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A Patient-Provider Engagement RCT in Primary Care for Diabetes Patients
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A Patient-Provider Engagement RCT in Primary Care for Diabetes Patients

By

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Abstract

A Patient-Provider Engagement RCT in Primary Care for Diabetes Patients
By Allison Pall

Background
Diabetes is prevalent, costly, and deadly. Patients living with chronic conditions can benefit from interventions that are intended to empower them to self-manage their conditions outside of their primary care visits as well as interventions that allow them to better communicate with their primary care physicians.

Methods
197 Diabetes patients were recruited and followed from 2015 to 2016 from a primary care center of a hospital in downtown Atlanta and randomized into one of two study arms. Intervention patients were provided with personalized, color coded printouts of their A1c, systolic blood pressure, and LDL cholesterol numbers over the last year or so at each visit. These materials were intended to help them understand their lab values, remind them of how to self manage their diabetes outside of their visits, and facilitate conversations with their providers about their trajectory and management. Control patients were given the same interviews as intervention patients, but not given the roadmap printouts.
Difference in differences methods were employed to assess the change in systolic blood pressure (SBP) from baseline to 3 and 6 month follow up times between groups. SBP was used as a marker for diabetes control because it was reliably taken at every visit (unlike A1c), used in the roadmaps employed by the study, and subject to fewer validity concerns than POCT glucose for this sample.

Results
The difference in differences tests were not found to be significant, however the intervention group did experience a small decrease of about 3 mmHg from baseline to 6 months while the control group stayed nearly identical.

Conclusion
Qualitatively, patients tended to have very positive reactions to the roadmap, however they also seemed to benefit from having additional time to discuss the roadmap with study interviewers. While the D-I-D models were insignificant, there may be different findings if a different metric were used in a future model for a similar study, such as fasting glucose or A1c.

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Background

Diabetes is a prevalent chronic disease in the United States, with 12% of the US population living with the condition in 2014. Diabetes management cost the US $245 billion in 2012, and the disease confers a higher risk of mortality: there is a 50% higher risk of death in diabetes patients. It is the 7th leading cause of death in the US, and the 5th leading cause of death in African Americans and Latinos. Efforts to mitigate the effects of the disease are a good use of resources in areas of the US that are highly affected by diabetes.

Low-cost education and empowerment interventions can be implemented to enhance the diabetes patient's relationship with his or her provider while educating the patient about their condition. Diabetes management largely hinges on patient's own everyday activities. Focusing on the patient and successfully encouraging his or her investment in diabetes management could improve such areas as medication adherence, satisfaction with care, and motivation, knowledge, and skills to self-manage diabetes.

Patient-Provider Engagement

Patient-Provider Engagement is vital for the control of chronic conditions that require self-management by the patient (Sapir et al., 2017). Patients are more likely to adhere to treatment and follow advice given by providers with whom they feel connected. Patients who are engaged in their care feel better about their treatment and experience better health outcomes (Gill, 2013). A breakdown of patient engagement defined alignment of objective, communication, information and encouragement, patient incentive, and provider effectiveness as five dimensions

of patient engagement that are significantly related to patient-reported health outcomes in primary care (Gill, 2013). Information and subsequently communication and provider effectiveness are two areas that can be supplemented by personalized information given to patients.

Patients are more satisfied with their care when communication improves between patients and providers. (Levinson et al., 1997).

Barriers to Engagement

Achieving diabetes control is difficult for many patients (Lang, Marković, & Kranjčević, 2015). When this patient-provider relationship breaks down or where communication is lacking, health outcomes suffer for patients. Several potential barriers exist that can impede this communication.

Fundamental differences in how disease is conceptualized exist between patients and physicians. One study found that there are large differences in how diabetes is perceived between patients with type 2 diabetes (T2DM) and providers (Brod et al., 2016). Providers are trained to think clinically and focus on lab numbers and specific medical outcomes such as A1c, or hypoglycemic events and other complications. Patients with T2DM, however, have broader and more subjective criteria for what diabetes control looks like (Brod et al., 2016). Patients may also be more inclined to consider diabetes control in more recent terms, that is, on the order of how things have gone the few days, while providers think more on the scale of A1c, that is, the last 3 months (Brod et al., 2016).

Clinical Inertia

Clinical inertia in diabetes treatment leads to poorer patient outcomes (Ziemer et al., 2005). Clinical inertia is defined as a failure to begin or advance treatment in a condition when either is warranted (Lang et al., 2015). Clinical inertia has been thought to occur for reasons related both to the patients and the providers. Some factors that are relevant to patient-provider engagement can have an impact on clinical inertia in diabetes treatment (Carratalá-Munuera et al., 2013) (Schwartz, Marling, & Shubrook, 2013) (Ziemer, Doyle, et al., 2006). These factors include patient noncompliance, low levels of diabetes knowledge, low motivation for self-management, short amounts of time spent in consultation, and lack of treatment goals (Lang et al., 2015).

