Grant Final Report

Grant ID: 1R18HS017855

Longitudinal Telephony & Multiple Disease Management System to Improve Ambulatory Care for Complex Patients

Inclusive Project Dates: 09/30/08 – 06/30/13

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Submitted to:
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Abstract

Purpose: To assess the effectiveness of Telephone-Linked Care for Complex Patients (TLC-C), an automated telephony system, in patients with multiple chronic diseases. The objective is to reduce preventable hospital utilization and improve quality of life. TLC-C monitors patients between their ambulatory care visits, detects and notifies clinicians about important clinical events and promotes patient self-care. Data collected through TLC-C are integrated into the patients' electronic health record (EHR).

Scope: Patients with multiple chronic diseases especially those with frequent hospitalizations and ER visits are a sub-group of the patient population where improved methods of clinical management are in great demand.

Methods: A multi-method study: a 2-arm randomized RCT of TLC-C versus usual care and three qualitative evaluations (a summative and a longitudinal evaluation of patients' views and a summative evaluation of physicians' impressions). A total of 245 patients enrolled in the study (control=126, intervention=119) followed for 6 months. Primary outcomes: unplanned hospitalizations and ED visits. Secondary outcomes included patient quality of life, satisfaction, and ambulatory appointment show rate.

Results: There was no significant difference between TLC-C and control subjects on primary outcome (hospital event (65.9% Control vs. 61.3% TLC-C, p=0.461), or in the mean number of hospital events (mean (sd) 2.1 (3.0) Control vs. 2.2 (3.4) for TLC-C, p=0.795 by Poisson regression). Separate analyses of hospitalizations and ER visits also showed no significant differences in the percent with any hospitalization (43.7% of Controls, 42.9% of TLC-C, p=0.900) or with any ER visit (49.2% of Controls, 41.2% of TLC-C, p-0.207).

Key Words: chronic disease management; health technology; complex patients

Final Report

Purpose

The aim of this study is to assess the effectiveness of an innovative technology, Telephone-Linked Care for Complex Patients (TLC-C), in the care of patients with complex health care needs defined as patients with multiple chronic diseases who have increased health-care utilization and other socio-economic vulnerabilities, frequently transitioning from inpatient to ambulatory care. The objectives are to prevent hospital utilization; improve quality of life, and increase satisfaction with ambulatory care.

Scope

Background & Context

Patients with multiple chronic diseases of moderate or greater severity represent a sub-group of the patient population where improved methods of clinical management are in great demand. This is especially true of the subset of these patients who have had frequent hospitalizations and emergency department visits which are markers of disease severity and liability, inadequate health care delivery, patient self-care failure, and other personal, social, medical and health care system inadequacies.

Settings & Participants

The settings for this study include the primary care and family medicine practices at Boston Medical Center, a 496-bed academic medical center located in Boston's historic South End. The hospital is the primary teaching affiliate for Boston University School of Medicine. The study targets Complex Patients, i.e., those with multiple chronic diseases who frequently transitioning from inpatient to ambulatory care.

Incidence & Prevalence

Patients with chronic medical conditions consume the majority of our medical resources and those with more chronic conditions consume even more. For example, the odds of incurring an inpatient admission were 7.5 times greater among aged Medicare beneficiaries with 1 chronic condition and 98.5 times greater among beneficiaries with 4 or more types of chronic conditions in comparison to their peers without a chronic condition; individuals with 2 or more types of chronic conditions represented 65% of aged Medicare beneficiaries, but consume 95% of Medicare expenditures; and 24.1% of aged beneficiaries have 4 or more chronic conditions with a mean per capita expenditure of $13,973, compared to $5,015 for all aged Medicare

beneficiaries.[1] Patients with certain chronic illnesses are especially at risk. For example, Lee *et al.*[2] found that dyads of chronic conditions in a VA population of diabetes mellitus (DM) and chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD), dementia and hypertension (HTN), COPD and HTN, depression and COPD, and DM and IHD had 5 year age adjusted mortality rates greater than 10% in a population were the overall rate was 7.1%. Patients with multiple chronic diseases of moderate or greater severity represent a sub-group of the patient population where improved methods of clinical management are in great demand. This is especially true of the subset of these patients who have had frequent hospitalizations and emergency department visits which are markers of disease severity and liability, inadequate health care delivery, patient self-care failure, and other personal, social, medical and health care system inadequacies. It is well known that ambulatory care is mostly episodic whereas the chronic health conditions being treated are constantly present for the patients and may change at any time.

Methods

Study Design

The study was a multi-method evaluation (quantitative and qualitative) and included a two-arm randomized clinical trial of TLC-C versus usual care. The qualitative evaluation consisted of in-depth interviews (summative and longitudinal) with patients and providers. Patients were recruited and signed informed consent in the hospital and were randomized to the intervention or control groups at that time. Upon randomization data were collected at baseline (index hospitalization) and subsequently at 3 and 6 months. The RCT recruited 245 subjects who were randomized (control=126, intervention= 119) and enrolled in the study.

Data source/Collection

Data were collected by interview at baseline (index hospitalization) and 3 and 6 months by human telephone interviewers. Data collection for eligibility determination was obtained from Boston Medical Center's databases supplemented by brief interviews by the research staff. Medical diagnosis information, including co-morbidities were obtained from the hospital EMR system. Socio-demographic data were obtained from BMC databases supplemented by brief interviews by the research staff during enrollment. The PHQ-9 for depression and the REALM for health literacy were administered during enrollment. The primary outcome was 'hospital events' defined as unscheduled hospitalizations and emergency department (ED) visits that were collected from BMC databases. We used study participants' self-report of hospital events at other hospitals. Secondary outcomes included participants' perceptions of their relationship with their physicians (AURA administered at T0 and T6), the degree of their confidence taking their medication (SEAMS administered at T0 and T6), quality-of-life (EQ-5D- quality of life instrument administered at T0 and T6), TLC use satisfaction (administered at T6), and ambulatory appointment show rate (BMC EMR). The qualitative evaluation included a

summative and a longitudinal component as well as in-depth exploration of the providers' opinions about the TLC-C system.

Inclusion Criteria

The inclusion criteria were used to include both RCT and qualitative evaluation participants. Patients were eligible to enter the RCT if they were: (1) 18 years or older; (2) on one of BMC's general medical services with an unscheduled hospitalization; (3) under the care of a primary care provider in the BMC GIM practice or Family Medicine practice, or were willing to be assigned a PCP at BMC GIM or Family Medicine practice upon discharge; (4) once discharged, planning to continue their primary care at BMC for the next 6 months; (5) able to communicate in English adequately.

Exclusion criteria

The exclusion criteria were used to exclude both RCT and qualitative evaluation participants. Patients were excluded from the study if they were: (1) admitted from hospice, nursing home or another institutional setting; (2) in police custody or had a suicide sitter; (3) not able to use a telephone unassisted or did not have regular access to either a land line or cellular telephone for the six-month duration of the study; (4) unwilling to accept calls to their phone for the next 6 months; (5) currently enrolled in this study or in the RED-Lit trial; (6) unable to independently consent to participate; (7) ill with sickle cell anemia; (8) suicidal as determined by the PHQ-9.

