION REPORTS, THE DATES WHEN THEY WILL BE SUBMITTED TO CONGRESS, AND CONTENTS

Report	Date to Congress	Contents
Second Interim Report	December 2003	• Update of implementation report with findings from follow-up telephone conferences with key demonstration staff • Description of cost simulation and generalization scenarios • Interim analysis of data on use of demonstration services • Interim impact analysis of the demonstration on access to care, quality of life, and satisfaction with care
Final Report	August 2004	• Update of implementation report with findings from in-person follow-up interviews • Analysis of cost-effectiveness • Analysis of use of demonstration services • Impact analysis of the demonstration on access to care, quality of life, and satisfaction with care

Second Interim Report to Congress. By late-2003, a second interim evaluation report will be prepared. This report will include an update of the progress in implementing the demonstration,

which will be derived from follow-up telephone conferences with key project-leadership staff and demonstration staff in New York City and upstate New York in early 2003. In addition, based on data to be provided by the Consortium in fall 2002, an interim analysis of the use of demonstration services will be conducted, as well as an interim analysis of the demonstration's impacts on access to care, quality of life, and satisfaction with care. Finally, this report will incorporate the development of simulation and generalization cost scenarios for the cost-effectiveness analysis.

Final Report to Congress. At the end of the evaluation period, Congress will receive a comprehensive independent-evaluation report on the IDEATel demonstration, which addresses all the issues laid out in the legislation that mandated the evaluation. The report will present findings of the four major analyses: (1) implementation of the demonstration; (2) cost-effectiveness of the demonstration; (3) use of the demonstration services; and (4) impacts of the demonstration on access to care, quality of life, and satisfaction with care.

By the time Congress receives the final report, interim findings from the analyses described above will already have been presented. The final report to Congress will update the implementation analysis with data to be collected in a second round of site visits; it will update the impact analyses with as much data on the experiences of demonstration participants as are available and will synthesize findings from all available independent-evaluation reports in a concise, comprehensive review of key findings and conclusions.

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APPENDIX A

ENABLING LEGISLATION FOR THE IDEATel DEMONSTRATION AND ITS EVALUATION

.

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.

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

SEC. 512. MISCELLANEOUS CHANGES AND STUDIES.

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

(1) in subsection (a)(1), by adding at the end the following: `The Secretary shall make an award for such project not later than 3 months after the date of the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. The Secretary shall accept the proposal adjudged to be the best technical proposal as of such date of the enactment without the need for additional review or resubmission of proposals.';
(2) in subsection (a)(2)(A), by inserting before the period at the end the following: `that qualify as Federally designated medically underserved areas or health professional shortage areas at the time of enrollment of beneficiaries under the project';
(3) in subsection (c)(2), by striking `and the source and amount of non-Federal funds used in the project';
(4) in subsection (d)(2)(A), by striking `at a rate of 50 percent of the costs that are reasonable and' and inserting `for the costs that are related';
(5) in subsection (d)(2)(B)(i), by striking `(but only in the case of patients located in medically underserved areas)' and inserting `or at sites providing health care to patients located in medically underserved areas';
(6) in subsection (d)(2)(C)(i), by striking `to deliver medical informatics services under' and inserting `for activities related to'; and
(7) by amending paragraph (4) of subsection (d) to read as follows:
`(4) COST-SHARING- The project may not impose cost sharing on a Medicare beneficiary for the receipt of services under the project. Project costs will cover all costs to patients and providers related to participation in the project.'.

APPENDIX B

STUDY METHODOLOGY

STUDY METHODOLOGY

The implementation analysis relies on data collected in a series of site visits and telephone conferences for the purpose of interviewing key informants involved with the IDEATel demonstration. A protocol was developed to collect information about the demonstration's original design, its evolution, and the reasons for the changes. The core protocol contained questions about the Consortium; targeting, recruitment, and retention of physicians and participants; the technology used in the demonstration; the clinical intervention; and the Consortium's evaluation of the demonstration (Table B.1). Shorter protocols were developed from the core protocol for interviewing the principal investigators, diabetologists, a dietitian, nurse case managers, recruitment managers, a data coordination manager, a systems manager, an installation manager, and a systems designer.[43] The protocols were reviewed and revised after the initial interview with the demonstration's principal investigator.

The interviews with demonstration leadership and staff in New York City took place in December 2001, except for one interview in January 2002. The interviews in upstate New York took place in January 2002. Telephone conference calls with staff from ATI (based in Eden Praire, Minnesota) also took place in January 2002. Teams of two individuals visited each site; interviews were restricted to one hour in duration, at the request of the demonstration's principal

[43]The consortium leadership would not permit interviews with demonstration physicians or participants without institutional review board (IRB) approval. Obtaining this approval would have required considerable time and resources. Thus, the first independent evaluation site visits did not include these interviews. IRB approval will be sought for the second round of site visits.

investigator. Table B.2 lists the individuals interviewed, their titles, and the dates when they were interviewed.