One clinical inertia study suggests that providers may also expect little from patients even when they believe that they have adequately conveyed the importance of diabetes self-management (Strain et al., 2014). These low expectations combined with patients' weak actual understanding of risks of complications from diabetes and the importance of diabetes control do not inspire success from the patient-provider relationship (Strain et al., 2014). Adequate communication and mutual understanding are crucial, and complacency on either side will be harmful. This study also found that the more individualized care and goals can be, the more successful the patient is likely to be in managing his or her health (Strain et al., 2014). Simply chasing general targets for lab numbers will be less meaningful to the patient. Treatment of diabetes may be moving away from universal algorithms which will hopefully be beneficial to patients and improve self-management outside of the clinical setting (Strain et al., 2014). One interesting and specific concern

brought up by this study is the fact that insulin use as treatment or escalation of insulin prescription is similarly resisted by both patients and providers. Both parties express concerns about complications or avoidance of the treatment while the benefits for quality of life are not fully addressed (Strain et al., 2014).

Health Literacy

Health literacy is the ability to understand medical information in different forms, and is required to make appropriate health decisions and navigate the healthcare system (Hersh, Salzman, & Snyderman, 2015). Lack of health literacy in diabetes patients has been shown to be associated with worse health outcomes (Watts, Stevenson, & Adams, 2017). While screening for health literacy is not known to be beneficial, ensuring that health information is universally accessible is more likely to improve health outcomes and make patients more comfortable with their care. Written materials should be at or below a fifth grade reading level and visual aids are likely to be useful (Hersh et al., 2015). In a study involving HIV patients (Dawson-Rose et al., 2016), another chronic condition that requires rigorous self-management, health literacy was shown to be influenced in one study by a patient's relationship with his or her healthcare provider. Improving health literacy in patients is a possible point of intervention to help patients conceptualize their own health problems and empower them with specific goals and targets.

Patient Empowerment

Empowerment of diabetes patients begins when providers acknowledge that patients are in control of managing their health day-to-day (Anderson and Funnell,

2010). Helping patients make informed decisions about self-management is key (Anderson and Funnell, 2010).

Patient empowerment has become prevalent in literature about managing health conditions such as diabetes (Barr et al., 2015). Within the health sciences, patient empowerment relates to health promotion and management of conditions (Cerezo, Juvé-Udina, & Delgado-Hito, 2016). Patient empowerment can be defined as a process by which people gain greater control over decisions and develop skills to influence factors that impact their health (Cerezo et al., 2016). In the context of chronic diseases, empowerment is a strategy to allow patients to be responsible for improving their own health outcomes to some degree by managing their conditions outside of the primary care setting and thereby control health expenditure and disease burden (Cerezo et al., 2016). Diabetes self-managing behaviors have been significantly associated with patient empowerment even when adjusting for confounders such as age, duration of diabetes, marital status, and gender (Yang, Hsue, & Lou, 2015), showing that patient empowerment may translate to an improvement in management of conditions such as diabetes outside of the physician's office. If tools can be introduced to empower patients in their diabetes care, hopefully diabetes management and outcomes can be improved.

A cohort study found that a patient empowerment program was associated with lower rates of cardiovascular disease events and all-cause mortality in patients with T2DM over a period of 2 years. It was posited that these lower rates were due to improved primary care and patients feeling like they could control their outcomes with self-management (Wong et al., 2015).

A randomized controlled trial studying a patient empowerment intervention in HIV patients in Namibia found patient empowerment was associated with improved quality of interactions between patients and their providers (Maclachlan et al., 2016). This is supported by studies that highly engaged (empowered) patients receive more personalized care from their providers, who are more willing to delve deeper into their condition than when patients are exhibiting lower engagement (Cegala & Post, 2009).

Nonadherence to treatment is a serious problem for patients with chronic conditions (Hain & Sandy, 2013), and empowering patients with these long duration diseases may help them achieve needed lifestyle changes that can lengthen and improve life. Shared power and autonomy in patient-provider relationships can bring about this kind of empowerment by building trust between the patient and his or her provider as well as allowing the patient to be involved in their care. (Hain & Sandy, 2013).

Study Population

Patients were recruited for this study from a primary care center in downtown Atlanta. Diabetes is a significant problem faced by the population that this hospital system serves. The patient population for the system as a whole (who live in metro Atlanta) was found to have 16% prevalence of diabetes in 2015, which is slightly higher than the national average. In the primary care center at the main hospital, this number doubles to 34% of patients.

Diabetes is a costly condition to this hospital system as well. 24% of dollars billed in the hospital system were related to diabetes diagnoses in 2009. In the

primary care center at the main downtown location for this hospital system, 40% of visits had diabetes diagnosis codes attached to them in 2015. Diabetes mellitus is both prevalent and costly to this hospital system, and particularly in the primary care centers where this study was based, therefore studying ways to aid patients in managing their own diabetes will help their own health outcomes and bring the burden of disease and cost from disease down for the hospital system and the metro Atlanta population.

Prior studies have tried to address patient engagement in this population (Barnes et al., 2006) (Ziemer, Tsui, et al., 2006). Other studies by this team have included similar "road maps" and other educational materials for patients or providers to what is used in this study to empower patients and promote engaging with their providers.

Engaged patients have specific skillsets and goals, and providers help patients set appropriate and useful goals by utilizing their medical knowledge. The intervention in this study was designed to facilitate creation of a shared plan between diabetes patients and their providers.

