# ASCEND STUDY PROTOCOL

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

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## ASCEND: ApproacheS to CHC implEmeNtation of SDH data collection and action

### 1. Protocol Title

ASCEND: ApproacheS to CHC implEmeNtation of SDH data collection and action

### 2. Objectives

ASCEND will test strategies for helping community health centers (CHCs) systematically identify and take action on social determinants of health (SDH). This work builds on our NIDDK-funded pilot study (R18DK105463), in which we developed a set of electronic health record (EHR) tools for SDH data collection and summary. These tools were activated in 440 primary care CHCs nationwide in June 2016. We propose to act on this unique opportunity to study: (i) SDH data collection / action in CHCs in 19 states; and (ii) the effectiveness of a set of implementation strategies at supporting CHCs in integrating SDH data collection and action into workflows and DM risk management care plans.

Note: The SDH intervention includes strategies to help CHC's systematically (i) collect SDH data in standard workflows using EHR tools and (ii) integrate SDH data from flowsheets into care plans (e.g., making referrals to social services; adapting treatment plans) for adults with / at risk for DM. The study team will provide intensive implementation support (in the form of technical assistance and training materials) to study CHCs.

Focusing on DM risk management and obesity prevention outcomes in adult patients, we will:

**Aim 1.** Conduct a mixed methods formative evaluation of SDH data collection uptake among CHCs that had SDH data tools activated in their EHR in June 2016. (Quantitative data will come from all 440 CHCs' shared EHR, qualitative data from up to 12 CHCs purposively recruited from this pool). Identify patterns of SDH data collection in these diverse CHCs, and clinic-level factors associated with variation in SDH data collection rates. Use results to fine-tune the SDH Action Plan intervention's strategies for helping CHCs systematically: (i) collect SDH data in standard workflows, and (ii) integrate SDH data into care plans (e.g., making referrals to social services; adapting treatment plans) for adults with / at risk for DM.

**Aim 2.** Conduct a pragmatic, stepped-wedge, cluster-randomized trial in 30 CHCs. The CHCs will be randomized to one of six wedges, with staggered timing. CHCs in each wedge will receive intensive implementation support (the SDH Action Plan). This scalable intervention includes both comprehensive technical assistance and training materials designed to help CHCs plan for and implement SDH data collection / action, and six months of remote access to an 'SDH Implementation Team' that will tailor implementation support to each CHC's needs, with an emphasis on the Building Blocks of Primary Care. (The SDH Action Plan will be fine-tuned based on Aim 1 results, and a baseline survey of the study CHCs.)

**Aim 3:** Conduct a process evaluation of whether and how the SDH Action Plan intervention improves: (i) SDH data collection in CHC workflows; (ii) integration of SDH data into DM risk management care; and (iii) clinical measures associated with effective DM risk management (controlled blood pressure, HbA1c, BMI, lipids, etc.; up-to-date preventive care). *H3a:* Intervention CHCs will have significantly greater increases in (i) SDH data collection, and (ii) actions taken to address SDH needs, compared to control CHCs. *H3b:* Patients at intervention CHCs for whom SDH data are collected will have significant improvements in DM / obesity risk management / receipt of related preventive care, compared to those at control CHCs.

### 3. Background

Research is needed on how to help community health centers (CHCs) start collecting and taking action on patient-reported SDH data. CHCs serve our nation's most vulnerable patients, whose DM prevalence and risk (notably, obesity rates) are higher than the general population's, and whose health is particularly impacted by SDH. At present, CHC staff may seek to identify whether SDH are impacting a patient's ability to act on care recommendations for DM prevention / management, and / or whether DM care plans should be modified to address these SDH. However, such efforts are typically ad-hoc, and rarely involve structured EHR data as recommended by public health leaders. There is a pressing need to identify barriers to CHCs

systematically screening for and acting on SDH using EHR-based tools, and to determine whether implementation strategies that support other practice changes can effectively address these barriers.

We propose to test a SDH intervention (also referred to as a set of strategies) for helping CHCs routinely identify and take action on the SDH-related needs of patients with / at risk for DM. The proposed work builds on our pilot study called Assess & Do (R18DK105463), which used a stakeholder-driven process to develop EHR-based SDH data collection / summary tools for CHCs. The ASESSS&DO study is Pro00005883 within the IRB system.

Please refer the end of this document for a bibliography.

