Implementation and Evaluation of a Diabetes Prevention Clinical Pathway in Primary Care

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Introduction

Abstract and Background:
Prediabetes is a significant public health problem affecting 88 million U.S. adults. Evidence suggests that the vast majority of people with prediabetes are unaware that they have this condition and many are not receiving appropriate care for prediabetes, including referral to evidence-based programs like the Diabetes Prevention Programs. In our retrospective cohort study of patients with prediabetes from Johns Hopkins Health Systems, we found that the rates of prediabetes clinical care activities are low. In our qualitative studies, we found that primary care physician (PCP) barriers include low knowledge about Diabetes Prevention Programs and misperceptions of insurance coverage of these programs and inadequate clinical staff to address prediabetes. Common patient barriers to taking action to prevent diabetes include lack of motivation, time and resources.

Primary Hypothesis: We hypothesize that the clinical pathway will result in increased clinician screening and intervention and improve patient engagement in diabetes prevention. We will compare results from the intervention clinic compared to a control clinic. If successful, we plan to implement and test the effectiveness of this clinical pathway across the entire health system.

Purpose of the Study Protocol: As described above, we have conducted several studies to under current practices in prediabetes care across the Johns Hopkins Health Systems. In our retrospective cohort study of patients with prediabetes from Johns Hopkins, we found that the rates of prediabetes clinical care activities are low. Within 12 months, 63.4% had repeat glycemic testing, yet only 10.4% had coded diagnoses of prediabetes, 1.0% were referred for nutrition services, and 5.4% were prescribed metformin. We were unable to evaluate uptake of Diabetes Prevention Programs (DPPs) since a referral order was not in place until recently. In our qualitative studies, we found that clinician barriers include low knowledge about DPPs and misperceptions of insurance coverage of these programs and inadequate clinical staff to address prediabetes. Common patient barriers to taking action to prevent diabetes include lack of motivation, time and resources.

Based on our prior research, comprehensive strategies are urgently needed to improve prediabetes care. Using these findings, we have designed and plan to implement a diabetes prevention clinical pathway which seeks to address some of these common clinician and patient barriers.

Study Objectives

Objective: Our primary objective to design and pilot test the diabetes prevention clinical pathway at a primary care clinic compared to a control primary care clinic.

Study Design

Overview: This is a non-randomized, quasi-experimental intervention study with one comparison group. Eligible patients include those on the prediabetes registry who are seen in the control and intervention clinics during the study period. Data is collected on eligible patients during the baseline (pre-implementation) period and prospectively during the 12-month implementation period.

Intervention Study Population Inclusion/Exclusion:

- Adults age 18 and older, on prediabetes registry, last A1c<6.5%
- Complete one visit (video or office visit) with PCP during intervention period

Blinding

While this study meets the NIH definition of a clinical trial, participants are not randomized or assigned at the patient level. The intervention is implemented clinic-wide and is intended to augment routine care (quality improvement). Therefore, the traditional terms of blinding in a clinical trial are not applicable.

Risks and Benefits

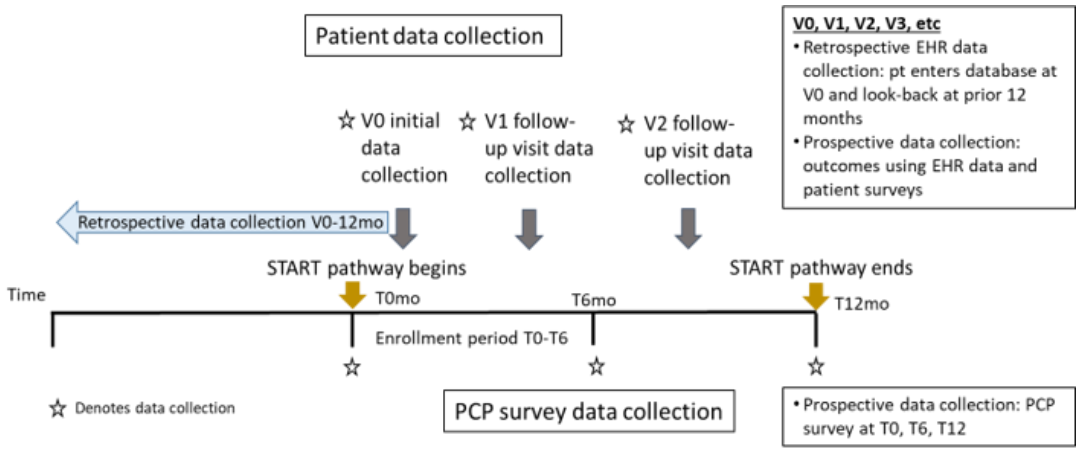
We believe the intervention involves minimal medical risk and is aligned with routine, evidence-based care. Participants may benefit from the intervention because of improved follow-up care (including visits, labs, and referrals) which may in turn result in a decreased risk of progression to diabetes. We aim to fill an important gap in knowledge about successful primary care clinic interventions to improve diabetes prevention. We hope to address the public health burden of diabetes by focusing on and improving the primary prevention of diabetes. We believe that the risks to subjects are low and reasonable given the anticipated benefits.