Patient-Subject Identification

All patients admitted to two specified inpatient general medical services at Boston Medical Center (BMC) were evaluated for study enrollment from August 16th, 2010 to June 15th, 2012. Each weekday morning, the research assistant (RA) used the BMC centralized registration system to identify all patients admitted to the general medical service in the last 24 hours who met inclusion criteria #1 and exclusion criterion #5. The study staff created a randomly ordered list of the names and room locations of the potentially eligible patients, which established the order in which the RA approached the patients for enrollment. Subsequently, the RA contacted an inpatient clinician whom the patient knew. Next, the RA would ask the clinician if potentially eligible patients met inclusion criteria #1-4 and #7 and exclusion criteria #1-2. If the patient appeared to be eligible so far, then the RA would ask the clinician for an introduction to the patient. Once introduced to a given patient and if the patient agreed to speak with the RA then, the RA: 1) discussed the study, 2) asked whether the patient was interested and if yes, 3) evaluated the remaining inclusion and exclusion criteria. If eligible, all IRB safeguards were discussed and an informed consent document (ICF) was described and subsequently read by the patient. Once the ICF was signed, the RA obtained permission for a medical record review as well as contact information from the patient. Finally, baseline demographic data were collected and study instruments were administered followed by random assignment to the TLC-C group or to a control group.

The RCT Randomization Process

Using a random numbers table, Dr. Heeren, the study's statistician, prepared and numbered a set of sealed study allocation envelopes prior to study start-up for enrolled patients. Once the patient was enrolled, the next envelope was opened and the patient assigned to one of the two study groups. This proceeded in blocks of 6 and 8, randomly assorted.

Intervention

Telephone-Linked-Care or TLC was developed by the Medical Information Systems Unit (MISU) at Boston Medical Center/Boston University Medical Campus. Previous studies of the TLC system have demonstrated statistically and clinically significant effects on disease control and on the frequency of acute clinical events and urgent/emergent health care episodes.[3-8] TLC assists with the delivery of care to chronically ill during the high risk transitions in care from acute hospital inpatient and emergency care services to ambulatory care. TLC can also address disease exacerbation by detecting clinical deterioration and by educating the patient and notifying the responsible clinician(s). TLC-Complex Patients (TLC-C) system used in this study utilized a conversational computer telephony to monitor patients' medication adherence and their adherence to their clinical office visits with their physicians. The system notified clinicians of important clinical problems such as medication and clinical office visit non-adherence. It also promoted patient self-care management, encouraged scheduled medical visit appointment attendance and patient preparation for ambulatory care visits. TLC-C utilized information reported by patients during the interaction and clinical information about the patients that reside in their providers' clinical data repositories, primarily sourced from electronic health records (EHR) and ambulatory care scheduling systems.

Measures

See Section 4.2.

Limitations

Subject enrollment difficulties and subjects' non-adherence to the TLC-C utilization protocol were the two significant limitations of this study. Recruitment of subjects began during the third quarter of 2010. However, the yields on eligible study subjects were substantially below those realized in our prior projects with similar study subjects using similar recruitment methods and eligibility requirement. To remedy this situation, we conducted direct observation reviews of the research assistants who approached and engaged potentially eligible study subjects in the hospital for recruitment into the study. These reviews demonstrated that the RAs were performing well. Nonetheless, we instituted a number of small design changes to improve recruitment, e.g., how the RAs presented the study to the potentially eligible patients. We also received IRB permission to recruit study subjects in all four inpatient general medical services at Boston Medical Center instead of the planned primary care and family medicine services. However, since recruitment yields remained low we expanded the inclusion criteria to allow recruitment of subject with one (rather than multiple) chronic disease (IRB approval received on 11/03/2010). Since this did not improve recruitment we eliminated the requirement of hospitalization due to any specific chronic disease (IRB approved on 12/22/2010). These changes finally improved recruitment and subject enrollment. However, as enrollment and randomization progressed further we realized that the rate of TLC-C utilization was significantly low among the subjects in the intervention group. As a result, we began calling subjects prior to their first TLC-C intervention call to remind them of their impending calls to the TLC-C system

thus encouraging and promoting utilization. Yet, this did not seem to have had significant impact. As a result, we established an incentive mechanism for intervention participants to encourage and enhance utilization. This incentive mechanism (approved by IRB on 5/26/2011) was establishment of a "lottery" with one "entry" for each time any participant used the TLC-C system (maximum of four entries per month). Each month, there was a random drawing and a prize of $500 in gift cards was awarded to the winner. This proved to be somewhat effective and the TLC-C utilization improved but it never piqued to the point at which all intervention group participants were using the system as suggested by the study protocol.

Results

Principal Findings & Outcomes

RCT Study Sample

We compared participants' demographic characteristics who were randomized to TLC-C with those in the control group. Overall the average age was 52.6 years, the ethnic make up w was largely black (59%) 60% with high school education or less. Only 23% of the sample was employed full time, with 31% disabled and 18% retired. The sample had relatively low literacy levels, with only 53% having a Realm Literacy Score greater than 60. There was a higher percent of females in the control group (66%) versus the intervention group (53%) and a lower mean Realm Literacy score for participants in the TLC-C group (means of 48.7 in control, 40.2 in TLC-C). There were no significant differences between the two study groups on race, education, employment, or marital status.

Qualitative Evaluations Samples; 1) the Patients-Subjects' Summative Qualitative Evaluation, 2) the Patients-Subjects' Longitudinal Qualitative Evaluation, 3) the Providers' Qualitative Evaluation

We conducted three separate qualitative evaluations in this project.

(1) A summative qualitative evaluation that explored the experience and perceptions of a sample of the study participants in the intervention arm upon completion of the study. The summative qualitative evaluation sample (n=27) was drawn from the pool of the RCT participants upon their completion of the study. All participants in the intervention arm who completed the RCT were contacted and those who accepted were interviewed (12 men, 15 women). The ethnic composition of the individuals who participated in the summative qualitative evaluation (20 Black, 4 Caucasian, 2 multi-race, and 1 other) to a large extent reflected that of the larger study population. The range of the system utilization among the interviewees was 1-26; with an average value of 9.62.

(2) A longitudinal qualitative evaluation that was a multiple-contact study of a separately recruited cohort of patients who used the TLC-C system and were interviewed 4 times over a six-month period. The Longitudinal study sample (n=10) was also recruited from Boston Medical Center's patient population who met the RCT's inclusion and exclusion criteria. The longitudinal qualitative evaluation study participants (8 African-American

females, 1 Hispanic male and 1 Caucasian male) were individuals with recent hospitalization at BMC. All longitudinal study participants signed informed consent forms specifically designed for the longitudinal study and approved by the IRB. Of the 10 longitudinal study participants, 3 were lost to follow-up after the initial meeting with the study staff as our subsequent repeated attempts to contact them failed. The fourth participant began the study by using the TLC-C system; however we soon learned that unfortunately the patient lacked sufficient dexterity to use the system and finally the patient withdrew. As a result, six individuals remained who used the system and were interviewed. However, one of the six was dropped by the study staff after two interviews as he did not qualify for the study any longer based on the exclusion criteria #2. We were able to conduct the complete set of four interviews with the remaining 5 study participants.

