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Could There Be a Role for Home Telemedicine in the U.S. Medicare Program?

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1. Introduction

Diabetes mellitus is a leading cause of mortality, morbidity, and health care costs among beneficiaries of the U.S. Medicare program. Serious and costly complications of diabetes include vision loss, kidney failure, nerve damage, coronary artery disease, cerebro-vascular disease, peripheral vascular disease, foot ulcers, lower extremity amputations, and infections. These complications often can be avoided through case management, monitoring, control of risk factors, and self-care (American Diabetes Association, n.d.[a], n.d.[b]). Unfortunately, geographic, linguistic, or cultural isolation keeps many Medicare beneficiaries from obtaining high-quality diabetes care. Isolation also may lessen beneficiaries' motivation to eat appropriately, exercise, and lose weight as advised by a physician. Beneficiaries most likely to suffer from diabetes and its complications, including those of African or Hispanic/Latino descent, also may be prone to isolation (Health Resources and Services Administation., n.d.).

Home telemedicine is the use of telecommunications technology to deliver diagnostic, monitoring, educational, and therapeutic services to health care users in their own homes. It may be a promising way to deliver such services to people living in medically underserved areas. Little is known about how well home telemedicine works for Medicare beneficiaries.

A congressionally mandated demonstration tested the clinical and cost outcomes of providing a particular type of home telemedicine service to a large number of Medicare beneficiaries who have diabetes and live in medically underserved areas of New York City and upstate New York. A consortium led by Columbia University College of Physicians and Surgeons and Columbia-Presbyterian Medical Center (the Consortium) performed the demonstration, which it called Informatics for Diabetes Education and Telemedicine, or IDEATel. Mathematica Policy Research was the independent evaluator. The Centers for Medicare & Medicaid Services (CMS) funded and oversaw the demonstration and evaluation. The demonstration was implemented in two four-year phases, from February 2000 to February 2008. Beneficiary enrollment began in December 2000.

Principal investigators for the Consortium have published results of their own analyses of the final effects of IDEATel on key clinical outcomes and costs (Shea et al., 2009); (Palmas et al., 2010). As in the independent evaluation (Moreno et al., 2009; Moreno et al., 2008), they found that the intervention positively affected participants' blood sugar, blood pressure,

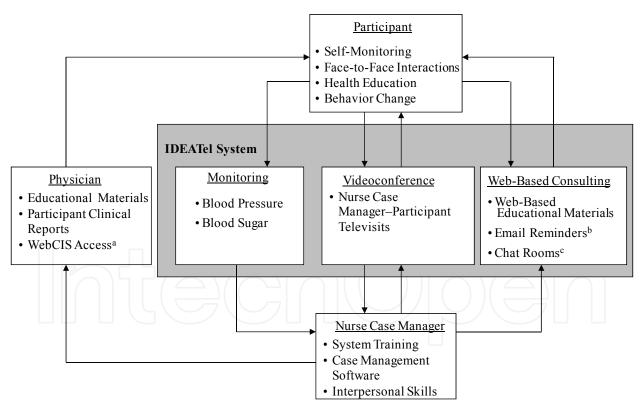
and lipid levels. These effects, however, must be considered in light of the intervention's acceptability to beneficiaries and potential cost savings to Medicare.

This chapter summarizes (1) participants' use of the telemedicine technology, (2) intervention effects on intermediate clinical outcomes, (3) intervention effects on the use and cost of Medicare services, and (4) costs of the demonstration during the two phases. It also discusses the policy implications of these findings in the context of recent U.S. health reform, particularly the potential role of home telemedicine in the Medicare program.

2. Demonstration overview

2.1 Goals

IDEATel's goals for participants were to (1) control blood sugar, high blood pressure, and abnormal lipid levels; and (2) reduce or eliminate obesity and physical inactivity. To help participants meet these goals, the Consortium designed an intervention to provide remote monitoring, case management, and web-based educational materials through a home telemedicine unit (HTU). IDEATel's goal for physicians was to increase provision of guideline-based diabetes care. To help physicians meet this goal, IDEATel diabetologists recommended guideline-based treatment adjustments when they believed changes were warranted. The Consortium also designed a web-based physician curriculum (Figure 1).



Source: Synthesis from Columbia University (1998) and other unpublished demonstration materials. ^a WebCIS access only available in New York City.

^b Email reminders were not systematically implemented in upstate New York.

^c Chat rooms were not implemented in either site.

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

Fig. 1. The IDEATel System Intervention

2.2 Recruitment

The Consortium first recruited primary care physicians in the demonstration target areas. Consenting physicians furnished lists of their Medicare patients to the Consortium, which screened patients for eligibility and attempted to recruit those who were eligible. Between December 2000 and October 2002, the demonstration recruited 1,665 eligible Medicare beneficiaries (775 in New York City and 890 in upstate New York) for Cohort 1 and randomly assigned them, in equal proportions, to a treatment or control group (Table 1). Between December 2004 and October 2005, the demonstration recruited 504 eligible Medicare beneficiaries (174 in New York City and 330 in upstate New York) for Cohort 2 and randomly assigned them to a treatment or a control group.

	9		
Evaluation Group/Cohort	New York City	Upstate New York	Total
Cohort 1			
Treatment	397	447	844
Control	378	443	821
Total	775	890	1,665
Cohort 2			
Treatment	86	163	249
Control	88	167	255
Total	174	330	504

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

Table 1. Distribution of Enrollees, by Site and Evaluation Group

Eligibility was limited to English- or Spanish-speaking Medicare beneficiaries age 55 or older who were being treated for diabetes by diet, oral medications, or insulin, and were living in a medically underserved or health professional shortage area in New York State. Beneficiaries with moderate or severe cognitive, visual, or physical impairment or with severe comorbid disease were excluded. Neither literacy nor prior computer experience were grounds for inclusion or exclusion. Consenting beneficiaries underwent a comprehensive in-person baseline assessment by Consortium staff that included a structured interview; measurements of body dimensions, weight, and blood pressure; blood and urine tests; and setup of a 24-hour ambulatory blood pressure monitor. The Consortium randomly assigned beneficiaries, in equal proportions, to a treatment or control group and sent laboratory results from the baseline assessments to the enrollees' physicians.