## 4. Study Design

ASCEND is a pragmatic trial which assesses whether / how an implementation support intervention impacts SDH data collection / action and DM risk management, in 30 CHCs. We will tailor the support provided to meet each CHC's needs, while ensuring that any support could be replicated in usual care, so that study findings are useful to healthcare decision-makers. Our intervention, delivered in routine care settings, addresses recent calls to study methods for adapting change management strategies to meet setting-specific needs.

We propose a mixed methods, stepped-wedge, cluster-randomized trial to assess the effectiveness of a set of evidence-based, pragmatic approaches to helping CHCs implement SDH data collection / action, in care for adults with / at risk for DM / obesity.

We hypothesize that intervention CHCs will have significantly greater increases in (i) SDH data collection, and (ii) actions taken to address SDH needs, compared to control CHCs. We also hypothesize that patients at intervention CHCs for whom SDH data are collected will have significant improvements in DM / obesity risk management / receipt of related preventive care, compared to those at control CHCs.

## 5. Study Population

### a. Number of Subjects

First, we will pull data on CHCs from the OCHIN membership database; OCHIN has agreements with their member CHCs for such data extraction and analysis.

Then, we will recruit CHCs from this pool based on high adoption rates at baseline (N=no more than 12). From these 10-12 CHCs, we will interview up to 6 CHC staff (total N=72) as part of formative data collection efforts.

Next, we will recruit up to 31 CHCs, and conduct block randomization to one of six study wedges for staggered receipt of the SDH Action Plan (N= up to 31). Thus, a maximum of 43 CHCs will participate in the study; although some CHCs that participate in the formative interviews may also opt to be included in the study phase, meaning we may not recruit 42 unique CHCs.

We will ask CHC champions in the 31 CHCs to oversee completion of a baseline survey before the SDH Action Plan intervention is implemented. The subsequent process evaluation will include a card study with selected providers at each clinic, and content analysis of interactions between the implementation support team and CHC staff.

Total maximum participants for each aspect of the study

CHCs: up to 43 total

CHC staff:

- Phone /in-person interviews: 72 (cross-section of staff)
- Baseline surveys: ~ up to 50 (project champions at each clinic)
- Card study: up to 62 (primary care providers)

- Content analysis of OCHIN's SDH implementation team interactions with study CHC staff (text data from recorded webinars, emails, online discussions between OCHIN implementation team and CHCs)

**b. Inclusion and Exclusion Criteria**

Quantitative Data

Inclusion Criteria:

- Any patient who had an encounter at an OCHIN member facility between June 24, 2016 (when tools went live) and December 31, 2022.
- Pregnant women
- Children
- May include some subjects with mental health conditions of various types; however, it is important to systematically address high DM /obesity risk in this population, because such patients may be at risk for elevated high DM /obesity risk and have often been excluded or underrepresented in previous research studies.
- Decisionally/cognitively impaired
- Economically/educationally disadvantaged
- Non-English Speakers
- Elderly

*Note:* Social determinants of health (SDH) information may be incidentally collected using the tools of this project at the discretion of the clinics. The project is designed to allow them to use the SDH tools in a way that best fits the individual clinics' needs. This study is looking specifically at the impact of SDHs on diabetes, however SDHs are important factors for many aspects of clinical care. Based on previous work around SDHs, clinics may collect SDH information for children or pregnant women in their practice as a tool to guide their care. As a result, the inclusion of SDH data for all patients that have been screen for SDH needs is important for the project to understand the extent of the tool's use across their entire patient population. The inclusion of pregnant women will be limited by the extent to which the participating clinics administer the tool to their patient population but will not be specifically targeted as a participation criterion. However, aggregated descriptive analyses will include an indicator for pregnancy to understand the frequency and utility for use of these tools in this population. All data will be housed securely in the EMR and only reported at an aggregate level. They will be part of the limited dataset for analyses and protected according to the data security procedures described in this protocol.

Exclusion Criteria:

- Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)
- Prisoners

*Note:* The investigators are not enrolling patients for this clinic-randomized study, but rather studying the uptake and impact of a set of EHR-based clinical decision support tools into regular care at the participating clinics. In this clinic-randomized trial, the intervention / randomization occurs at the clinic level. The intervention targets clinic processes that are part of the regular care patients receive and will not require special visits.

