PEER REVIEWED STUDY

DIABETES PROGRAM

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Diabetes Type 2 Program Outcomes

1.8pts reduction

as reviewed by

JOURNAL of MANAGED CARE MEDICINE

Patients participating in our Diabetes Type 2 Program saw a 1.8 point reduction in HbA1C across the entire population.*

*HbA1C improvement of 1.8 points within 6 months, and 3.3 points for those who completed the program to goal.

71% of hypertensive subset within BP targets within 6 months.

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Telehealth Program for Medicaid Patients with Type 2 Diabetes Lowers Hemoglobin A1c

Telehealth Program for Medicaid Patients with Type 2 Diabetes Lowers Hemoglobin A1c

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Summary

Diabetes telehealth research to date has provided minimal description of its clinical protocols, including strategies used to foster behavior change and procedures to deliver diabetes self-management education (DSME) and medical care. Also, there has been a focus on time-limited research interventions but little on working clinical programs. We describe here an effective diabetes telehealth program *(HouseCalls)* that serves an urban Medicaid population living with poorly-controlled type 2 diabetes (T2DM). We also discuss barriers to the future scalability and long-term sustainability of such programs that our health care system will need to overcome if we are to provide population-level telehealth solutions for the growing epidemic of T2DM.

Key Points

- T2DM affects 7.8 percent of the U.S. population, with only 7 percent of these individuals meeting the guidelines for control of hyperglycemia, hypertension, and dyslipidemia.
- *HouseCalls* uses a system of in-home remote monitoring devices- blood glucose (BG) meters and blood pressure (BP) monitors- that upload readings electronically to a secure website. A nurse-led team provides telephone support: rapid feedback regarding the remote monitoring data, self-care advice, education, and timely clinical follow-up.
- Data from 330 urban dwelling, T2DM Medicaid patients showed a clinically and statistically significant improvement in mean glycosylated hemoglobin (HbA1c) of -1.8 percent (SD = 2.2).
- Despite such positive outcomes, practical barriers exist that threaten the scalability and long-term financial viability of T2DM telehealth. Emerging models, including *HouseCalls*, provide evidence that telehealth can improve access and quality of care, and reduce health care costs.