2.3 The Intervention

During the demonstration, control group members received diabetes care as usual from their primary care physicians. Treatment group participants also continued to see their primary care physicians, and they received a HTU. (Enrollees are eligible Medicare beneficiaries enrolled in the demonstration. Participants are enrollees in the treatment group, regardless of whether they received the intervention and used the services offered.) For Phase I of the demonstration, the HTU (Generation 1) consisted of a personal computer with audio/video communication capabilities and devices for measuring blood sugar and blood pressure (Figure 2, right panel). For Phase II, the Consortium redesigned the HTU to address several features that Cohort 1 participants had found unappealing, such as its large size and difficulty of use. The redesigned HTU (Figure 2, left panel) is known as Generation 2 or Generation 3, depending on the manufacturing date. The Generation 3 HTU had several advantages, such as a cast aluminum case, higher screen resolution, and smaller "footprint," that is, the table area it occupied (Columbia University, 2005).

Demonstration participants could use the HTU:

- To measure and monitor blood pressure and blood sugar and transmit their measurements to a nurse case manager; readings were stored in the HTU until participants performed an upload of the data (Generation 1 HTU) or the HTU transmitted them through periodic automatic uploads (Generation 2 and 3 HTUs)
- To communicate with a nurse case manager through audio/videoconferences known as "televisits"
- To access web-based chat rooms and educational materials available only to participants: chat rooms were implemented in both sites; Email reminders were not systematically implemented in the upstate site; and WebCIS access was operational only in New York City (U.S. Department of Health and Human Services, 2005).



Generation 2

Generation 1

Source: Foster et al. (2006).

Fig. 2. The Generation 2 HTU and Its Predecessor

Televisits were a major component of the IDEATel intervention. By providing regular interaction between participants and nurse case managers at workstations in New York City or Syracuse, they were expected to help participants learn more about diabetes and self-care, improve their attitude toward their disease, and change their behavior. Televisits were to occur every two weeks, be scheduled in advance, and last about 30 minutes each.

2.4 Intended effects

Nurse education and coaching through televisits and self-tracking of progress through other HTU functions were expected to improve self-care behaviors such as monitoring blood sugar and blood pressure, and adhering to diet, exercise, foot care, and medication regimes. By giving physicians guideline-based recommendations, IDEATel also aimed to promote better prescribing patterns, which could improve physiologic outcomes. Better blood sugar control, weight loss, and improved fitness might help participants feel better in the short

run. Improved control of blood sugar, lipids, blood pressure, weight loss, and improved fitness might help them avoid serious complications such as blindness, kidney failure, stroke, heart disease, and lower extremity infections and amputations in the long run. Better health, in turn, could reduce use of acute care services and Medicare costs.

3. Related research

Published studies of programs that use remote monitoring and web-based education to manage diabetes have generally used much smaller samples than IDEATel and have not focused on the Medicare population. Nonetheless, some diabetes management programs have demonstrated clinical effectiveness with relatively simple interventions. Aubert et al. (1998), The California Medi-Cal Type 2 Diabetes Study Group (2004), and Taylor et al. (2003) have used randomized experiments to test the clinical effects of providing nurse case management services to patients by telephone. All three of the tested interventions favorably affected hemoglobin A1c levels.

Other researchers have tested the effects of automated telephone systems on diabetes control. Piette et al. (2000) performed a randomized study of a computer system that called enrollees and asked questions in a recorded human voice. Enrollees responded by depressing buttons on a regular touch-tone telephone, prompting appropriate follow-up questions (Piette, 2000). Significant positive effects were found on self-reported self-care, self-efficacy, days of disability, communication with health care providers, and hemoglobin A1c. Delichatsios et al. (2001) found favorable effects on blood sugar control and satisfaction in a nonrandomized study of a similar intervention. Finally, several small studies of interventions featuring simple glucometers that allowed patients to record blood sugar measurements and upload them through a telephone modem showed favorable effects on diabetes-related behaviors and hemoglobin A1c (Ahring et al., 1992; Meneghini et al, 1998; Shultz et al., 1992).

Although not formally evaluated, many relatively inexpensive home telemedicine products are commercially available. Like the IDEATel HTU, such units use regular telephone lines and feature two-way videoconferencing, glucometers, blood pressure cuffs, and store-and-forward capability. Unlike the IDEATel HTU, however, these units are not PC-based, do not use the Internet, and do not allow for web browsing, electronic messaging, or software for tracking personal progress in diet, weight loss, or exercise (AmericanTeleCare, n.d.; HomMed, n.d.).

Few studies provide evidence about costs or both costs and clinical effectiveness. In 2004 the Congressional Budget Office (CBO) examined peer-reviewed studies for evidence of the cost-effectiveness of disease management in treating chronic illness (Congressional Budget Office, 2004). Thirty-one of the studies targeted diabetes and many featured telemedicine or another form of remote monitoring. Although many programs favorably affected process of care and intermediate outcomes, few studies measured effects on long-term health outcomes, health care use, and costs. Those attempting to address costs failed to account for the costs of the interventions themselves. Around the time of the CBO review, however, Villagra and Ahmed published the first-year results of a multistate diabetes management program sponsored by CIGNA HealthCare (Villagra & Ahmed, 2004). The intervention used telephone outreach by nurses, dietitians, or health educators; web-based education; remote monitoring devices; and mailed reminders and educational materials. Using two quasi-experimental methods, investigators found that, among members observed for at least 10

months, the intervention reduced overall health care costs by 8 to 25 percent per member per month (based on claims and encounter data), depending on the analytic method. Although these savings purportedly exceeded the cost of the intervention under both analytic methods, intervention costs were not reported. Moreover, since only 7 percent of the CIGNA subjects were age 65 or older, relevance to the Medicare program and comparability to IDEATel are limited.

4. Study methods

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

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

Source: Columbia University (2007a, 2007b, 2007c, 2007d).

^aMathematica selected samples of physicians and participants who had consented to be interviewed from lists prepared by the Consortium following its IRB's guidelines.

^bTo ensure confidentiality, the Consortium collected these data and shared them with Mathematica *without* individual-level identifiers. The evaluation used Medicare Part A and Part B claims data; Part D had not yet been implemented during the period covered here.