Withdrawal of Subjects

The intervention is intended to improve and augment routine care. Since it is implemented clinic-wide, patients will not have the option to opt out of the intervention. Furthermore, there is no outcome of treatment failure since we are not assigning patients to a particular treatment. They will receive treatments based on individual discussions with their doctor.

Study Procedures

This is a pre-/post-evaluation of a diabetes prevention clinical pathway that will be implemented over a 12-month period at the intervention clinic. Eligible patients include those on the prediabetes registry who are seen in the control and intervention clinics during the study period. Their first visit with the PCP will be considered V0 (initial data collection) and data will be collected retrospectively (12 months prior to V0) and prospectively at that visit and subsequent primary care visits (V1, V2, V3, etc.) during the 12-month intervention period (see Figure).



The diabetes prevention clinical pathway will focus on the following steps: 1) Screen/test- testing of eligible patients for prediabetes/diabetes, 2) Education- PCPs will be encouraged to take an online learning module and in-person group training on prediabetes management, and patients with prediabetes will receive a handout about prediabetes prior to their upcoming PCP visit, 3) Action- PCPs will use a shared decision-making guide and treatment algorithm to discuss options with patients at their visit, 4) Referral- patients may be referred to DPPs and/or medical nutrition therapy (MNT), and 5) Treat- patients will be scheduled for a follow-up visit within 3-9 months with their PCP or care team (NP) to continue addressing prediabetes.

Group 1 Intervention clinic patients

PCPs in the intervention clinic will be invited and encouraged to attend the 1-hour clinician training session at the beginning of the intervention. This is considered continuing medical education, and we may be able to provide continuing medical education credit for their attendance. The training session will include information on prediabetes treatment guidelines, use of EPIC clinical decision support tools and use of the patient handout to discuss treatment options. There will be interactive skills practice incorporated. This training session may occur on up to 2 occasions to capture all PCPs. We may also record the training session so that PCPs who could not attend can view it later asynchronously.

Patients with prediabetes (e.g., “active” on prediabetes registry) presenting for a routine visit in the intervention clinic will be identified using an EPIC workbench report run the week prior to their upcoming visit. These patients, presenting for in-person or video visits, will receive the handout as an attachment either via MyChart or via email sent from REDCap.

During the visit, the patients will be encouraged to bring the prediabetes handout to review with their PCP who can use the shared-decision making guide and treatment algorithm to discuss options with the patient. Several Epic clinical-decision support tools have been built to facilitate this discussion, including a prediabetes orders smartset (which includes the DPP referral) and prediabetes smart texts that PCPs can use to send patients information.

Patients who complete their visit will be invited via email (or MyChart if no email on file) to complete an online REDCap survey. They will first receive an email to complete the e-consent form which explains the study and the potential risk/benefits of joining the study. When the e-consent is completed, the patient will automatically receive a link to the survey. The survey is voluntary and will include up to 10 questions regarding their engagement in diabetes prevention behaviors and treatment, and satisfaction and acceptability of the intervention. The timing of the survey emails and reminders will be as follow: e-consent sent within 7 days of their visit and survey reminder 3 days after first invite. We will call patients who do not complete the e-consent form within 7 days of receipt and call patients who do not complete the survey within 5 days of receipt of the survey reminder. During the calls, we may offer to fill out the survey questions with the patient since our survey response rate has been low and this may increase uptake. Patients will be offered a $10 gift card if they complete the survey. Regardless of whether patients fill out the survey, we will collect their medical record data using the PMAP database.

At the end of the visit, the patient will be encouraged to schedule a 3-6 month visit with their PCP or care team member to continue addressing prediabetes. At this follow-up visit, the same diabetes prevention clinical pathway steps will apply (i.e., handout sent before visit, survey to be completed after visit). The PCP or care team member will use the same shared-decision making guide and treatment algorithm to continue discussing treatment options with the patient.

Group 2 Control clinic patients

Patients with prediabetes (e.g., “active” on prediabetes registry) who present for a routine visit in the control clinic will be identified using an Epic workbench report. Their PCP will address prediabetes as they usually do (i.e. usual care). They can refer patients to the same interventions (DPP, MNT) or start metformin. PCPs will have access to the same Epic clinical-decision support tools as the intervention clinic does but not the shared-decision making guide and treatment algorithm to facilitate discussion. Patients will not receive the prediabetes handout.