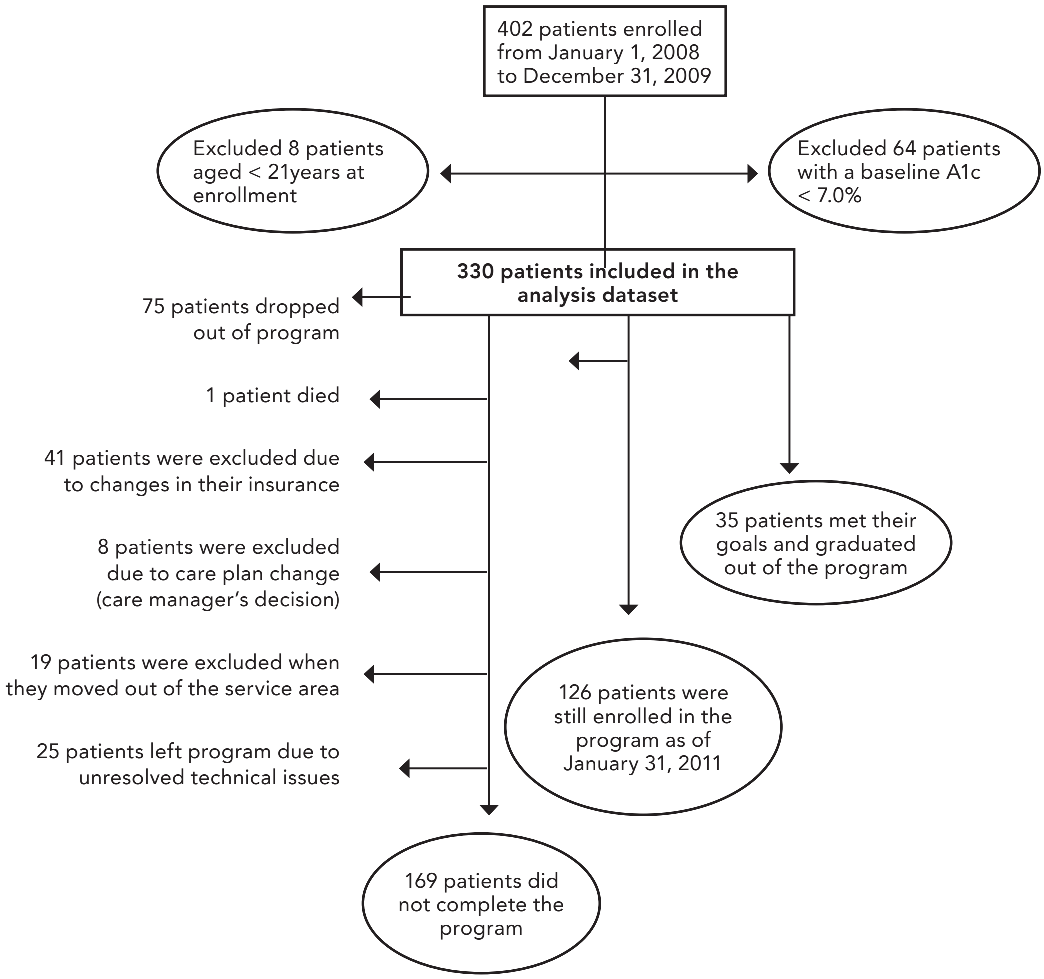
Introduction

LANDMARK STUDIES OF T2DM HAVE DEMonstrated significant clinical benefit from intensive management of elevated BG and BP.[1,2] However, there is a significant gap between evidence-based recommendations for T2DM and the medical care currently delivered. Only 7 percent of diabetes patients in the U.S. meet recommended goals: HbA1c less than 7 percent, BP <130/80 mmHg, and LDL <100 mg/dL. The percentage of patients receiving recommended annual screenings for early detection of diabetes-related changes in the eyes, kidneys, and feet remains suboptimal.[3]

From the patient's perspective, T2DM is a complex and demanding chronic illness.[4,5] Patients must initiate or modify many daily lifestyle behaviors to benefit from the treatment plan.[6] DSME, delivered in individual or group outpatient sessions, is the cornerstone of clinical support for behavior change.[6]

Telehealth has emerged as a patient-centered strategy for the delivery of DSME that leverages communication and information technologies to provide more timely and convenient support in the patient's home.[7] Remote patient monitoring (RPM) enables patients to monitor and transmit biometric data from home, including BG, BP and body weight. These monitors upload readings to a secure server by landline or cellular modem, and patients cannot alter or delete readings. Patients can answer questions about symptoms and self-care be-

Exhibit 1: Patient eligibility criteria and final sample size.



haviors via automated telephony or an LCD screen on the modem.

Telehealth nurses typically track trends and out-of-range readings using a web-based interface that provides decision support, automated alerts via email for severely out-of-range readings, and communication protocols to coordinate care with the primary care provider (PCP). Telephone support to the patient provides rapid feedback on RPM data patterns, self-care advice, education, and follow-up.

The literature documents a growing level of intervention complexity over the past 30 years, from simple BG uploads to more comprehensive monitoring and nurse support programs.[8] Patients report high satisfaction levels, but clinical findings are mixed.[9-14]

Recently, four large, well-designed trials have demonstrated improved outcomes and cost-effectiveness. The Diabetes Education and Telecare Demonstration project (IdeaTel) showed a reduction in mean HbA1c from 8.4 to 7.4 percent, with improvements in HbA1c, LDL-cholesterol and BP sustained over five years.[16]

