Medicare payments, healthcare service use, and telemedicine implementation costs in a randomized trial comparing telemedicine case management with usual care in medically underserved participants with diabetes mellitus (IDEATel)

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ABSTRACT

Objective To determine whether a diabetes case management telemedicine intervention reduced healthcare expenditures, as measured by Medicare claims, and to assess the costs of developing and implementing the telemedicine intervention.

Design We studied 1665 participants in the Informatics for Diabetes Education and Telemedicine (IDEATel), a randomized controlled trial comparing telemedicine case management of diabetes to usual care. Participants were aged 55 years or older, and resided in federally designated medically underserved areas of New York State.

Measurements We analyzed Medicare claims payments for each participant for up to 60 study months from date of randomization, until their death, or until December 31, 2006 (whichever happened first). We also analyzed study expenditures for the telemedicine intervention over six budget years (February 28, 2000—February 27, 2006).

Results Mean annual Medicare payments (SE) were similar in the usual care and telemedicine groups, $9040 ($386) and $9669 ($443) per participant, respectively (p>0.05). Sensitivity analyses, including stratification by censored status, adjustment by enrollment site, and semi-parametric weighting by probability of dropping-out, rendered similar results. Over six budget years 28,821 participant/months of telemedicine intervention were delivered, at an estimated cost of $622 per participant/month.

Conclusion Telemedicine case management was not associated with a reduction in Medicare claims in this medically underserved population. The cost of implementing the telemedicine intervention was high, largely representing special purpose hardware and software costs required at the time. Lower implementation costs will need to be achieved using lower cost technology in order for telemedicine case management to be more widely used.

INTRODUCTION

Telemedicine case management of chronic diseases, such as diabetes mellitus, holds substantial promise in overcoming barriers to care in various geographic and socio-economic settings.1 In rural areas the barriers include geographic distance, weather, lack of public transportation, and provider shortages.2,3 In underserved urban areas with predominantly minority populations, obstacles include language, low educational attainment, disempowerment, and lack of social reinforcement for health-related behaviors and activities.4 Older participants are particularly vulnerable to those barriers, and may thus benefit significantly from telemedicine case management.5,6 However, the efficacy of telemedicine case management interventions for diabetes, their effect on healthcare utilization, and the costs of their implementation, remain poorly characterized.7,8

We conducted a large randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved participants with diabetes mellitus in urban and rural settings, the Informatics for Diabetes Education and Telemedicine (IDEATel) study. Over 5 years of follow-up, the telemedicine case management resulted in significant improvements in hemoglobin A1C, systolic blood pressure, and low density lipoprotein cholesterol, as compared to usual care.2 The telemedicine case management was highly acceptable to participants and their primary care providers,10,11 enhanced the participants’ self-efficacy for diabetes care,12 and enabled the detection and remediation of medically urgent situations.13

In the USA, people with diabetes incur more than twice the amount of medical expenditures as those without diabetes; approximately 50% of these expenditures correspond to inpatient care, whereas physician office visits represent less than 10%.14 Thus, there is great interest in interventions that may reduce preventable hospital admissions in people with diabetes. In addition to hypotheses regarding the feasibility, acceptability, and clinical benefit of the telemedicine-based intervention, we hypothesized that improvement in diabetes care in IDEATel would result in a detectable decrease in healthcare expenditures through a reduction in hospitalizations caused by preventable complications. Therefore, we undertook a study of Medicare claims data in IDEATel participants to assess the effect of the telemedicine case management on
health resources utilization, as measured by Medicare claims. Claims data were analyzed for five resource utilization categories, including inpatient and outpatient care. In addition, we examined the costs incurred in developing and implementing the telemedicine intervention, and, in order to facilitate comparisons with other interventions, estimated the mean cost per participant/month of intervention delivered.15 16