TABLE B.1

CORE PROTOCOL FOR SITE VISITS AND INTERVIEWS WITH
IDEATel DEMONSTRATION STAFF

CONSORTIUM These questions address the origins and history of the consortium, its objectives, the role and function of consortium members, communication and decision-making within the consortium, and recommended changes to the consortium.		
CON-1.	Please describe the history of the consortium.	Probe: When was the consortium formed? *(What was the timing in relation to the BBA 97 and the demo RFP?)* Had consortium members worked together before? Probe: Who initiated its development? Probe: Were there influences or factors that had an important effect on the development of the consortium? Probe: For example, the tech and dot-com market, financial and market situation of NY hospitals and/or academic medical centers, New York State government telemedicine initiatives
CON-2.	Have any organizations left the consortium? Joined? *The consortium original members included:* *Columbia University* *Div. of General Medicine* *Dept. of Medical Informatics, Berrie Diabetes Center, and Office of Scholarly Resources* *SUNY Upstate* *Joslin Diabetes Center* *Dept. Family Med., and Telemedicine Program* *Hebrew Home* *Harlem Hospital Center, Harlem Renaissance Network, ADA* *Arnot Ogden Hospital,* *Olean General* *Samaritan Hospital* *Bell Atlantic* *American Telecare* *Olsten,* *Caresoft*	☐ No ☐ Yes: who, when, and why *(Caresoft?)* ☐ No ☐ Yes: who, when, and why *(Bassett? Telergy? Crosshair?)*
CON-3.	What motivated your organization to join the consortium?	

TABLE B.1 *(continued)*

CONSORTIUM These questions address the origins and history of the consortium, its objectives, the role and function of consortium members, communication and decision-making within the consortium, and recommended changes to the consortium.		
CON-4.	What does each member contribute to the consortium? Please list/confirm which organization (s) in the consortium are performing the following functions in the demonstration:	Recruiting patients: *Physicians* Recruiting physicians: *Columbia University Gen Med, Harlem Hospital, Harlem Renaissance, SUNY Syracuse Family Med, Arnot Ogden, Olean, Samaritan, Bassett* Developing recruitment materials: *?* Screening potential demonstration applicants: *?* Performing baseline data collection: *Hebrew Home/Columbia University* Training staff: *Gentiva + ?* Performing care coordination: *Berrie + Joslin* Accounting/purchasing: *?* Randomizing demonstration participants: *Hebrew Home* Managing demonstration data: *Hebrew Home*
CON-5.	What roles have the project's consultants played in the project thus far?	☐ No role ☐ Who. What would you consider to be the most significant contributions each has made? Probe: Have you used any additional consultants?
CON-6.	Does the consortium plan to work together after the completion of the IDEATel demonstration? Are there plans for future telemedicine projects either for the consortium or for your organization individually?	☐ No ☐ Yes. What are they?
CON-7.	What are the strengths of the consortium?	
CON-8.	In retrospect, are there ways in which you think the consortium should have been structured or functioned differently?	Probe: In its membership, objectives, structure, other aspects of the way it functions?

TABLE B.1 *(continued)*

CONSORTIUM These questions address the origins and history of the consortium, its objectives, the role and function of consortium members, communication and decision-making within the consortium, and recommended changes to the consortium.		
CON-9.	Can you tell me who you report to on the project? Does anyone report to you? Which members of the project team do you talk to or work with directly? What percent of your time is devoted to the project? Do you feel the level of authority and delegation is about right? *(Refer to the organizational chart to define lines of reporting and communication between individuals.)*	
CON-10.	Do the organizations participating in the consortium hold regular formal meetings?	☐ No ☐ Yes. How often do they meet? Probe: What is the purpose of these meetings? Probe: Are the individuals who attend these meetings the same as those who are involved in the day-to-day operations of the demonstration?
CON-11.	What about the people involved in the day-to-day operations? Do they meet?	☐ Yes. Regularly scheduled face-to-face meetings/conference calls. Probe: How often are meetings held? What types of issues are addressed? ☐ Yes. Not regularly scheduled, more ad hoc. Probe: What types of issues or events would trigger a meeting? ☐ No. No meetings of the entire demonstration team.
CON-12.	Are there smaller groups of project team members who meet to work on particular issues?	☐ No. ☐ Yes. List workgroups. Probe: Who leads these work groups? Who participates in each workgroup?
CON-13.	How are decisions made on operational issues?	Probe: For example, the proposal stated that the nurse case managers would handle initial triage of calls from patients having technical difficulties. Suppose that procedure needed changing. Who would be involved in the decision to modify it, and how would that happen?
CON-14.	How are decisions made on clinical issues?	Probe: For example, what if important new clinical trial data came out on the treatment of diabetes. Would the protocols be changed, who would decide that, and how would that happen?

TABLE B.1 *(continued)*

TARGETING, RECRUITMENT, RETENTION These questions address the population targeted for the demonstration, inclusion and exclusion criteria, sources of referral to the demonstration, and participant enrollment and retention.		
Participants		
TRR-1.	Please confirm that these are the demonstration's patient inclusion and exclusion criteria? *(Verify from list.)*	Probe: Have any of these changed since the start of the demonstration *(We are especially interested in the issue of the screen for cognitive impairment. The 3rd progress note seems to suggest it was not applied initially)*
TRR-2.	Where are you getting most of your potential eligibles from (e.g., Columbia-Presbyterian faculty physicians—particular ones?, private practice physicians, Harlem Renaissance network, hospitals, etc.)	
TRR-3.	Have the estimates in the proposal of the target population size changed?	Probe: the proposal estimated the number of persons with diabetes $\geq$ 65 in northern Manhattan to be 6,792, and 6,132 in upstate NY, based on a prevalence of diabetes of 10%.
TRR-4.	What percent of the potential eligibles that you screen turn out to actually be eligible?	Probe: Has this changed over the course of the demonstration? If yes, why?
TRR-5.	Have there been any changes in the processes by which potential eligibles: Are identified? Have their eligibility verified? Undergo telephone screening? Have baseline data collected Are randomized? *(Refer to flow chart materials and verify process.)*	Probe: Describe the reasons for any changes.
TRR-6.	Is the demonstration being promoted directly to potential eligibles (not just going through PCPs)? If so, how?	Probe: For example, through PSAs, senior centers, churches, etc.?
TRR-7.	What are the main concerns or questions of potential participants about the demonstration?	
TRR-8.	What percent of eligibles (those who have passed the telephone screen) go on to be randomized into the study? ***(Ask for documentation.)***	Has this changed over the course of the demonstration? If yes, why?
TRR-9.	Please describe trends in enrollment in the demonstration. How many participants are currently enrolled. ***(Ask for enrollment statistics by time.)***	Probe: Has the number of new enrollees per month increased, decreased, or remained constant since the beginning of the demonstration? Probe: Have you observed any dips or spikes in enrollment? (If yes - Why?)