The Patient Provider Engagement study sought to examine whether an individualized, computerized "roadmap" (Fig. 1) detailing trajectory of health measures relevant to diabetes management as well as current levels would improve patient-provider engagement, patient self-management of diabetes outside of provider visits, and health outcomes for diabetes patients in primary care in a downtown Atlanta hospital. We used systolic blood pressure taken at each patient encounter as a metric for diabetes control, as this measure was available at each

encounter for every patient. It was hypothesized that patients receiving the intervention would show more improvement of diabetes control measures than patients in the control group.

Study Methods

Diabetes patients were recruited in the waiting room at regularly scheduled follow up visits with a physician in the primary care clinic. Patients were randomized into one of two study arms: control or intervention. Randomization was performed using a random number generator.

At every visit, intervention patients were given an individualized "roadmap" that showed their A1c, systolic blood pressure, and LDL cholesterol measurements from approximately the last year. These measurements were color coded to match a traffic light by age-specific recommended values from ADA guidelines (green indicates "good," yellow indicates "caution," and red indicates "danger"). The systolic blood pressure from triage that day was manually added to the appropriate timeline on the roadmap and color-coded, and the blood glucose taken at triage (with consideration of whether it was random or fasting) was notated and color-coded as well. Intervention patients also received a weightlifter page that showed the same information on the roadmap, but presented in the context of "How hard is this value on your body?" These pages presented the most recent A1c, blood glucose, systolic blood pressure, and LDL cholesterol with the same traffic light color-coding. The roadmap and weightlifter pages were discussed with the intervention patients to make sure they understood what was being presented. Finally, intervention patients were given the option to take a communication card about A1c, blood pressure, or LDL cholesterol. These cards had common myths about these three measurements on one side, and possible conversation-starting questions for their providers on the other side.

Before the physician visit, all participants were given a multiple choice knowledge questionnaire (KQ) asking them questions such as "How well do you think your diabetes is under control?" and "Do you know what your A1c should be?" After their doctor visit, patients were interviewed a second time. They were given the same knowledge questionnaire, as well as a questionnaire about the content of the visit (CQ) that asked questions such as "Did your doctor talk to you about how your diabetes/blood pressure/cholesterol are doing?" Intervention patients were also asked about how useful they found the roadmap and whether their provider looked at it or discussed it with them at this time. Additionally, there were two questions about the usefulness of the communication cards. Finally, all participants were given the 21-question Medical Interview Satisfaction Scale (MISS-21) survey to assess how happy they were with their provider encounter. This survey has 4 subscales: Communication Comfort, Distress Relief, Rapport, and Compliance Intent.

Until approximately a year after the beginning of recruitment, enrolled patients were approached at all physician walk-in or follow up visits in the primary care clinic and given the same interview and intervention patients received the same materials with updated or added values as they were available from new lab results and discussion about the materials. From visit 2 onward, intervention patients were asked a few additional questions in the before visit interview about what they did with their roadmap after leaving the hospital. For instance: "Did you share the roadmap with family or friends?" and "Did you hang the roadmap on your refrigerator?" were asked at this time.

The number of attempted visits with each patient was capped at 8, but this only ended up applying to one participant. Occasionally, patients were missed before or after a visit for an interview, and in those cases, attempts were made to call the patient and perform the after visit interview. Visits that were skipped entirely by patients were not counted toward their visit total, but encounters where the physician visit did occur, but interviewers missed the patient for any reason or the patient refused the interview were counted, whether or not the data could be collected.

Analysis

All analyses were performed in SAS. Descriptive statistics at the first visit for participants for both study arms were compared to assess the success of randomization. Study arms were compared using two-way paired t-tests for continuous variables and Chi suqare tests for (Table 1). Bivariate analyses of associations of the study outcome (SBP) with selected predictors split by study arm were performed and correlation coefficients were calculated for continuous variables and Chi square tests were performed for categorical variables (Table 4).

The visit data for the participants was consolidated into baseline (every first visit), and time periods 1-3 as available. This was done by using whichever completed visits were as close as possible to 90 and 180 days after visit 1 as available. For data with defined “before” and “after” time points where the trajectory between them does not matter, a difference in differences model is appropriate for analysis. This model analyzes the change in one group while controlling for baseline differences between groups, and the change experienced by

the comparison group. A difference in differences technique was applied comparing the SBP at each time period to baseline between groups, since randomization should presumably control for covariates (Table 3).

The MIXED procedure was used to run D-I-D models for the two "after" time points defined as close to 90 days and 180 days after enrollment as possible. These models included only terms for study arm, time period, and an interaction term for study arm*time since other covariates were controlled for in the randomization process. The significance of the interaction term shows whether the intervention arm experienced a significantly different change over time than the control arm experienced.

Results

Descriptive results

The presence of significant differences between study arms was calculated for baseline values of potential confounders (age, race, marital status, education, work status, insurance status, household income, and the visit 1 associated values for POCT glucose, LDL, A1c, BMI, SBP and DBP). None of these were found to be significantly different between study arms, and this suggests that randomization was successful (Table 1). Overall, patients were 59.9 years old on average. 94.42% of the participants identified as African American. About a third of the sample had never been married, and nearly 38% were separated or divorced. 16.6% were widowed, and about 12% were married. Nearly 40% had finishing high school/GED as their highest level of educational attainment, while 8.2% had finished college and 2.6% had a graduate degree. 5.6% reported working full time, about 7% reported being unemployed, 23% were retired, and just over 50% reported being disabled. 53% reported having Medicaid, 52% reported having Medicare, and many of those reported both. 22.6% were uninsured, and 4.5% were on either individual or group plans. 73% of participants reported an annual household income of $15,000 or less, with 20% of participants reporting <$5,000.