Table 2. Analytic Approach Summary

The analyses were conducted separately for the New York City and upstate sites for two main reasons. First, some aspects of the intervention implementation at the sites were quite

different. Specifically, the upstate intervention team solicited referring physicians' advance permission to adjust participants' diabetes treatment (for example, medication dosage), whereas the New York City team made recommendations to physicians and asked participants whether its suggestion was implemented. Second, enrollees from each site differed markedly on many major characteristics.

4.1 Qualitative description of the intervention implementation

To assess implementation of the demonstration, the analysis synthesized information from site visits, telephone calls, and demonstration documentation (U.S. Department of Health and Human Services, 2003, 2005). Site visits and telephone discussions with Consortium leadership and staff took place during fall/winter 2001, fall 2002, fall 2003, winter 2005, and winter 2007. The interviews with participating physicians and treatment group enrollees took place in winter 2007 (Foster et al., 2008).

4.2 Estimation of HTU use

To assess participants' interactions with the HTU, the analysis examined the time between home installation of the HTU and its first use, frequency of use, and patterns of use over time from log-use data. It also compared the experiences of Cohort 1 and Cohort 2 participants in the first two years after the start of HTU installation for each phase (December 2000 through February 2007 for Cohort 1 and December 2004 through February 2007 for Cohort 1 and December 2004 through February 2007 for Cohort 2), controlling for standard baseline characteristics. The analysis sample consisted of 753 Cohort 1 participants (out of 844) and 230 Cohort 2 participants (out of 249). For Cohort 1, the analysis excluded 50 participants whose records had a missing installation date, 6 who had dropped out before their HTUs were installed, 29 whose records did not specify the type of HTU they had received, and 6 whose records did not indicate when their HTU was upgraded from Generation 1 to Generation 2. For Cohort 2, the analysis excluded 17 participants whose installation date was missing and 2 whose records did not specify the type of HTU they had received.

4.3 Estimation of intervention effects

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

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

In both the behavioral, physiologic, and health analyses; and the Medicare service use and cost analyses, enrollees were analyzed in the group to which they were originally randomized (in other words, these were intent-to-treat analyses). However, enrollees who dropped out of the study could not be included in the behavioral, physiologic, and health analyses for time points after the times they left the study, since they had no further survey

and laboratory data. All randomized enrollees were included in the Medicare service use and cost analyses since Medicare claims data were available whether or not they had dropped out.

Finally, to assess the costs of the demonstration implementation, the analysis synthesized information from demonstration documents and market prices of products and services used in the demonstration, according to a methodology developed for the Phase I analysis (Starren et al., 2002;U.S. Department of Health and Human Services, 2005).

4.4 Sample characteristics

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

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

4.5 Enrollee attrition

By the fourth year of follow-up interviews, Cohort 1 sample sizes for health outcomes analyses declined substantially in both sites. The overall dropout rates in Cohort 1 were 30 percent in New York City and 58 percent upstate. As discussed in Section 5.3, the loss of these sample members substantially decreased the evaluation's ability to detect impacts. Loss of sample size also compromised the statistical power of the Cohort 2 analyses. After one year of follow-up interviews, the Cohort 2 attrition rate was 13 percent in New York City and 19 percent upstate. As with Cohort 1, however, numbers relative to the original sample were small, and there were no great differences between treatment and control dropouts in baseline characteristics.

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

relative to the original sample. Finally, the intention-to-treat impact estimates based on Medicare claims data are not affected by differential dropout, since claims data are available for all enrollees whether or not they remained in the demonstration.

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

4.6 Limitations

Our evaluation has three main limitations. First, the demonstration was not designed to provide evidence on the marginal benefit of the intervention's components – use of the HTU and interactions with the nurse case managers. Thus, the evaluation cannot determine whether the clinical impacts of the demonstration resulted from the telemedicine intervention, the intensive nurse case management, or both (U.S. Department of Health and Human Services, 2005). Second, the high attrition rate in both sites limited any conclusions from the survey and in-person data. For instance, the high attrition rate in the upstate site between baseline and year 4 raises the possibility of bias of unknown magnitude and direction in the estimated impacts. The loss of sample in the New York City site also greatly reduced the evaluation's statistical power to detect impacts there. Finally, for Cohort 1, data on the fifth and sixth follow-up annual interviews were not available for enrollees whose annual interview data had not come up by the end of the study period (that is, February 27, 2007). Therefore, the analysis did not include these data. For Cohort 2, data on the second follow-up interview were available only for a small number of enrollees. As a result, the analysis did not use data from this round of in-person interviews.

5. Findings

5.1 IDEATel implementation

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

5.2 HTU use

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

5.2.1 HTU design, implementation, changes, and problems

5.2.1.1 Initial HTU design

During Phase I, The Consortium had difficulty engaging the participants in HTU use. Many participants had difficulty connecting to televisits. To connect with the Generation 1 HTU, participants had to answer a regular telephone call from a nurse, hang up, activate the HTU, and then answer a second call from the nurse using the HTU launch pad. This process confused many participants and could be interrupted by other incoming calls. Nurses and participants were frustrated that part of many televisits was devoted to connecting and other technical issues, rather than to the participants' clinical and behavioral progress. By the end of Phase I, staff said most participants who were still taking part in the intervention were able to connect to televisits. Between televisits, IDEATel participants were supposed to measure their blood sugar and blood pressure levels and share the information with their nurse case manager. With the Generation 1 HTUs, participants shared their measurements by uploading the data themselves. According to the nurse case managers interviewed late in Phase I, most participants were able to upload their blood pressure and blood glucose measurements, and many were able to monitor their clinical data. Sometimes, however, participants forgot to perform the upload or inadvertently uploaded the same data multiple times – the HTU gave no indication as to when transmission had succeeded.

Participants could also use the HTU to exchange email with nurse case managers and visit the web pages of the American Diabetes Association (ADA). According to the nurses, only about half the participants knew how to access email late in Phase I. Although the nurses thought about half the participants also knew how to access the ADA web pages, they believed few had done so. In addition, Consortium staff reported that few participants had used their HTUs to enter behavioral goals (such as for exercise), record their exercise activity, or send email to nurse case managers. Consortium staff said that chat rooms were never used, with one exception (U.S. Department of Health and Human Services, 2005).