METHODS
Study design, participants, and setting
The IDEA-Tel study was initially funded for four years, from February 28, 2000 to February 27, 2004, and was subsequently extended until February 27, 2008. We report here data for the 1665 participants who were randomized in the initial phase of the study. These are the same participants for whom we reported clinical outcomes at 5 years of follow-up.9 As previously described,17 participants were enrolled through primary care practices in New York City, with the enrollment hub at Columbia University Medical Center, and in upstate New York, where the enrollment hub was at State University of New York (SUNY) Upstate Medical University at Syracuse. Randomization to telemedicine case management or to usual care was assigned within primary care provider strata immediately upon completion of the baseline exam. The study design, the telemedicine intervention, and the clinical outcomes have been reported previously.9 17–19 Written informed consent was obtained from all participants, and the study was approved by the Institutional Review Boards at Columbia University Medical Center, SUNY Upstate Medical University at Syracuse, all participating hospitals and healthcare provider organizations, and Abt Associates, Inc.

Medicare payments and healthcare service use data
Medicare payments and service utilization data were obtained from the Centers for Medicare and Medicaid Services (CMS), based on claims submitted and paid, and linked to each IDEA-Tel participant. We calculated the total and per person average payments for all services, inflated to 2006 dollars using the Total Medicare Economic Index. Average yearly payments are presented separately for all services combined, and also for each type of service (inpatient, physician/supplier, outpatient, durable medical equipment, home health, skilled nursing facilities, and hospice services). Participants who did not have claims for a particular type of service in any given month were assigned a value of zero dollars for payments in that type of service for that month. For inpatient claims, there are institution-specific rates for Medicare reimbursements. We therefore computed standardized inpatient payments by multiplying the diagnosis-related group (DRG) weight for each hospitalization by the base CMS payment per discharge ($4823) for 2004. However, results obtained using standardized and non-standardized inpatient payments were similar, and non-standardized payments are reported here.

The goal was to estimate Medicare expenditures over a period of approximately 5 years, but, at the time of these analyses, Medicare claims data were available up to December 31, 2006. Thus, we extracted claims data for the period starting on each participant’s date of randomization in IDEA-Tel and extending for 60 months from date of randomization, or until death, or until December 31, 2006—whichever happened first. The main intention-to-treat (ITT) analysis corresponds to the entire sample of 1665 randomized participants, using all claims data available for that analytic period. However, given the overlap of recruitment and follow-up, participants recruited later in the study contributed claims data for a shorter time than those recruited earlier on (the first IDEA-Tel participant was recruited on December 20, 2000). Similarly, participants who died before the end of our analytic period contributed claims data for a shorter time, compared to those who remained alive in the study until the end of that period. Thus, to assess the robustness of our analysis, we compared expenditures between the two treatment groups for 36, 48, and 60 months of follow-up.

In addition, the ITT claims analyses may be downwardly biased because censored participants contributed less than non-censored participants to the numerator (payments) but were not removed from the person-time denominator, following the principles of ITT analysis. We therefore performed an additional analysis in which claims data for censored and non-censored participants were considered separately. Participants who experienced censoring, due to drop-out or death prior to December 31, 2006, or who did not complete 60 months in the study were considered ‘censored’ (n=750). Participants who completed 60 study months or remained in the study up to December 31, 2006 were considered ‘non-censored’ (n=915). Other sensitivity analyses included models that adjusted by participant recruitment site (rural vs urban), and a semi-parametrically weighted model that weighted the individual participant’s study time (and associated Medicare payments during that time) by the cumulative probability of completing study participation (not dropping out or dying). The advantage of the weighted regression analysis is that it takes into account only the data from person-time of participants while in the study.

Project intervention costs
Project cost analyses were based on actual expenditures, not project grant budgets. Because individual participants entered the intervention on different dates, intervention costs could not be calculated on a calendar-derived time basis. Instead, intervention costs for a six-year budgetary period (February 28, 2000 to February 27, 2006) were determined from expenditure records and divided by the number of participant-months of intervention delivered over those years. In analyses of project costs, all right censored participants (dropouts and deaths) were removed from the tabulation of intervention-months at the time of censoring. Annualized cost estimates included both fixed and variable costs. Total costs were tabulated for each expenditure category, as follows.

