THE INFORMATICS FOR DIABETES AND EDUCATION TELEMEDICINE (IDEATEL) PROJECT

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ABSTRACT

Telemedicine is a promising but largely unproven technology for providing case management services to patients with chronic conditions who experience barriers to access to care or a high burden of illness. We conducted a randomized controlled trial comparing telemedicine case management to usual care, with blinding of those obtaining outcome data, in 1,665 Medicare recipients with diabetes, aged 55 years or greater, and living in federally designated medically underserved areas of New York State. In New York City, 98% of participants were black or Hispanic, 69% were Medicaid-eligible, and 93% reported annual household income $\leq$\$20,000. In upstate New York, 91% were white, 14% Medicaid eligible, and 50% reported annual household income $\leq$\$20,000. A baseline survey found that 95% of participants in New York City and 67% in upstate New York reported that they did not know how to use a computer. The primary endpoints were HgbA1c, blood pressure, and low density lipoprotein (LDL) cholesterol levels. In the intervention group (N = 844), mean HgbA1c improved over 1 year from 7.35% to 6.97%, and from 8.35% to 7.42% in the subgroup with baseline HgbA1c $\geq$7% (N = 353). In the usual care group (N = 821), mean HgbA1c improved over 1 year from 7.42% to 7.17%. Adjusted net reductions (1-year minus baseline mean values in each group, compared between groups) favoring the intervention were as follows: HgbA1c, 0.18% ($p = 0.006$), systolic and diastolic blood pressure, 3.4 ($p = 0.001$) and 1.9 mmHg ($p < 0.001$), and LDL cholesterol, 9.5 mg/dl ($p < 0.001$). In the subgroup with baseline HgbA1c $\geq$7%, net adjusted reduction in HgbA1c favoring the intervention group was 0.32% ($p = 0.002$). Mean LDL cholesterol level in the intervention group at one year was 95.7 mg/dl. The intervention effects were similar in magnitude in the subgroups living

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in New York City and upstate New York. A satisfaction survey of intervention group participants (N = 346 respondents) showed high levels of satisfaction with major intervention components. A satisfaction survey of participating primary care physicians (N = 116 respondents) showed positive perceptions for acceptability, impact on patients and communication. Telemedicine case management improved glycemic control, blood pressure levels, and total and LDL-cholesterol levels at 1 year of follow-up. Telemedicine is an effective method for translating modern approaches to disease management into effective care for underserved populations.

An estimated 20.8 million adults in the U.S. have diabetes (1), with the prevalence increasing as the population ages and obesity increases (2,3). Type 2 diabetes accounts for 90–95% of diagnosed cases in adults, increases markedly with age and obesity, and is more common in African-Americans and Hispanics compared to non-Hispanic whites (1,4). The costs of diabetes in 2002 exceeded $132 billion including $92 billion in direct medical costs (1). Those over 65 years of age account for two-thirds of all costs (5). The long-term chronic complications of diabetes are responsible for most of the morbidity, mortality and cost, with most diabetes-related mortality due to macrovascular disease, specifically coronary artery and cerebrovascular disease (6). Treatment of hypertension and dyslipidemia in patients with diabetes decreases these complications and is cost-effective (7–13). The microvascular complications of diabetes, including neuropathy, nephropathy and retinopathy and blindness, can be reduced by improving control of glycemia and blood pressure (7,14–18). Thus, extensive evidence supports the benefit of improving management in type 2 diabetes for preventing morbidity and mortality from both macro- and microvascular disease. Despite the development of modern approaches to case management and care for patients with diabetes, many patients do not achieve optimal outcomes. One approach to improving care for chronic conditions that has received recent attention is telemedicine.

Although a variety of technical approaches have been developed, the relative scarcity of rigorous telemedicine evaluations has been noted by several authors (19–22). This lack is related to multiple issues, including the underlying difficulty and cost of conducting robust evaluation, lack of studies using randomized designs with concurrent controls, small sample sizes, short-term follow-up and lack of multidisciplinary evaluation teams. Thus, despite the obvious promise of telemedicine, the clinical effectiveness of this technology, both in general and in specific clinical contexts, remains poorly documented. The Informatics for Diabetes Education and Telemedicine project (IDEATel) (23,24) was therefore undertaken as a prospectively randomized

clinical trial of health services delivered electronically directly to patients with diabetes in their homes.