5.2.1.2 Changes to the Initial HTU Design

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

Based on the expert's findings, Consortium staff made several changes. They resolved software incompatibilities to increase the user-friendliness of the HTUs' screens; revised the

video tutorial; and, most important, retrained all participants on the use of the HTU. Between July 2002 and January 2003, staff were able to train 203 of 359 participants in New York City (57 percent) and 350 of 379 in upstate New York (92 percent). The retraining effort required the hiring of a new staff member to train some participants in New York City in Spanish, and the rehiring of two nurses who originally installed the HTUs in upstate New York. In New York City, many participants reportedly were unavailable for this training or broke their appointments for it (U.S. Department of Health and Human Services, 2005).

5.2.1.3 HTU Redesign and Implementation Challenges

As with Phase I, the Consortium achieved most of its intended improvements with respect to the HTU. Unfortunately, most Cohort 1 participants never experienced the improvements. The redesigned HTU—the Generation 2—was much smaller and less cumbersome than its predecessor. The tabletop unit (pictured in Figure 2) consisted of a small flat screen, a large green answer button, a top-mounted camera, a pliable and "indestructible" keyboard, and a blood pressure cuff and glucose monitor. The unit featured built-in speakers and touch screen technology rather than a stand-alone launch pad.

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

For both technical and financial reasons, newly enrolled Cohort 2 participants did not receive HTUs—or any form of intervention—as quickly as they had been told they would. Cohort 1 participants had no choice but to continue using their Generation 1 HTUs. Rather than wait out the supply shortage, the Consortium and its subcontractor began to design another model, the Generation 3 HTU. From the user's viewpoint, the Generation 3 HTU featured the same technical improvements as its immediate predecessor: simple connection to televisits, automatic clinical data uploads, and easy-to-navigate user interface.

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

5.2.1.4 Changed Expectations About HTU Use

Much of the difficulty with connecting to televisits was resolved in Phase II. The large green button on the Generation 2 HTU (or on the screen of the Generation 3 HTU) seemed an effective solution for most participants with these models, according to nurse case managers. However, some participants who had to keep their Generation 1 HTUs, and even a few with the newer models, never overcame their uncertainty about how to connect. Nurses reported that 10 to 15 percent of televisits were affected by poor transmission of audio or video data or by disconnections. Nurse case managers attributed this problem to aging telephone lines. When audio or video was inordinately poor, nurses opted to interact with participants by telephone rather than through the HTU. Missed televisits, which had been a concern during Phase I, were not troublingly high during Phase II, according to nurse case managers. Except for a small number of participants the nurses described as "chronic missers," others participated in visits unless they were away or in the hospital. If participants were less likely to miss visits in Phase II than in Phase I, it may simply have been because, as noted, fewer visits were scheduled.

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

By the time Phase II began, Consortium staff had drastically lowered their expectations about participants' use of advanced HTU functions, such as visiting the ADA web pages and exchanging email with nurse case managers. Access to ADA web pages that had been developed for IDEATel was discontinued in November 2003. Thereafter, participants could access only ADA pages available to the general public, but the Consortium did not track those visits. By that time, staff also tended to downplay the importance of these functions to participants' well-being and motivation for self-care. Nonetheless, the user interfaces of the Generation 2 and 3 HTUs were designed to be much easier to navigate than the interface of the Generation 1 HTU, which should have facilitated the use of advanced functions. According to interviews conducted in 2007, use of advanced functions was as rare in Phase II as it had been in Phase I, except for a few participants with prior internet experience.

5.2.2 HTU learning curves, and frequency and intensity of use

Cohort 1 members had steeper learning curves than their Cohort 2 counterparts. Since some HTU functions were more complex than others, comparing the learning curves in the two cohorts may suggest whether the redesign of the HTU resulted in a more user-friendly device. For several HTU functions, Cohort 1 participants took longer than their Cohort 2 counterparts to use their HTUs for the first time. For example, the median amounts of time for monitoring and uploading clinical readings were substantially higher for Cohort 1: 284 versus 179 days after installation for monitoring, and 19 versus 3 days for uploading (Moreno et al., 2005). In contrast, the median time to first measurement of blood sugar or blood pressure was the same for both cohorts (1 day), as was the time from HTU installation to the first televisit (23 and 21 days, respectively). Note that taking blood pressure and blood sugar measurements did not require logging into the HTU, and most participants had been using home blood pressure machines and home glucometers before the demonstration began. For complex functions, between 6 and 23 percent of Cohort 1 participants had learned how to use these functions 12 months after installation. For Cohort 2, these percentages ranged from 2 to 7 percent.

Cohort 1 participants were as likely as Cohort 2 participants to use the basic HTU functions during roughly the first 27 months after the start of HTU installation for each phase (December 2000 and December 2004). For example, in New York City, virtually all Cohort 1 participants (99 percent) participated in a televisit at least once during the follow-up period, compared with 97 percent among Cohort 2 participants – a difference that is not statistically significant. Likewise, in upstate New York, all Cohort 1 and 2 participants attended a televisit at least once during the follow-up period. In contrast, use of the complex HTU functions was rare for participants in both phases, although Cohort 1 participants in both

sites were significantly more likely than their Cohort 2 counterparts to monitor clinical readings. Furthermore, Cohort 1 participants were also significantly more likely to read and send electronic messages in both sites and to enter behavioral goals in upstate New York. These differences are partly explained by the Consortium's decision to de-emphasize the use of complex HTU functions during Phase II, a result of the difficulties participants experienced during Phase I (U.S. Department of Health and Human Services, 2005).

Participants were asked to attend televisits every two weeks (about 24 times a year), and more often if necessary (Columbia University, 1998). The intensity of HTU use was higher for Cohort 2 than for Cohort 1 participants for five of the eight functions examined, although differences were statistically significant for only four (Table 3). For example, in New York City, Cohort 2 participants used the televisit function significantly more often than their Cohort 1 counterparts - about every 8 and 12 weeks, respectively. The frequency of selfmonitoring recommended to each participant depended on the clinical circumstances and was determined by the nurse case managers, with support from the clinical guidelines and supervising diabetologists (U.S. Department of Health and Human Services, 2003). Likewise, in upstate New York, Cohort 2 participants attended televisits significantly more often than their Cohort 1 counterparts-about every five weeks versus every seven, respectively. Furthermore, in both sites, Cohort 2 participants measured their blood sugar and blood pressure significantly more often than Cohort 1 participants. Because of the datapulling feature of the Generation 2 and 3 HTUs, Cohort 2 participants in both sites uploaded their blood pressure and blood sugar readings between seven and nine times more often, on average, than their Cohort 1 counterparts. For the complex functions, such as monitoring clinical readings, the between-cohort differences in the average frequency of use of HTU functions were small and not statistically significant.