TABLE B.1 *(continued)*

TARGETING, RECRUITMENT, RETENTION These questions address the population targeted for the demonstration, inclusion and exclusion criteria, sources of referral to the demonstration, and participant enrollment and retention.		
TRR-10.	Do you track reasons on why potential demonstration participants refuse to participate?	☐ No ☐ Yes. Probe: What are they? Have you used this information to revise your recruitment materials or recruiting strategy? Probe: Are there any differences in the characteristics of potential demonstration applicants who agree to participate versus those who refuse to participate?
TRR-11.	What is the dropout rate among demonstration participants? Have any participants been asked to leave? Why? ***(Ask for documentation on drop out rate and reasons.)***	Probe: Among treatments? Among controls? Probe: Under what circumstances to you consider a participant to have dropped out? *(8/31/01 progress report says they consider a treatment a dropout when equipment is removed, but don't declare a control a drop out until the one-year follow-up).* Probe: How is it decided when to "de-install" the equipment? Probe: Do people change their minds before equipment delivery? Probe: Do you have any data on why these participants dropped out of the study?
TRR-12.	What is the average number of days between participant randomization and the installation of the HTU?	Probe: Is the average increasing, decreasing, or staying the same? Probe: Have there been challenges in timely installation of the HTUs after randomization to treatment status? If so, what have they been? Probe: Do the case managers and participants have any contact or interaction before the HTUs are installed?
PCPs, Other Referral Sources		
TRR-13.	Has the program been marketed or promoted to physicians? If so, how?	
TRR-14.	Have there been changes in the way the demonstration has been promoted to physicians? Why?	
TRR-15.	Are there promotion methods that are more effective than others in getting physicians to participate?	
TRR-16.	Are you focusing on any particular type of physician?	
TRR-17.	Are there any types of physician more likely to refer than others?	Probe: For example: younger vs. older physicians, physicians in private practice vs. university faculty physicians, US med school grads vs. International Medical Grads, generalist physicians (family practice, general internal medicine) vs. specialists (endocrinologists, cardiologists, etc.)
TRR-18.	How many physicians have referred participants to the program?	

TABLE B.1 *(continued)*

TARGETING, RECRUITMENT, RETENTION These questions address the population targeted for the demonstration, inclusion and exclusion criteria, sources of referral to the demonstration, and participant enrollment and retention.		
TRR-19.	What types of physician concerns or questions have you had to address?	
TRR-20.	Have any physicians refused to participate or dropped out? Why?	Probe: Under what circumstances do you consider a physician to have dropped out?
TRR-21.	Have you approached other organizations, such as community organizations, churches, etc. or other hospitals not currently in the consortium as a source of potential referrals?	

TABLE B.1 *(continued)*

<table>
<tr><th colspan="6">TECHNOLOGY</th></tr>
<tr><td colspan="6">This set of questions is about the technology involved in the telemedicine demonstration. These questions are meant to help us understand the key components of the overall system that uses the telemedicine technology to improve participant outcomes and generate data for research.</td></tr>
<tr><td colspan="6"><u>Staff</u></td></tr>
<tr><td rowspan="2">TEC-1.</td><td rowspan="2">Please list all technical staff working on the demonstration.</td><td>Name/Title</td><td>Affiliation</td><td>Function</td><td>FT/PT, % time on project</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="6">System Components and Design: By “system” we mean the telemedicine hardware, software, the users of the hardware and software, and whatever procedures, including written protocols, that users must conform to in interfacing with the hardware and software.</td></tr>
<tr><td>TEC-2.</td><td>Please confirm that these are the major hardware components of the telemedicine system:</td><td colspan="4">PC/monitor/keyboard/mouse
Modem
Videocamera
BP monitor
Glucometer
Network
Getting patients’ homes wired
Communications within CPMC and SUNY-Upstate?
Communications between CPMC, HHAR, and SUNY-Upstate</td></tr>
<tr><td>TEC-3.</td><td>What are the major software components of the telemedicine system?</td><td colspan="4">• Case management software
• Software that allows the IDEATel case management software to “talk to” Columbia University’s Web-based Clinical Information System (WebCIS).
• Data security measures</td></tr>
<tr><td>TEC-4.</td><td>Have you had to change any of the hardware or software since the submission of the proposal or the start of the demonstration to handle unanticipated issues?

How about updating the hardware or software to reflect normal technological progress?</td><td colspan="4">☐ No
☐ Yes. How?