(3) A study of the physicians' opinions about their patients' participation in the study and their reflections with regards to such technologies as TLC-C. We interviewed 5 physicians (2 females [Asian and Caucasian]; 3 males [2 Caucasian, 1 Hispanic]). To be eligible, physicians were required to: 1) be a primary care or Family physician at BMC; and 2) have two or more patients participating in the intervention arm of the RCT. A total of 12 physicians met these criteria but only 5 responded to our interview request.

RCT Analytical Methods

We utilized an intent-to-treat approach to the analysis, in that all subjects were included in the analyses regardless of their level of compliance with their assigned intervention (TLC-C or control) and their availability for follow-up assessment. Our primary outcome of hospital events (ED visits and unplanned hospitalizations) was determined from the medical record and was available for all patients regardless of whether they are interviewed at 3 and 6 months. Quality of life measure was obtained through interviews at 3 and 6 months. We performed both last-value-carried-forward analyses and, if warranted, multiple imputation analyses, to include all randomized subjects in our intent-to-treat analyses. Participants randomized to TLC-C and control groups were compared at baseline on demographic variables including minority status and health literacy, diagnoses through the two-sample t-test for measurement variables and the Chi-square test of independence for categorical variables. For the primary outcome of hospital events (unscheduled hospitalizations plus ED visits), we compared the two study groups on time to first hospital event through Kaplan-Meier survival methods and the log-rank test. Cox proportional hazards regression also compared the two study groups on time to first hospital event controlling for baseline demographic, health status, and diagnostic data. Furthermore, we compared the rate of hospital events per person month over the 6 months of follow-up between the two study groups through Poisson regression. We checked the variance assumption of the Poisson model, and accounted for over-dispersion or under-dispersion as appropriate. Baseline demographic, health status, and diagnostic data was included in these Poisson regression models to control for patient characteristics when comparing the two treatment groups. The TLC-C and control groups were also compared on the secondary outcomes of patient satisfaction with their health care and provider measured through the show rate for scheduled ambulatory care office visits, and quality of life measured by the EQ-5D.

Qualitative Evaluations Analytical Methods

The analytical methods used to process the interview data were standard qualitative research methods which, in the case of the summative qualitative evaluation, included both content analysis and narrative analysis. Content analysis allows the analyst to establish the existence and frequency of certain concepts or constructs in the qualitative data. Narrative analysis on the other hand explores the relationship between concepts already identified and thus provides a more meaningful and deeper understanding of different dimensions of the data. To conduct the former, several concepts or constructs were identified and subsequently the frequency of their occurrence in the transcripts was examined. On the other hand, to conduct the narrative analysis, we followed the following methods: a) Data Organization: the process of summarizing the collected information;[9] b) Coding and category generation: attaching meaningful labels to data collected in order to make the data manageable. In this stage, data is deconstructed into segments and coded accordingly;[9-10] c) Category and theme generation: identification of salient themes, recurring ideas or concepts and patterns of belief that links interviewees and meaningful concepts together. In this stage, the codes are integrated to what may be called concepts or constructs. As coding progresses, the scheme is refined through addition, collapse and redefining of categories and themes by further examination of the data;[10-11] d) Report: once "information saturation" was reached, i.e., examination of themes and categories yielded redundancy and thus nothing was added to the knowledge already acquired from the accumulated data,[10-13] analytical work ended and the results were written up.

RCT Study Results

Baseline Health Status

The health status of the study sample at baseline was compared between the control and TLC-C groups. The most common diagnoses among study participants were hypertension (51%), diabetes (34%), and asthma (21%), while only 7% reported coronary artery disease, 7% congestive heart failure, 8% COPD. On the EQ-5D (quality of life questionnaire), 47% reported at least some mobility problem, 66% reported experiencing moderate or extreme pain, and 34% reported either moderate or extreme anxiety/depression. There were no significant differences between the control and intervention groups on health status at baseline.

RCT Baseline Health Care Utilization

There were no significant differences between the control and TLC-C groups on health care utilization at baseline, with a mean (sd) number of ER visits and hospitalizations at BMC of 2.6 (2.3) for Controls and 2.7 (2.4) for those receiving the intervention, p=0.954. Also, study participants reported very few ER visits or hospitalizations outside of BMC over this period, with 84% of controls and 83% of those receiving TLC-C reporting no visits outside of BMC, p=0.982, and a mean number of visits of 0.3 (0.9) and 0.3 (0.8) in the two study groups. There were 975 BMC ambulatory appointments among participants in the control group (n=126) and 933 among the TLC-C participants (n-119). Participants in the control group did not keep 41% of these appointments (either canceled or did not show), while TLC-C participants did not keep 40% of these appointments.

RCT Follow-up

At 3 months, 77% of Control and 61% of TLC-C study participants were followed, and at 6 months 60% of controls and 44% of TLC-C participants were followed. Follow-up rates were significantly lower for TLC-C participants than for control group participants (p=0.005 at 3 months and p=0.013 at 6 months). Other factors that were significantly associated with follow-up at 6 months were employment and disease status, with lower follow-up among part-time (33%) and unemployed (40%) workers, and better follow-up among full-time (55%), retired (65%), and disabled (56%) workers. Follow-up was also lower among patients with diabetes (47%) than among non-diabetic patients (61%).

TLC-D Utilization among the Intervention Group Participants

Of the 119 patients randomized to TLC-C, 52% never called the system, 7% made 1 call, 21% made between 2 and 5 calls, 10% made between 6 and 10 calls, 6% made between 11 and 20 calls, and 4% made more than 20 calls.

RCT Primary Outcome Analysis

The two study groups were compared on time to first hospital event (unscheduled hospitalizations plus ED visits) through Kaplan-Meier survival methods and the log-rank test. Cox proportional hazards regression also compared the two study groups on time to first hospital event controlling for baseline demographic, health status, and diagnostic data, and we compared the rate of hospital events per person month over the 6 months of follow-up between the two study groups through Poisson regression. Data for these analyses came from the BMC electronic record, and all patients were included regardless of whether or not they completed a follow-up interview. Given the low number of ER visits and hospitalizations outside of BMC reported at baseline, the BMC electronic record should capture the large majority of visits for these patients.

Over the 6 month follow-up, there was no significant difference between TLC-C and control group participants on the percent of patients with any hospital event (65.9% of controls vs. 61.3% of TLC-C, p=0.461), or in the mean number of hospital events (mean (sd) 2.1 (3.0) for controls vs. 2.2 (3.4) for TLC-C, p=0.795 by Poisson regression). Separate analyses of hospitalizations and ER visits also showed no significant differences in the percent with any hospitalization (43.7% of controls, 42.9% of TLC-C, p=0.900) or with any ER visit (49.2% of controls, 41.2% of TLC-C, p-0.207).