The average POCT glucose value taken at visit 1 for the whole study sample was 168.57. LDL was 89.51, A1c was 7.79, BMI was 34.13, SBP was 137.66, and DBP was 74.91.

107 participants were enrolled in the intervention arm of the study, and 90 were enrolled in the control arm. Three participants were withdrawn: 2 enrollees

were found to not be diabetic after enrollment, and 1 enrollee was discovered to be suffering from dementia and it was decided that they should be withdrawn.

The 197 participants retained in the study were attempted to be interviewed at each walk in or follow up visit that they had with their physician until the end of the study period. Occasionally participants could not be interviewed at their visits. Sometimes they were missed in the waiting room, sometimes they refused to be interviewed that day, and rarely they were admitted to the hospital directly from their visits. Additionally, some patients would miss scheduled visits. The number of completed visits by each participant varied due to the ability of interviewers to catch them in the waiting room, and how many visits were scheduled for each participant. There were 101 completed "before" baseline visits for the intervention arm and 85 for the control arm. Since consenting patients took some time, there was not always enough time to get through all of the questionnaires and roadmap materials if applicable before patients spoke with their doctors, and while patients were called if after questionnaires were not completed, there was no way to try to capture the before visit information once the visit had already taken place. 77 visit 2's were completed for the intervention group and 62 visit 2's were completed for the control group. For visit 3, there were 42 intervention visits with before questionnaires completed and 37 control visits with before questionnaires completed. For visit 4, there were 19 intervention visits and 10 control visits. After that, the data are too sparse to consider analyzing, but one control patient was followed up through visit 8.

While there was severe, though not unexpected, attenuation in the number of encounters that could be used for analysis in both study arms for the follow up periods used in the D-I-D models, the difference between the counts for the 3 month and 6 month follow up time definitions was minimal for the intervention group (60 visits at 3 months versus 62 visits at 6 months) and wider for the control group (54 visits at 3 months and 44 visits at 6 months). These counts are shown in the top row of Table 3.

Bivariate results

Correlation coefficients and associated significance were calculated for systolic blood pressure and age, race, POCT glucose, LDL, A1c, and BMI at baseline and at the three month and six month follow up periods. The only significant values were seen in the control arm of the study, where BMI was significantly associated with SBP at baseline and the three month period, and age was significantly associated with SBP at the 6 month period only (Table 4).

Questionnaire results

There was very little change over time in the before visit knowledge questionnaire survey results between study arms at the three examined time periods, and also only small differences in confidence and correctness of answers between arms. (Table 3)

D-I-D Models

D-I-D models were run using PROC MIXED in SAS comparing SBP at baseline by study arm to each of the two defined follow up periods: 3 months and 6 months after baseline as well as a model using all three time points. None of the interaction

terms in the models were found to be significant (Table 6). The p-value of the interaction term in the 3 month model was 0.88, the p-value of the interaction term in the 6 month model was 0.46, and the p-value for the model with all three time periods was 0.47.

Discussion

Little change was observed in either group's SBP over the study period. At the 6 month time period, the intervention group had dropped by about 3 mmHg from the baseline measurement, but this is a small and not clinically meaningful difference. The choice of metric and length of time of the study could contribute to this statistical insignificance.

Despite insignificant D-I-D models, intervention patients tended to report positive reactions toward the roadmap and other materials given by the study and generally seemed to appreciate the extra coaching and an opportunity to discuss what the doctor said after the visit.

Qualitatively, patients and doctors seemed to discuss improving diet, increasing exercise levels, and adhering to or changing medication regimens most frequently when discussing what might improve diabetes control. Some other discussions were about weight loss, reducing alcohol consumption, meal timing, stress reduction, and eating less salt. While some patients reported very nonspecific answers (single word answers like "diet" or "exercise"), other patients gave quite detailed descriptions of the advice they were given by their providers. These differences could beg the question as to whether the patients that could report more detailed advice from their providers "got more" from the encounter and are more likely to act on lifestyle changes that were proposed in the encounter. A qualitative examination of the descriptions of the advice given by their doctors cross-referenced with answers to questions like those asked of the intervention arm about

their success in changing their lifestyles could answer this question in future studies.

A nearly identical pattern emerged when patients discussed how to improve systolic blood pressure control specifically with their doctor as well. Medication adherence or change and diet, especially sodium intake, were most commonly cited as what was discussed in the visit with the provider.

Limitations

Although this was certainly not the case for everyone, it is possible that some of the participants in this study felt discouraged from reporting dissatisfaction with their providers to interviewers due to a perceived "medical" role that the study interviewers may have had (hospital badge, office space in waiting room, etc). Since correctly capturing the patients' perceptions of their interactions with their doctors is certainly relevant to patient empowerment, any errors or biases in these measurements are concerning when considering the internal validity of study results.

Attempts to account for differences in follow up time between participants were made in analysis. Specifically, completed visits that happened as close as possible to 3 months and 6 months after enrollment were used as "after" points. However, follow up times for patients were determined by how appointments were scheduled independently of the PPE project. This means that patients who were more ill with complications from diabetes or who had other significant health issues were likely to be scheduled many times in a shorter period, and therefore more of their data was likely to be missed by this analysis. Analyses that somehow use all

collected data points would give a more complete picture of how effective the intervention was, since the methodology employed for this study omitted a lot of encounters.