The IDEATel study design (23), technical implementation (24), and one-year results (25) have previously been reported. This report summarizes these findings together with information on patient and provider satisfaction and preliminary findings from analysis of Medicare claims data.

Methods

Eligibility and Exclusions

Criteria for inclusion were age 55 years or older, being a current Medicare beneficiary, having diabetes mellitus defined by a physician's diagnosis and being on treatment with diet, an oral hypoglycemic agent or insulin, residence in a federally designated medically underserved area (either of two federal designations, Medically Underserved Area [MUA] or Health Professional Shortage Area [HPSA]) in New York State, and oral fluency in either English or Spanish. Exclusions were moderate or severe cognitive, visual, or physical impairment or the presence of severe comorbid disease.

Study Design

Subjects 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. Recruitment in the upstate area spanned a geographic area of approximately 30,000 square miles. Systematic review of patient panels was conducted at participating practices in order to identify potentially eligible patients. Randomization to telemedicine case management or to usual care was assigned in a 1:1 ratio immediately upon completion of the baseline examination. Randomization began in December, 2000 and was completed in October, 2002. Subjects were randomized within clusters defined by primary care provider patient panels. For subjects assigned to intervention, an appointment was made by telephone for installation of the home telemedicine unit within two weeks. A follow-up examination was conducted one year after the baseline exam. Personnel conducting these examinations were blinded to intervention status and were not involved in supporting the technical aspects of the intervention or in delivering diabetes case management services. Written informed consent was obtained from all subjects. The study was approved by the Institutional Review

Boards at Columbia University Medical Center, SUNY Upstate Medical University at Syracuse and all participating hospitals and health care provider organizations.

Intervention

Participants randomized to the intervention group received a home telemedicine unit (HTU) developed specifically for IDEATel (American Telecare, Inc.; Eden Prairie, MN). The HTU consisting of a web-enabled computer with modem connection to an existing telephone line. The HTU provided four major functions: (i) videoconferencing over plain-old-telephone-service (POTS) connections at 8 to 15 frames/second allowing patients to interact with nurse case managers at the Berrie Diabetes Center at Columbia University or the Joslin Diabetes Center at SUNY Upstate Medical University; (ii) remote monitoring of glucose (One Touch Sure Step; Lifescan, Inc., Milpitas, CA) and blood pressure (UA-767 Blood Pressure Monitor; A&D Medical; Milpitas, CA) with electronic upload and integration with the Columbia EMR(57) (iii) dialup ISP access to a web portal providing access to patients' own clinical data and secure web-based messaging with nurse case managers; and (iv) access to an educational web site created for the project by the American Diabetes Association in English and Spanish and in regular and low-literacy versions in each language (30). Patients were able to upload data from home glucose and blood pressure monitoring via secure internet connection to the New York Presbyterian Data Repository.

Intervention subjects were assigned to a project case manager under supervision of diabetologists at the Joslin or Berrie Diabetes Centers (upstate and New York City subjects, respectively). Case managers interacted with patients using the home telemedicine unit and case management software that incorporated the Veterans Health Administration Clinical Practice Guidelines for the Management of Diabetes Mellitus in the Primary Care Setting. These guidelines are flexible, annotated, evidence-based and algorithmic in format. The primary care physicians of intervention patients retained full responsibility and control over their patients' care. The case managers' notes were reviewed by the supervising diabetologist, and when a change in management was suggested, the primary care physician was contacted by e-mail, fax, letter or phone.

Usual Care

Patients in the usual care group remained under the care of their primary care providers. These primary care providers cared for pa-

tients in both the intervention and usual care groups, following the design whereby randomization was clustered within clinical practice. The primary care providers received a mailing with current guidelines for the care of patients with diabetes. The clinical care that patients in the usual care group received was delivered by their primary care providers, without other guidance or direction from study personnel.

Endpoints

Prespecified endpoints were hemoglobin A1c, blood pressure and low-density-lipoprotein (LDL) cholesterol levels. Subjects were instructed to come to the baseline and follow-up examinations fasting and having held their glycemic control medications. For New York City subjects, all examination data were collected at Columbia University Medical Center. For Upstate subjects who could conveniently travel to Syracuse, these data were collected at the SUNY Upstate Medical University, while for those living too distant, examinations were performed in regional medical centers and medical offices. For subjects unable to travel, home visits were made by trained nurses. Blood pressure measurements and blood and urine samples were obtained in the fasting state in the morning. Methods for data collection were previously reported (23). Blood pressure values were communicated to participants at the time of the exam. Hemoglobin A1c and lipid levels at the baseline and follow-up exams were communicated by mail to participants and their primary care providers for both the intervention and control groups. Data collection for the one-year follow-up examination was completed on October 31, 2003.

