ASCEND STATISTICAL ANALYSIS PLAN

ASCEND: ApproacheS to CHC ImplEmeNtation of SDH Data Collection and Action

NCT03607617

Version: November 18, 2022

ASCEND Statistical Analysis

Data source and trial design. OCHIN, Inc. is a non-profit health center-controlled network. Its members (109 CHC organizations, operating 593 clinic sites in 16 states, as of September 2018) share a single instance of the Epic EHR. This stepped-wedge trial included 31 CHCs recruited from OCHIN's member CHCs; they are located in California, Georgia, Massachusetts, Montana, Ohio, Oregon, Washington, and Wisconsin. Recruitment occurred in two waves (14 in spring 2018 and 17 in fall 2019) to ensure that no recruited clinics waited more than a year for the intervention. Each set of clinics was block-randomized to wedges 1-3 and 4-6, respectively. A stepped wedge trial was chosen as an effective design for when an intervention under study cannot be rolled out simultaneously for everyone yet allows all to eventually receive the intervention. Clinics were eligible to participate if they were interested in implementing or expanding social risk screening / referral activities. They had to commit to identifying staff members to serve as a Clinician Champion and / or Operational Champion for the project and allowing those staff to participate in intervention activities ($\geq$2 hours / month interacting with the implementation support team).

Intervention. The intervention details and conceptual frameworks underlying this study are previously described. In brief, study clinics received six months of technical assistance in the use of relevant EHR tools and practice coaching in how to use these tools in clinic workflows, both tailored to individual clinics' needs. (The relevant tools in the study clinics' shared Epic EHR supported: identifying patients due for social risk screening; customizing which patients were considered due; documenting and reviewing screening results; and ordering social service referrals.) An EHR trainer and a practice coach guided study clinics though a five-step implementation process: (1) secure leadership buy-in; (2) set goals; (3) develop workflows; (4) orient staff; and (5) implement and iterate. They met with clinic representatives 2-3 times monthly throughout a six-month intervention period, and tracked clinic progress through these steps. All meetings were conducted via video conferencing, a feature intended to enhance the intervention's potential scalability. The intervention was designed to address barriers to social risk screening / referral implementation identified in a prior pilot study (R18DK105463) and as reported in the literature. Prior evidence suggested that each intervention component – practice coaching / facilitation, technical assistance, interdisciplinary support teams, tailored support, staff training, feedback data, goal identification, leadership engagement, peer-to-peer learning, orientation materials, and 'how-to' guides – had the potential to effectively support practice changes in primary care settings.

Study period. The study period was March 2018 through December 2021 and included six 6-month intervention wedges. The first (wedge 1) 6-month intervention began in September 2018, and the last (wedge 6) began January 2021. This allowed for at least six months of data collection before each wedge started, and after the last wedge ended. Thus, all months prior to the 6-month intervention periods were considered 'pre-intervention,' the six months of the intervention were the 'intervention phase,' and all months from the intervention period's end through December 2021 were 'post-intervention.' Of note, wedge 4 began in February 2020 as the COVID-19 pandemic began impacting care delivery in the study clinics.

Outcome measures. Patient- and encounter-level data were aggregated to the clinic level, limited to persons 18 years or older. Patients seen only for COVID-19 vaccination / testing were excluded (n=3,720; 0.7% of total study sample). Primary analyses centered on social risk screening and related referrals, and

included two outcome measures. The first was the monthly clinic rate of social risk screening, measured as the number of patients with documented social risk screening among those with a face-to-face clinical encounter in the measurement period (excluding those only for COVID testing / vaccination). Domains of social risk screening included child / family care insecurity, education, employment, financial strain, food insecurity, health insurance, health literacy, housing instability, inadequate physical activity, relationship safety, social isolation, stress, transportation needs, and utilities insecurity. The second outcome was the monthly clinic rate of provision of social risk-related referrals, measured as the number of patients with a documented referral among all patients seen in the measurement period (regardless of whether social risk screening was documented). This outcome included referrals internal (e.g., to a social worker) or external to the clinic (e.g., to housing services). As the EHR enabled documenting when patients declined to answer social risk screening questions or declined offered referrals, documented declinations were considered to indicate that screening or referral actions were taken, and included in the numerators described above.