☐ No
☐ Yes. How?</td></tr>
</table>

TABLE B.1 *(continued)*

<table>
<tr><td colspan="5">TECHNOLOGY

This set of questions is about the technology involved in the telemedicine demonstration. These questions are meant to help us understand the key components of the overall system that uses the telemedicine technology to improve participant outcomes and generate data for research.</td></tr>
<tr><td rowspan="10">TEC-5.</td><td rowspan="10">Which subcontractors provide each of the following system components and services:</td><td>Component/Service</td><td>Subcontractor</td><td>Major Responsibilities</td></tr>
<tr><td>Hardware (HTU, video camera, medical attachments)</td><td>ATI</td><td></td></tr>
<tr><td>Encryption software

Web page, e-mail, chat room

Case management software</td><td>Crosshair

Unspecified subcontractor to ADA

Siemens</td><td></td></tr>
<tr><td>Installation of HTUs</td><td>Gentiva</td><td></td></tr>
<tr><td>Installation of phone lines, ISP connectivity</td><td>Verizon</td><td></td></tr>
<tr><td>Training (of participants, nurse case managers, and physicians)</td><td>Gentiva</td><td></td></tr>
<tr><td>Help desk/ Technology support</td><td>Gentiva</td><td></td></tr>
<tr><td>Network services connecting CPMC, HHAR, SUNY-Upstate</td><td>Verizon (Telergy?)</td><td></td></tr>
<tr><td>Other</td><td></td><td></td></tr>
<tr><td>TEC-6.</td><td>Was HIPAA compliance an issue in the design of the system?</td><td colspan="3">☐ No
☐ Yes. How so?</td></tr>
<tr><td colspan="5">Participant-System Interfaces</td></tr>
<tr><td>TEC-7.</td><td>Have there been any problems installing the HTUs and peripherals in participants' homes?</td><td colspan="3">☐ No
☐ Yes. Describe.

Probe: For example, do urban participants have sufficient space for the HTUs? Are telephone jacks in appropriate locations? (In Manhattan): Is theft a concern? (If specific problems listed) What proportion of installations has such problems?

Probe: Any differences between urban and rural participants?</td></tr>
<tr><td>TEC-8.</td><td>How long does the average installation take, (if problems described in TEC-7): How does that problem affect the installation time?</td><td colspan="3">Probe: Are there differences between urban and rural sites?

Probe: What about travel time?

Probe: For example, relocation or installation of a telephone jack?</td></tr>
<tr><td>TEC-9.</td><td>Who trains participants in HTU, peripheral, and software use? How many people are involved? What is their</td><td colspan="3">(the next several questions: a major concern is whether elderly patients w/o any computer experience will be able to handle this intervention).</td></tr>
</table>

TABLE B.1 *(continued)*

TECHNOLOGY This set of questions is about the technology involved in the telemedicine demonstration. These questions are meant to help us understand the key components of the overall system that uses the telemedicine technology to improve participant outcomes and generate data for research.		
	background/experience? Are they full or part time staff?	Probe: Have you had any issues with continuity, i.e., the person coming to the home to do the training is not the same person the patient will be interacting with by video.
TEC-10	How long does participant training take, and how easy is it for participants to become proficient in using the system?	
TEC-11	What does the tech support staff report as the main problems participants report in using the system? How are those problems being resolved?	Probe: What kinds of problems are dealt with by phone and what kinds of problems require a visit to the participant's home? Probe: could you give me an idea of the frequency of problems encountered by participants? Is there a difference between urban *(e.g. theft/abuse)* and rural sites *(lightning/surge protection)*? Probe: Do the participants have a "learning curve," i.e., does the frequency of problems decline as participants become more familiar with the equipment?
TEC-12	Do participants find the help desk responsive to malfunctions or other problems? Who staffs the help desk, and what is their background/experience	Probe: Who are participants supposed to call with problems? Probe: What procedures to technical support staff have in place to be responsive to participant needs?
Nurse Case Manager-System Interfaces		
TEC-13	Who supports the nurses and the case management software in case of malfunctions? How many people are involved? Are they full or part time?	
TEC-14	In a typical month, how much time is devoted to maintaining the case managers' computers and software?	
TEC-15	Who trains nurse case managers in the use of the case management software? How many people are involved? Are they full or part time staff?	
TEC-16	How much time does the nurse case manager training take?	Probe: How long was the initial training for the case managers on how to use the system? Probe: Is there ongoing system training? ☐ No ☐ Yes. How often? How much?

TABLE B.1 *(continued)*

TECHNOLOGY This set of questions is about the technology involved in the telemedicine demonstration. These questions are meant to help us understand the key components of the overall system that uses the telemedicine technology to improve participant outcomes and generate data for research.		
TEC-17	What does tech support staff report as the main problems the case managers have in using the case management software? How are these problems being resolved?	
Tech Support Staff-System Interfaces		
TEC-18	Are there aspects of the HTU, peripherals, and software that tech support staff find difficult to maintain?	Probe: What are they and why?
TEC-19	Are there data available from the helpdesk on call volume, hold time, abandonment rate, log and tracking of caller questions, call triage, etc.	
TEC-20	How many tech support staff are kept available to assist: Participants Nurse case managers Any other users? Are these the same personnel?	Probe: Are these full time, part time, or on-call workers? What type of workers are they *(background/experience)*? Participants_____ Nurse case managers_____ Any other users?_____

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
Nurse Case Managers and Other Clinical Staff		
INA-1.	How many nurse case managers are there now?	☐ Upstate ☐ New York City Probe: When were they hired? Probe: How many hours a week do they work on the project?
INA-2.	Which organization(s) actually hire and employ the nurse case managers?	
INA-3.	Are the nurse case managers paid a salary, an hourly wage, or are they paid based on the number of participants they manage?	
INA-4.	What are the educational and professional backgrounds of the case managers? Are those the same job requirements as when the project first started?	☐ BSN ☐ MSN ☐ Telemedicine experience ☐ Diabetes experience ☐ Outpatient experience ☐ Language skills: ☐ Other: ☐ Yes ☐ No (explain):
INA-5.	In addition to the training on the case management software, did the case managers have any other training for the project? *(e.g., training in the VA diabetes guidelines)*	☐ No. ☐ Yes. Probe: Describe what training consisted of, who led the training, and how long did it take. Probe: Would the training need to be modified in any way if you had more case managers or if you were to expand the program into other areas? If so, how?
INA-6.	Was it difficult to recruit qualified nurse case managers?	☐ No. ☐ Yes. Why: ☐ Nursing shortage ☐ No qualified personnel ☐ Salary offered was too low ☐ Temporary nature of job ☐ Other: _____
INA-7.	Do you plan to hire any additional case managers?	☐ No. ☐ Yes. Why:
INA-8.	What are the nurse case managers' responsibilities?	
INA-9.	How is liability insurance for the case managers handled?	Probe: Did special arrangements have to be made? Who provides this?
INA-10.	Who supervises them?	