Patients who complete their visit will be invited via email to complete an online REDCAP survey. They will first receive an email to complete the e-consent form which explains the study and the potential risk/benefits of joining the study. When the e-consent is completed, the patient will automatically receive a link to the survey. The survey is voluntary and will include up to 10 questions regarding their engagement in diabetes prevention behaviors and treatment, and satisfaction with prediabetes care. The timing of the survey emails and reminders will be as follow: e-consent sent within 7 days of their visit and survey reminder 3 days after first invite. We will call patients who do not complete the e-consent form within 7 days of receipt and call patients who do not complete the survey within 5 days of receipt of the survey reminder. During the calls, we may offer to fill out the survey questions with the patient since our survey response rate has been low and this may increase uptake. Patients will be offered a $10 gift card if they complete the survey. Regardless of whether patients fill out the survey, we will collect their medical record data using the PMAP database.

Group 3 Intervention clinic PCPs

PCPs in the intervention clinic will be recruited to provide feedback using an online REDCap survey through an in-depth survey sent via email at 0m, 6m and 12m to gather feedback on intervention components and acceptability/satisfaction with the intervention. PCPs will receive an email from REDCap with the e-consent form. Once that is completed, the PCP will receive the survey link. All survey participants will receive a $25 gift card for completion of the in-depth survey.

Safety and Adverse Events

Enrolled participants will be monitored throughout the study for untoward incidents (e.g., “Adverse Events”) occurring during the study. The Principal Investigator (and other designated individuals, if necessary) will conduct regular monitoring for safety concerns and provide general oversight for human subject safety requirements. Where necessary these occurrences will be evaluated for severity, attribution, and possible trends. All adverse events that are anticipated or described in the informed consent form will be logged appropriately and reported to the IRB on at least an annual basis (e.g., at continuing review).

Any Unanticipated Problems or unexpected “Serious Adverse Events” *related* to the study intervention or affecting the risk/benefit profile of the study, will be reported to the IRB promptly, and, in all cases, within 10 business days of discovery. Unplanned and non-emergent deviations from the IRB approved protocol will be logged and reported to the IRB annually at continuing review; all planned deviations will be submitted as a Change in Research to the IRB for approval and prior to implementation. All other event reporting requirements will be followed and all necessary parties will be notified of events/problems encountered in the study and/or changes in research, in accordance with all applicable regulations and guidelines.

Statistical Plan

Sample Size Determination and Power

We estimate that 1200 patients with prediabetes will be seen over the 12-month intervention period within each clinic (total sample of 2400 patients). Based on this sample, we estimate we will have 100% power to detect a change in rate of referral to DPPs from 0% to 25%. Additionally, we estimate that we will have 100% power to detect a change in documented prediabetes diagnosis from 10% (baseline rate estimated from Johns Hopkins data) to 34% (national estimate of the prevalence of prediabetes), follow-up lab testing completed from 50% (baseline rate estimated from Johns Hopkins data) to 60%, and referral to nutrition from 1% (baseline rate estimated from Johns Hopkins data) to 10%. In our analysis, we will assess the differences in trend of the outcomes in the baseline, intensive implementation, and sustainment periods.

Primary outcome variable

The primary outcome is whether patients with prediabetes are referred to a DPP and/or medical nutrition therapy and/or start metformin.

Secondary outcome variables

The secondary outcomes are whether patients: 1) enroll in the DPP, 2) attend a medical nutrition therapy visit, 3) complete follow-up glycemic testing, 4) fill metformin, 5) achieve weight loss ≥5% and 6) complete PCP/team follow-up visit.

Other process outcomes we will look at include whether MyChart messages with the prediabetes handout are read.

Statistical Methods

For the analysis, we will include patients with prediabetes (identified by prediabetes registry) who have completed at least once PCP visit during the first 6 months of the 12-month intervention period. We will compare the primary outcomes and other secondary outcomes between the intervention and control clinics.

We will conduct an interrupted time series analysis to evaluate the differences in trend of the outcomes in the baseline (V0-12m), intensive implementation (T0-T6m), and sustainment periods (T6m-T12m) at the patient level. We will compare these outcomes in the pre- and post-intervention periods using logistic regression models with generalized estimating equations to account for repeated observations within patients. We will use multivariate logistic regression models to determine predictors of these outcomes adjusting for race, age, and baseline HbA1c. We may adjust for clinic-level characteristics, such as patient safety culture using GLINT survey data from 2021 and 2022 if available. We will only request aggregate data from the clinic-level on safety culture.

Study Administration

Funding Source

Funding for this study is provided by the National Institute of Diabetes and Digestive Kidney Diseases under Award Number K23DK118205 (PI: Tseng).

Subject Stipends and Payments

Patients who complete the survey will receive a $10 gift card, either mailed to their home address or sent as an e-gift card based on patient preference. The last survey question will ask them to provide this information, which will not be linked to other responses. Clinicians who

complete the survey will get a $25 e-gift card sent to the email address they provide. Again, their response to this question will not be linked to other responses.