The MISS survey measuring patient satisfaction yielded results that were not compelling. Patients tended to answer all questions with the same value, perhaps due to boredom with the surveys (MISS was the last survey administered, and was the longest one), and they nearly always responded completely positively. Further, patients tended to be confused by the backwards-coded questions. There were certain statements on the survey that many patients found not to be applicable to their experiences as well. In particular, "I have a good idea of how long it will be until I am well again" and "This is a doctor I would trust with my life" most commonly caused participants to balk in answering. Regarding the former, patients either did not consider themselves to be "sick" or understood diabetes to be incurable in the first place, and in either case, the concept of "getting well" becomes nonsensical. Somewhat often, patients would respond to the latter question by saying that they "don't trust anyone with their life." Issues like these hinder any analysis that might be performed on the MISS survey, and the subscales employed by this tool become harder to use with confidence if misconceptions and other issues with certain questions are widespread in the study population.

Using systolic blood pressure as a diabetes control marker is not without problems, and despite the advantages (continuous for easier modeling, universally available at all visits), it is subject to variation and measurement error. POCT glucose would have had similar variability, but, for this study, would come with

added complications. Only some measurements were taken on fasting patients, and there was no way to verify which values were fasting for all encounters, particularly in encounters with control arm patients. Random measurements were more common than fasting, and are highly dependent on what was eaten and how long ago. A1c values would be ideal, but these values were not neatly available for all patients at all visits.

With any relevant health outcome measurement, more time than this study had usable amounts of data for is likely required to observe clinically relevant changes. It may be useful to implement this kind of intervention concurrently with providers and patients if possible, rather than simply presenting speaking with the provider about the roadmap as an option to the patient.

Appendix

Variable	Intervention(%)	Control(%)	Total(%)	Prob
N	107	90	197	
Age	60.7(9.6)	59.1(10.5)	59.9(10.0)	0.268
Race				0.444
White	4(3.74)	3(3.33)	7(3.55)	
Black	100(93.46)	86(95.56)	186(94.42)	
Other	3(2.80)	1(1.11)	4(2.03)	
Marital Status				0.066
Never Married	30(28.85)	35(39.33)	65(33.68)	
Married	12(11.54)	11(12.36)	23(11.92)	
Separated/divorced	41(39.42)	32(35.96)	73(37.82)	
Widowed	21(20.19)	11(12.36)	32(16.58)	
Missing	3	1	4	
Education				0.478
</=8th grade	8(7.62)	5(5.56)	13(6.67)	
Some high school	19(18.10)	22(24.44)	31(21.03)	
High school/GED	43(40.95)	32(35.56)	75(38.46)	
Some college/tech school	20(19.05)	25(27.78)	45(23.08)	
College grad (bachelor's)	11(10.48)	5(5.56)	16(8.21)	
Graduate degree	4(3.81)	1(1.11)	5(2.56)	
Missing	2	0	2	
Work				0.48
Full time	6(5.71)	5(5.56)	11(5.64)	
Part time	6(5.71)	6(6.67)	12(6.15)	
Unemployed/looking	5(4.76)	4(4.44)	9(4.62)	
Unemployed/not looking	9(8.57)	4(4.44)	13(6.67)	
Homemaker	1(0.95)	0	1(0.51)	
In school	0	0	0	
Retired	27(25.71)	18(20.00)	45(23.08)	
Disabled	50(47.62)	51(56.67)	101(51.79)	
Other	1(0.95)	2(2.22)	3(1.54)	
Missing	2		2	
Insurance				
Individual	3(2.86)	2(2.22)	5(2.56)	0.78
Group	3(2.86)	1(1.11)	4(2.05)	0.392
US Government	0	0	0	-
Medicaid	50(47.62)	54(60.00)	104(53.33)	0.085
Medicare	56(53.33)	46(51.11)	102(52.31)	0.757
None	26(24.76)	18(20.00)	44(22.56)	0.429
Missing	2	0	2	

Income				0.392
<$5000	19(19.79)	17(20.73)	36(20.22)	
$5000-$9999	29(30.21)	22(26.83)	51(28.65)	
$10,000-$14,999	23(23.96)	20(24.39)	43(24.16)	
$15,000-$19,999	12(12.50)	6(7.32)	18(10.11)	
$20,000-$29,999	6(6.25)	9(10.98)	15(8.43)	
$30,000-$39,999	5(5.21)	3(3.66)	8(4.49)	
$40,000-$49,999	1(1.04)	2(2.44)	3(1.69)	
$50,000-$59,999	0	1(1.22)	1(0.56)	
$60,000-$69,999	1(1.04)	1(1.22)	2(1.12)	
>$70,000	0	1(1.22)	1(0.56)	
Missing	11	8	19	
Visit 1- Associated Values				
POCT glucose	169.52(70.08)	167.47(73.78)	168.57(71.61)	0.85
LDL	94.02(39.77)	83.99(31.69)	89.51(36.62)	0.06
A1c	7.88(2.39)	7.68(1.90)	7.79(2.18)	0.52
BMI	33.64(7.90)	34.73(7.48)	34.13(7.71)	0.33
SBP	136.79(19.64)	138.70(18.63)	137.66(19.16)	0.49
DBP	73.58(11.71)	76.49(10.70)	74.91(11.33)	0.07

Table 1: Descriptive analysis of potential confounders split by study arm. Chi square tests performed on categorical variables, and t-tests performed on continuous variables. No significant findings suggest successful randomization.