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-11.	How is their performance evaluated and by whom?	
INA-12.	Has there been any turnover among the nurse case managers?	☐ No ☐ Yes. How many, when, and why:
How Nurses Use the System		
INA-13.	Please list all of the functions of the case management software that the nurses use.	Probe: For example, checking e-mails from patients, reviewing blood pressure and blood sugar readings.
INA-14.	Do you find the software easy to use?	Probe: How does it compare to other case management or telemedicine software you may have used?
INA-15.	Please take me through a typical day as you arrive at work and log on.	Probe: What do you do first?
INA-16.	What participant data do the nurse case managers have access to?	*IDEATel data are those the patients enter on BP, glucose, meds, diet, exercise, and goals.* Probe: do they have access to all data on Columbia University's Web Clinical Information System (WebCIS)? *Log data asked about below in INA-40*
INA-17.	Would you add, eliminate, or otherwise change anything about the software? How about your own role?	
How Patients Use the System		
INA-18.	Please explain *how* the intervention is expected to work—what are the pathways or mechanisms through which changes in participants' behavior and care will occur?	

TABLE B.1 *(continued)*

<table>
<tr><th colspan="7">INTERVENTION ACTIVITIES

The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.</th></tr>
<tr><td rowspan="13">INA-19.</td><td rowspan="13">Please list the ways in which the participants use or interact with the system. (Enter Minimum Frequency, if any and who initiates the interaction).

(Ask about log data. If there are log data, ask for statistics on each of the activities listed to the right.)</td><td rowspan="2">Interaction:</td><td rowspan="2">Minimum frequency (daily, weekly, none, as desired)</td><td colspan="3">Interaction Initiated By:</td></tr>
<tr><td>System prompt</td><td>Participant</td><td>Case Manager</td></tr>
<tr><td>Using BP monitor</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Using glucometer</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Using web to access educational material</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Setting goals</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Recording diet and exercise</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Tracking and reviewing their own data</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Using e-mail</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Using bulletin board</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Using chat room</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Other</td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>INA-20.</td><td>Does the IDEATel program set specific clinical or behavior change goals for participants?

Are there instances of patients who do not set goals, or do not set appropriate goals?</td><td colspan="4">Goals appear to be set by the patients.

☐ No
☐ Yes. Describe typical goals and how progress is measured. What happens if there is little or no progress?

Who has input into setting these goals?
☐ Case manager
☐ Other clinical staff working on IDEATel
☐ Participant's own physician(s)
☐ Participant
☐ Others. Describe:
_____

Probe: How are those situations handled?</td></tr>
<tr><td>INA-21.</td><td>How would a typical participant use the system during a typical week?</td><td colspan="4"></td></tr>
</table>

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-22.	Are there instances of patients who are not entering data as often as they should or whose data appears unlikely to be correct?	☐ No ☐ Yes. How often does that occur? What sorts of data seem to cause difficulty? How do you deal with it, if at all?
INA-23.	What was the time line or schedule for the completion of the ADA Web site educational materials?	
INA-24.	What educational topics on the Web site do participants access most frequently? ***Ask for printouts of educational pages.***	
INA-25.	Have the education materials on the Web page been updated or revised?	☐ No ☐ Yes. How often? By whom? How? Probe: Has feedback from participants or case managers on content/information been incorporated? Probe: Can you provide some examples of revisions?
INA-26.	Are chat room conversations and bulletin board exchanges monitored or moderated by the nurse case managers or some other project staff member?	☐ No. ☐ Yes. Probe: Please describe the monitoring or moderating process. Is this difficult, since chats occur in real time 24/7, or is there some way of recording them for review later?
INA-27.	Do the nurse case managers participate in chat room discussions? Does any one staff person do this?	☐ No. ☐ Yes. How often? In what ways?
INA-28.	Could you give me examples of some of the common topics discussed in the chat rooms and bulletin boards?	
INA-29.	Has the chat room had any effect on participants?	☐ No. ☐ Yes. How? *(Provides support, education, information on resources?)*
INA-30.	Do participants have concerns about privacy?	Probe: For example, in using the chat rooms or having their personal information accessible on the system.
INA-31.	How easy do participants find the system to use?	
INA-32.	What aspects of the system or the intervention do the participants like or dislike?	