Table 1. BMC Hospital Events (Hospitalizations + ER) over the 6 months following study entry

	Control (n=126)	Intervention (n=119)	Significance
Any ER/Hospital Visit %	65.9	61.3	0.461
Number of Visits M (sd)	2.1 (3.0)	2.2 (3.4)	0.795*
Number of Visits %			
0	34.1	38.7	
1	19.8	19.3	
2	19.1	10.9	
3	9.5	13.5	
4	6.4	4.2	
5+	11.1	13.4	

* from Poisson regression RR(Visit, Intervention vs Control) 1.02 (0.86 , 1.21)

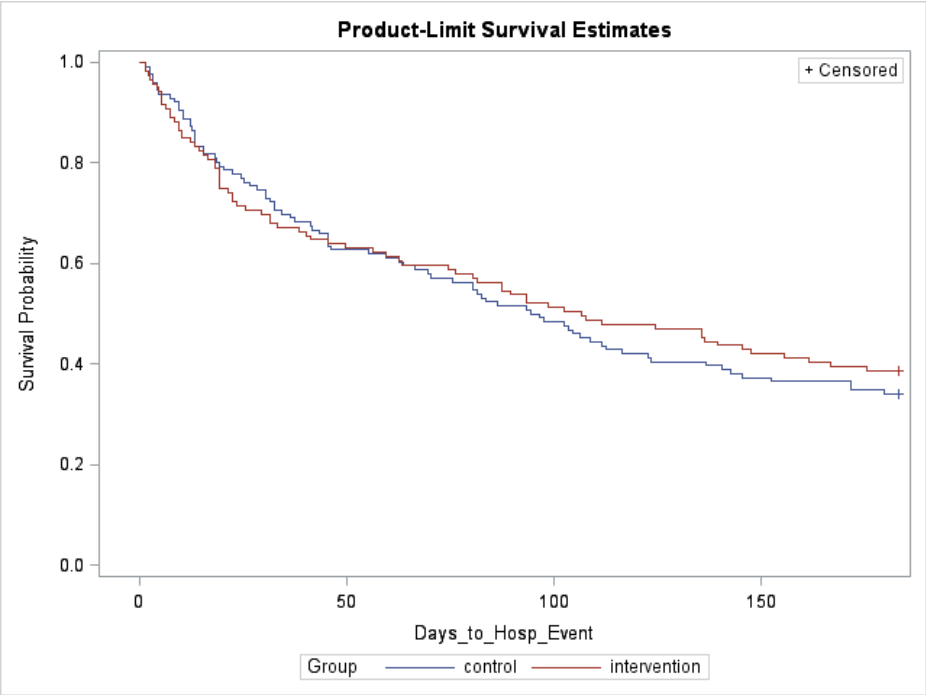
Table 2. BMC Hospital Events (Hospitalizations + ER) over the 6 months following study entry

	Control (n=126)	Intervention (n=119)	Significance
Any ER %	49.2	41.2	0.207
Number of Visits M (sd)	1.10 (1.9)	1.17 (2.47)	0.592**
Number of Visits %			
0	50.8	58.8	
1	22.2	16.8	
2	17.5	6.7	
3	4.0	10.9	
4	2.4	2.5	
5+	3.1	4.3	
Any Hospitalization %	43.7	42.9	0.900
Number of Visits M (sd)	1.0 (1.7)	1.0 (1.7)	0.850***
Number of Visits %			
0	56.3	57.1	
1	21.4	21.0	
2	11.1	9.2	
3	2.4	4.2	
4	1.6	3.4	
5+	7.2	5.1	

* from Poisson regression RR(Visit, Intervention vs Control) 1.07 (0.84 , 1.35)
* from Poisson regression RR(Visit, Intervention vs Control) 0.98 (0.76 , 1.25)

There was no significant difference between the TLC-C group and those in the control group on time to first hospital event, as described in the following Kaplan-Meier survival curves (p=0.608 by the log-rank test).

Figure 1. Kaplan-Meier survival curves for study, control groups



Cox Regression examined the TLC-C effect controlling for potential confounding by gender, age, and literacy score, which differed between the two study groups at baseline. In the following Table, a hazard ratio for TLC-C less than 1.0 indicates a reduction in the risk of a hospital event for TLC-C relative to control participants. There was no significant difference in the adjusted risk of a hospital event for TLC-C vs. control participants, p=0.695.

Table 3. Hazard ratio (95% CI) for first BMC hospital event

	Model 1 Unadjusted		Model 2 Adjusted	
Variable	HR	p	aHR	p
Intervention	0.92 (0.67 , 1.26)	0.609	0.94 (0.68 , 1.30)	0.695
Age (yrs)			1.00 (0.99 , 1.02)	0.886
Sex Female			1.18 (0.85 , 1.63)	0.332
Realm Literacy			1.00 (0.99 , 1.01)	0.631

Separate analyses of hospitalizations and ER visits also found no significant differences between TLC-C randomized participants those in the control group.

RCT Secondary Outcomes Ambulatory Appointments

Over the 6 months of study follow-up, there were 1,200 ambulatory appointments made by participants in the control group and 1,414 by TLC-C participants. Study participants in the control group did not show up for 23% of appointments and canceled 21% of appointments; TLC-C participants were no shows for 21% and canceled 19% of appointments. Excluding 'bumped' appointments that were rescheduled by BMC, TLC-C participants kept 59.7% of

appointments vs. 55.5% kept by control group participants; there was no significant difference in the percent of appointments kept between TLC-C and control participants, p=0.199 by GEE logistic regression accounting for multiple appointments per patient.

Table 4. BMC Ambulatory Appointments over the 6 months following study entry

	Control (n=1200)	Intervention (n=1414)	Significance
BMC Ambulatory Appts %			
Arrived	54.6	58.6	
Canceled	20.7	18.5	
No Show	23.2	21.1	
Bumped	1.6	1.8	
Kept Appt*	55.5	59.7	.199**
Not Kept*	44.5	40.3	

*Excludes bumped appointments
** from GEE logistic regression accounting for multiple appointments per patient
OR(Kept, Intervention vs. Control) 1.21 (0.91 , 1.60)

RCT Secondary Health Outcomes

For those followed at 6 months (n=73 controls and n=51 TLC-C patients), there were no significant differences on the EQ VAS Health Scale (mean (sd) 70.2 (24.2) for Controls, 63.8 (27.4) for TLC-C, p=0.171). There were also no significant differences between the TLC-C and control group participants on the EQ-5D measures of mobility (p=0.136), self-care (p-0.594), usual activities (p=0.603), pain/discomfort (p=0.832), or anxiety/depression (p=0.127).