	Intervention	Control	Total
Visit 1 (N)	101	85	186
Visit 2	77 (76.2)	62 (72.9)	139 (74.7)
Visit 3	42 (41.6)	37 (43.5)	79 (42.5)
Visit 4	19 (18.8)	10 (11.8)	29 (15.6)
Visit 5	2 (2.0)	1 (1.2)	3 (1.6)
Visit 6	0	0	0
Visit 7	0	1 (1.2)	1 (0.5)
Visit 8	0	1 (1.2)	1 (0.5)

Table 2: counts of visits with before visit interview completed for participants split by study arm.

Baseline

Question	Intervention	Control
	N(% yes/correct)	N(%) yes/correct)
Do you know what an A1c is?	51(49.51)	47(56.63)
What should your A1c be?	35(32.71)	34(38.2)
What should your SBP be?	45(42.06)	32(35.96)

3 Months

Question	Intervention	Control
	N(% yes/correct)	N(%) yes/correct)
Do you know what an A1c is?	32(60.38)	29(63.04)
What should your A1c be?	25(40.32)	22(40.74)
What should your SBP be?	23(37.10)	19(35.19)

6 Months

Question	Intervention	Control
	N(% yes/correct)	N(%) yes/correct)
Do you know what an A1c is?	32(65.31)	22(61.11)
What should your A1c be?	23(37.10)	20(45.45)
What should your SBP be?	21(33.87)	16(36.36)

Table 3: breakdown by study arm of answers to selected questions from the before visit administration of the knowledge questionnaire

Intervention				Control			
Variable	ρ with SBP(t)			Variable	ρ with SBP(t)		
	Baseline	T1	T2		Baseline	T1	T2
N	106	60	62	N	89	54	44
mean SBP	136.8	137.3	135.9	mean SBP	138.7	139.0	138.3
Age	- 0.01(0.939)	0.17 (0.20)	-0.17 (0.18)	Age	0.02 (0.84)	-0.05 (0.75)	-0.35 (0.02*)
Race	-0.02 (0.73)	-0.13 (0.12)	-0.10 (0.05)	Race	-0.17 (0.08)	0.02 (0.02)	-
White				White			
Black				Black			
Other				Other			
Biological Vars				Biological Vars			
POCT glucose	0.02 (0.82)	-0.07 (0.64)	-0.28 (0.03)	POCT glucose	0.04 (0.74)	-0.07 (0.65)	-0.05 (0.74)
LDL	0.13 (0.18)	0.03 (0.80)	0.07 (0.61)	LDL	-0.01 (0.96)	0.24 (0.09)	0.08 (0.63)
A1c	-0.12 (0.21)	-0.07 (0.58)	-0.14 (0.18)	A1c	0.03 (0.75)	0.21 (0.14)	-0.10 (0.52)
BMI	0.06 (0.56)	0.13 (0.34)	-0.06 (0.63)	BMI	0.22 (0.04*)	0.38 (0.004)*	0.11 (0.48)

Only African American Race at T2 for Control group

Table 4: Correlation coefficients of selected covariates with SBP over time points selected

	Intervention	Control	Total
Baseline (N)	101	85	186
~90 days (% retention from baseline)	52 (51.5)	47 (55.3)	99 (53.2)
~180 days (% retention from baseline)	49 (48.5)	36 (42.4)	85 (45.7)

Table 5: Number of completed "before visit" encounters. 90 day period includes up to days >30-135, and 180 day period includes >135-225. only 1 "after period" visit per participant per "after period" definition

Model	F Value	P-value
Baseline-3 mo	0.02	0.88
Baseline-6 mo	0.55	0.46
Baseline-3 mo-6 mo	0.85	0.47

Table 6: D-I-D analysis results for baseline to 3 months, baseline to 6 months and all three time points.

