Official Study Title: Managing Diabetes to Gain Opportunities for a More Active Life (My Diabetes GOAL)

Unique Protocol ID: IRB18-0425

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Detailed Protocol

1. Background:

   Health systems are striving to optimize chronic disease management, improve health outcomes, enhance patient safety, and control health care costs. An important high risk population in health care systems is older adults living with diabetes. Patients over 65 years of age represent over 40 percent of patients living with diabetes.[1] In the coming decades, this population is expected to grow exponentially.[2] This population suffers from high rates of cardiovascular and microvascular complications as well as hypoglycemia, a consequence of treatment.[3] Despite these poor outcomes, optimal approaches to providing diabetes care for this population have not been adequately established. Clinical trials of intensive glycemic control have demonstrated long-term benefits but short-term harms.[4-6] In light of the mixed trial results, multiple organizations have called for the personalization of risk factor goals, medication management, and self-care plans among older patients.[7,8] For instance, the American Geriatrics Society (AGS)[9] and the American Diabetes Association (ADA)[10] have published recommendations urging individualized glycemic (hemoglobin A1C (A1C) <7.5% vs. <8.0% vs. <8.5%) and blood pressure (BP) control targets (<140/80 vs. <150/90 mmHg) and statin use for three strata of older patients (healthy, complex, very complex). The guidelines also acknowledged the importance of overcoming barriers to self-care management in older patients. Despite the release of these guidelines, studies of multiple national datasets have demonstrated that care of older patients is not currently being personalized based on health status.[11,12] The failure to personalize care may lead to both overtreatment of the sickest patients, as well as undertreatment of healthy patients. The barriers to providing personalized care for older people may be due to a lack of care support interventions that can be integrated into busy practices. Many clinical organizations have diabetes quality improvement systems in place, but these efforts typically do not promote individualized goals and do not have a geriatric orientation.

2. Purpose or Hypothesis:

   The purpose of this novel patient-facing disease management intervention, **My Diabetes GOAL,** is to develop and test a system embedded within the electronic medical record to engage patients in personalized goal setting and chronic disease management by: 1) establishing personalized goals of care based on comorbidities and preferences, 2) tracking diabetes measures against personalized goals, and 3) selecting the route and intensity of care management to help patients achieve their goals (e.g., telephonic care management, in-person care management, and self-care resources). This application can be used to individualize care, increase engagement with patient portals, and improve patient self-efficacy, as they take a more active role in their care.

3. Description of Protocol Methodology:

   We will conduct a 6-month randomized controlled trial comparing My Diabetes GOAL vs. usual care within University of Chicago clinics (endocrinology, primary care group, and geriatrics). After agreeing to participate, patients will be randomly assigned to each arm, for a total of 50 patients per arm. Patients that are enrolled in the intervention arm will receive an email message via MyChart to complete the initial questionnaire. If there is an initial non-response, we will try three additional times over a one month period. Completion of the questionnaire will be required prior to initiating risk factor tracking and opening the portal to requests for care management support. Patients enrolled in the usual care will receive the My Diabetes GOAL survey with a 6 months delayed start.

Prior to receiving the survey, they will be able to continue to receive routine diabetes care and education provided by diabetes educators and clinical staff. Upon completion the study, all patients will receive a post-survey via MyChart.Electronic Health records will be a critical source of data on key processes of care that are affected by My Diabetes GOAL including goal setting measures (documenting personalized goals of diabetes care, proportion following ADA recommendations, proportion choosing alternative goals) as well as referrals to care management and frequency of phone contacts. The EHR will also be the primary source of data for risk factor levels (glycosylated hemoglobin, blood pressure, cholesterol levels), medications, and health care utilization (outpatient visits, care management services, ER visits, and hospitalizations). These data are continually collected as a part of routine care.

4. Duration:
   The initial MyChart survey should not take more than 10 minutes to complete. The post-survey should not take more than 5 minutes to complete. Enrollment in services or receipt of telephonic care management is up to the patient, and dependent on their responses to the survey questions. After 6 months, we will terminate telephonic care management follow-up phone calls.

5. Exact Location:
   The surveys will be conducted online.

6. Special precautions: n/a

7. Experimental controls:

   50 control patients will receive a delayed intervention so we can compare usual care versus the intervention arm, but still distribute the survey and potential telephonic care management to the control arm at a later date. Patients will be the units of randomization. We will enroll patients over 65 years of age with active MyChart accounts, diagnosis of type 2 diabetes, and outpatient clinic visit in the prior year. Because of the general purpose of the intervention, we will not exclude patients with comorbid illnesses or functional impairments. We plan to enroll 100 patients. We will determine trial arm assignment through a random number generator.

8. Outcome measures:

   The primary endpoint is documention of a personalized goal for diabetes care (e.g., A1C target) (yes or no) in 6 months. Secondary endpoints include patient engagement with MyChart, patient selection of personalized goals, patients' ability to reach their personal treatment goals. We will also collect data on hypoglycemia, psychosocial measures, and health care utilization. It is also possible that changes in patient reported outcomes and utilization will occur earlier than expected through mechanisms that are separate from changes in drug prescribing and risk factor control.