RCT Secondary Outcomes; Relationship with Doctor and Confidence in Taking Medication

A summary score based on the 4 AURA questions measuring relationship between patient and doctor had a Cronbach's alpha of 0.87 in our sample. There was no significant difference in quality of relationship for TLC-C (14.3 (2.9)) vs. control (14.7 (2.7)) patients, p=0.424. A summary score based on the 13 SEAMS items measuring confidence n taking medications had a Cronbach's alpha of 0.91 in our sample. There was no significant difference in confidence scores for TLC-C (32.6 (6.6)) vs. control (33.7 (6.2)) patients, p=0.341.

RCT Secondary Subgroup Analyses

Subgroup analyses were conducted to explore whether TLC-C had differential effects for minority (Black or Hispanic n=87 control, 86 TLC-C) patients, or those with low health literacy (n=53 control, n=63 TLC-C) or high health literacy (n=73 control, n=56 TLC-C) patients. Given the small number of caucasian patients in the sample (n=20 control, n=25 TLC-C), subgroup analyses were not performed for this group. No significant TLC-C effects were found in any of these subgroup analyses.

RCT Secondary Compliant Patient Analyses

57 of the 119 patients randomized to TLC-C made at least one call to the system where they selected a topic for discussion. Comparison of these 57 compliant TLC-C subjects to all n=126 control patients found no significant TLC-C effect for time to first hospital event (p=0.259 for the log-rank test) or for the percent with any hospital event (65.9% of controls, 56.1% of TLC-C patients, p=0.207). Compliant TLC-C patients did have significantly fewer hospital events (mean (sd) 1.6 (2.3) TLC-C vs. 2.1 (3.0) control, p=0.040 from Poisson regression), where TLC-C patients had a 22% reduction in the risk of a hospital event (i.e., a relative risk of 0.78) over the follow-up period (with a 95% confidence interval for the percent reduction in risk from 1% to 38%).

Results of the Summative and Longitudinal Qualitative Evaluations

The results of the summative and longitudinal evaluations are merged in this report as the two evaluation studies demonstrated very similar results even though one (summative) captures the views of the TLC-C users after only one interview and the other (longitudinal) depicts users' opinions after 4 interviews conducted over time. The following narrative describes the themes and categories that emerged upon the completion of the analytical work for both evaluations:

Accuracy of Medication List Derived from the EMR

In the medication adherence module, the TLC-C system begins the interaction with patients by going through their medication list. Such monitoring seemed to have had a comforting and reassuring impact on patients as most were pleased to know that the medication information in their Electronic Medical Record (EMR) was correct. However, a smaller number (in both qualitative evaluations) complained about inaccuracies such as TLC-C listing outdated medications. These inaccuracies clearly had given rise to some concern and anxiety. Obviously, these patients were aware that nowadays EMRs are an integral component of health care delivery and consequently expected the BMC EMR to contain an accurate list of their medications. The comments expressed by these participants demonstrated that the EMR's inaccuracies are considered by patients to be detrimental to receiving effective health care. This was, however, unrelated to TLC-C system operation. We explored the source of this problem and learned that typically it was the patients' primary care physicians who updated the medication lists on the medical center's EMR system. Since the TLC-C system retrieved the patients' medication list from the EMR, if a list was not updated (by a PCP), then the TLC-C system's precision was adversely affected. We communicated this to responsible clinicians through email alerts.

Participants' Attitudinal Disposition: Medication Adherence Module

The majority of the interviewees (both summative and longitudinal evaluations) were quite positive about their interaction with the TLC-C system. The positive statements were related overwhelmingly to the most oft-quoted view of the system, i.e., perception of the TLC-C as a "reminder" that promotes "awareness." In this vein, the majority of users (in both summative and longitudinal evaluations) felt that the medication monitoring component of the TLC-C

system was an effective "reminder" and that "reminders" function as helpful tools to keep patients "aware." In addition to the "reminder" function, the system was considered to be a support system; something to rely on. For example: "it is there to fall back on as opposed to having –living alone. I thought it was a good thing for people who live alone." This tied in to the system's advice about taking medications as prescribed and at the right time. At least two patients said that the module helped them take their medications on time. An interesting corollary was that even though the majority of the participants stated that they did not need to have a "reminder" still they admitted that the system's advice was helpful. For example, a participant said: "I didn't have any problems; but it would benefit someone else if they forgot. You know it is good information for patients to have." A person who said the system was a "tiny bit" helpful added: "it made me think oh yeah it is important to take these meds. I already knew it is important but it was kind of like a gentle nudge." During the longitudinal interviews we were particularly interested in detecting change both in the way the study participants perceived the TLC-C system and in their health behavior and possibly their health status. The positive opinions of the longitudinal study participants did not change over time. Yet again, similar to summative interviews, the positive expressions included a caveat that was often brought up during the interviews. This was typically a statement related to the effectiveness of the system and its impact on the patients' *own* behavior and their *own* health status. Such statements revolved around the notion of "this-is-great-for-others." Nevertheless, all longitudinal study participants also appreciated having a reminder available. Furthermore, it seems that the system's reminder functions over time gave rise to a watchful attentiveness to issues related to medication adherence for the longitudinal evaluation participants. For example, one participant with severe asthma and frequent hospitalizations said that even though she pays much attention to her medication-taking regimen sometimes she forgets the second dose and that the system has made her more aware about that particular dose. Another participant who felt the system was helpful because "it helps me …remember my – when I am supposed to take and if I forget…," immediately added "but I, I, I remember to take my medication every day." This participant, during subsequent interviews, expressed a more specific and tangible opinion about the system as in her third interviews she stated that "I am learning how to really focus on my medications better." Alas, by the last interview, our principal understanding of this patient's opinion was that she felt she was doing fine without the system even though using a system such as the TLC-C could be helpful (especially for others who are not as adherent as she is). Also, another longitudinal participant who stressed that he is extremely adherent both to his medication-taking and clinical office visits commented that these two modules function as a "trigger" by keeping medication adherence on the user's mind. Such continuous mindfulness helps those who might slacken in the long run. In general, all longitudinal study participants continued to hold positive opinions about this module throughout their four interviews. In fact, one of the patients who was dropped out after two interviews because of a life-event, and who did not optimally used the system, had this to say about the medication adherence module after we asked why he stated that it is helpful: "It helps you double check yourself; it does." This person also said that after listening to the medication adherence module he decided to buy a pill tray.

Participants' Attitudinal Disposition: Clinical Office Visit Adherence Module

Interaction with TLC-C about clinical appointments is optional. It seems that most participants in both evaluations (summative and longitudinal) chose to use this module and most in both groups were positive and considered it helpful. A person who had used this module several times said that he liked it because he usually had several appointments and the module was a reminder. But, the module had its critics such as a summative study participant who let slip that it was not helpful because he did not need it. The Module also provided an additional component that promoted learning by providing a number of "tips" for patients to use during the clinical visit in order to get the best out of their visit with their physicians. This component was considered informational by some participants. One said that he actually made a list of the "tips" and made sure he remembered them. Another person stated: "Of course I have senior moments sometimes; [*the system*] made you make a list and write down things and take notes…and keep it readily available when you need it and I thought it was excellent." In general, the majority of participants in both summative and longitudinal evaluations liked this module and considered it helpful and informative. However, most also admitted that they are very good at keeping their clinical appointments.