In the VA Care Coordination Home Telehealth program, 445 T2DM veterans had a 50 percent decrease in hospitalizations, an 11 percent decrease in emergency room visits, and a significant improvement in three quality of life dimensions.[17] Baker and colleagues later reported cost reductions of 7.7 to 13.3 percent for Medicare patients with T2DM and other chronic conditions, using a telehealth program similar to that used by the VA.[17,18]

The United Kingdom's Department of Health Whole System Demonstrator program[19] is the largest clinical trial of telehealth conducted to date, involving 6,191 patients with diabetes, heart failure, and

Exhibit 2: Patient characteristics by follow-up status

Enrollment Status	n	Mean Age (SD)	% Female	Duration of Follow Up: Mean (SD)	Duration of Follow Up: Range	Base HbA1c Mean (SD)
Goals met (graduated)	35	52.9 (8.3)	62.9	16.8 (8.6)	3.4 - 33.5	9.7 (2.2)
Still in program	126	55.2 (8.6)	69.8	25.5 (6.5)	13.3 - 36.3	9.8 (1.9)
Excluded	94	56 (9.5)	67.0	10.1 (6.4)	0.3 - 27.4	9.8 (2.1)
Dropped out	75	52.4 (11.9)	65.3	8.5 (6.4)	0.4 - 26.4	10.1 (2.3)

Note: Groups do not differ in terms of age, gender distribution, or baseline HbA1c. Groups did differ significantly in terms of duration of follow up ($p<.001$)

chronic obstructive pulmonary disease. Outcomes included significant reductions in urgent visits and admissions, elective admissions and bed days, and a 45 percent reduction in mortality.

In contrast, the Medicare Health Support Pilot Program (MHSPP) examined eight disease management vendor programs for diabetes and/or heart failure and found only modest improvements in quality-of-care measures and no demonstrable reduction in costs of care.[20] Patients received health-coaching calls from nurses every 2.7 months (on average) and were given literature, videos, and Internet resources regarding their conditions. The poor results may reflect a lack of key program ingredients, including a need for frequent contact with patients, integration of disease management programs into the patient's routine medical care, and use of RPM strategies to activate and engage the patient for self-management behavior change.

One important weakness of diabetes telehealth research is the minimal description of the clinical protocols and procedures employed in telehealth interventions, including the behavior change techniques and telehealth protocols used by nurses to deliver DSME and clinical care. Studies to date have typically involved time-limited research-oriented interventions in which clinical care is paid for by research funding. Discussion of program scalability and long-term financial viability is largely absent. This issue is critical, as most public payers and commercial health plans do not currently cover telehealth.[21] Some hospital-based diabetes telehealth programs are partly integrated into local clinical care networks and have service contracts in place with local health plans. Often these programs are not reported in the telehealth literature, but insights obtained from them could inform research in this area.

To address this gap, we describe an established diabetes telehealth program that has been in place since 2006, including details of its clinical procedures and protocols, and we discuss barriers to its scalability and long-term sustainability that must be overcome if our health care system is to provide a realistic solution for the growing T2DM epidemic.

Methods

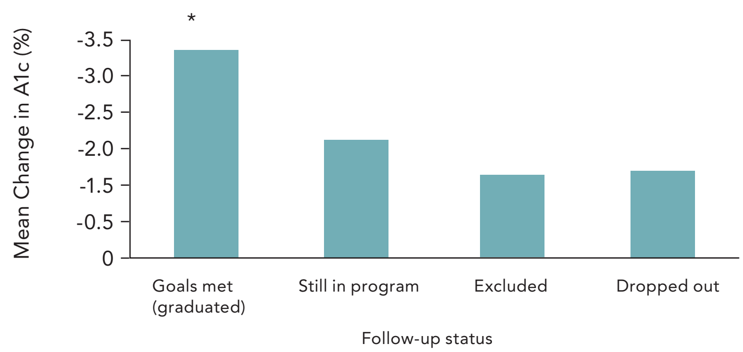
Description of *HouseCalls*, the Diabetes Telehealth Program

New York City Health and Hospitals Corporation (HHC) is one of the largest hospital and health systems in the country, serving 1.3 million people including 400,000 uninsured. The prevalence of diabetes is estimated at 12.5 percent, and of those, 59 percent are African American or Hispanic.[22] In 2006, HHC initiated the *HouseCalls* diabetes telehealth program in collaboration with MetroPlus, HHC's Medicaid health plan.