Statistical Analysis

Analysis of covariance was used to adjust for baseline values of the outcomes and the design feature of clustering, with each primary care provider treated as a random effect. Additionally, the group heterogeneity in cluster and residual variances was modeled in order to satisfy model assumptions and improve model fit, using SAS PROC MIXED (26).

Results

The one-year follow-up examination was completed by 1,417 of the 1,665 randomized subjects (85.1%). Of the 248 subjects who did not complete the exam, 144 were assigned to intervention and 104 to usual care. Subjects who did not complete the one-year follow-up exam did not differ from those who did at the $P \leq 0.05$ level with respect to age,

sex, race/ethnicity, baseline levels of hemoglobin A1c, blood pressure and LDL-cholesterol.

The intervention and usual care groups did not differ with respect to baseline demographic and clinical characteristics. Mean age was approximately 71 years (median 70) in both groups. Subjects living in the New York City region were younger, more likely to be Hispanic and African American, have lower educational attainment and annual household income, to be eligible for Medicaid, to live alone and to respond "No" to the question "Do you know how to use a computer?" compared to subjects living in the Upstate region (Table 1).

At one year of follow-up, mean hemoglobin A1c level decreased in the intervention group from 7.35% to 6.97% (Table 2). The net adjusted reduction in hemoglobin A1c in the intervention group compared to the usual care group was 0.18% ($p = 0.006$), despite a reduction in the control group from 7.42% to 7.17% over this time. In the intervention subgroup with hemoglobin A1c $\geq$7% at baseline ($N = 353$), mean A1c level decreased from 8.35% to 7.42%, with net adjusted reduction of 0.32% ($p = 0.002$). For the study sample as a whole, mean systolic and diastolic blood pressure level decreased in the intervention group from 142/71 mmHg to 137/68 mmHg. The net adjusted reductions for systolic and diastolic blood pressure were 3.4 mmHg ($p = 0.001$) and 1.9 mmHg ($p < 0.001$). For total and LDL-cholesterol these net adjusted differences were 11.06 mg/dl and 9.5 mg/dl ($p < 0.001$ for both). Changes over one year in the control group in blood pressure and lipid levels were small. Mean LDL cholesterol level in the intervention group at one year was 95.7 mg/dl.

One-year follow-up results were also analyzed separately in the Upstate New York and New York City regions because of the baseline differences in subjects recruited in the two areas and also because of the potential for heterogeneity in the intervention, which was delivered to each of these two groups of subjects from a single diabetes center in Syracuse or New York City, respectively. The intervention effect was similar in magnitude in the two regions for each of the clinical outcomes (Table 3, Panels A and B).

A survey of participants ($N = 346$ intervention group respondents) using a 26-item questionnaire with a 5-point response scale showed satisfaction with various aspects of the intervention at a level of 4 or greater on all items (27). A telephone survey of primary care providers participating in the rural Upstate NY component of the project ($N = 116$ respondents) showed a generally high level of satisfaction with participation in the project (28).

TABLE 1
Baseline Characteristics of the Subjects (N = 1,665), by Region of Recruitment (Percentages Except Where Noted).

Characteristic	Site		P value
	New York City N = 775	Upstate New York N = 890	
Age at randomization (years)			0.042[a]
55–64	10.7	13.1	
65–69	37.0	30.6	
70–74	26.3	25.7	
75–79	18.3	17.4	
≥80	7.6	13.1	
Sex			<0.001[a]
Male	30.5	43.0	
Female	69.5	57.0	
Race/Ethnicity			<0.001[a]
African-American (non-Hispanic)	23.9	7.1	
Hispanic	74.1	1.3	
White (non-Hispanic)	1.0	91.5	
Other	0.9	0.1	
Born in the U.S.			<0.001[a]
Yes	22.2	95.8	
No	77.8	4.2	
Primary language			<0.001[a]
English	25.7	95.5	
Spanish	73.3	1.2	
Other	1.0	3.3	
Annual household income (dollars)			<0.001[a]
<5,000	4.8	2.9	
5,001–10,000	78.6	16.7	
10,001–20,000	10.6	33.1	
20,001–30,000	1.0	20.6	
30,001–40,000	0.0	7.5	
>40,000	0.5	9.7	
Data missing	4.5	9.4	
Eligible for Medicaid			<0.001[a]
Yes	67.4	14.5	
No	32.6	85.5	
Participant “knows how to use a computer”			<0.001[a]
Yes	5.4	32.7	
No	93.9	66.0	
Data missing	0.6	1.3	

[a] Analysis of variance or chi-square. [b] T test.