Qualitative Data

Inclusion Criteria:

- CHC staff: Employees who are specifically and intentionally targeted to be included in this study population because of their workplace and/or employee status

Exclusion Criteria:

- None

**c. Vulnerable Populations**

As mentioned above, we will exclude the following vulnerable populations from the study:

- Neonates of uncertain viability or nonviable neonates (up to 28 days post birth)
- Prisoners: Prisoners are excluded or not anticipated to become study subjects

**d. Setting**

OCHIN, Inc., is a non-profit, community-based health center-controlled network. Its members (>480 CHCs, in 19 states) share characteristics of other CHCs, so results will be generalizable to many CHCs. As the nation's largest CHC network with a single EHR system, OCHIN pioneered the development of EHR tools for CHCs. OCHIN's member CHCs share a single Epic© EHR, which is unduplicated, centrally maintained, and network-wide. Data are standardized and quality-checked: thus, validated data are already linked between all study sites.

OCHIN will rely on CHR's IRB for IRB review. As with previous studies, OCHIN will submit their cede letter after we are funded. We anticipate that OHSU (Dr. Miguel Marino; lead biostatistician with expertise in complex biostatistics, cluster-randomized, stepped-wedge design) and University of Massachusetts Medical School (Dr. Arvin Garg; co-investigator with expertise in SDH data collection in pediatric care) will cede IRB approval as well.

**e. Recruitment Methods**

This study has no formal patient recruitment, as 'participants' will be the CHCs that volunteer to take part in the study. Patients will interact with clinicians as they normally would; the intervention will give clinicians tools for managing patient data during encounters and panel management. We will collect qualitative data from CHC staff as described in the proposal. Below is a summary of recruitment.

CHCs will be recruited by an OCHIN research associate. Materials used for recruitment of clinics will include a participation information sheet, a slide deck with information about study participation, and a recruitment card with a brief description of what we are offering clinics.

CHC staff:

- Phone / in-person interviews: up to 72 (cross-section of staff) will be recruited by OCHIN staff, in partnership with CHR's qualitative team
- Baseline surveys: ~50 (project champions at each clinic)
- Card study: up to 62 (primary care providers)
- Content analysis of OCHIN's SDH implementation team interactions with study CHC staff (text data from recorded webinars, emails, online discussions between OCHIN implementation team and CHCs)

**f. Consent Process**

We are requesting a waiver of informed consent for all data collection activities; details below. ASCEND is a pragmatic trial and obtaining signed consent would unnaturally restrict our study sample, diminishing the external validity of our findings. The project is promoting standard clinical care and quality improvement in the CHC setting. We believe that a waiver of informed consent will not adversely

impact clinic staff. For this study, we are simply overseeing CHC interactions with OCHIN about their workflow implementation. We are not asking for any personal information from staff or patients. It would be impractical to ask for consent as anybody in the clinic could ask for OCHIN support over these 6 months, and we'd inevitably miss someone. No data will be collected from or about patients.

**Formative: Semi-structured phone or in-person interviews with CHC staff:** We will ask for verbal consent prior to conducting the interviews. We have submitted a copy of the ASCEND Study Fact Sheet and Interview guide with this IRB application. This Fact Sheet includes the key elements of consent.

**6. Study Procedures**

**Aim 1**

Clinic Recruitment

- Up to 12 CHCs will be recruited from OCHIN's pool of clinics to participate in semi-structured interviews.

Mixed Methods Formative Evaluation

- The qualitative team will conduct semi-structured interview to explore barriers / facilitators to EHR-based SDH data collection / use in DM-related care, with a focus on contextual factors. At each CHC, we will conduct ≈6 phone / web interviews with a cross-section of staff including, as appropriate, medical directors, primary care providers (MD, PA, NP) / team members (MA, RN), and staff members responsible for QI (clinic managers, care managers) / ad-hoc SDH management (e.g., social workers). We will ask how SDH information is now used to inform care, challenges to collecting / using SDH data, experiences with the EHR's SDH data tools, and how to facilitate SDH data collection / action. Verbal consent will be obtained pre-interview.

- The quantitative team will collect baseline data from 6/24/16-12/31/17 for the 440 CHCs that share OCHIN's EHR. We will measure clinic-level SDH data collection rates as percentage of adult patients seen in 6/24/16-12/31/17 for whom patient-reported SDH data from the IOM's list are recorded, on a monthly basis. We will assess variation in rates of SDH data collection and identify clinic-level factors associated with this variation, using standard statistical methods. The distribution of the outcomes of interest and eligible population will be examined before selecting an analysis model; specific models will be refined iteratively, guided by the hypotheses and conceptual model.

Fine-tune the SDH Action Plan

- Results from the formative evaluation (semi-structured interview and baseline data analyses) will be used to fine-tune the SDH Action Plan.