Participants' Attitudinal Disposition: the Coronary Artery Disease Module

The TLC system also included an additional module that provided advice and monitored patients with coronary artery disease (CAD). However, it seems that only two participants among the 27 summative evaluation interviewees and one among the longitudinal interviewees used this module. The person who used this module in the longitudinal evaluation said that she felt she did not need this module while the two individuals who participated in the summative interviews stated that they learned a lot and the module was very helpful. In response to the question of what did using this module do for you, one participant with CAD said: "made me confident in myself and confident in my health knowing that I am doing the right thing."

Repetition as a Health Promotion Strategy

In each module the system frequently repeated several important topics in order to reinforce the impact. We were interested to explore whether such repetitions were received positively by study participants. At least half of the summative study participants and 4 longitudinal study interviewees did not feel there was much repetition while the remaining individuals said that they recognized that there were some repetitions but that they felt it was helpful and not out of place. One person commented: "sometimes you don't understand something and it is good that the system goes over certain things and repeats itself so you can understand it."

System's Impact on Health and Quality of Life

It was important to understand whether system utilization had affected users' health behaviors or their overall health. The majority of the participants in the summative study and all

of the longitudinal participants admitted that the study had not affected their health behavior or improved their health. However, six in the summative study said that since using the system they took their medications regularly and on time and made sure that they get their refills before they run out of medication. Furthermore, two individuals in the summative evaluation who had CAD told us that they had experienced a better quality of life. Both said that they had become more physically active and as a result happier. “I can do a little exercise. I do walking and I do exercise and it made me stronger.” None of the longitudinal study participants admitted to behavior change or an improved health status.

Human or Computer

We also explored to what extent participants might prefer a computer to a human health professional. Twenty individuals in the summative evaluation responded that they prefer a person to a computer. One of the most common reasons for this preference revolved around the fact that a human being responds to questions and gives feedback: “if you ask questions from the machine, you would not have an answer just like a person would.” Two participants said that they do not have a preference and two said a computer is preferable. The reasons provided were “computers are faster” and “it would be more accurate.” All of the longitudinal study participants, initially, said that they preferred interaction with a human to a computer. However, over time, we detected some change in the participants’ opinions as it seems that a few participants developed some liking for the system. One person, at her first interview said that she prefers the computer but was not able to elaborate why. In the next interview she said that she likes the computer but again could not really explain why. However, after further probes she responded to why she likes the computer: “I don’t know; she is easy to talk to. I don’t know.” Or, one participant who stated during her 1-3 interviews that she preferred a human to a computer at her final interview said that she had no preference: "At first I did, but now I don't. I like the computer." Similarly, another participant who during his first interview had stated he preferred a human to a computer, during the second interview expressed ambivalence: “I would go either way. I…the computer is good; but I don’t know.”

Suggestions

Finally, study participants in both evaluations provided us with suggestions as follows: 1) Improve the system’s pronunciation of words and phrases and/or preferably use a human voice. 2) Allow “barging in,” i.e., entry of response before the system has finished the question. 3) Have a real/live person involved or available in case a user needs to connect to a live person during interaction. 4) Enhance the system with the capability of directly connecting patients to their clinician’s office. 5) Enable the system to respond to questions. Or, provide an opportunity for users to leave a message if they need feedback about their interaction with the system. 6) Make sure that the medication lists in the electronic medical records are updated. 7) Spice up the system by adding additional health topics or tidbits such as brief but useful health information, e.g., advice on what to avoid if you are in a low sodium diet. 8) Add sections to guide patients on what to do in case of emergency (TLC-C system already has this function). 9) Inform patients when they are going to need a prescription refill. 10) Add a component informing patients that they no longer need to take certain medications.

Evaluation of Physicians' Opinion

The in-depth interviews with clinicians focused on their reactions to participation of their patients in the study and the TLC-C system's various features particularly its alert reporting functions. The interviews were conducted after each physician's patient(s) had completed participation in the study. The TLC-C system generated alerts if a provider's patient seemed to be non-adherent or deviated from his/her medication regimen as well as being a no-show for clinical office visits.

Recall

The initial questions posed to the physicians were whether they remembered the study and whether any of their patients had discussed the study with them? Almost all of the five physicians admitted that they did not remember anything about the study and did not recall any of their patients discussing the study with them. One of the physicians, while laughing, said: "I have another guy in a study and I almost never discuss it. I-like- 'oh you are in a study? Yes, OK! Next?'" Another physician had a vague memory of one of his patients talking about a study but he was not sure what the study in question was about. Furthermore, none of the physicians remembered receiving any of the alerts that the study staff had emailed to them. The physicians' response was negative to the question 'whether they remembered any changes in their patients' behavior that might be attributed to these patients' participation in the study?' However, one of the physicians, after giving some thought to the question, stated that he could remember that one of his patients who participated in the study was more attentive during his clinical visits and asked poignant questions.

Physicians' Perceptions of Barriers that Impede Utilization of Innovative Technologies

A) Physicians are overwhelmed. An important concern for designers of innovative health technologies is whether the technology is going to be utilized by the intended users. It was clear to the interviewers that the majority of physicians perceived utilization of health technologies as a burden to their workload. In fact, even when the physicians advocated the use of such technologies for patient management they suggested that the task should be carried out by a member of the clinical staff. For example, when discussing the topic of utilization of technology (by both patients and clinicians) for improving management of complex patients, one physician said that he "loves" the idea of patients using technology. In fact, he said that even though the patient population at BMC is "different," still most patients have smart phones which could function as a useful tool for tracking and follow-up. However, when asked whether he would have time to track such patients himself, he said: "ideally, in my mind, there would be a nurse practitioner that could keep track of the information." This physician felt that he does not "have to be involved" and that chronically ill patients can be followed-up by nurses in accordance with the "medical home" model. Another physician corroborated that "there is a lot of information I would want to know. We just don't have the time to deal with it. I can do stuff. It is not that I can't do stuff. It's just- the question is- I just don't have the time built in." A related conversation revolved around the constant and heavy stream of patients and the issue of other duties [than

patient care] and responsibilities that overwhelm physicians. One of the physicians explained: "people [*clinicians*] in the middle of the thing [*clinical office visit*] are so frazzled that they don't even think about some study." This physician explained that most visits do not revolve around one particular problem or issue such as hypertension and that much more is discussed. According to this physician the clinical visit is not just a sick or a follow-up visit and frequently such visits turn into social visits. "You know, you say 'let's talk about your high blood pressure,' and the person is telling you their mother died. There are so many other things." Clearly, this physician is referring to the role physicians play as healers which also include tending to their patients' personal, mental and emotional needs. Tending to the myriad of patients' needs hardly leaves any time for anything else. Thus, the concern that came through loud and clear was that lack of time and heavy clinical and sometimes "other" responsibilities lower the physicians' threshold for learning and using additional technologies except those mandated by their institutions.

