Study title: INTEGRATE-D: A Pilot-test of Implementation Strategies to Support Integration of Medical and Psychosocial Care for People with Type II Diabetes

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The INTEGRATE-D Intervention

INTEGRATE-D was an implementation support intervention designed to help clinics align care with ADA recommendations.[4] The intervention was initially comprised of 15-months of tailored external support that included three evidence-informed implementation support strategies: (1) Audit and feedback–assisting clinics in accessing actionable data reports to identify care gaps;[16,17] (2) Skill-building resources–expert training on ADA-recommended care, DD, pragmatic screening and treatment strategies, and education in the medical aspects of type 2 diabetes targeted to BHCs;[18-21] and (3) Facilitation–monthly, tailored support to help clinics identify and implement changes to align care with ADA recommendations utilizing Plan Do Study Act (PDSA) cycles and the Bodenheimer Building Blocks.[22-24]

We modified INTEGRATE-D to accommodate strains due to COVID-19 and to align with what we learned from baseline assessments. Table 1 shows clinics received monthly facilitation remotely rather than in person. IC1 received 15 once monthly facilitation meetings; IC2 received 11 due to the delayed intervention start. Facilitation was tailored and included PDSA cycles that tested workflows to incorporate psychosocial screening; facilitators did not use audit and feedback data. We delivered two remote expert trainings to IC1. Trainings were recorded and shared with IC2.

Table 1. Intervention Components, Description, Frequency and Timeline

Intervention Component	**Who Provided Support**	**Description**	**Frequency and timeline**
Expert Training	Physician, BHC, and expert in implementing DD	Education for clinical teams in ADA recommendations and self-management support materials 1. Psychosocial care, type 2 diabetes and DD training for all clinical roles delivered by a physician and DD expert 2. BHC training about the role of the BHC in caring for patient with type 2 diabetes delivered by a clinical	IC1 received these remotely March and May 2021 IC2 was given a recording of these trainings. We do not

		psychologist with expertise in integrated behavioral health and primary care	know if these were reviewed by IC2.
Facilitation	Practice Facilitator	Customized remote once-a-month meetings with an experienced practice facilitator using Bodenheimer's Building Blocks framework utilizing Plan Do Study Act (PDSA) cycles. Meeting topics were tailored to the clinic's experience and aligned with ADA recommendations and included: • Patient education materials for BH and self-management support • Implementation of systematic screenings for DD, depression, anxiety • Identifying changes in roles/responsibilities, new processes/workflows for screening and treatment • Identify cross-functional practice team, train team in QI • Proactive outreach to patients regarding DMII, self-management status, community and family needs • Pre-visit planning and huddling, scheduling BHC visits with warm handoffs	IC1: December 2020-February 2022 IC2: June 2021-May 2022

IC=Intervention Clinic; BHC=Behavioral Health Clinician; DD=Diabetes Distress; QI=Quality Improvement; DMII=Type 2 Diabetes Mellitus; ADA=American Diabetes Association

Data Sources and Measures

Table 2 shows the data sources and measures used to assess the feasibility and effect of INTEGRATE-D.

Table 2. Study measures, variables and data sources

Assess the feasibility, appropriateness and acceptability of INTEGRATE-D		
VARIABLE/ DEFINITION	DATA SOURCE	DATA COLLECTION / ANALYSIS
Acceptability – extent to which intervention is agreeable, palatable, satisfactory	Assessed via survey[15] and semi-structured interview. Survey had four questions per variable. See Online Appendix for items.	Collected from clinic members exposed to the intervention (intervention clinics) at the end of the intervention. Descriptive analysis for ICs only. Survey scores, which ranged from 1 (strongly disagree) to 5 (strongly agree) for each clinic member response were averaged at the clinic-level.
Appropriateness – extent to which intervention fits and is compatible for addressing issue or problem		
Feasibility – extent to which an intervention can be successfully used or carried out		
Compare changes in use of quality-improving strategies		
Clinics' ability to implement quality improving strategies related integrated type 2 diabetes care	Assessed via survey using 14 items from the Change Process Capability Questionnaire (CPCQ).[30] See Online Appendix for items.	One person at intervention and control clinics completed the survey at the same time, pre- and post-intervention. Survey scores, which ranged from -2 (strongly disagree) to +2 (strongly agree), were summed for each clinic with possible sums ranging from -28 to +28. Average aggregate scores were compared between intervention vs. control clinics
Compare changes in process of care screening rates		
A1C screening – binary variable indicating whether the patient was screened at least once during the period	Electronic Health Record (EHR) data abstracted through manual and automated methods	Operationalized at the patient level for pre- and post-intervention periods, means aggregated at the clinic-level for intervention and control clinics. Pre-intervention defined as the time during the 12 months before the intervention; post-intervention defined as any time during the 12 months following the start of the intervention.
Cholesterol screening - binary variable indicating whether the patient was screened at least once during the period		
Nephropathy screening - binary variable indicating whether the patient was screened at least once during the period		
Psychosocial screenings – binary variables indicating whether the patient was screened at least once during the period for depression (PHQ-2 and/or PHQ-9) and / or for diabetes distress (DD)[1]		
Compare changes in clinical outcomes (PHQ-9 scores and A1C levels)		
Behavioral health – change in symptoms (PHQ-9) for patients with depression symptoms (PHQ-9>9); data abstracted through manual and automated methods	Operationalized at the patient level for pre- and post-intervention periods, means aggregated for intervention and control clinics; pre-intervention defined as score closest to the intervention start date; post-intervention defined as score closest to the intervention end date.	
Diabetes Management – change in A1C for patients diagnosed with type 2 diabetes		
Confounding Variables - Patient socio-demographics, comorbidity, insurance, and utilization		
Age, gender, language preference, race/ethnicity, income/federal poverty level, insurance type, physical, mental/behavioral health comorbidity, healthcare utilization	EHR data abstracted through manual and automated methods	Operationalized at the patient level