**Aim 2**

Clinic Recruitment and Randomization

- CHCs will be recruited in two separate waves for the pragmatic trial. Wave 1 (wedges 1, 2, and 3) will be recruited prior to the start of wedge 1. Wave two (wedges 4,5,6) will be recruited roughly 1 year later, prior to the start of wedge 4. Each wave of CHCs will be block randomized by baseline rates of SDH data collection.

Pragmatic, Stepped-wedge Trial

- The implementation support team will provide tailored implementation support for SDH data collection / action to each CHC's needs for six months (one wedge at a time).
- CHC Staff Baseline Survey: Using the 'Building Blocks of Primary Care' (BBPC) model, we will assess the study CHCs' baseline status of four foundational components/'building blocks': (1) Engaged leadership; (2) Data-driven improvement using EHRs; (3) Empanelment; and (4) Team-based care. The survey will be completed by project champion at each clinic. We will send a survey asking about the CHCs' structural characteristics (payment, staffing, etc.), external policies and incentives that might have an impact, and other potentially impactful organizational characteristics not identifiable in EHR data, OCHIN member records, or the other baseline data. This information will help us understand the impact adoption of SDH data collection / action.
- Baseline EHR data: Aim 1 baseline data will be used to identify baseline SDH data collection / action in the trial CHCs, and to indicate which of these CHCs may need targeted assistance. These data will be pulled in the month prior to wedge implementation.
- Card study (short provider survey): Two providers at each CHC will be asked to complete a brief survey ("card") within the EHR following selected patient encounters. Patient encounters will be selected based on the clinic's specified target population for SDH screening. These card studies will be administered over approximately 3 weeks in month 5 of each study wedge. OCHIN will identify two providers that see the majority of their clinics' specified target population and work with the clinic project champion to recruit the providers to participate in this survey. If clinics do not identify a target population, then OCHIN or the study CHC will identify the two providers who screen the most patients for SDH or identify two providers who see the most patients. Each provider will be asked to complete one card immediately after an office and / or telehealth encounter with a patient. PCPs will access the card study questions via a link built into the EHR. Responses will be pulled from the Clarity database by the OCHIN analyst. Each "card" will be associated with the following characteristics: responses from provider for card study questions, SDH screening reported, SDH need(s) documented, reason for visit, patient demographics, and provider and site information.

  The card study questions will ask questions such as: (1) Whether / how SDH data informed clinical decisions / actions; (2) How the SDH data was obtained (e.g., via the EHR tools); (3) Whether any desired SDH data were unavailable; and (4) Estimated time spent looking up SDH data. Answers will be fixed-choice with an "other" option and space for free text. No PHI will be captured, and provider answers will not be stored in patients' charts.

  The qualitative team will present a card study information sheet to the clinics in month 4 of each wedge.
- Member checking survey: The qualitative team will prepare clinic specific paragraphs of our learnings, barriers, and facilitators. We will ask up to 2 clinic champions per clinic to review this paragraph and answer questions about their SDH screening post-end wedge. The survey will be sent out via email within the body of the email or using a survey platform link. The study team will send a reminder email within one week of sending out the survey.
- Content analysis of CHC / implementation support team interactions: Prior to study participation, we will notify CHC staff that their exchanges with the implementation support team will be analyzed for research purposes. Staff participation will serve as implied consent. There is no contact with patients. We are observing to identify barriers and facilitators to implementation (akin to document review, which we have used in previous studies for email exchanges, clinic meeting minutes, etc.).

All exchanges with study CHCs will be used in content analysis; calls and webinars will be recorded (with permission) and transcribed; emails / online discussions will be collected. The OCHIN and CHR teams may incidentally view and record PHI while helping clinics implement the SDH EHR tools as part of the webinar sessions. Recording PHI is not intended to contribute to the research question and any PHI inadvertently captured would be deleted before the data is used in analysis.

When each wedge ends, the qualitative team will record a debrief session with the SDH Implementation Team to capture their understanding of implementation at each CHC in that wedge. We will also collect 'trouble-tickets' about the SDH tools submitted to OCHIN's member support system.

- Assess the relationship between clinic context and implementation strategy adaptation: We will track context and implementation strategies including planned, unplanned, enacted, and adapted strategies and justifications for strategy adaptation. We will use a comparative case study approach to compare strategies between sites, document adaptations, and explore preliminary patterns of association between context, strategies, and outcomes.