HTU Function	Cohort 1	Cohort 2	Difference (<i>p</i> -Value ^a)
	Basic Functions		(* • • • • • • • • • • •
Measure Blood Sugar			
New York City	161.1	208.6	47.5
,			(.048)
Upstate New York	237.0	386.2	149.2
			(.000)
Measure Blood Pressure			
New York City	147.4	199.1	51.7
			(.013)
Upstate New York	163.8	245.6	81.8
1			(.000)
Co	omplex Functions		, <i>t</i>
Upload Clinical Readings	•		
New York City	9.3	128.5	119.2
,			(.000)
Upstate New York	14.7	169.4	154.7
1			(.000)
Monitor Clinical Readings			× /
New York City	5.5	6.8	1.3
,			(.697)

			Difference
HTU Function	Cohort 1	Cohort 2	(p-Value ^a)
Upstate New York	8.7	6.7	- 2.0
			(.737)
Participate in Televisits			
New York City	4.5	6.4	1.9
			(.000)
Upstate New York	7.0	10.5	3.5
			(.000)
Read Electronic Messages			
New York City	2.1	0.5	- 1.6
			(.869)
Upstate New York	4.8	3.1	- 1.7
			(.878)
Send Electronic Messages			
New York City	1.1	0.5	- 0.6
			(.897)
Upstate New York	1.5	1.3	- 0.2
			(.893)
Enter Behavioral Goals			
New York City	3.0	0.6	- 2.4
			(.806)
Upstate New York	1.6	1.5	- 0.1
			(.503)
Sample Size ^b	753	230	-

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

Notes: Estimates weighted based on length of enrollment between HTU installation and the dropout date or the cutoff date (February 15, 2003, for Cohort 1 and February 27, 2007, for Cohort 2). In Cohort 1, most participants used only Generation 1 HTUs; in Cohort 2, 226 participants used Generation 2 HTUs and 4 used Generation 1 HTUs. Excludes results for the following functions because no Cohort 2 participants used them: consult American Diabetes Association web pages, enter medications, and enter exercise activities.

^aControlling for participants' characteristics at baseline.

^bThe sample size varies by site and function.

HTU = home telemedicine unit.

Table 3. Mean Annual Number of Times HTU Function Was Used During the Intervention, by Cohort and Size

Cohort 1 participants used more functions than Cohort 2 participants (Table 4). In New York City, Cohort 1 participants used 4.3 HTU functions, on average, compared with 2.5 functions for Cohort 2. The averages for upstate New York are very similar (4.5 and 2.7, respectively). As noted, these differences are partly explained by the Consortium's decision to de-emphasize the use of complex HTU functions in Phase II due to the difficulties experienced in Phase I. Furthermore, by the end of the follow-up period, none of the Cohort 2 participants in both sites had used all the functions, though between 2 and 6 percent of Cohort 1 participants (New York City and upstate, respectively) had used all of them.

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

HTU Function	Cohort 1	Cohort 2	Difference (p-Value ^a)
Any Function (Percentage) ^b			(p-value)
New York City	99.6	99.3	- 0.3
New Tork City	· · · · ·	55.0	(.602)
Upstate New York	100.0	99.9	- 0.1
I			(.580)
All HTU Functions (Percentage) ^b			
New York City	2.4	0.0	- 2.4
, i i i i i i i i i i i i i i i i i i i			(.233)
Upstate New York	5.7	0.0	- 5.7
-			(.017)
Number of Functions Used ^b			
New York City	4.3	2.5	- 1.8
			(.000)
Upstate New York	4.5	2.7	- 1.8
			(.000)
Average Duration of Televisits			
(Minutes) ^c			
New York City	24.3	29.4	5.1
			(.000)
Upstate New York	31.2	33.0	1.8
			(.004)
Sample Size ^d	753	230	-

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

Notes: Estimates weighted based on length of enrollment between HTU installation and the dropout date or the cutoff date (February 15, 2003, for Cohort 1 participants and February 27, 2007, for Cohort 2 participants). In Cohort 1, most participants used only Generation 1 HTUs; in Cohort 2, 226 participants used Generation 2 HTUs and 4 used Generation 1 HTUs.

^a Controlling for participants' characteristics at baseline.

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

^cThe number of participants participating in televisits varies by function.

^d The sample size varies by site.

HTU = home telemedicine unit.

Table 4. Patterns of HTU Use During the Intervention, by Cohort and Site

The analysis of HTU use for Cohort 1 and Cohort 2 participants has four limitations. First, without a suitable control group to account for secular trends against which to compare changes in use in both cohorts, it is not possible to determine whether the redesign of the HTU is the sole factor behind the higher use by Cohort 2 participants of the array of HTU functions. Second, because communications between participants and providers are confidential, Mathematica was unable to determine whether any instances of HTU use were self-initiated or whether they occurred only after reminders from nurse case managers during televisits or in electronic messages. Furthermore, the use of the data-pulling feature in Generation 2 HTUs could have changed Cohort 2 participants' use of other functions by relieving them of the need to upload their glucose and blood pressure readings between televisits. Thus, it is unclear how much effort Consortium staff expended to generate the levels of use observed and how this varied by HTU type and cohort. Third, the sample size for Cohort 2 participants was small. Thus, it is likely that the estimates from this group are less robust than the estimates for the Cohort 1 sample. Finally, the Consortium stopped collecting data on use of the ADA web pages - an important intervention component - in November 2003. Therefore, it is not possible to assess the extent to which participants in both phases used these educational materials, particularly after Cohort 1 participants were retrained on HTU use during the third year of the demonstration.

5.3 Intermediate clinical outcomes

The intervention had substantial, statistically significant favorable impacts on blood sugar control and lipid levels in both demonstration sites. In New York City and upstate, blood sugar control was better in the treatment group than in the control group, and total cholesterol levels were about 5 to 6 percent lower, on average (Figure 3). In the upstate site only, the improvement in blood sugar control was greater for participants with poorly controlled blood sugar at baseline than it was for others. The intervention also affected inperson blood pressure measurements, but more so upstate. In New York City, mean systolic and diastolic readings were 2 percent lower in the treatment group than in the control group, although the difference was not statistically significant. Upstate, the mean differences were about 3 percent and were highly significant.