Given the known association between social risks and diabetes outcomes, secondary analyses assessed intervention impacts on diabetes control and receipt of relevant diabetes care. Patients with an encounter during the study period and established diabetes prior to the second month of their clinic's baseline period comprised this subpopulation cohort (excluding pregnant women). Guideline-concordant diabetes-related care was considered monthly for this cohort and included whether patients were up to date on receipt of their (1) annual lipid panel and (2) biannual hemoglobin A1c (HbA1c) screening. Three diabetes control measures were assessed monthly, among patients screened that month: (1) blood pressure (BP; <130/80 mmHg), (2) HbA1c (<7.0%), and (3) low-density lipoprotein (LDL; <100 mg/dL).

Baseline covariates. The baseline period was defined as the six months before each clinic's wedge began. Analyses accounted for clinic-level baseline measures: number of years since the clinic began using their current EHR; whether the clinic conducted screening at or above the 50th percentile for all study clinics (to capture prior experience with such screening), and patient characteristics aggregated to the clinic level. We also accounted for whether the clinic was concurrently involved in the Centers for Medicare and Medicaid Services (CMS) Innovation Center's Accountable Health Communities (AHC) Model, a large national demonstration project targeting implementation of social risk screening and navigation services. Participants involved in this demonstration received modest financial incentives but only minimal implementation support.

Statistical analysis. Clinic-level outcomes were monthly from March 2018 through December 2021 (totaling 1,384 monthly time points across 31 clinics). Generalized Linear Mixed Models (GLMMs) were used to assess intervention effect by comparing outcomes during time periods in clinics which had versus had not yet participated in the intervention. GLMMs were used to account for a general time trend and flexibly model the intervention effect over time post-intervention. Negative binomial mixed-effects modeling was used to evaluate the primary outcomes; mixed-effects linear regression was used to evaluate secondary outcomes. Each GLMM fit flexible time effects by treating time as a categorical variable and included random effects for clinics, adjusted for baseline covariates, and utilized robust standard errors. Average differences are reported comparing the pre-intervention period to (1) the six-month intervention period and (2) the post-intervention period. Rate ratios (RR) for the primary

outcomes, rate differences for the secondary outcomes, and corresponding 95% confidence intervals (CI) are reported. A more detailed description of the GLMM model is provided by:

The general model is:

$\log(Y_{it} \mid b_i) = \beta_0 + \boldsymbol{\beta_1} t + \boldsymbol{\beta_2} I_{it}(t - s_i) + \beta_3 Z_i + \boldsymbol{\theta} C + b_i + \log(e_{it})$

Y_{it} is the number of patients in practice *i* whom had any SDH data collected during period t.

t is a categorical variable denoting the observation month for t in (0, 1, ..., 46), where $t = 0$ is the baseline month.

I_{it} is an indicator variable where $I_{it} = 1$ if practice *i* has been assigned to the intervention at period t, and $I_{it} = 0$ otherwise.

s_i is the period (month) when the intervention begins for practice *i*.

Z_i is a practice-level term to denote baseline rates of SDH data collection, where $Z_i = 1$ if practice *i* has high rate of SDH data collection (above 50th percentile) and $Z_i = 0$ if low rate (below 50th percentile).

C is a matrix of potential confounders with corresponding vector of coefficients θ.

b_i denotes a random effect term for practice *i* with mean 0 and variance σ_b^2.

E_{it} is the number of patients seen in the practice during the observation month *t* in practice *i* and the $\log(E_{it})$ term is considered the 'offset' in the Poisson regression model.

The estimation via the above model takes into account the general time trend, and allows for the intervention effect to grow over time following intervention implementation. The model estimates the intervention effect with the within-site difference between SDH collection rates pre- and post-intervention, averaging across practices and accounting for possible secular trends which might confound with the timing of the intervention implementation.

Note on protocol deviation. The GLMM model specifications written at the time of trial registration were based on the then-flagship paper for analysis of stepped-wedge clinic-randomized trials. This approach utilized continuous variables for modelling the general time-trend of the outcomes without intervention, and estimating the added intervention effect that accrues over time following intervention initiation. This approach originally provided an estimate for the intervention effect that appears in the first time period (month) of intervention. Since trial registration, advances have been made in the analysis of such study designs that improve ability to estimate intervention effects. We updated the GLMM specifications in these analyses to reflect these advances by using the more flexible, categorical time variables. Additionally, we dropped the stand-alone estimator for intervention effect in the first month of intervention as it is unlikely the effect was immediate and constant; instead this estimator was absorbed into the categorized estimator for added intervention effects. Ultimately, these modifications resulted in changes to our reported outcomes. Instead of reporting intervention effect in the first month of intervention and the added intervention effect beyond the first month until study end, we report the average intervention effect for the 6 months of hands-on intervention and for the post-intervention period. We only report estimates from the updated models in the main results. We provide a comparison of estimates using both the original and updated models.