Patients were referred to the program based on poorly-controlled T2DM (HbA1c > 7 percent in the previous three to six months) and, optionally, a history of diabetes-related emergency department and unscheduled office or clinic visits, hospital or home care admissions, and inconsistent follow-up care. Clinical staff from 17 HHC facilities referred patients to the program. PCPs communicated individualized treatment plans to the telehealth nurses, including high and low BG parameters for RPM alerts. The telehealth nurses provided weekly telephone education and counseling based on the patients prescribed treatment plan. The telehealth nurses had no face-to-face contact with the patients.

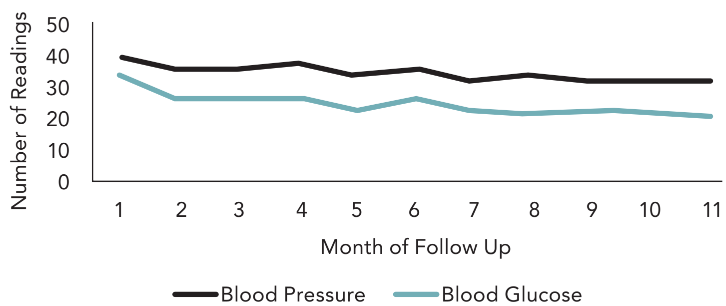
Patients were given a BG monitor (LifeScan One Touch Ultra®) connected to a landline telemonitoring modem (AMC Health®) to use at home. Patients with hypertension were also given a digital auto-inflate BP monitor (A&D Medical 767PC®) for transmission of BP data via the same telemonitoring modem. After taking readings, the patient pressed a button on the modem to transmit the readings to the program's secure website. In recent years, a cel-

Exhibit 3: Mean change in HbA1c by patient follow-up status.



* Change (improvement) in HbA1c was significantly larger in those patients who graduated from the program as compared to the other groups ($p<0.001$).

Exhibit 4: Mean number of blood pressure and blood glucose readings by month in telehealth program.



lular modem was provided if patients did not have a landline telephone. A technician from the RPM vendor installed the modem in the patient's home, trained the patient to use the equipment, and provided telephone-based or in-home technical support, as needed.

Nurses reviewed BG and BP data on the RPM vendor's secure website. The protocol set a red (high) alert for BG and BP values greater than 20 percent above or below parameters preset by the patient's PCP. High alerts prompted a nurse response call within two hours of notification between 6 a.m. and 5 p.m. weekdays. Patients were instructed to call 911 emergency services or report to the nearest emergency room for any physical distress, falls, severe dizziness or lightheadedness not relieved by rapid-acting glucose. Nurses reviewed yellow alerts (BG and BP readings above or below the normal range but not in the alert range) with follow-up as needed. Daily reports listed patients who had not transmitted RPM data for 24 hours.

Telehealth nurses used the secure *HouseCalls* website to track and manage patients' status, document care plans, and record communication with PCPs. DSME support focused on insulin titration, medication adherence, appointment reminders and problem solving skills training. Use of the American Diabetes Educators (AADE-7) behavior change guidelines was enhanced by use of open questions in telephone discussions with reflections and brief summaries to help patients explore barriers to self-care (BG monitoring, diet, medication adherence and physical activity). Rapport, coaching, and feedback were used to improve patient-provider communication and strengthen patient motivation and engagement with self-management, while the immediate response to patient alerts helped patients make accurate connections between their behaviors and their out-of-range readings. Patients received weekly 10-20-minute phone calls from their nurse, with regular motivational discussions of DSME goals and problem solving. Additional calls were made in response to significant hypoglycemia, hyperglycemia, or hypertension. All communications were HIPPAA/HITECH compliant.