  We will synthesize meeting notes, transcripts, and email which document interactions between the research team and each clinic, internal planning meetings between research team members, and clinics' use of intervention guidance and decisions tools.

**Aim 3**

<u>Mixed methods process evaluation</u>

- We will analyze the quantitative data and qualitative data to understand whether and how the SDH Action Plan intervention improves:

  1. SDH data collection in CHC workflows;

  2. integration of SDH data into DM risk management care; and

  3. clinical measures associated with effective DM risk management (controlled blood pressure, HbA1c, BMI, lipids, etc.; up-to-date preventive care).

- We will also analyze the quantitative and qualitative data to:
  - Examine the impact of screening domain, patient characteristics, clinical encounter characteristics, and clinic factors and on accepting on refusing help to address a social need.
  - Characterize variability in food insecurity and other social risk screening implementation before and during the COVID-19 pandemic, with an emphasis on screening during telehealth encounters, using multilevel data.
  - Identify barriers and facilitators to food insecurity and other social risk screening implementation before and during the pandemic, with an emphasis on screening during telehealth encounters

**Data Collection**

<u>Quantitative data points</u>

- Aim 1 data points - We will collect baseline data from 6/24/16-12/31/17 for the 440 CHCs that share OCHIN's EHR. We have extracted similar EHR data in prior research. We will measure

clinic-level SDH data collection rates as percentage of adult patients seen in 6/24/16-12/31/17 for whom patient-reported SDH data from the IOM's list are recorded, on a monthly basis. We will assess variation in rates of SDH data collection and identify clinic-level factors associated with this variation, using standard statistical methods. The distribution of the outcomes of interest and eligible population will be examined before selecting an analysis model; specific models will be refined iteratively, guided by the hypotheses and conceptual model. Results from these analyses will inform clinic recruitment and fine-tuning of the intervention as described below.

- Aim 2 & 3 data points -
  - Monthly rate of targeted patients for whom SDH data are documented in the EHR.
  - Monthly rate of patients for whom an SDH-related referral is made (exclude if 'patient declined referral' is documented).
  - Control of DM risk management biomarkers: (i) BP control (<140/80 mmHg); (ii) A1c control (<7.0%); (iii) BMI <30; (iv) LDL control (l<100 mg/dL).
  - Rates of incident comorbidities, e.g. retinopathy, nephropathy, neuropathy (among patients with DM).
  - Rate of patients up-to-date on DM key tests (e.g. lipid panel annually, HbA1c within 6 months,.)

*Qualitative data points*

- Aim 1: Formative, semi-structured interviews.

- Aim 2 & 3: Baseline survey at study clinics, card study (short provider survey), exchanges between CHC staff and implementation support team (can include, but is not limited to: emails, webinar recordings, meeting notes, ASCEND SDH Toolkit, etc.), and the member checking survey.

**7. Data Analysis**

**a. Analysis Plan**

Quantitative data analysis plan

All quantitative analyses will be led by co-I Dr. Marino from OHSU. This stepped-wedge cluster randomized trial will evaluate the impact of the proposed intervention on our dependent variables (see Table 6 in proposal): adoption of SDH data collection / action, and impact of this adoption on DM risk management. Outcomes will be measured monthly in all clinics at every period, so that each wedge provides data points in both control and intervention conditions. Practices in each wedge will be block-randomized by baseline rates of SDH data collection to balance SDH collection adoption across wedges. The main goal of this trial is to establish whether the intervention is effective and to what degree. Our evaluation includes a rigorous design so we may attribute positive findings to the intervention. To compare the effect of the intervention with usual practices on SDH outcome measures in a stepped-wedge design, we will utilize Generalized Linear Mixed Models (GLMMs).

Quantitative data analyses will use elements from The Limited Data Set. Data elements will contain the following variables and/or variables that have been derived from these variables (such as counts, means, etc.) ("Data Elements") between June 24, 2016 and December 31, 2022:

**DATA ELEMENTS**

| Category | Examples include, but are not limited to: |
|---|---|
| Demographics | Patient ID, sex, date of birth, race, ethnicity, primary language, annual income, FPL, primary payor, state of residence, urban/rural |
| Encounter | Encounter ID, patient ID, admit date, provider ID, facility location, encounter type, facility id, admitting source, primary payor, site ID |
| Diagnosis | Diagnosis ID, patient ID, encounter ID, encounter type, admit date, provide ID, diagnosis, diagnosis type, diagnosis source, site ID, comorbidity index score |
| Procedures | Procedures ID, patient ID, encounter ID, encounter type, provider ID, procedure date, procedure code, procedure type, procedure source, site ID |
| Vital | Vital ID, patient ID, encounter ID, measure date, measure time, vital source, height, weight, diastolic blood pressure, systolic blood pressure, original BMI, blood pressure position, smoking, tobacco, tobacco type, site ID |
| Lab Result CM | Lab result cm ID, patient ID, encounter ID, lab name, specimen source, raw lab name, lab loinc, result location, lab procedure, lab procedure type, lab order date, result date, result quality, result number, result modifier, result unit, norm range low, norm range high, norm modifier high, abnormal result indicator, site ID |
| Condition | Condition ID, patient ID, encounter ID, report date, onset date, resolve date, condition status, condition, condition type, condition source, site ID |
| Prescribing | Prescribing ID, patient ID, encounter ID, ID provider ID, Rx order date, Rx start date, Rx end date, Rx quantity, Rx refills, Rx days supply, Rx frequency, Rx basis, Rx norm concept identifier, site ID |
| Clinic Characteristics | Patient portal use, years on EHR, AHC participation |
| Provider Characteristics | Sex, credentials, specialty, years practicing at clinic, number of visits, SDH tool use |
| Social Determinants of Health | SDH need, education, financial resource strain, housing insecurity, food insecurity, intimate partner violence, inadequate physical activity, social isolation, stress, request for help |

Additional quantitative data analyses will include assessing SDH data collection / action, overall and among the subset of clinics that are both OCHIN-member clinics and part of the Accountable Health Communities (AHC) study at OHSU, as well as all OCHIN member CHCs during a time when federal initiatives are emphasizing this change. We will track SDH data collection rates in these CHCs over study years 1-4, in descriptive analyses.

We will also use a generalized estimating equation (GEE) approach to assess factors associated with patients' acceptance of a resource to address an identified social need (see model specification below). Acceptance of help will be calculated using the proportion of patients who screened positive for one or more social need who accept a help to address that need. GEE produces a population average effect that accounts for group-level correlation and is appropriate for repeated or correlated observations. To account for the likely correlation between patients within a clinic, the model will include clustering at the clinic level. GEE takes into account the specified correlation structure while selecting the final parameter estimates and generally controls for clustering more effectively than using post-processing adjustment. We will test exchangeable and unstructured correlations structures and compare models using Quasi-Likelihood AIC (QIC) test. We will select the model with the lower QIC value. Using the

preferred model, we will assess predictors of positive screening including screening domain, patient characteristics, encounter characteristics, and clinic characteristics.

$$Y_{i\ Patient\ acceptance} = \beta_0 + \beta_1 X_{i Screening\ domain} + \beta_2 X_{i Patient\ characteristics} + \beta_3 X_{i Encounter\ characteristics} + \beta_4 X_{i\ Clinic\ characteristics} + u_i$$

To characterize variability in food insecurity and other social risk screening implementation before and during the COVID-19 pandemic, we will use a multilevel mixed-effects model to predict implementation of screening based on site, provider, patient, and visit characteristics. Variables will include urbanicity at the site level; profession at the provider level; race/ethnicity, age, and number of diet-related chronic conditions at the patient level; and location (in-person v. telehealth) at the visit level.

Qualitative data analysis plan

Data from each case will be 'merged' for analysis, then compared within and across clinics to confirm, expand on, or challenge each site's finding. Data collection and analysis will be parallel and iterative; analysis will begin at the end of the first wedge and continue as data from each wedge is collected. A grounded theory approach and immersion-crystallization process will be used to identify data themes and patterns.

Qualitative data analyses for the card study will use elements from the below data set. Data elements will include, but are not limited to the following variables:

| **Category** | **Description and Variable Name** |
|---|---|
| Provider Characteristics | Sex, credentials, specialty, years practicing at clinic, number of visits, SDH tool use |
| Encounter characteristics | Encounter date, type, reason for visit |
| Card study responses | What factors influenced the care you provided, how did you know the patient's SDH information, How long did it take to look up the patient's SDH information, how much did SDH influence your clinical decisions |
| Patient-level SDH | SDH need, education, financial resource strain, housing insecurity, food insecurity, intimate partner violence, inadequate physical activity, social isolation, stress, request for help |

Card study response data will be summarized by provider, clinic, and wedge. Analyses will be Ns and percentages of each survey item response and descriptive patient demographic data for the patients whose encounters were selected for inclusion in the card study (e.g., patient sex, age category, race/ethnicity, preferred language, and whether they had any discrete SDH screening data recorded in the EHR).