Vendor costs were determined by review of individual contracts. These included home telemedicine unit (HTU) development, deployment, maintenance and technical support by American Telecare Inc. In addition, American Telecare Inc provided data-consolidation servers, and developed and deployed two generations of home telemedicine unit (HTU); the second-generation HTU was introduced at the beginning of the study’s second phase—that is, during project years 5 and 6.20 This 6-year timeframe, as compared to the 5 years of subject follow-up in our Medicare claims analysis, was intended to capture the costs of upgrading the HTU technology in years 5 and 6. Cross Hair Technology, Inc was responsible for the design, configuration, and implementation of the security modules. Development, licensing and installation of the case management software were provided by Siemens, Inc. Verizon, Inc provided telephone line, internet service provider, and virtual private network services, while the American Diabetes Association developed the Educational Web Portal in English and Spanish. Additional costs were incurred for wide area network connectivity and data transfer, and for maintenance fees on software and security systems. The Department of Biomedical Informatics at Columbia University was responsible for overseeing and managing all
technological aspects of the study, including the relationship with and supervision of the above noted commercial vendors. Department faculty and staff were responsible for hardware and software development and for implementation and maintenance of the telemedicine system, which included participant training. We included personnel expenses related to those activities. We excluded faculty and staff expenses related to the research evaluation of the technology or to the development of conceptual frameworks for telemedicine use and patient training. We included as project costs expenses incurred by the two clinical diabetes case management teams, one located at the Joslin Center, SUNY Upstate Medical University in Syracuse, NY, and the other at the Naomi Berrie Diabetes Center, Columbia University, in New York City. Each clinical team comprised two full-time nurse diabetes case managers, one half-time nutritionist, and a part-time endocrinologist, who provided guidance and supervision.

STATISTICAL ANALYSES
In the ITT claims analysis, a two-sample t test was used to compare unadjusted mean annual Medicare payments between intervention and usual care groups, using a pre-specified two-tailed significance level of 0.05. In sensitivity analyses, performed in order to assess the robustness of the intent-to-treat comparisons over different lengths of participation, the mean annual expenditures were estimated over 36, 48 and 60 months. Estimates for each period use Medicare claims from participants who were recruited early enough in the study and then remained alive to contribute data for that number of months. We also performed comparisons between treatment groups separately for censored and non-censored subgroups. In sensitivity analyses, we compared payments using generalized linear models that simultaneously adjusted for randomization group and location (Upstate New York or New York City). Based on a modified Park test, the γ distribution with a log link function was used. The unit of analysis for these regression models is a participant-month. Coefficients from these regression models are not easily interpreted, thus we used the coefficients to compute predicted payment amounts, which are interpreted as average monthly amounts as functions of the predictors of interest. We then multiplied the predicted payment values by 12 to estimate mean per annum amounts. Paralleling the main analyses discussed above, these regression models were estimated for the ITT, censored, and non-censored samples. In addition, to account more fully for unequal censoring across participants, another regression model weighted the participant-level payment data using semi-parametrically derived weights that reflected the cumulative probability of completing study participation (ie, of not being censored).

We report arithmetic means, the customary approach to reflect costs incurred by all participants, as well as those consuming a disproportionately high volume of services. All standard errors were adjusted for the design feature of clustered randomization within primary care physicians.

RESULTS
The intervention and control groups were equivalent with respect to baseline demographic and socioeconomic characteristics (table 1). As expected in a medically underserved population, about half of the participants reported an annual household income ≤$10,000. In addition, 38% were foreign born (mostly Caribbean Hispanics), and about 50% belonged to an ethnic or racial minority. The proportion of participants ever eligible for Medicaid benefits was around 40%.

Table 2 displays unadjusted mean Medicare payments with adjusted standard errors (SE), for the telemedicine and control groups in the ITT sample (all randomized participants), and the non-censored and censored samples shown separately. In the ITT comparisons, there was no significant difference in payments for all services combined between the telemedicine and usual care groups. Mean annual payments were estimated as $9040 ($386) and $9669 ($443) for the usual care and telemedicine groups, respectively. The comparisons between telemedicine and usual care were similar over different lengths of participation (figure 1). This was also the case for all subclasses of services other than durable medical equipment, where payments in the telemedicine group were larger than those in the control group (p=0.05). Total payments were substantially greater in the group of participants who were censored, consistent with the highest cost of end-of-life care for those in this group who died. In the non-censored sample, the usual care group incurred larger expenditures than the telemedicine group in two categories: home care and skilled nursing facilities (p=0.02 and 0.01, respectively). These comparisons should be interpreted with caution because of asymmetric censoring, with more dropouts, although similar rates of deaths in the telemedicine group.