The patients' PCPs received BG and BP RPM results for the prior 30-60 days via secure email before scheduled appointments. Telehealth nurses provided coordination of care and decision support for PCPs, endocrinologists, nurse practitioners, physician assistants, chronic care coordinators and home health agency clinicians by phone, email and fax.

Patients could request discharge from the program at any time and could be discharged: (1) at the request of their PCP; (2) for non-adherence to the program protocol; (3) for loss of home telephone service; (4) for abusive behavior to program staff; (5) for disenrollment from the managed care plan; or (6) because the patient had achieved program goals (i.e., HbA1c less than 7 percent, BP<130/80 mmHg). Discharge from the program for goal achievement was a three-step process, with PCP approval. Step 1 was reached when the BG level was predominantly <135 mg/dL for three months or HbA1c progressively decreased to less than 8 percent for three consecutive readings. At this stage, DSME calls were reduced from weekly (plus as-needed calls) to every two weeks (plus as-needed calls). Step 2 was achieved with HbA1c trending down and with typical BG readings of 80-120 mg/dL. Discharge (Step 3) was achieved when HbA1c was below 7 percent for three months. Patients, PCPs, and the managed care company were then notified. The program was reimbursed by the health plan at a negotiated monthly rate of $10 per patient per day.

Data Collection and Statistical Analysis

Data analyses were conducted with SAS 9.2© (SAS Institute Inc.). Age and gender, as well as repeated measures of systolic and diastolic BP and HbA1c, were collected from patients who were enrolled in *HouseCalls* from January 1, 2008 through December 31, 2009. Patients were excluded if they were less than 21 years of age at enrollment or had a baseline HbA1c less than 7 percent (Exhibit 1). All data were stripped of patient identifiers and analyzed to identify trends and to test for significant changes among variables.

For this analysis, patients were divided into four groups: (1) Still Enrolled (patients still in the program at the end of the follow-up period, n=126;(2) Graduates (patients who were disenrolled after meeting and maintaining program goals, n=35); (3) Discharged (patients who were no longer members of the health plan, no longer had a land-line telephone or were otherwise unable to participate in the program, n=94); and(4) Dropouts (patients who voluntarily left the program without reaching goal, n= 75). Analyses were also conducted based on two aggregates in which Graduates and Still Enrolled patients (Successful) were compared to Dropouts and Discharged patients (Unsuccessful). Analysis of variance was used to test for differences in age, duration in program, and baseline HbA1c across these groups, and the chi-square test was used to test for differences in gender. Change in HbA1c was calculated by comparing baseline HbA1c levels to levels obtained at the end of follow-up (i.e., graduation from program, time of discharge/dropout, or most recent value for those still enrolled at the end of follow-up). Paired t-tests were used to test whether changes in HbA1c were significant.

Adherence to the program was measured using BG and BP RPM data. Frequency of BG and BP measurements was recorded and averaged by month. Mean BP over time was collected for patients who were hypertensive at baseline and was analyzed for Successful vs. Unsuccessful, using a repeated measures analysis of variance. BMDP program 5V[23] was used for the analysis, with month of measurement used as the within (repeated) factor. This allows for an unbalanced design in which each subject is not measured on each occasion. It also allows for various covariance structures.[24] Compound symmetry was used as the covariance structure. Linear contrasts determined whether there was a linear change in BP over time. Wald's test was used to test these hypotheses. A maximum likelihood procedure using the Newton-Raphson algorithm was used to obtain estimates of the regression and covariance parameters.[25]

Results

Data were available for a total of 330 patients who met the inclusion criteria (Exhibit 1). Mean age (SD) at enrollment was 54.0 (9.7) years and 67 percent of patients were female. Follow-up duration differed significantly among groups ($p<0.001$): Dropouts and Discharged had the shortest duration (8.5 and 10.1 months, respectively), while patients who successfully completed the program did so in an average of 16.8 months (Exhibit 2).