[1] Diabetes distress (DD) screening was implemented by intervention clinics; clinics did not screen for this pre-intervention

Data Collection

We evaluated quantitative data 12 months before the first facilitation visit (pre-intervention) to six-months after the last facilitation visit (post-intervention). Pre-intervention interviews and survey data were collected between November 2020 and July 2021. We delayed the intervention start for Intervention Clinic 2 (IC2) to allow them to prioritize their COVID response, adjusting data collection for IC2 and its matched control clinic 2 (CC2). Monthly check-in calls with ICs started in the month following the first intervention visit (December and June, respectively) and continued for the duration of the intervention. Post-intervention survey and interviews were conducted between March and June 2022 for IC1 and between June and July 2022 for IC2.

Survey data. We conducted two surveys. One was completed by the office manager or clinical leader from each clinic (N=4). This survey collected clinic demographic data and 14 items from the Change Process Capability Questionnaire (CPCQ), which was modified to assess a medical groups use of quality improvement strategies aligned with improve type 2 diabetes care. Demographic data were collected once, pre-intervention. The CPCQ was completed pre- and post-intervention (see Appendix 2).[30] ICs and CCs completed this survey with a 100% response rate. The second survey assessed the feasibility, acceptability and appropriateness of INTEGRATE-D using three psychometrically assessed measures developed by Weiner et al.[15] This survey was distributed to clinical team members exposed to the intervention (N=17) after the intervention ended, with an 82% response rate. Surveys were conducted using REDCap.

EHR data. EHR data were abstracted through a combination of manual and automated reporting, both of which followed a protocol.[31,32] Research staff assisted clinic staff with creating a list of patients with type 2 diabetes seen in the clinic at least once in the 15 months prior to the

intervention start and once during the intervention. Using a random number table, we selected 50 patients from this list. The same procedure was used to generate a list of 30 patients who had depression symptoms (PHQ-9 >9) or for elevated DD using the 2-question or long screener.[33] Of those patients, chart auditors further assessed behavioral health outcome measures. The A1C measure was assessed for these two groups. Staff conducting chart audits were trained to determine which individuals to include in numerators and denominators, which clinical data to include and appropriate parameters to record.

Interviews. Experienced qualitative researchers conducted semi-structured interviews (see Online Appendix) and monthly checks with clinics. Pre-intervention clinic member interviews (n=19) explored experiences with delivering psychosocial care to patients with type 2 diabetes. Post-intervention interviews (N=5) and one email interaction complemented post-intervention surveys. Interviews were conducted with those exposed to the intervention and explored their experience with the intervention and the changes they implemented. Monthly phone check-ins were conducted with one person from each IC to monitor progress; notes were prepared from these conversations. Patients from the two ICs (N=5) were interviewed to explore their experiences of integrated psychosocial and diabetes care and how it may have changed.

Practice facilitator data. The facilitator completed notes following each session documenting what they worked on with the clinic, resources shared, progress, planned quality improvement cycles, successes and challenges. Monthly study team check-ins with the facilitator complemented these notes and allowed for monitoring progress and fidelity. Notes were developed to document these conversations.

Clinic member and patient interviews generally lasted 30-45 minutes, were conducted via telephone or web platform, audio-recorded with permission, professionally transcribed, and reviewed for accuracy. Qualitative data were de-identified and organized into Atlas.ti7 for management and analysis.

Analysis

Feasibility, acceptability and appropriateness of INTEGRATE-D were assessed post-intervention among ICs. For the other quantitative variables, we compared differences in values pre- and post-intervention among ICs and CCs. For the CPCQ as well as for feasibility, acceptability and appropriateness, we performed clinic-level analyses. For process-of-care measures, we performed patient-level analyses, with results summarized by clinic. When testing the effect of INTEGRATE-D on these outcomes, the independent variables were exposure to the intervention (whether the patient was associated with a clinic randomized to the intervention) and time period where baseline represented the closest measure available for the patient before the start of the intervention and follow-up represented the closest measure after the end of intervention.

To assess the effect of the intervention on A1C and PHQ-9 outcomes, we compared ICs and CCs performing a patient-level analysis using linear mixed effects models. We modeled the outcome of interest as a function of the indicator for period (post vs. pre), indicator for intervention arm (IC vs. CC), and the interaction between period and intervention, using random effects to account for repeated measures within the same patient over time. We adjusted for potential confounding using a range of patient-level characteristics (see Table 2). Statistical tests were two-side (α=0.05) and performed in R (version 4.2.0).

Qualitative researchers with expertise in primary care, integrated care and implementation science conducted analyses. We used a group process to analyze qualitative data, tagging text to assign codes that were aligned with emerging patterns/findings. When codes were clearly defined (i.e., we had a codebook) and used consistently among the team, we transitioned to individual data analysis. The team continued to meet to review work and discuss emerging findings. Tagged data was analyzed a second time to examine the similarities and differences across the two ICs. Qualitative findings were summarized and connected with quantitative findings to explain the study results.