In other sensitivity analyses, adjustment in generalized linear models by geographical area and by the probability of completing study participation (semi-parametrically weighted), rendered similar results, which are summarized in table 3.

The telemedicine arm of IDEATel delivered 28,821 participant/months of intervention over 6 years. Project intervention costs were estimated as US $622 per participant/month of intervention delivered (table 4). More than 57% of those expenditures were incurred by the commercial vendors.

DISCUSSION
Telemedicine case management, as compared to usual diabetes care, did not reduce Medicare payments for services rendered in this medically underserved population. Both study arms incurred similar expenditures for both outpatient and inpatient care.
These findings were robust in that they were replicated in all sensitivity analyses. Thus, costs saving to CMS were not realized through lower expenditures in inpatient care or substitution of electronically delivered case management services for in-person services. Expenditures in durable medical equipment were higher for telemedicine participants, but that did not significantly affect overall expenditures, of which they represented less than 5%. Overall, Medicare claims payments were similar to those described for similar elderly populations with diabetes. It is possible that participants in the telemedicine arm of the study sought additional services as a result of their interactions with the diabetes case managers, and that this effect offset reductions that might otherwise have been observed had the study been conducted in a population that was not underserved. However, there is no evidence to support that explanation against its counterpart, that the telemedicine intervention did not have any effects on resource utilization. Furthermore, sensitivity analyses did not identify any significant effects on Medicare costs by the telemedicine case management intervention.

Our main analytic approach to the Medicare claims data was ITT, which is viewed as the most valid approach to analysis of randomized trial data. In the ITT analysis all randomized participants continued to contribute person time to the denominator of the Medicare payments analysis and payments to the numerator, through the end of follow-up (or until death), regardless of whether they dropped out of the study. ITT analysis is unbiased with respect to the original randomization, but it is potentially vulnerable to biases that may arise due to missing data, in general, and to the influence of data from participants who dropped out of the intervention arm differentially and received little or no intervention. In our study, there were a similar number of deaths in the treatment and usual care groups, but a larger number of dropouts in the intervention group. Dropouts in the intervention group were related in part to difficulties in accommodating the home telemedicine device in the home and/or to learning to use it, as we have previously reported. Given the potential limitations of the main ITT analysis, we also compared Medicare claims between telemedicine and usual care after stratification by censored status, after adjustment by recruitment site (rural vs urban), and in semiparametrically weighted models that weighted the individual participant’s study time (and associated Medicare payments...
Table 3 Adjusted and semi-parametrically weighted mean annual Medicare payments per participant in the IDEATel Study; December 15, 2000 through December 31, 2006

<table>
<thead>
<tr>
<th></th>
<th>Semi-parametrically weighted mean annual payments (SE)</th>
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<th>Adjusted mean annual payments (SE)</th>
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| All means are adjusted by enrollment site (Upstate New York/New York City). Semi-parametrically weighted means are also adjusted by the cumulative probability of not being censored. 95% CIs, estimated from robust standard errors, which were adjusted for clustering by primary care physician practices. Only p values <0.05 for the comparison between the usual care and telemedicine groups are shown.

during that time) by the cumulative probability of completing study participation (not dropping out or dying). All those analyses provided results consistent with the ITT findings, with no statistically significant difference in overall Medicare payments between the intervention and usual care groups in average overall Medicare payments over 5 years.

In our view, the costs of implementing the intervention were high. The lack of other randomized trials with a similar scope makes it difficult to frame a discussion of the cost findings. Adler-Milstein et al developed a model to predict the costs of technology-enabled diabetes management interventions. The costs we observed were substantially larger than those predicted by their models in the categories of ‘remote monitoring’ and ‘self-management’. However, this difference may simply reflect the discordance between overly optimistic predictions and the realities encountered when implementing a highly innovative technological intervention in underserved populations. We are not aware of other long-term, large randomized trials of telemedicine case management in which claims data were reported.