Although the Consortium prespecified blood sugar, blood pressure control, and lipid levels as the main study outcomes, it collected data on several other clinically important outcomes. According to our analysis, IDEATel did not affect ratios of microalbumin to creatinine (an indicator of kidney damage from diabetes), 24-hour ambulatory blood pressure measurements, body mass index, overweight or obesity, waist-to-hip ratio, or abdominal girth in either site. In addition, the intervention had no effects on mortality.

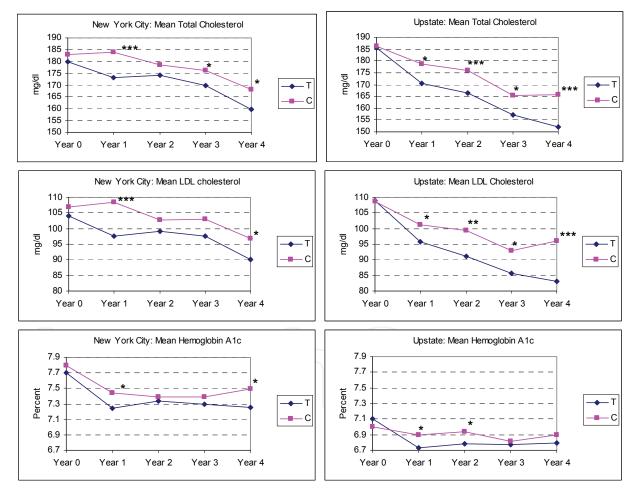
The attrition rate was high in both sites, especially among treatment group members (about 23 percent in New York City and 16 percent upstate between baseline and year 1). The substantial attrition rate among enrollees poses two serious problems. First, the reduction in sample size limits the power to detect impacts. For example, for a single comparison of treatment and control group means, the 30 percent loss of sample in the New York City site would result in minimum detectable differences (MDDs) roughly 25 percent greater than for the full sample, while the 58 percent loss of sample in the upstate site would increase the MDDs by about one-third. Second, and perhaps more important, depending on the mechanism for attrition, impacts calculated only on enrollees who remain in the study could be biased. Bias can occur if the dropout rate of enrollees with unmeasured characteristics

that predict outcomes (for example, motivation or psychological distress) is greater in one intervention group than the other. Such differential dropout threatens the benefits of random assignment. Differential dropout cannot be directly ascertained. However, an examination of the recorded reasons for enrollee dropout and the characteristics of enrollees who dropped out, as well as sensitivity tests consisting of imputed possible values of outcome variables for those who dropped out surprisingly suggested no likelihood of bias.

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5.4 Medicare service use and costs

IDEATel had no effects on treatment group members' use of Medicare-covered hospital, skilled nursing facility, or physician services. Upstate, however, use of home health care was statistically significantly higher for treatment group enrollees than for their control group counterparts. It also did not affect receipt of dilated eye examination, hemoglobin A1c testing, low-density lipoprotein testing, and urine microalbumin testing.



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

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

Fig. 3. Impacts of IDEATel on Cohort 1 Enrollees' Selected Key Clinical and Laboratory Outcomes, Baseline to Year 4

The mean annual Medicare expenditures were higher for treatment group members than for control group members in both sites, but the differences were not statistically significant (Table 5). In New York City, the mean annual Medicare expenditures were \$13,845 in the treatment group and \$12,961 in the control group. Upstate, mean annual expenditures were \$9,566 in the treatment group and \$8,450 in the control group. By service type, statistically significant treatment-control differences were few. However, treatment group members had higher expenditures in all service categories except physician office visits, outpatient hospital, and laboratory services in New York City.

	$(\longrightarrow) ($					
	New York City		Upstate New York		York	
	Treatment	Control	Difference	Treatment	Control	Difference
Component/Service	Group	Group	(p-Value)	Group	Group	(p-Value)
Cohort 1 (Both Phase	es)					
Total Expenditures			\$884			¢1 116
for Medicare-	\$13,845	\$12,961		\$9,566	\$8,450	\$1,116
Covered Services			(.476)			(.094)
Total Intervention-	\$8,662	0	n.a.	\$8,662	0	n 0
Related Costs ^a	Φ 0,00 2	0	11. a .	\$0,00Z	0	n.a.
Total Costs	\$22,507	\$12,961	\$9,546	\$18,228	\$8,450	\$9 <i>,</i> 778
	ΨΖΖ,507	<i>ψ12,9</i> 01	(.001)	ψ10,220	ψ0,±00	(.000)
Cohort 2 (Only Phase	e II)					
Total Expenditures			\$245			- \$2,244
for Medicare-	\$11,906	\$11,661	(.931)	\$6,450	\$8,694	(.132)
Covered Services			(.931)			(.132)
Total Intervention-	\$8,437	0	n.a.	\$8,437	0	n.a.
Related Costs	ψ0,407	0	11.a.	Ψ0,±07	0	11.a.
Total Costs	\$20,343	\$11,661	\$8,682	\$14,877	\$8,694	\$ 6,183
	φ20,343	ψ11,001	(.000)	ψ14,077	ψ0,094	(.000)
Cohort 1 Sample	379	358		446	442	
Size	519	556	-	11 0	774	-
Cohort 2 Sample	82	84		161	164	_
Size	02	04	-	101	104	-

^aTotal demonstration service costs for Cohort 1 are based on the arithmetic average of demonstration costs for Phase I and Phase II, weighted by the average length of time that Phase I participants were enrolled during each phase. n.a. = not applicable.