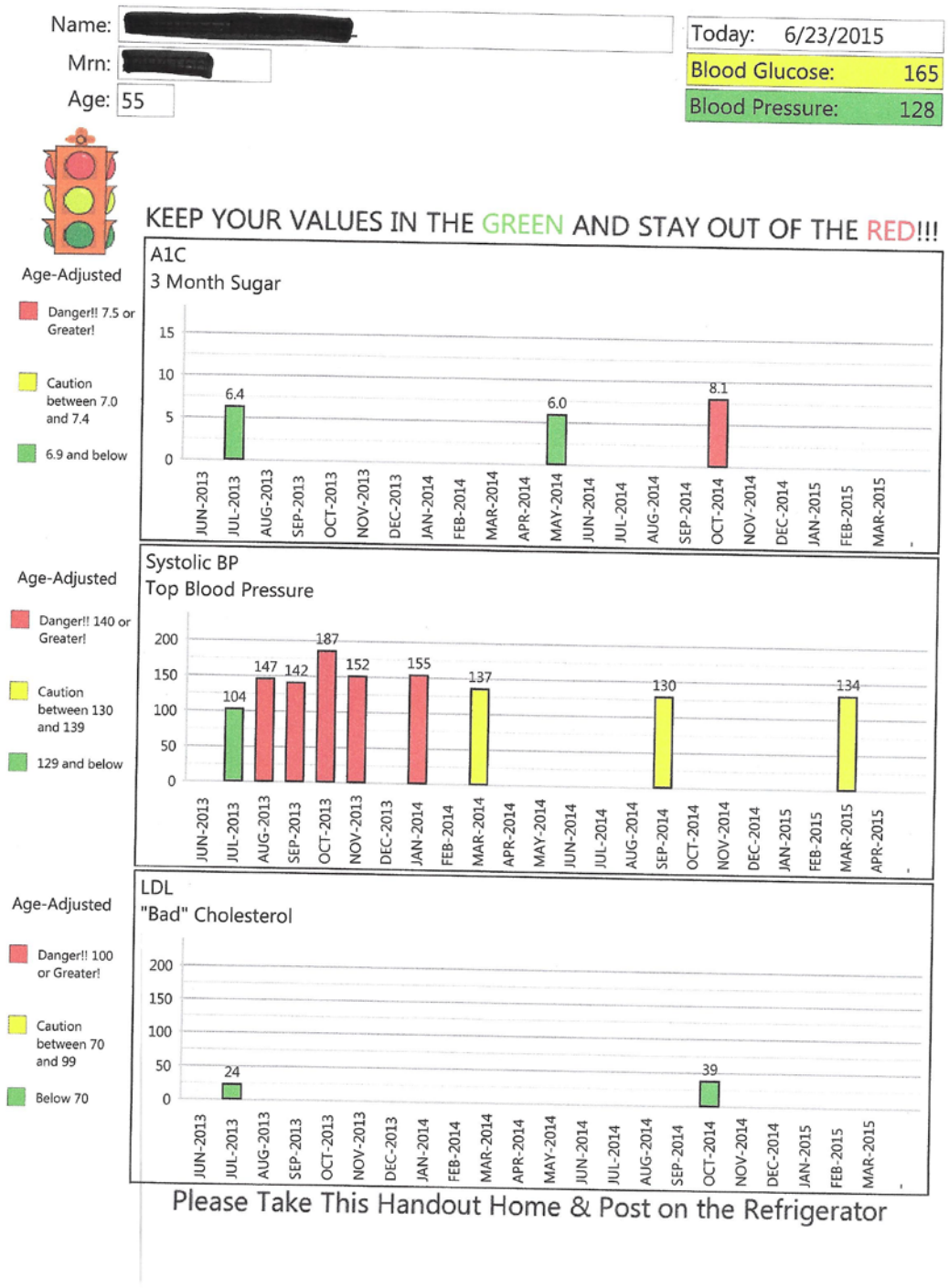

Figure 1: Sample Roadmap

Figure 2: Questionnaires

BEFORE VISIT **Patient Knowledge: Please help us by answering the following as best you can.**	**MRN:**	**DATE:**

1. How well is your diabetes under control? [Select one]
    a. Totally under control
    b. Under good control
    c. Somewhat under control
    d. Under bad control
    e. Totally out of control
    f. I don't know how well my diabetes is under control

2. Do you know what an A1C is? No Yes

3. What should your A1C be? [Select one]
    a. Less than 5.5
    b. Less than 6.0
    c. Less than 6.5
    d. Less than 7.0
    e. Less than 7.5
    f. Less than 8.0
    g. Other _____
    h. I don't know what my A1C should be

4. What should your sugars be before meals? [Select one]
    a. Less than 70
    b. Less than 90
    c. Less than 130
    d. Less than 150
    e. Less than 200
    f. Other _____
    g. I don't know what my sugars should be

5. What is a *normal* systolic (top number) blood pressure? [Select one]
    a. Less than 110
    b. Less than 120
    c. Less than 130
    d. Less than 140
    e. Less than 150
    f. Other _____
    g. I don't know what my systolic blood pressure should be

6. What is a *normal* diastolic (bottom number) blood pressure? [Select one]
    a. Less than 60
    b. Less than 80
    c. Less than 90
    d. Less than 100
    e. Less than 110
    f. Other _____
    g. I don't know what my diastolic blood pressure should be

7. Do you know what LDL (bad) cholesterol is? No Yes

8. What should your LDL (bad) cholesterol be if you have high blood pressure or smoke?
    a. Less than 60
    b. Less than 70
    c. Less than 80
    d. Less than 90
    e. Less than 100
    f. Other _____
    g. I don't know what my LDL (bad) cholesterol should be

BEFORE VISIT

MRN:	**DATE:**

INTERVENTION ONLY:

1. What did you do with the roadmap when you got home? _____
   _____
2. Did you hang the roadmap up on your refrigerator? Yes No
3. Did you share your roadmap with a family member or friend? Yes No
4. Did the roadmap make you think about changing any behaviors? Yes No
   What behaviors? _____
   _____
5. Did you change any behaviors? Yes No
   What behaviors? _____
   _____

AFTER VISIT **Patient Knowledge: Please help us by answering the following as best you can.**	**MRN:**	**DATE:**

1. How well is your diabetes under control? [Select one]
   a. Totally under control
   b. Under good control
   c. Somewhat under control
   d. Under bad control
   e. Totally out of control
   f. I don't know how well my diabetes is under control