TABLE 2

Differences at one year of follow-up in clinical outcomes between intervention and usual care groups, adjusted for clustering and for group heterogeneity in cluster and residual variances. Adjusted difference score refers to the difference between intervention and usual care groups adjusted for the baseline value of the variable. Values in parenthesis are actual (unadjusted) differences. ANCOVA refers to analysis of covariance, used to compute a test statistic on the difference between groups at one year adjusted for the baseline value of the variable. Data are shown for subjects who completed the baseline and one-year follow-up examinations.

Outcome Variable	N's for Analysis		Baseline				T-test P-value	One-Year Follow-up				Adjusted Difference Score	ANCOVA P-value
	Usual Care	Intervention	Usual Care		Intervention			Usual Care		Intervention			
			Mean	SD	Mean	SD		Mean	SD	Mean	SD		
Hemoglobin A1c (%)	685	670	7.42	1.58	7.35	1.41	0.41	7.17	1.40	6.97	1.12	−0.18 (−0.20)	0.006
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	353	352	8.52	1.47	8.35	1.24	0.10	7.78	1.47	7.42	1.19	−0.32 (−0.36)	0.002
Systolic blood pressure (mmHg)	709	697	141.75	23.47	142.13	23.13	0.76	140.62	22.92	137.40	21.24	−3.42 (−3.22)	0.001
Diastolic blood pressure (mmHg)	709	697	70.91	10.47	71.42	11.21	0.37	70.05	11.05	68.44	9.91	−1.94 (−1.61)	<0.001
Total cholesterol (mg/dl)	679	666	184.89	38.56	182.89	37.27	0.33	182.64	41.72	170.70	35.52	−11.06 (−11.94)	<0.001
LDL cholesterol (mg/dl)	678	664	107.97	35.48	106.40	33.54	0.41	105.92	39.62	95.69	31.77	−9.50 (−10.23)	<0.001

TABLE 3

Analyses at one year of follow-up for Upstate New York and New York City subgroups separately, showing differences in clinical outcomes between intervention and usual care groups, adjusted for clustering and heterogeneity in cluster and residual variances. Adjusted difference score refers to the difference between intervention and control groups adjusted for the baseline value of the variable. Values in parenthesis are actual (unadjusted) differences. ANCOVA refers to analysis of covariance, used to compute a test statistic on the difference between groups at one year adjusted for the baseline value of the variable.

Panel A. Upstate New York.

Outcome Variable	N's for Analysis		Baseline				T-test P-value	One-Year Follow-up				Adjusted Difference Score	ANCOVA P-value
	Usual Care	Intervention	Usual Care		Intervention			Usual Care		Intervention			
			Mean	SD	Mean	SD		Mean	SD	Mean	SD		
Hemoglobin A1c (%)	339	338	7.01	1.22	7.05	1.25	0.65	6.87	1.25	6.75	0.92	−0.18 (−0.12)	0.03
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	148	154	8.05	1.09	8.05	1.17	1.00	7.51	1.36	7.14	0.97	−0.50 (−0.37)	0.001
Systolic blood pressure (mmHg)	362	364	142.12	22.86	142.13	22.96	1.00	139.87	23.98	135.97	21.51	−3.98 (−3.90)	0.006
Diastolic blood pressure (mmHg)	362	364	70.91	10.10	70.80	11.09	0.88	69.59	10.93	67.53	9.63	−2.13 (−2.06)	0.003
Total cholesterol (mg/dl)	337	338	186.55	38.72	185.75	38.23	0.79	179.31	42.10	169.57	36.01	−10.02 (−9.74)	0.001
LDL cholesterol (mg/dl)	336	336	108.60	35.98	108.42	34.30	0.95	101.62	38.04	95.04	30.90	−6.89 (−6.58)	0.01

Panel B. New York City.