The four groups did not differ at baseline in terms of gender ($p=0.83$) or mean HbA1c ($p=0.68$) (Exhibit 2). Groups differed in age ($p=0.06$) but the differences do not appear to be clinically significant (Exhibit 2).

We used an intention-to-treat analysis, and the primary outcome, mean change in HbA1c for the entire population, was -1.8 percent (SD: 2.2),

($p<0.001$) a clinically significant improvement. Graduates had larger reductions in HbA1c than Still Enrolled, Discharged and Dropouts ($p < 0.001$) (Exhibit 3). In the last three groups, there were no significant differences in change in HbA1c. The Successful patients had a larger reduction in HbA1c than the Unsuccessful patients (-2.2 percent vs. -1.4 percent, respectively; $p = 0.002$).

Enrolled patients were adherent to the program, as demonstrated by their regular measurements of BG and BP. At baseline, the average number of BG readings per month was 38.2 (SD: 27.3), while at 12 months the average was 34.1 (28.0) (Exhibit 4). Among patients with hypertension at baseline (n=253) the average number of BP readings was 32.7 (20.3) at baseline, while at 12 months the average was 20.2 (16.5).

Among patients who were hypertensive at baseline, there was a significant reduction in mean systolic BP over time for the first 12 months for all participants combined (Chi-sq=40.2, df=11, $p<0.0001$). There was no significant difference between groups (Successful vs. Unsuccessful) in terms of trends in systolic BP over time ($p=0.88$). Results were similar for diastolic BP, such that there was a similar significant reduction in diastolic BP over time for all subjects combined (Chi-sq=67.7, df=11, $p<0.001$), but there was no difference between groups in terms of reduction in diastolic BP over time.

Discussion

The mean change in HbA1c among all patients enrolled in the *HouseCalls* program was both statistically and clinically significant. Overall, patients enrolled in the program saw a 1.8 percent reduction in HbA1c. To put these clinical findings in perspective, the landmark T2DM United Kingdom Prospective Diabetes Study showed that a 1 percent reduction of HbA1c was associated with a 35 percent reduction in macrovascular endpoints, an 18 percent reduction in myocardial infarction, and a 17 percent reduction in all-cause mortality.[2] It was notable that even patients withdrawing early from the program (as a result of loss of phone service or insurance or personal decision not to participate) received 8.5 to 10 months of treatment and achieved significant clinical benefit in BG control (mean change in HbA1c: -1.4 percent).

We examined the pattern of patient participation in the program as well as the reasons for discontinuing participation. Patients who were actively engaged demonstrated sustained participation in regular self-management tracking behaviors (i.e., measurement of BG and BP) with an average of 32 to 37 BG measurements per month during their first year in the program. Patients also consistently took part in weekly nurse-led DSME sessions delivered by phone over a 12-month period. Of the 330 patients included in this analysis, approximately half dropped out or were excluded before meeting the program goals. Patients could drop out actively, or dropout could be inferred through non-compliance (i.e., patient stopped taking RPM readings or responding to telehealth nurses). Reasons for exclusion are detailed in Exhibit 1, and included moving out of the service area, changes in insurance coverage, and unresolved technical issues.

Given the impressive improvements in HbA1c observed in this population, future refinements could focus on retention to further improve outcomes for the subset of patients who do not complete the program. For example, cellular RPM technology could be provided for patients who have no landline telephone for data upload. Additionally, voluntary dropouts could trigger an automatic nurse outreach to provide education and feedback to the patient on the value of the program in an attempt to ensure that the patient makes an informed decision.