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-33.	Are there particular types of participants who are most likely to use the intervention? Least likely?	Probe: For example, are there differences by educational level, English versus Spanish speaking, presence of diabetic complications, urban versus rural, prior history of compliance? ☐ No. ☐ Yes. Please describe and explain: ☐ No. ☐ Yes. Please describe and explain:
Case Manager - Patient Interactions		
INA-34.	Please go through a typical teleconsultation with me	Probe: What do you do if there is a medical emergency during the tele-consultation?
INA-35.	Are participants assigned to a specific case manager or do they interact with whoever is available?	Probe: How well do you get to know the participants? Is there a rapport established between patients and case managers?
INA-36.	INA-37. How many participants is each nurse case manager responsible for?	___ Currently ___ Expected when program is at full enrollment
INA-37.	Could you go through how you arrived at the contact frequency of every two weeks discussed in the proposal?	Probe: Did the contact frequency determine how many case managers to hire?
INA-38.	How many teleconsultations does a nurse case manager have in a typical week?	Teleconsultations with video and audio_____ E-mails_____ Probe: Do you ever just call patients on the telephone? Probe: What percent of teleconsultations are initiated by: *Ask for documentation* ☐ Case manager ☐ Physician/other provider ☐ Participant ☐ Other. Describe:
INA-39.	*(If log data are recorded)* Do the case managers have access to these data and use them to manage the patients or to change the intervention?	
INA-40.	Can the clinical guidelines or protocols be tailored to the circumstances of individual patients?	☐ No ☐ Yes. Probe: Could you give me examples? How well can they be individualized?
INA-41.	Do the case managers provide any formal or informal patient education in addition to the material located on the web pages?	☐ No ☐ Yes. How?

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-42.	Overall, what impact do you think the demonstration is having on participants?	Probe: Do you think the demonstration has impacts on participants: Probe: Do you see the stress after 9-11 affecting patients' compliance? If so, how? Knowledge of their condition: ☐ No. ☐ Yes. Why? Compliance with medication regimens: ☐ No. ☐ Yes. Why? Ability to keep appointments with physicians or other providers ☐ No. ☐ Yes. Why? Diet regimen: ☐ No. ☐ Yes. Why? Weight loss goals: ☐ No. ☐ Yes. Why? Exercise regimen: ☐ No. ☐ Yes. Why? Smoking cessation goals: ☐ No. ☐ Yes. Why? Glucose control: ☐ No. ☐ Yes. Why? Self care goals: ☐ No. ☐ Yes. Why?
PCP Role		
INA-43.	Does the program provide any education to physicians or other providers?	☐ No ☐ Yes. On what topics and how? *(Proposal discusses development of a telemedicine curriculum)* ☐ Distributing clinical practice guidelines ☐ Giving lectures ☐ Talks in physicians' offices ☐ On-line information ☐ Other:
INA-44.	Does the program attempt to change primary care physician behavior in any way?	☐ No ☐ Yes. How? Probe: Do you follow-up to see if your efforts to change physician behavior have been effective?
INA-45.	Does the program provide physicians with data or information about their patients?	☐ No ☐ Yes. What types of data/information are provided? What types of data from IDEATel go into Columbia University's WebCIS? Probe: What percent of the physicians have access to Columbia University's WebCIS and do you know if they have used the IDEATel information?

TABLE B.1 *(continued)*

INTERVENTION ACTIVITIES The questions in this section address the nurse case managers and their responsibilities, how participants and case managers use the demonstration system, and the ways in which case managers, participants, and primary care physicians (PCPs) interact.		
INA-46.	The technical proposal says "when a CM believes that a change in management is indicated, he or she will contact the PCP (by e-mail, fax, or phone) just as would a visiting nurse going physically to the home." The proposal also gives a scenario in which the PCP electronically countersigns the CM's e-mail. Is this, in fact, how it is working?	☐ No. Probe: What is happening? ☐ Yes. Probe: Would you please describe how this process works?
INA-47.	Do the nurse case managers interact with the participants' physicians or other providers to discuss individual participants?	☐ No. Please explain. ☐ Yes. What is the frequency of contact and how? ☐ Regular contact, every _____ ☐ Contact as needed. Issues/events triggering contact: ☐ Fax ☐ Phone ☐ E-mail_____ Probe: What types of data/information are provided? Probe: Percent of physician/case manager interactions initiated by: ☐ Case manager ☐ Physician/other provider ☐ Participant/family request
INA-48.	What have been the physicians' reactions to the contacts they have had with the case managers and with the program overall?	Probe: Have physicians expressed any concerns over their own liability?
INA-49.	Have there been any physician complaints about the program?	☐ No ☐ Yes. Probe: What are they? Is there a mechanism to address these complaints?

TABLE B.1 *(continued)*

EVALUATION ACTIVITIES The questions in this section deal with the randomization and the data collection processes.		
REA-1.	Please describe the baseline assessment, informed consent, and randomization process.	*(Confirm from documents)* Probe: Are there any physicians with both treatment and control participants? Probe: If so, do you think the treatment of the control patients of those physicians is affected?
REA-2.	How quickly after enrollment are participants randomized and notified?	
REA-3.	Please list all the research support personnel and their responsibilities.	
REA-4.	Are there any project staff members who have both research and demonstration operations functions?	☐ No ☐ Yes. Can you estimate the percentage of each person's time devoted to these functions?
REA-5.	Would you briefly confirm the main categories of data that are collected at the baseline, three-month, and annual evaluations? ***Ask for new versions of data collection instruments if they have changed.***	Probe: Have any of the data collection procedures changed since the start of the demonstration?
REA-6.	The technical proposal discusses a survey of physicians (p. 35). Is this being done? What is the response rate?	
REA-7.	Please confirm that, other than the baseline and annual data collection efforts, the program staff have no contact with control group members	Probe: Is any information fed back to physicians on control group members?
REA-8.	What has the response rate been for the quarterly data collection? For the annual data collection *(are there patients who have reached the 1 year mark?)*?	
REA-9.	When will the research staff begin to look at the study data?	Probe: Does that include the log data?