Table 5. Estimated Annual Per-Person Expenditures for Medicare-Covered Services, Demonstration Costs, and Total Costs

5.5 Demonstration costs

We estimated that the IDEATel intervention cost about \$34.8 million or about 61 percent of the total demonstration budget. Depending on the study phase, between 11 and 15 percent of the total budget was for intervention design; between 46 and 50 percent was for implementation; and less than 1 percent was for closeout (for example, deinstalling HTUs when participants disenrolled or died). For Phase I, implementation costs (\$12,905,572) divided by the number of treatment group enrollees (844) over the length of the intervention

(2 years) provides an estimate of the annual implementation cost per participant, or \$7,645. For Phase II, implementation costs (\$14,338,429) divided by the number of treatment group enrollees (514 treatment group members from Cohort 1 who were still participating in the demonstration at the beginning of Phase II [February 2004], and all 249 Cohort 2 treatment group members), gives a per-participant cost estimate of \$7,029. To calculate the total annual costs per participant per cohort, the analysis assumed that Phase I lasted two years, as stated in the Consortium's original proposal, and that Phase II lasted an average of 2.67 years (three years for Cohort 1 and two years for Cohort 2 [Columbia University, 1998]). Design and closeout costs were depreciated over four years for Cohort 1 and over three years for Cohort 2 (U.S. Department of Health and Human Services, 2005). The final cost per participant is \$8,662 for Cohort 1 (both phases), and \$8,437 for Cohort 2 (only Phase II). When the intervention's annual cost per participant is added to the annual Medicare expenditures of treatment group members, the treatment group's costs are about two and one-half times larger than the control group's costs. Thus, based on experiences of enrollees through December 2003, the demonstration substantially increases total costs. Even if the

intervention had eliminated the treatment group's need for all other Medicare expenditures, that group's costs would have exceeded the control group's costs (upstate) or be within 5 percent of these costs (New York City).

5.6 Summary of findings

The IDEATel demonstration met Congressional implementation requirements. However, the intervention as delivered was neither as intensive nor as technologically sophisticated as originally designed, since the Consortium encountered unexpected challenges and deliberately departed from its plans in some areas. Had the Consortium retained its original target to hold televisits every two weeks with all participants—the most popular component of the intervention—participants might have been more motivated to use their HTUs and interact more frequently with their nurse case managers. In addition, this would have allowed nurse case managers to provide more guidance to participants on using other HTU functions, such as setting behavioral goals, which might have resulted in better clinical outcomes. Similarly, had the redesigned HTU been cheaper and less sophisticated, participants' acceptance of this technology might have increased and the costs of the demonstration might have been more reasonable.

IDEATel was clinically effective over the medium term in only one of two sites, which made it difficult to determine why it was more effective among participants upstate than in New York City or whether some demonstration features are essential for long-term impacts. The expectation that the demonstration could generate offsetting savings for Medicare services did not materialize, in spite of the six-year follow-up. The main driver of these costs was the size of the cooperative agreement allocated to the demonstration's operations, compounded with the use of very expensive HTUs. Table 6 summarizes the key findings from the evaluation of IDEATel.

While an ongoing program similar to IDEATel could potentially have lower costs, it would be virtually impossible for such a program to generate cost savings, particularly because the intervention-related costs of the demonstration were excessive by any standard. Given the absence of effects on costs or services, however, even a less expensive version of this demonstration would not produce sufficient Medicare savings to offset demonstration costs. Furthermore, while IDEATel had clinical impacts similar to those of other interventions for individuals with diabetes, it cost far more. For instance, *Project Dulce* (a diabetes casemanagement and self-management training program) had clinical impacts (derived from a comparison of program participants to a matched control group) similar in size to those produced by IDEATel. While the program was cost-effective according to commonly accepted standards, Project Dulce cost an estimated \$662 to \$1,537 per participant per year to implement – about an eighth the cost of IDEATel (Gilmer et al., 2007).

In sum, the results are clear: the IDEATel program cannot be cost neutral, given its large costs and the complete absence of any savings in traditional Medicare costs for hospitalizations and other covered services. Even if costs were halved and the intervention reduced hospitalizations by 50 percent (both highly unlikely scenarios), the program would still increase total costs to the government.

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

^a Findings are for all four years for which follow-up survey data were available. Table 6. Summary of Findings by Site

6. Discussion

6.1 Implications of the IDEATel evaluation for home-based telemedicine

Mathematica's overall findings about IDEATel are consistent with those from a CBO review of disease management programs for diabetes in which clinical improvements were not associated with long-run reduced costs (implied to be over a time frame of at least one year) (Congressional Budget Office, 2004). They are not consistent, however, with findings from a commercial diabetes management program that seemed to yield clinical improvements *and* cost savings in one year's time (Piette et al., 2001;Villagra & Ahmed, 2004). Because the

CBO-reviewed studies and the Villagra-Ahmed study rely on evaluation designs of different credibility and robustness, the above findings should be interpreted cautiously.

What mechanisms might have produced the modestly improved clinical outcomes? By providing participants free blood sugar and blood pressure meters, nurse case managers to encourage use of these meters, and a means of uploading the meter readings, the intervention set the stage for timely and aggressive treatment of diabetes symptoms. Specifically, the nurses conveyed concerns to supervising diabetologists. These physicians suggested different doses of guideline-recommended prescription drugs to participants' primary care physicians, who made the changes and participants responded favorably.

The problems with the HTU suggest that IDEATel's positive clinical effects may have been due more to the nurses' telephonic interactions with the patients than to the expensive HTU equipment. The intervention as implemented had limited acceptability among participants. For example, many participants found the HTU used during Phase I of the demonstration somewhat unappealing. In addition, participants found the HTU cumbersome or physically imposing (5 and 28 percent of Cohort 1 treatment group members refused installation between baseline and year 4 in New York City and upstate New York, respectively). They also found the more advanced functions difficult to perform (4 and 5 percent of Cohort 1 treatment group members left the study citing difficulty with the HTU between baseline and year 4 in New York, respectively).

Although demonstration staff said participants who attended televisits enjoyed interacting with nurse case managers, participants attended televisits much less often than the Consortium requested (especially in New York City). Technical difficulties may have made the HTU more of a distraction than an asset for purposes of case management. As noted in section 4, the evaluation cannot definitively attribute the intervention's positive impacts to using the HTU, interacting with nurse case managers, or both because the demonstration was not designed to measure each component's marginal benefits. Nonetheless, these problems with the HTU suggest that this expensive component of the intervention may not have been the essential factor for producing the favorable effects on clinical indicators.