We also asked about the untidy conditions of the patients' electronic medical records and the fact that frequently old medications are not eliminated from the EMR and as a result a technology such as TLC-C that retrieves the patients' medications list from the EMR provides incorrect information to the patients. Again the reason was mostly attributed to the lack of time. One physician stated that in some institutions other professionals such as pharmacists or pharmacy students visit the patient before the attending doctor arrives and they clean up the records as well as organizing it.

B) Some physicians are not technologically-inclined. There was another reason why many physicians might not respond to the introduction of innovative technologies into their work routine. We were reminded that different physicians respond differently to technology. Some physicians are "old school" particularly those who are middle aged or older. For example, when discussing the physicians' preferences, one of the physicians brought up the BMC's electronic medical record system, Logician We were told that Logician, in and of itself, creates much frustration among some of the physicians who have difficulty dealing with the platform. One physician elaborated: "some providers have been using the same system for several years. They have no clue what half the buttons do. Physicians are very similar [*to patients*]. Do they know what the hell they are doing with the computers? It sounds stupid but you really have to dumb it down for them. There is volume overload in terms of the study; but there are like twenty other things telling them to click on this button or this button. People can't keep up. [*Laughing*] You talk to doctors and they are typing away until 1:00 o'clock in the morning."

ALERTS: are they important or necessary?

We were particularly interested in the physicians' opinions about alerts. Two physicians who had received several email alerts admitted that they probably would not have done anything about these alerts for the following reasons: 1) physicians regularly receive a multitude of alerts most of which are sent via email from insurance companies, pharmaceutical companies, etc. These alerts are filled with meaningless information and addressing them is a waste of time. As a result, these emails are not reviewed by physicians. In fact, it is possible that the TLC-C's alerts were chucked together with the other alerts. 2) Clinicians are not always in the clinic and thus they may not be around at the time when an email alert arrives. One physician, however, asked even if he had printed out the emailed alert, what was he supposed to do with it? This physician told us that if he is expected to discuss any information about a patients' clinical status with that

patient, then he should be receiving that information at the point of care, i.e., only when he is meeting with that patient and not before. Otherwise, he suggested that he should learn about urgent or emergent concerns through the medical center's paging system. Thus: "…let us know if something is going to kill our patients" via a page. Furthermore, it was suggested by one PCP that we could email our routine (non-urgent) alerts to the patients and ask them to bring them to their next clinical visit and show them to their physicians. 3) The third reason stated by all of the interviewed physicians was that they have too much to do within a very short time span during the clinical visit and that it is unlikely that they will remember to check their emails and review a specific email related to a study in which a patient is participating.

As for the Alerts' appearance and content, one of the physicians who reviewed the alerts said the alerts are too wordy and sometimes address issues that are not significant (such as a patient taking an additional dose of aspirin). Similarly, two other clinicians told us that the information contained in the alerts was not important. It was reiterated that taking an extra dose of aspirin or Prilosec is not going to harm a patient. As for alerting physicians about a patient's medication non-adherence, one of the physicians pointed out that improving adherence may be extremely difficult due to multi-dimensional aspects of non-adherence. For example, forgetting medications or not obtaining medication refills usually stem from complex personal and social problems. Thus, unless all the other factors are addressed, non-adherence will persist. This physician stated that it would be difficult to design systems such as TLC-C due to the fact that most doctors make clinical decisions based on context and the context is the first thing that gets lost in such technologies. "Not every medication is important in every context. So, like Lisinopril is one of those that serves many many different purposes. So, if it is used for heart failure- I am going to be more anxious and concerned about that. Whereas, the person who is just on it for blood pressure, alright, the last blood pressure was fine; they missed a few doses. It is not a big deal." This sentiment was repeated almost verbatim by two other clinicians one of whom said: "they took an additional dose of something. That is not a big deal." All physicians interviewed seemed to agree on one issue: that they would prefer their Clinic's nursing staff to receive and handle alerts.

Discussion and Conclusions

In this population of complex patients with multiple health issues, the TLC-C system was not found to significantly reduce hospital events (the primary outcome of unscheduled hospitalizations or ER visits). Also, the intervention did not significantly affect the secondary outcomes and did not demonstrate significant change in participants' adherence to the ambulatory visits and their relationship with their clinicians as well as their views on adherence to their medication regimen. Furthermore, comparison of quality of life showed no significant differences between the intervention and control groups. We have described in the Limitation Section of this report (Section 3.5.) that once the study was in the field subject recruitment became a significant concern. The inadequate recruitment had an immensely disruptive effect on the study's timetable, overwhelmed the study staff and reduced the RCT's ability to detect change. However, it was not entirely the recruitment problems that proved so deleterious to the study's success. By the time the RCT arrived at the T3 follow-up visit time point, we realized that the study had lost a large number of subjects to follow up and withdrawal. At 3 months, 77% of subjects in the control group and 61% in the TLC-C group were followed while at 6 months only 60% of subjects in the control group and 44% of the intervention subjects were

followed. Follow-up rates were significantly lower for TLC-C patients than for those in the control arm of the study ($p=0.005$ at 3 months and $p=0.013$ at 6 months). Factors that were significantly associated with follow-up at 6 months were employment and disease status, with lower follow-up among part-time (33%) and unemployed (40%) workers, and better follow-up among full-time (55%), retired (65%), and disabled (56%) workers. Follow-up was also lower among patients with diabetes (47%) than among non-diabetic patients (61%). These data clearly demonstrate that the causes for both recruitment and retention problems were multidimensional. The vulnerable patients who were recruited for this study usually have an array of socio-economic and health issues that challenge the traditional models of recruitment and retention for research. Many patients may be too ill to continue to participate in a study while others may suffer from unstable and chaotic real life situations (sudden loss of shelter, absence of money to pay for utilities and/or for food, problems with law enforcement, etc.). It should be pointed out that during the summative qualitative evaluation we interviewed a subset of patients who participated in the RCT. However, for the longitudinal qualitative evaluation we recruited 10 new patients. It took several months to recruit only 10 patients and within a short period of time we lost at least four either due to loss to follow-up or to withdrawal. We ended up with only 6 individuals for the longitudinal in-depth interviews. Of these, one was incarcerated in the middle of the study and thus we had to drop that person to comply with exclusion criterion #2. Clearly, in this study, complexity of patients' health condition together with their challenging socio-economic situations and other life events played a significant role in making both recruitment and retention problems more acute because these factors occur in combination with a variety of other unique issues that relate specifically to this population. One important lesson learned was that adequate recruitment and retention require intimate knowledge of the characteristics of the target population's lifestyle and needs. Such knowledge can help the study designers establish better strategies for promoting participation and reducing noncompliance and attrition before recruitment begins.