TABLE B.1 *(continued)*

EVALUATION ACTIVITIES The questions in this section deal with the randomization and the data collection processes.		
REA-10.	The latest progress report on the demonstration describes the creation of a special purpose database to capture data documenting the specific components of the intervention. Would you please describe the need for this database and its contents?	Probe: Who will use it and how will it be used?

TABLE B.2

IDEATel DEMONSTRATION STAFF INTERVIEWED FOR IMPLEMENTATION ANALYSIS

Interviewee	Title	Date of Interview
Steven Shea	Project Director/Principal Investigator Professor of Medicine and Director, Division of General Medicine, Columbia University	December 14, 2001
Leslie Field	Project Manager, New York City	December 18, 2001
Walter Palmas	Assistant Professor of Clinical Medicine, Columbia University	December 18, 2001
Charlyn Hilliman	Implementation Manager, Columbia University	December 18, 2001
Justin Starren	Co-Principal Investigator Assistant Professor of Medical Informatics, Columbia University	December 18, 2001
Jessica Rivera	Nurse Case Manager, New York City	December 20, 2001
Renee Bachman	Nurse Case Manager, New York City	December 20, 2001
Robin Goland	Associate Professor of Medicine, Columbia University and Director, Naomi Berrie Diabetes Center	December 20, 2001
Jeanne Teresi	Senior Research Associate, Hebrew Home for the Aged at Riverdale Senior Research Scientist, Columbia University	January 4, 2002
Ruth Weinstock	Co-Principal Investigator Professor of Medicine and Chief, Division of Diabetes, Endocrine, and Metabolism, SUNY Upstate Medical University Director, Joslin Center for Diabetes	January 10, 2002
Paul E. Knudson	Associate Professor of Medicine, SUNY Upstate Medical University Associate Medical Director, Joslin Center for Diabetes	January 10, 2002
Phil Morin	Project Manager, Upstate New York	January 11, 2002
Susan Fox	Nurse Case Manager, Upstate New York	January 11, 2002
Carina Lagua	Dietitian, Upstate New York	January 11, 2002
Karen Boril	Project Manager, American TeleCare, Inc.	January 16, 2002
Richard Abbruscato	Vice President, Engineering & Manufacturing, American TeleCare, Inc.	January 25, 2002

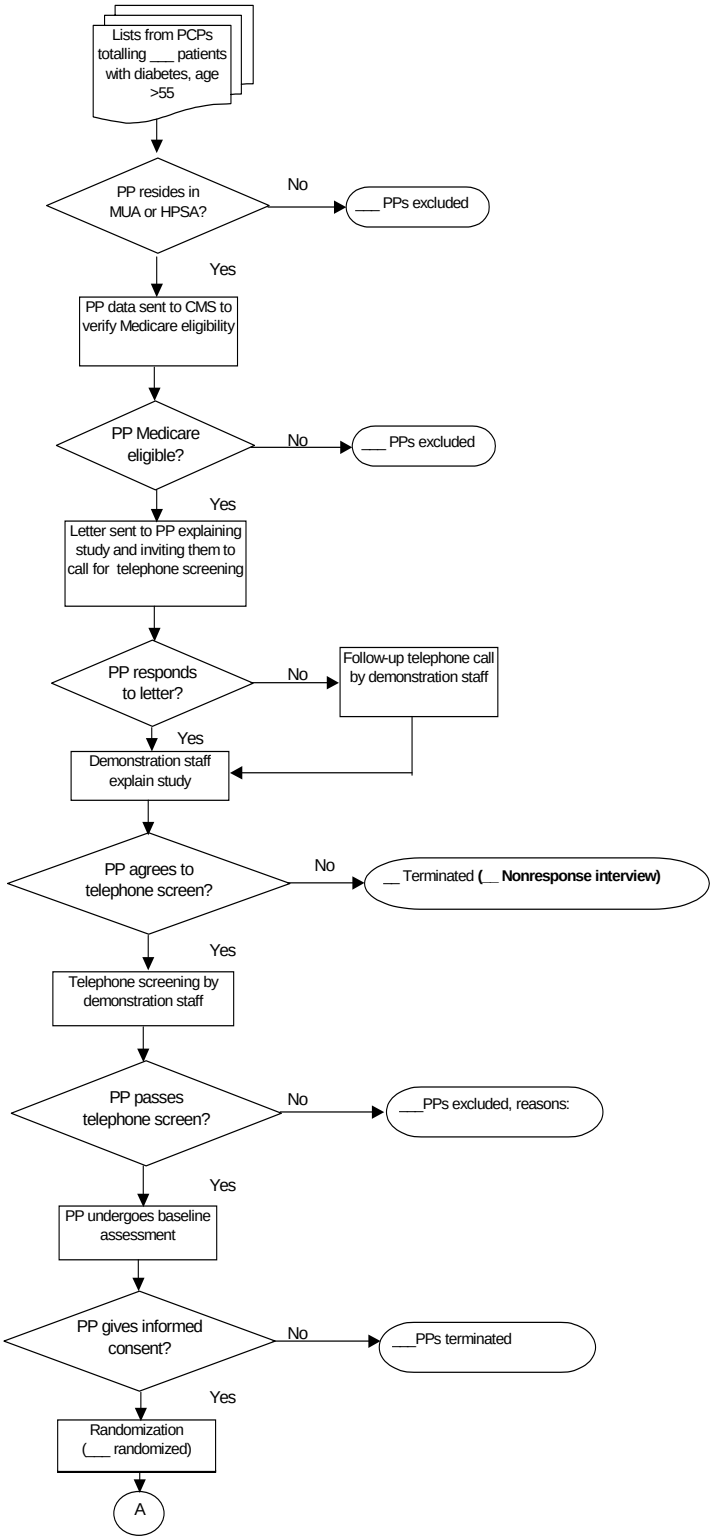
Notes taken during the site visit interviews were prepared within two weeks after the interview and were reviewed by each member of the visit team. All the notes were transferred to the core protocol and discussed in a meeting on February 8, 2002.