The finding that the intervention did not affect participants' use of Medicare-covered services, including diabetes-specific preventive services, was disappointing to program operators, but perhaps was not altogether surprising. First, televisits were not meant to substitute for regular physician visits, so no savings were expected in visits. Second, the provision of free annual hemoglobin A1c, lipid, and urine microalbuminuria testing to both the treatment and control groups during annual assessments would have blunted any between-group differences that might have arisen for these outcomes. It may also have attenuated effects on hospital use had these tests not been conducted for the control group absent the demonstration (to the extent that knowledge of problems with such indicators could lead to behavior or treatment changes that would ward off such exacerbations). Third, the demonstration's duration for Cohort 1 may have been too short to detectably reduce the need for hospitalizations or other health service use through the prevention of heart attacks, stroke, kidney failure, eye damage, and other complications. Fourth, enrollees may not have been at high risk for costly hospitalizations. Baseline hemoglobin A1c, lipid, and blood pressure levels suggested that enrollees were relatively well controlled in the three measures.

It is slightly disappointing that the intervention did not affect receipt of dilated eye exams; between 87 and 95 percent of control group enrollees received them, compared to between 88 and 98 percent of treatment group enrollees (in upstate New York and New York City,

respectively). One would expect IDEATel nurse case managers to remind participants to have the exam, a widely accepted component of diabetes treatment guidelines. While nurses may have neglected to make reminders because they faced competing priorities during televisits or their case management software was not programmed to issue such reminders, this would not excuse such omission from their interactions. It could also be that participants ignored reminders, but this would suggest that the nurses were unsuccessful in developing enough trust and rapport with participants to encourage at least some of them to have this important exam. Baseline rates were also fairly high; perhaps physicians willing to participte in the study were already providing high quality care and beneficiaries willing to enroll were already adherent to recommended care. It may have thus been difficult for the intervention to effect substantial additional improvements above the already high baseline rates.

Given the absence of effects on service use, finding no effects on Medicare costs was not surprising. The higher Medicare expenditures for the treatment group may have been strictly a chance difference or may be because IDEATel identified the need for some health services among medically underserved beneficiaries. The expectation that the demonstration could generate offsetting savings for Medicare services did not materialize, in spite of the six-year follow-up. The main driver of these costs was the size of the cooperative agreement allocated to the demonstration's operations, compounded with the use of very expensive HTUs.

6.2 Potential role of home telemedicine in the Medicare program

Although the promise of home telemedicine has long been recognized by experts and policymakers, its use in the U.S. health care system is far from widespread, particularly in the Medicare program, the largest health insurer in the U.S. There are several studies that show that home telemedicine for Medicare can be efficacious, but they are limited by small sample sizes, inadequate length of follow-up, and inconclusive results (Hersh et al., 2006). Consequently, the failure of the IDEATel demonstration to provide a conclusive assessment of the potential of home telemedicine-improve access to care for Medicare beneficiaries with chronic conditions, provide cost-effective care to the Medicare population, and generate cost savings for the Medicare program-was disappointing for those expecting such changes in outcomes, such as the Agency for Healthcare Research and Quality, which sponsors a periodic systematic review of the effects of telemedicine for Medicare beneficiaries. Furthermore, in early 2008, at the end of the demonstration, the optimism among program developers, implementers, health care providers, and policymakers about whether and how home telemedicine could play a role in the Medicare program seemed to be fading away. This resulted primarily from the shift in emphasis from telemedicine to electronic health records that the federal government adopted starting in 2004.

A turnaround point for this impasse was the largest legislative push on health information technology (IT) ever in the U.S. In 2009, recognizing the unrealized potential of health IT to improve the quality and delivery of health care, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act. The goal of HITECH is to promote the adoption of health IT in public insurance programs, including the potential use of home telemedicine in Medicare to support key principles of the patient-centered medical home to improve health care quality and efficiency (Moreno et al., 2010). Recent health reform legislation (Patient

Protection and Affordable Health Care Act [P.L. 111-148]) offers promising prospects for home telemedicine, including an Innovation Center within CMS, the agency of the U.S. Department of Health and Human Services that administers Medicare. This center will test, evaluate, and expand in Medicare (as well as in Medicaid and the Children's Health Insurance Program) different payment structures and methodologies to reduce program expenditures while maintaining or improving quality of care, a role that telemedicine could fulfill. Other mandates of the health reform legislation that could directly or indirectly facilitate the adoption of home telemedicine in the program include a Federal Coordinated Health Care Office within CMS. The mission of this office is to more effectively integrate Medicare and Medicaid benefits and improve coordination between the federal government and states in order to improve access to and quality of care and services for dual-eligible beneficiaries (that is, those eligible for both Medicare and Medicaid), who typically have many care-coordination needs. There are many other health-reform legislative dispositions that could influence the adoption and use of home telemedicine, but we do not discuss them here because they are in early stages of development and implementation.

In sum, HITECH, the health-reform legislation, and other pre-HITECH legislation are intertwined and highly relevant to home telemedicine in the Medicare program. Despite our finding that IDEATel was unlikely to be cost-effective given that the demonstraton had modest clinical impacts at excessive cost, the concept of home telemedicine is still promising. One of the factors that has greatly enhanced the prospects of home telemedicine is the continous decline in health IT prices, such as those for smartphones, personal digital assistants, intelligent devices, and web-based applications. This unique alignment of policies and affordable technology raises hopes that there can be positive synergies in the immediate future to build a solid basis for home telemedicine in the Medicare program.

7. References

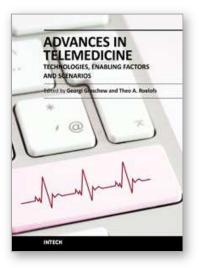
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Advances in Telemedicine: Technologies, Enabling Factors and Scenarios

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Innovative developments in information and communication technologies (ICT) irrevocably change our lives and enable new possibilities for society. Telemedicine, which can be defined as novel ICT-enabled medical services that help to overcome classical barriers in space and time, definitely profits from this trend. Through Telemedicine patients can access medical expertise that may not be available at the patient's site. Telemedicine services can range from simply sending a fax message to a colleague to the use of broadband networks with multimodal video- and data streaming for second opinioning as well as medical telepresence. Telemedicine is more and more evolving into a multidisciplinary approach. This book project "Advances in Telemedicine" has been conceived to reflect this broad view and therefore has been split into two volumes, each covering specific themes: Volume 1: Technologies, Enabling Factors and Scenarios; Volume 2: Applications in Various Medical Disciplines and Geographical Regions. The current Volume 1 is structured into the following thematic sections: Fundamental Technologies; Applied Technologies; Enabling Factors; Scenarios.

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