Outcome Variable	N's for Analysis		Baseline				T-test P-value	One-Year Follow-up				Adjusted Difference Score	ANCOVA P-value
	Usual Care	Intervention	Usual Care		Intervention			Usual Care		Intervention			
			Mean	SD	Mean	SD		Mean	SD	Mean	SD		
Hemoglobin A1c (%)	346	332	7.82	1.77	7.66	1.50	0.19	7.45	1.49	7.19	1.26	−0.18 (−0.26)	0.06
Hemoglobin A1c (%) in subgroup with A1c ≥7% at baseline	205	198	8.86	1.61	8.59	1.25	0.06	7.98	1.52	7.64	1.30	−0.23 (−0.34)	0.10
Systolic blood pressure (mmHg)	347	333	141.37	24.11	142.12	23.34	0.68	141.40	21.77	138.96	20.87	−2.76 (−2.44)	0.06
Diastolic blood pressure (mmHg)	347	333	70.90	10.86	72.10	11.32	0.16	70.54	11.17	69.44	10.13	−1.73 (−1.10)	0.02
Total cholesterol	342	328	183.26	38.39	179.95	36.07	0.25	185.92	41.15	171.86	35.01	−12.23 (−14.06)	<0.001
LDL cholesterol (mg/dl)	342	328	107.35	35.03	104.34	32.66	0.25	110.14	40.72	96.34	32.67	−12.25 (−13.80)	<0.001

Comment

We found that diabetes case management delivered using telemedicine improved hemoglobin A1c, blood pressure and LDL cholesterol levels in older patients with diabetes mellitus at one year of follow-up, compared to usual care. The intervention effect on diabetes control was greater in the subgroup with hemoglobin A1c ≥7% at baseline, with an absolute change from 8.35% to 7.42% within the intervention group. We also found generally high satisfaction with participation in the project among both patients and their primary care providers.

The higher level of Medicare claims in the intervention group observed in preliminary analyses requires further dissection. One interpretation may be that study participants, all of whom were required by the study eligibility criteria to be resident in federally designated medically underserved areas, experienced greater awareness of their health care needs or had encouragement from their nurse case managers to seek needed care which they were not otherwise receiving.

Diabetes control in the usual care group, as measured by mean hemoglobin A1c level, improved over the one year of follow-up by 0.25% and in the subgroup with hemoglobin A1c ≥7.0% at baseline, by 0.74%. These improvements in the usual care group are consistent with secular trends in improved diabetes care nationally (29), spill-over effects of the intervention or both. Secular trends in diabetes care may have resulted from national educational and quality improvement programs (30,31), publication of standards of care (32) and recent availability of new classes of drugs (33). Spill-over effects may have occurred because all participating physicians received educational materials on diabetes management as well as communications from the study case managers regarding management of specific intervention patients. The study design randomized subjects within physician practices and most participating physicians managed patients in both the intervention and control groups.

The IDEATel project differs from prior studies in a number of ways. The most obvious difference is scale. The IDEATel results indicate that the benefits described in smaller studies can be delivered to large numbers of patients across broad geographic expanses and substantial sociodemographic diversity. To our knowledge, it is the first telemedicine study to report simultaneous improvements in HbA1c, blood pressure and lipids. The study is also unusual in that the recruitment process did not target patients with poor glycemic control, neither did it require computer experience or computer literacy for eligibility. As

such, we believe it may be more representative of the population at large. Unlike most other studies, IDEATel included large numbers of medically underserved and ethnic minority subjects. The IDEATel intervention spanned hundreds of independent practices. Most prior studies have utilized stand-alone systems. The IDEATel system demonstrates the feasibility of tight, standards-based integration between a remote case management system and a large electronic medical record and also the feasibility of data captured directly from home monitoring devices into a longitudinal, comprehensive EMR.

A number of obstacles remain to be overcome before the full potential of telemedicine can be brought to bear on the health care delivery system. Foremost among these is the cost of technology and personnel for effective case management. In addition, Medicare claims were greater in the intervention group compared to the usual care group during the one year of follow-up, a finding consistent with the fact that enrollment occurred only in federally designated medically underserved areas and with the inference that the intervention contacts increased needed utilization of health care services. The IDEATel study provides evidence that medical informatics and telemedicine technology can help to translate advances in treatment of chronic diseases into effective health care.

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DISCUSSION

Gotto, New York: Steve, very nice study and presentation. Do you have any data about the instance of hypoglycemia in the two groups, and is it possible that with better treatment you actually had more medical complications from hypoglycemia?