We will assess the relationship between clinic context and implementation strategy adaptation, we will code implementation strategies and barriers deductively and using ERIC and CFIR respectively and inductively based on themes that emerge from the data. We will incorporate

additional categories proposed based on the application of ERIC categories across several large interventions and analyze data as comparative case studies.

We will also analyze clinic communications using a constant-comparative approach and merge that with quantitative data in joint display tables to characterize variability in food insecurity. An implementation framework will be used to develop a model of facilitators and barriers to food insecurity screening.

**b. Sharing of Results with Subjects**

The study results will not be shared with subjects. This study does not carry the risk of incidental findings. This study does not involve laboratory results.

**c. Data and Specimen Banking**

Not applicable.

## 8. Privacy, Confidentiality, and Data Security

Quantitative data management, sharing and protection:
Datasets will be created with data from OCHIN's web server and data shared by OHSU for the AHC-participating clinics, imported into SAS, and securely maintained at OCHIN. Data will be extracted for all target patients seen in study CHCs and stored (limited data set) in a secure repository. Data from subsequent encounters is stored and linked to the same patient. Identified patient data will be transferred from OHSU (ORPRN) for the subset of patients seen in OCHIN+AHC clinic sites; these data will include patient identifiers sufficient to match them to their EHR record in the OCHIN system (e.g., name, date of birth, medical record number), as well as SDH screening data necessary for analysis. After matching is conducted, all PHI will be stripped from these datasets and will not be accessed for analysis or transferred back to OHSU as part of Limited Data Sets for analysis.

OCHIN and CHR have expertise in high-quality and secure data management, project operations, and multisite research collaborations. Data structures will remove personal identifiers. Analyses will be done in SAS® v9 or higher. Limited data sets will be shared between OCHIN, OHSU, UNC, and WSU. Please note that OCHIN will send the same final limited dataset to OHSU and WSU. Limited data sets will be password protected for transfer and exchanged via a secure data transfer method. Quantitative data will be securely stored on Dropbox or on an institutional server. Only aggregate EHR data will be shared outside of the study team.

Qualitative data management, sharing and protection: Qualitative data will be securely stored at CHR, OCHIN, UNC, and WSU. All data work will be done on password-protected workstations, in a secure environment (HIPAA-compliant). Data will be catalogued within 1 week of collection, and field notes within 24 hours.

- Interviews will be recorded and professionally transcribed by an outside vendor (with who KPCHR and OCHIN have a Business Agreement with). Recordings will be sent via secure file transfer (SFT) to the transcriptionist.

- Online meeting software recordings (e.g. Zoom or Microsoft Teams) of the monthly webinars will be sent from OCHIN to CHR via SFT, encrypted email, secure site, or Box. Recordings will be sent via

secure file transfer to an approved transcriptionist with whom the study team has an established BAA. The transcriptionist will be instructed to delete any identifiable patient information in the transcript (e.g., [*Name*]) and to delete the recording once the transcription is complete. Recordings have the *potential* to contain PHI as a result of the Epic environment that may be used in SDH tool demonstration; transcripts will NOT contain any PHI and PHI will not be used in analysis. The transcript will be sent back to the qualitative study team via secure file transfer (access to the secure file transfer site will be limited to appropriate members of the research team); recordings and transcripts will be stored securely at both CHR, OCHIN, UNC, and WSU. Transcripts will be entered into QSR NVivo or Dedoose. Recordings will be deleted at the end of the study.

- Card study data will be sent via secure site, encrypted email, Secure File Transfer or Box between OCHIN and CHR.

All qualitative data work will be done on password-protected workstations, in a secure environment (HIPAA-compliant). At CHR, only study team members have access to the saved data. At OCHIN, access to study data is limited to the research department. At UNC and WSU, access is limited to study team members. Data files will be password protected for transfer; data sharing agreements / protections will be established as necessary.

Other qualitative data will be entered into QSR NVivo and Dedoose; data files will be password protected; data sharing agreements / protections will be set as necessary; transfers will use a secure website or encrypted email.

Confidentiality measures: All research staff at CHR, OCHIN, OHSU, and WSU who handle data sign confidentiality pledges and receive IRB and HIPAA training/certification.