APPENDIX C

PROCESS OF PARTICIPANT FLOW IN THE IDEATel DEMONSTRATION

FIGURE C.1

PROCESS OF PARTICIPANT FLOW IN THE IDEATel DEMONSTRATION

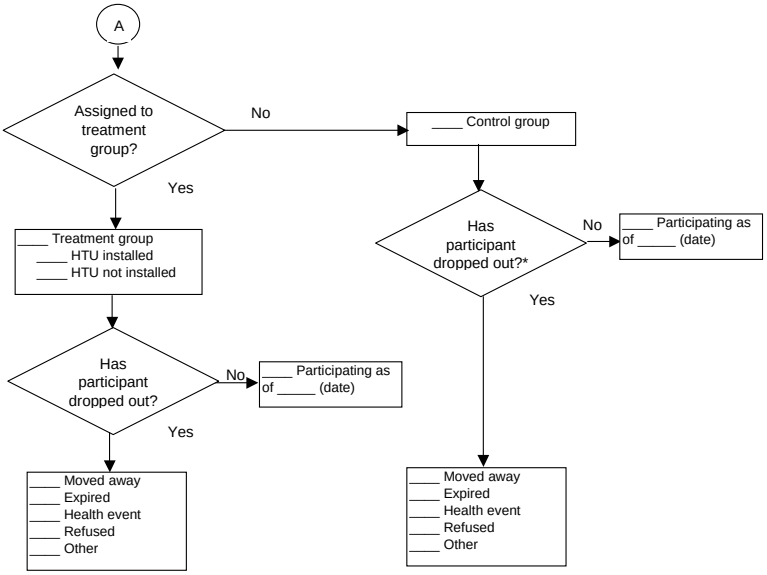


PP = potential participant; MUA = medically underserved area; HPSA = health professional shortage area; CMS = Centers for Medicare & Medicaid Services; HTU = home telemedicine unit.

Source: Columbia University (2002).

FIGURE C.1 (continued)

PROCESS OF PARTICIPANT FLOW IN THE IDEATel DEMONSTRATION



* Known from quarterly, telephone interviews.

APPENDIX D

CONSORTIUM CASE MANAGEMENT STAFF

The New York City site has two nurse case managers, both of whom have bachelor's degrees in nursing. The first was hired by the project in fall 2000 and started managing participants at the start of the intervention in December 2000. The second nurse case manager started in October 2001. The demonstration leaders planned this staggered hiring because they did not need a second case manager until recruitment had increased and it was clear they would be able to recruit enough participants. The first nurse case manager had never worked with diabetes patients, but did have case management experience with substance abusers and HIV-infected children. She underwent three months of diabetes training at the Naomi Berrie Diabetes Center before beginning work with demonstration participants. At the time of the site visit interviews, she anticipated that she would have had enough clinical experience through the project to obtain her Certified Diabetes Educator (C.D.E.) certification by February 2002.

The second nurse case manager is a registered dietitian, in addition to her nursing credentials. She has had extensive diabetes case management experience and is a C.D.E. She started in October 2000 and was managing less than 100 participants at the time of the site visit interview in December 2001. Because of her background as a dietitian, she had taken over some participants with nutrition-related problems from the other nurse case manager, but the majority of her participants were new. She was in the process of making her initial televisits to her participants and had not yet started any follow-up televisits.

The upstate site has two nurse case managers, both bachelor's-prepared, and a registered dietitian. The dietitian has been with the project since the beginning. She is very experienced in both diabetes and geriatrics, having worked with pregnant women with diabetes in the high-risk obstetrics clinic for several years and, before that, with veterans with diabetes at the Syracuse Veterans Administration Medical Center.

When nurse case managers identify participants with dietary issues during initial televisits, they refer them to the dietitian. The dietitian works with all the upstate-site participants who have dietary goals, essentially all of the participants. She performs individual televisits with her participants, in addition to the visits performed by the nurse case managers, often alternating visits monthly with the nurse case manager, although she also has the option of seeing participants more frequently if they have a greater educational need. If the dietitian discovers a nursing issue during a televisit with a participant, she has the ability to book that participant in with the nurse case manager (and vice versa). She completes clinical notes, just as the nurse case managers do, which are reviewed by the diabetologists and sent on to participants' primary care physicians.

The nurse case manager positions in upstate New York have experienced greater turnover than those in New York City. One nurse case manager started in March 2001, replacing the nurse case manager who was present at the start of the demonstration. The new nurse had also taken a leave of absence between her start date and the time of the site visit in January 2002, so her employment with the project was not continuous. She had worked in psychiatric nursing but had no experience in diabetes nursing. She underwent three months of training at the Joslin Center for Diabetes. The other nurse case manager, who started only in late December 2001, is experienced in diabetes case management and has her C.D.E. The upstate New York site used nurses from the Joslin Center for Diabetes to conduct televisits during time periods when there were no demonstration nurse case managers.

APPENDIX E

WebCIS FORMS USED BY CASE MANAGERS

IDEATel Initial Visit Form

NOTE: No compatible electronic file was available for these forms; a copy is provided in the printed version of this appendix.

IDEATel Followup Visit Form

IDEATel Dietary Form

IDEATel Missed Contact Note

IDEATel External Laboratory Report

IDEATel Internal Laboratory Report