Shea, New York: I don't have data on hypoglycemia, because it's not so easy, with the patients living at home, to define a hypoglycemic event and to capture it. What we did do, Roberto Izquierdo who is a diabetologist at Syracuse, systematically collected a set of anecdotes of events that occurred during the study where the nurses were able to intervene, and it turns out that there were a whole series of medical events, not a large number, but they were critical medical events, of patients who had serious medical events at home who were able to call the nurses who, in turn, facilitated early intervention. There were no episodes of hypoglycemia in that compendium of events, but we can't be sure that that was fully ascertained. So, the potential for more intensive management here having led to greater hypoglycemia has to be accepted as a possibility, and I don't think we can address that fully.

Gotto: The education part of your program addressed what to do with hypoglycemia?

Shea: Yes, it did.

Colwell, Charleston: I would like to thank you for a very innovative approach to taking care of underserved people with diabetes. This has been a two year study with modest differences between the two groups. This was also shown, of course, in the UKPDS, a very long-term study; and with a long-term study, there tends to be an escape from glycemic regulation. I was wondering if you have any plans to carry this on beyond two years?

Shea: Well, we were continued. We are in a second phase, and we are collecting the data, and we haven't looked at them yet. So we hope to have more long-term data. We

also hope to have some harder outcome events, but we are underpowered. This is a huge study for telemedicine but small compared to UKDPS and other large studies where the harder outcomes are available. So we are going to collect the data, but we didn't prespecify that as an outcome, and we may not have the power to really do it.

Powe, Baltimore: Steve that was a very nice and important study. I had a couple of questions. One is, you alluded to that you had some insights about why the utilization. I imagine you have diagnostic data, diagnosis codes and claims data that you can look at, of what that utilization was more specifically for. So that's my first question is whether you are going to do that.

Shea: The answer is yes, and yes it's being done and yes it's widespread. It's not focused on one or two diagnostic codes.

Powe: The second is: I presume the payments don't include payments for medication. Is that true?

Shea: These are Medicare claims data limited only very slightly by fairly small numbers of Medicare HMO patients where there are no claims data. So this is virtually everybody, and Medicare, at that time, was not paying for medications and now only pays for them through HMOs where claims data are not useful. So that's correct, these are not medications.

Powe: Did you collect any data on medications used otherwise?

Shea: Yes, but I don't have that data for you.

Ludmerer, St. Louis: I just had an observation. At this presentation, and thank you for it, because it's a very important and very nice presentation. It certainly ties in with the presentations yesterday on education. Abraham Flexner didn't know this form of medical practice, and William Osler didn't practice in this fashion. I think it really underscores the urgencies of the papers that we had yesterday on education. The challenge to medical education is to keep up with changing times and for academic medical centers, not only to teach well, but to lead the changes in practice.

Shea: Thank you for that comment, and I couldn't agree more that we need to educate physicians for the future, and this is part of it.

Chan, Houston: I would like to point out that there have been studies on better follow up and control versus just conventional control, and in short-term studies like that, it's not surprising that the reimbursement and medical cost is actually higher. The question is what will happen long-term? So, it's been shown before, not for telemedicine, but just tighter control actually costs more money.

Rutherford, Dallas: I am wondering if this is the tip of the iceberg of opportunity in the following sense. Part of my work involves looking at the people who come through the front door with high hemoglobin A1c's. I wondered whether you had underserved patients who had sort of made contact with a doctor, and, therefore, they got into your system versus underserved patients who haven't had that contact; and I wonder if this is even a greater opportunity for help than we actually see in the data.

Shea: Well thank you for pointing that out, because it's a critical comment. To be in this study, you have to have Medicare, because the study is funded by CMS. They are only interested in Medicare beneficiaries. Fortunately, they care a lot about Medicare beneficiaries, and they are very interested in improving care. So your observation that the Medicare beneficiaries are in the healthcare system and have doctors is right. Also, in order to be in the study, you had to have a doctor, because we had to have a doctor to communicate with. So, I think that's why their baseline A1c levels were quite good. We know from many, many studies, that people who are not getting care at all are doing much worse, and that that population is complicated. They are uninsured; many have substance abuse problems; many of them have criminal problems; they have problems of living; they are very poor; they have

language gap problems; and they're disadvantaged socially in many ways outside the healthcare system, even if they have access on paper, and many of them don't even have that. There, the indicators of control are much worse, not only for A1c, but for blood pressure and lipids. So, if we are going to reach that population, we are going to have to take the next step.