2. Do you know what an A1C is? No Yes

3. What should your A1C be? [Select one]
   a. Less than 5.5
   b. Less than 6.0
   c. Less than 6.5
   d. Less than 7.0
   e. Less than 7.5
   f. Less than 8.0
   g. Other _____
   h. I don't know what my A1C should be

4. What should your sugars be before meals? [Select one]
   a. Less than 70
   b. Less than 90
   c. Less than 130
   d. Less than 150
   e. Less than 200
   f. Other _____
   g. I don't know what my sugars should be

5. What is a *normal* systolic (top number) blood pressure? [Select one]
   a. Less than 110
   b. Less than 120
   c. Less than 130
   d. Less than 140
   e. Less than 150
   f. Other _____
   g. I don't know what my systolic blood pressure should be

6. What is a *normal* diastolic (bottom number) blood pressure? [Select one]

a. Less than 60
b. Less than 80
c. Less than 90
d. Less than 100
e. Less than 110
f. Other _____
g. I don't know what my diastolic blood pressure should be

7. Do you know what LDL (bad) cholesterol is? No Yes

8. What should your LDL (bad) cholesterol be if you have high blood pressure or smoke?
   a. Less than 60
   b. Less than 70
   c. Less than 80
   d. Less than 90
   e. Less than 100
   f. Other _____
   g. I don't know what my LDL (bad) cholesterol should be

AFTER VISIT

MRN:	**DATE:**

1. Did your doctor help you understand how your blood pressure is doing? Yes No
2. Did your doctor tell you your blood pressure values? Yes No
3. Did your doctor discuss goals related to blood pressure? Yes No
4. Did your doctor discuss any issues that would help improve your blood pressure? Yes No
   If yes, explain: _____
   _____
5. Did your doctor help you understand how your diabetes is doing? Yes No
6. Did your doctor tell you your A 1c values? Yes No
7. Did the doctor tell you that your diabetes is: In control Out of control
   Almost in control Did not discuss this
8. Did your doctor discuss goals related to diabetes? Yes No
9. Did your doctor discuss any issues that would help improve your diabetes? Yes No
   If yes, explain: _____
   _____
10. Did your doctor help you understand how your cholesterol is doing? Yes No
11. Did your doctor tell you your cholesterol values? Yes No
12. Did your doctor discuss goals related to cholesterol? Yes No
13. Did your doctor discuss any issues that would help improve your cholesterol? Yes No
    If yes, explain: _____
    _____

INTERVENTION ONLY:

14. Did you find the roadmap useful? Yes No
15. Did you find the roadmap more useful than a list of your lab numbers? Yes No
16. Did you discuss the roadmap with your doctor? Yes No
17. Did your doctor review the roadmap? Yes No
18. Is the roadmap something you would like to receive again? Yes No
19. How often would you like to receive the roadmap? Each visit
    Every 3-4 months
    Every year
    Would not like to receive
20. Is the roadmap easy to understand if given as a handout (no one explains it)? Yes No
21. Did you find the communication card useful? Yes No
22. Did you read the communication card out loud to your doctor? Yes No

AFTER VISIT	**MRN:**	**DATE:**

The Medical Interview Satisfaction Scale (MISS – 21)

How strongly do you agree with each of these statements? Please circle the one number that applies.

	Very Strongly Disagree	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree	Very Strongly Agree
1. The doctor told you just what your trouble is.	1	2	3	4	5	6	7
2. After talking with the doctor, you know just how serious your illness is.	1	2	3	4	5	6	7
3. The doctor told you all you wanted to know about your illness.	1	2	3	4	5	6	7
4. You are not really certain about how to follow the doctor's advice.	1	2	3	4	5	6	7
5. After talking with the doctor, you have a good idea of how long it will be before you are well again.	1	2	3	4	5	6	7
6. The doctor seemed interested in you as a person.	1	2	3	4	5	6	7
7. The doctor seemed warm and friendly to you.	1	2	3	4	5	6	7
8. The doctor seemed to take your problems seriously	1	2	3	4	5	6	7
9. You felt embarrassed while talking with the doctor.	1	2	3	4	5	6	7
10. You felt free to talk to this doctor about private matters.	1	2	3	4	5	6	7

	Very Strongly Disagree	Strongly Disagree	Disagree	Uncertain	Agree	Strongly Agree	Very Strongly Agree
11. The doctor gave you a chance to say what was really on your mind.	1	2	3	4	5	6	7
12. You really felt understood by your doctor.	1	2	3	4	5	6	7
13. The doctor did not allow you to say everything you had wanted about your problems.	1	2	3	4	5	6	7
14. The doctor did not really understand your main reason for coming.	1	2	3	4	5	6	7
15. This is a doctor you would trust with your life.	1	2	3	4	5	6	7
16. The doctor seemed to know what (s)he was doing.	1	2	3	4	5	6	7
17. The doctor has relieved your worries about your illness.	1	2	3	4	5	6	7
18. The doctor seemed to know just what to do for your problem.	1	2	3	4	5	6	7
19. You expect that it will be easy for you to follow the doctor's advice.	1	2	3	4	5	6	7
20. It may be difficult for you to do exactly what the doctor told you to do.	1	2	3	4	5	6	7
21. You're not sure the doctor's treatment will be worth the trouble it will take.	1	2	3	4	5	6	7

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