   The **documentation measures** (utilization of MyChart, documenting personalized goals of diabetes care, proportion following ADA recommendations, proportion choosing a goal different from the ADA recommendations) will be assessed by comparing results from the EHR at baseline (6 month lookback) and at 6 months of the trial. For **short-term clinical outcomes**, we will evaluate changes

in the proportion of patients with out-of-range A1Cs (A1C>9.0%, A1C<6.5% taking insulin/sulfonylureas) and blood pressures (BP>150/90, BP<120/65). We will also assess changes in the proportion of patients taking statins and specific glucose lowering agents. These analyses will be done for the overall population along with comparisons of drug use by the ADA risk strata. To evaluate **health care utilization**, we will again utilize the EHR to determine the frequency of referrals to telephone care management, the source of referrals (population management, physician), the patient predictors of referrals, and to characterize frequency and content of telephonic management.

9. Statistical analysis:

For the primary endpoint analysis, we will use the Fisher's exact test, and the logistic regression model to compare the two groups. We will also use both the generalized linear mixed model (GLMM) and the generalized estimating equation (GEE) to model % documentation over time (at baseline and 6 months) and test the effects of treatment, time, and interaction between treatment and time. We will first fit unadjusted model and then adjust for potential risk factors such as age, gender, race, and its baseline outcome. Within-subject correlation will be taken into account.

For the analyses of secondary endpoints, we will conduct between-cohort analyses for those outcomes which can be obtained for both groups, mainly through EHR, and conduct within-cohort analyses for those outcomes which can be collected only in the intervention group.

For between-cohort analyses, for the repeated-measured continuous outcomes such as A1c and BP, we will use a linear mixed model (LMM) to model the outcome over time and test the effects of treatment, time, and treatment-by-time interaction. For the repeated-measured binary outcome such as utilization of MyChart and following ADA recommendations, the same statistical methods as for the primary endpoint will be applied. A Wilcoxon's rank-sum test, and the bootstrapping method will be used to compare frequencies of each type of health care utilization (primary care, emergency room, and hospital visits) for prior 6 months, at baseline and 6 months, and their changed frequencies at 6 months from baseline, respectively. A GEE will also be used to model the frequencies of health care utilization over time.

For within-cohort analyses, i.e., within the intervention group, for the continuous outcome (which will be measured once during the study) such as patient engagement with MyChart, a multiple linear regression will be performed to test the time tread, i.e., conduct self-comparison (post versus before). For the repeated measured binary outcome such as patients' awareness of their A1c goal, both GLMM and GEE will be used to test the time trend. For the binary outcome (which will be measured once during the study) such as achieving their A1c goal at 6 months, the logistic regression model will be used to test the time trend.

We will repeat the analysis plan above, if necessary, at 12 months for the available outcomes from EHR for sustainability check between the groups and/or within cohort.

Power and sample size justification: The primary outcome is documenting personalized goals of diabetes care in 6 months. We expect that at baseline, in both groups, there would have <5% patients whose charts have been documented their personalized goals. We presume that the intervention group will have more than 50%. Using the Fisher's exact test, a total sample size of 44 subjects (22 per group) is needed to obtain at least 90% power to detect the difference between the two groups at a two-sided significance of 5%. With a total sample size of 100, the power will be >0.99.

10. Potential risks and benefits to subjects: The risks include loss of confidentiality. The potential benefits include an improvement in their health through additional screening for risks associated with their chronic disease, improved communication with their physician, referrals to beneficial resources that they may not be aware of, which could improve patient outcomes.

11. Monitoring of safety of subjects: The subjects will be monitored via the survey responses and screened for any potential risks for harm. If the diabetes care manager conducts telephonic care management with patients, they will also be monitored for safety by a registered nurse. There is no DSMB for the study as there are no unanticipated risks to the subjects.

12. Payment to subjects: Subjects will not be paid for this study.

13. Procedures to obtain and record informed consent: We will call patients and ask them if they would be interested in participating in the study. If they are interested, we will either email, fax, or mail a copy of the informed consent document. Once received, we will review the document together and if the patient consents to participate, they will sign the document and either fax or email a scanned copy of the consent back to the research office, or mail it back to the study research office. Once the signed consent form is received, the patient will receive an email via MyChart inviting them to participate in a survey.

14. Procedures which will be used to maintain confidentiality: All information obtained for analysis will de-identified. All informed consent forms will be kept in a locked cabinet. All data will be stored on secure network drives and any written information will be kept in locked cabinets.

15. Bibliography: Please refer to the end of the document.

16. Description of recruiting methods: Subjects were identified via an ACRES report. There will be no advertisement for this study.

17. Description of how the subject's primary physician will be notified of and, as appropriate, involved in the proposed research: Subjects' primary care physician will be sent an email asked to assent for their patient to participate in the study prior to the study staff reaching out to individual patients.

18. A rationale for excluding women, minorities and/or children from participation: Children will not be included in this study as they are not in the population under study. This study is investigating adults with diabetes that are 65 years or older as they are a population with complex health needs (see background).

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