Costs in IDEATel included the design, development and implementation of a secure and complex telemedicine infrastructure, which supported user-friendly interfaces for participants, diabetes case managers, and primary care physicians. The capability to support the major functionalities of the home telemedicine devices—two-way video teleconferencing with case managers, home monitoring with automated data upload, and internet access to information and educational resources—was unique and innovative in the year 2000, when it was first deployed. Furthermore, the IDEATel study supported the development of new, special purpose technology by the vendors, at a substantial cost. This was much less efficient from a provider perspective than an alternative model, in which technical design and development costs would be absorbed by the vendors. In addition, we hired and trained an ad hoc clinical team. Thus, our implementation costs data are not necessarily applicable to future clinical telemedicine programs; costs in other settings can be expected to vary greatly depending on vendor-supported technology, available infrastructure, and local technical expertise, as well as the ability of pre-existing clinical teams to absorb additional demands generated by the program. In other words, costs will greatly depend on pre-existing capacity, which is evolving rapidly, as well as on technology costs, which are likely to continue falling.

Moreno et al recently published an analysis of costs in the IDEATel study. There are several important differences between our report on IDEATel project costs and Medicare claims and the paper by Moreno et al With respect to the project costs, Moreno and associates did not analyze actual project expenditures. Rather, their analyses were based on grant budget data and six additional sources, including input from a telemedicine consultant. The problems of using budget data instead of actual expenditures are exemplified by the fact that, when estimating the total cost of the IDEATel project (see online appendix, page 10, fourth paragraph) “the estimated sum exceeded the actual amount of the cooperative agreement”. This occurred because amounts significantly less than the budget were expended in some years, and then carried forward to the following year through a mechanism that involved sequential one year grant awards. Our paper reports actual expenditures. To estimate annualized per-participant intervention costs Moreno and...
colleagues divided the average cohort estimates by the number of participants in each phase, and then weighted those means by the average length of participation during each phase. We measured the actual number of participant/months of intervention using the study participant tracking data, which registered date of randomization and date of completion, dropout, or death for each participant. Finally, our report categorized project expenditures by class of expenditure, while the estimates by Moreno et al did not take into account re-budgeting across expenditure classes.

Our study has several limitations. We performed a cost analysis, but not a cost-effectiveness analysis. IDEATel lacked statistical power to assess the potential effects of telemedicine on diabetes-related morbidity (eg, myocardial infarction, stroke) and mortality; the study was designed and the sample size determined based on the primary study outcomes of blood pressure, low-density lipoprotein cholesterol, and hemoglobin A1c. As a result, we could not perform cost-effectiveness analyses of the telemedicine intervention to reduce mortality or morbidity outcomes, which would have been more informative from a societal perspective. The Medicare claims analysis was performed from the perspective of the payer (CMS), and the Medicare claims data we used are inherently valid for that perspective. Examining the accuracy of individual Medicare claims was beyond the scope of our study. This limitation does not compromise the validity of our comparisons of telemedicine versus usual care Medicare claims. A limitation of our cost analysis is that we did not measure participant-level transportation costs, which may be substantially reduced by telemedicine in rural areas.

The costs of telemedicine as a strategy for comprehensive chronic diabetes management from a societal perspective will depend on several, rapidly evolving factors, including existing capacity of case management personnel, cost and availability of telemedicine devices, and the underlying communications and data management infrastructures at different institutions. Hand-held devices that are owned and maintained by the patients, and that combine many of the capabilities of personal computers and telephones, may have the potential to reduce the costs of remote patient-provider interactions.

In conclusion, telemedicine case management did not reduce Medicare claims for clinical services in the medically underserved older adult population enrolled in the IDEATel project. The costs of implementing the telemedicine intervention were high, compared to other diabetes case management interventions evaluated in the literature. In order for the benefits of telemedicine-based case management for chronic diseases, similar to those we previously reported in IDEATel, to be viable and adopted in clinical settings, less costly technology will be required, most likely incorporating mobile phone technology and computers that are owned and maintained by participants.

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