As mentioned in the Limitations Section, another important impediment to the success of the RCT was the intervention participants' lack of enthusiasm to utilize TLC-C as suggested (once/week for six months). The establishment of a lottery did in fact enhance utilization and the additional analyses to determine outcomes for subjects who were more adherent to using the TLC-C system (Section 4.6. Secondary Compliant Patient Analyses) demonstrated that the participants who were more adherent to TLC-C utilization had a reduction in hospital events. However, this finding needs to be interpreted cautiously given the smaller number of these "adherent" subjects and the fact that non-adherent participants in the control group were not excluded from the comparison.

Related to the issue of non-utilization, it should pointed out that at the end of the summative qualitative evaluation we were able to contact four individuals in the intervention group who had never used the system and administered a brief instrument, the Health Technology Questionnaire. As the following table shows, a variety of reasons were offered by patients to account for non-utilization of the system ranging from personal concerns to system-related issues.

Table 5. Technology Utilization Questionnaire (Section A): Questions only address issues that prevented Utilization and was administered to 4 patients

Non-Use Descriptive Statistics		**Non-Use Descriptive Statistics**	
Major Disruptions in Life	**N (%)**	**Travelling**	**N (%)**
TRUE	2(50)	TRUE	0(0)
FALSE	2(50)	FALSE	4(100)
Was Busy	N (%)	**Not Right for Me**	**N (%)**
TRUE	4(100)	TRUE	2(50)
FALSE	0(0)	FALSE	2(50)
I Forgot	**N (%)**	**Lost Users' Guide**	**N (%)**
TRUE	3(75)	TRUE	**2(50)**
FALSE	1(25)	FALSE	**2(50)**
Not Motivated Enough	**N (%)**	**Health Issue Not Important to me**	**N(%)**
TRUE	3(75)	TRUE	0(0)
FALSE	1(25)	FALSE	4(100**)**
Problems Accessing System	**N(%)**		
TRUE	3(75)		
FALSE	1(25)		

Finally, the qualitative summative and longitudinal evaluations point towards an important central theme one which relates to the targeting of the intervention. Similar to the RCT, neither summative nor the longitudinal evaluation demonstrated change in the study participants' health status or their health behavior. For example, in both evaluations, it was demonstrated that all participants appeared to be adherent to their medication regimen and to their clinical office visits. Furthermore, participants tended to be fairly involved in their treatment management process. For example, most participants appeared to have a thorough knowledge of their medications and the regimens they needed to follow to obtain the best results. They believed in the effectiveness of their treatment regimens and were sufficiently motivated to follow them. As a result, non-adherence events among these individuals were negligible or rare. Clearly, the TLC-C system would do significantly better with non-adherent patients. Interestingly, the subjects in longitudinal evaluation also belonged to minority groups and most were socio-economically disadvantaged. Low socio-economic status is considered a barrier that affects adherence to treatment regimen.[14-15] However, this did not appear to be the case in our small qualitative sample. We could speculate that the existing safety net in Massachusetts has helped prevent the deleterious impact of financial distress on many of the Massachusetts' residents' health status as our subjects were either on the Commonwealth Care which is a free or subsidized health care coverage program for eligible Massachusetts residents or were on disability insurance. Thus, some of the barriers to adherence such as medication costs, lack of transportation, etc., did not influence these patients' health behavior. Nevertheless, as was observed in the summative in-depth interviews, it seems that most participants in both evaluation studies were quite positive about the TLC-C system and a small number said that they benefited from it. All participants admitted that the medication adherence module made them more aware and focused their attention on their medications as well as how they were taking them and that the clinical office visit adherence module was helpful in ensuring that they attend their scheduled clinical office

visits. Furthermore, the clinical office visit adherence module seems to have communicated important and useful knowledge leading to some degree of patient activation.

More importantly, we learned that even though interaction with TLC-C might not have led to a tangible personal gain such as improved health status, the study participants realized intuitively that health promotion advice and guidance to improve disease management is helpful and perhaps that is why those who used the system found the system useful even though "for others." Furthermore, we learned that as long as patients know and realize that there is something advantageous in their interactions with automated systems they demonstrate a great deal of tolerance for quirks inherent in these systems such as "voice with strange cadence," "programming bugs," "system crashes" and "repeated questions."

On the other hand, our interviews with the physicians demonstrated that even though physicians are used to function in a highly pressured and time-sensitive environment, they tend to be ambivalent about innovative technologies designed to assist with patient management. Clearly, the interviewed physicians were concerned about their patients' adherence to treatment regimen. Yet, their priority seemed to be an individual patient's array of medical and personal problems and needs only one of which may be non-adherence to treatment regimen. Consequently, receiving, reading and responding to an alert is the farthest thing in a physician's list of priorities. Physicians listed lack of time and overwhelming amount of clinical work, meaningless or trivial information in the alert reports as well as prior knowledge of the reported problem as factors that contributed to their reluctance to use alerts generated by technologies such as the TLC-C system. We may also make an assumption that research studies in general may not provide immediate benefits to a practice and thus they are not considered to be vitally important by the physicians. This might explain why most physicians who were interviewed relegated the task of handling the alerts to their nursing staff and is important for the design and development of systems such as TLC-C in the future. Perhaps it would be more beneficial if future designs focus on enabling patients to become the recipient of such reports or any other communication relayed by an automated system. Reports could be emailed or mailed to patients who in turn can take them to their next clinical visit and discuss them with their physicians at point of care as requested by the interviewed physicians. The results may be a more activated patient population and a reduction of physicians' burden.

Significance and Implications

The burgeoning health promotion and disease prevention technologies are undoubtedly finding their niche in the American health care system. The dissemination of these technologies, however, has not always been a smooth one. In fact, there is a large literature regarding the problematic adoption of innovative technologies in healthcare.[16-17] Evidently, the acceptance and spread of innovative healthcare technologies vary among different groups. In fact, one of the important challenges facing the dissemination of these technologies is how to better understand the exact needs of patients and/or physicians who use these systems as such needs often seem less obvious than apparent. Even though the present study presented with problematic technology adoption, our previous research of TLC technology's promotion of healthy dietary behavior and exercise has shown positive results and impressive utilization rates.[3-8] Understanding the reasons for such divergence is of utmost significance that will impact the design of systems such as TLC-C in the future. Considering the problems that the study encountered, perhaps it is fair to admit that such technologies should not be aimed at complex

patients with several chronic ailments who also are socio-economically indigent. The above-mentioned TLC projects that demonstrated positive outcomes and had high utilization rates were designed for healthy middle class consumers. The conjecture may assume more weight when we compare the ratio of participants who used the TLC-C system before (12%) and after (36%) we established a lottery to be won by those who used the system. Nevertheless, providing such incentives in real life may be too complicated or not appropriate as monetary rewards or material incentives are not usually offered to foster health behavior change even though the idea has been tossed around.[18-20] Finally, as described in the Conclusion/Discussion Section, the qualitative evaluations demonstrated that the physicians were as reluctant to use an innovative technology such as TLC-C as patients were. Consequently, the system designers will accomplish more if they spend a substantial amount of time to acquaint themselves with the targeted study participants before the grant writing process.

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