Security measures: Multiple measures are in place to ensure security of PHI. Data transfer to and from the EHR (at OCHIN), and the web display (accessed at OCHIN member CHCs) uses a Simple Object Access Protocol (SOAP) with Secure Sockets Layer (SSL) encryption over a Hypertext Transfer Protocol Secure (HTTPS) computer network.

**9. Provisions to Monitor the Data to Ensure the Safety of Subjects**

This study involves data from OCHIN's network of safety net clinics, 42 of which will be recruited for formal study participation. All EHR data from OCHIN clinics are stored at OCHIN. Each clinic has business use agreements with OCHIN to handle and manage PHI from their clinical data. EHR data will be linked using OCHIN's unique patient identification codes, in order to create clinic-level aggregate data and a limited data set.

All data sources will be linked into a secure relational database at OCHIN. The de-identification process replaces the original identifiers on sensitive or confidential fields with arbitrary pseudo-identifiers. Access to the "crosswalk" tables that contain mappings of original- to pseudo-identifiers is limited to authorized OCHIN staff; crosswalk tables will not be shared with OHSU or CHR. We will de-identify the following fields:

- Patient ID
- Provider ID
- Encounter ID

Data analysis will be conducted at OCHIN, OHSU, UNC, and WSU. If necessary, to share PHI, we will use a secure data transfer method (e.g., sFTP) with access limited to appropriate members of the research team. IRB and HIPAA approval will be obtained for all study steps. CHR, OHSU and OCHIN have expertise in high-

quality data and secure management and project operations and multisite research collaborations. Data structures are typically designed to separate personal identifiers from other critical data, further enhancing protections.

CHR, OHSU, and OCHIN standards meet or exceed requirements for patient data safety established in the federal HIPAA guidelines. Data structures will derive from the data confidentiality, security, and privacy standards that CHR, OCHIN, and OHSU have in place to meet or exceed all current HIPAA requirements. Quality control will begin with real-time, inter-field checks in the data at OCHIN. Additional back-end checks (for missing data and logical inconsistencies) will be conducted to ensure the highest standards of data reliability. We will examine the distribution and measurement properties of variables before making final decisions about analyses.

## 10. Risks and Benefits

### a. Risks to Subjects

The ASCEND study poses minimal risk. We do not anticipate any physical, psychological, social, legal or economic risks.

### b. Potential Benefits to Subjects

Overall benefits: This research has the potential to provide valuable information on how best to support uptake of standardized collection of patients' SDH data using EHR-based tools, and integration of SDH data into DM / obesity risk management in CHCs.

Quantitative: Patients at the study CHCs will have no defined personal benefit from this project.

Qualitative: Care team members at the study CHCs will have no defined benefits from participating in this project. However, the intervention is designed to optimize identification and management of adult subjects with elevated DM risk. Some providers exposed to this potentially useful CDS may use it to improve their clinical care during the study or after.

## 11. Costs to Participants

CHC patients: There are no new costs to patients as a result of this study; however they will continue to pay for co-pays, routine treatment costs, etc. as part of normal care at their CHC.

CHC staff: There are no costs to staff as a result of this study; other than time spent during interviews and observations.

## 12. Compensation to Participants

CHCs: During Year 1, the recruited CHCs (N=up to 12) will receive an impact fee in the amount of $300 for participation in formative data collection.

CHC patients: None

CHC staff: During Years 1-4, CHC staff will receive a gift card in the amount of $25 or $50 for participation in the interviews and the card study (short de-identified provider survey).

**Resources Available**

No special resources or expertise are required to conduct this study.

**13. Drugs or Devices**

Not applicable.

**14. Multi-Site Coordination**

CHR will act as the coordinating center for this study. We will ensure that:

- All sites have the most current version of the protocol, consent document, and HIPAA authorization.
- All required approvals have been obtained at each site (including approval by the site's IRB of record).
- All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.
- All engaged participating sites will safeguard data as required by local information security policies.
- All local site investigators conduct the study appropriately.
- All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.
- Communication of problems, interim results, and study closure.

**15. Community-Based Participatory Research**

<u>This study has system-level support:</u> OCHIN's leadership strongly supports SDH data collection in its member CHCs, which aligns with OCHIN's ongoing efforts to improve care and outcomes in CHCs via EHR-based strategies. In all study steps, the study team will engage OCHIN's operational leadership (including co-I Karen Parr, a CHC clinician and informaticist). We will also engage OCHIN CHC clinicians via existing communication structures. OCHIN has a long history of engaging stakeholders in all system-wide efforts; CHC clinicians serve on standing committees that direct all changes made to OCHIN's EHR.

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