The *HouseCalls* program is an integral part of the HHC healthcare system and as such, the telehealth team (nurses and physicians) has access to the local clinical informatics network and implements the treatment plan provided and documented in the patient's electronic medical record by the PCP. Disappointing findings from a recent evaluation of commercial disease management telehealth programs suggested that clinical integration and the use of RPM to engage patients and track vital signs, neither of which were part of the programs that were evaluated, may be key ingredients of successful telehealth programs. Further research is needed to examine the effect of these components.

The economic sustainability of nurse-led telehealth programs remains a significant challenge as numerous barriers limit their scalability, including technology interoperability, institutional program support, Federal regulations, and low patient and provider awareness.[26-28] A further significant barrier concerns the lack of program reimbursement by Medicare, Medicaid and most private insurance companies in the U.S. By contrast, the *HouseCalls* program has been sustained since 2006 by a local service contract negotiated with HHC's own health plan to provide diabetes care for high-risk members. This contract was instituted as part of a citywide public health initiative targeting T2DM. Given this political context around the birth of the *HouseCalls* program, the clinical outcomes reported here provide important evidence that the city initiative of providing nurse-led telephone support to patients participating in this program has improved care outcomes and that these improvements may be sustainable as a result of cost savings related to preventable emergency room visits and hospital stays. The *HouseCalls* program costs $300/month, Medicare home health services cost approximately $41/day over a typical 60 day episode of care, whereas skilled nursing facilities cost $358/day and a hospital stay costs $1805/day.

Nationally, the U.S. lacks a coherent public and private telehealth policy, and reimbursement to support telehealth is lacking.[27] Reimbursement reform should provide not only payment for nurse-led telephone-based diabetes care that is equivalent to face-to-face visits, but also payment for program development, and the installation and maintenance of RPM systems.[27] It is helpful to learn from other systems that have embraced telehealth as part of their chronic care management plan and now provide reimbursement for fast growing telehealth programs as part of broader communication and information health care strategies. For example, the VA managed 31,000 chronically ill patients in 2010 using telehealth applications and plans to have 92,000 patients enrolled by 2012 for programs targeting diabetes, heart failure, and mental health medical conditions. The reimbursement is funded through U.S. Congressional approval of a $163 million VA telehealth budget included within the larger national Department of Defense budget. The UK Department of Health is planning to provide telehealth over the next five years to three million high risk patients with diabetes, heart failure, and pulmonary disease following the success of its recent large clinical trial.[27]

While these large scale programs being developed by the U.S. VA and UK Department of Health may provide some impetus for change in the U.S., a more potent influence may be the current U.S. health care reforms, including the introduction of the Patient Centered Medical Home (PCMH) model that links coordinated networks of health care providers, Accountable Care Organizations, (ACOs) that link reimbursement to clinical outcomes, and other emerging models of payment that have financial incentives aligned with better clinical care. Importantly, these changes will support a transition from a volume-based, fee-for-service payment system to a risk-based payment system tied to clinical outcomes and efficiency.[27] One specific recommendation within the PCMH model is the use of telehealth with a provider-led team model that may include greater use of nurses, community health workers (CHWs) and patient caregivers to support patient self-management at lower cost. Future refinements of the *HouseCalls* program could include a broadening of the telehealth care team to include trained CHWs and patient family supports that also monitor, educate, and motivate the patient and improve outcomes and quality of life.

In summary, the results from the *HouseCalls* program showed improved patient outcomes, access to care and care quality, while potentially reducing the health care cost for a population of urban dwelling patients with T2DM. The details of clinical protocols and procedures utilized were shared along with identified strategies to improve the program by promoting increased engagement of the participants that dropped out and by exploring the addition of support systems. Although most health care payers in the U.S. have been reluctant to fund programs such as *HouseCalls* due to skepticism about their effectiveness and a general cutting back of all ‘non-essential’ health care services, PCMHs and ACOs may be a promising new care model that will support telehealth and more patient-centered care while improving access and quality, and reducing costs.

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