Statistical Analysis Plan (SAP)

The PACE Study

Post Affordable Care Act: Evaluation of Community Health Centers

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A partnership between:
Oregon Health & Science University
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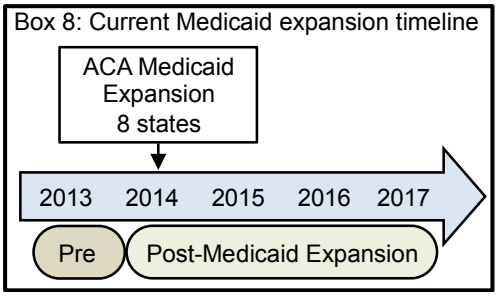
B.4.4 Statistical Analysis.



We will use validated OCHIN data and Medicaid claims data to assess the impact of Medicaid expansion on healthcare access, receipt of healthcare services, and Medicaid expenditures. We will summarize baseline measures using descriptive statistics and data visualization methods (*e.g.,* histograms, scatter plots) across clinic and state groups. Our primary criteria for studying Medicaid expansion will be estimating differences in outcomes described in Box 7 (above) between individuals and clinics in (a) expansion versus non-expansion states over the 12-months pre- and at least 24-months post-Medicaid expansion time periods (Aim 1), (b) in expansion states only (Aim 2), and (c) in Oregon (Aim 3). As seen in Box 8, the ACA-Medicaid expansion took effect January 1, 2014. Eight states in the OCHIN EHR data adopted Medicaid expansion at the start of 2014. Their pre-period is 12-months prior to 2014 (*i.e.*, 2013) and their post-period extends from the time of expansion to the end of the project. (For most expansion states, the post-period will be 2014 through 2017; however, we are aware that some non-expansion states may expand during the study period, so we will take this into account in our analyses). Our primary methodological approach will utilize difference-in-differences (DID) methodology. The DID approach has been frequently used by health services researchers to account for potential secular effects and changing policies that would affect both expansion and non-expansion states over time, while adjusting for potential confounders.[167-172]
The general analysis for **Aim 1** is represented by the following equation:

$$Y_{ijkt} = f\left(\alpha + \beta M_k + \gamma \tau_t + \theta M_k \tau_t + \delta Z_{ijkt}\right)$$

where Y_{ijkt} represents individual *i*'s performance on an outcome measure of interest (*i.e.*, insurance coverage,) nested within the *j*th clinic in state *k* at time *t*; M_k represents a dummy variable taking a value of 1 in expansion-state and zero otherwise; and τ_t is a dummy variable taking a value of 1 if the observation took place after Medicaid expansion and 0 otherwise, Z_{ijkt} is a matrix of potential individual, clinic, or state confounders and *f* represents a general function that captures our intent to model a variety of outcome types through generalized linear mixed models (GLMMs).[173] The coefficient α is an overall intercept representing average baseline performance for all individuals; β represents the incremental baseline performance differential between clinics in expansion and non-expansion states and γ represents the change in performance pre- and post-expansion for all clinics. The coefficient of interest θ captures the relative performance improvement in outcomes for the patients in expansion versus non-expansion states over time. In this model, non-expansion states will serve as the reference. This equation is very general but can be adapted to include dummy variables for each time period or a continuous variable to capture linear time trends.

To address Aims 2 and 3, we can use a modification of the equation presented above. For **Aim 2**, the indicator M_k will be replaced with two indicator variables to represent the three insurance groups (newly insured, already insured, and uninsured) of interest. **For Aim 3**, the indicator M_k will be substituted by a binary variable denoting newly insured versus already insured. This equation can also be adapted to have the clinic serve as the unit of measurement instead of the individual. There are multiple options for estimating our DID approach. Our preferred method is to implement state random effects in clinic-level analyses and both clinic and state random effects in patient-level analyses to control for correlation of observations nested in clusters (*e.g.,* individuals nested in clinics which are nested in states). Clinics and

states will be treated as random effects because Medicaid expansion may vary across clinics and states. However, we recognize that the assumption for random effects may not be met and we will also assess the robustness of our assumptions by running models that treat clinics and states as fixed effects. We will formally test the validity of the random effects using the standard Hausman test[174] and assess overall qualitative differences that may arise between the random and fixed effects models.

We will use GLMM,[173] which offer flexible regression modeling to accommodate different sources of correlations (serial, intra-clinic, and intra-state), categorical and continuous covariates, and fixed and time-dependent covariates. These methods offer a wide range of parametric distributions to model the dependent variables, including logistic regression (binary data), beta regression (percent data), Poisson regression (count data), and Gaussian regression (normally distributed data). For example, to assess a change in services utilized, a logistic mixed-effects regression model can analyze services received in pre- and post-expansion periods as a function of whether a patient belongs to CHC in a state that did or did not expand Medicaid and other possible confounders (*e.g.,* predisposing factors; need for services). The distribution of the outcomes of interest will be examined before selecting an analysis model; specific models will be refined through an iterative process, guided by the hypotheses, conceptual model, and preliminary analyses. If we find significant patient panel or clinic differences in states that did or did not expand Medicaid (Aim 1) or in patients who are newly insured, already insured, and uninsured (Aim 2), we will use propensity score weighting methods to reduce the observed bias, help minimize external threats to the validity of the results and adjust for imbalances between intervention and comparison clinics.[174] Dr. Marino (PhD biostatistician) will lead these decisions and determine the need for additional models.

*Econometric analyses for **Aim 3**.* Using DID methods, we will calculate the average pre-post difference in total Medicaid expenditures attributable to the subpopulation of newly insured patients in Oregon OCHIN CHCs, subtracted by the average difference among the already insured patients. We will assess changes in spending immediately after Medicaid expansion in Oregon clinics as well as comparing subsequent years post-expansion. Specifically, we will first assess the initial increase in Medicaid expenditure after the expansion (post t_1). In this case, because newly insured were uninsured at the pre-period, thus incurring no cost to Medicaid, their cost will be equal to $0. Next, we will assess the change between post at t_1 (*i.e.*, 2014) versus post at t_2 (*i.e.*, 2015) versus post at t_3 (i.e., 2016) to evaluate whether the initial cost-increase is reduced overtime and by how much. Changes in spending after Medicaid expansion among newly insured vs. spending changes in already insured will 'net out' any secular changes not related to Medicaid expansion. Any remaining significant differences in outcome – DID – are attributed to Medicaid expansion. These findings will help to assess whether Medicaid expansion can help reduce costs, and if so, whether the reduction comes from lowering the spending associated with unnecessary or inefficient use of services external to CHCs. We note that CHCs do not have incentives to act as gatekeepers to this care. Therefore, reductions in spending for these external services would most likely reflect improvements in care delivery within CHCs. Analytically, the DID estimate is represented by the marginal effect on the interaction between a dummy variable indicating that the observations occur in the post-Medicaid expansion period and a dummy variable indicating newly insured individuals. We will also include patient-level variables to account for predisposing factors and need for services, as identified by the Aday and Andersen model. A variety of factors must be addressed in our DID estimation: *Accounting for clinic-level effects.* Our study will focus on the 'treatment-effect' of the Oregon Medicaid expansion: How does expanding Medicaid affect healthcare spending? Since this is our main focus, our approach is to use clinic-level fixed effects to net out any time-invariant differences in clinic-level outcomes. However, recognizing the potential interest in clinic-level effects, in secondary analyses we will test hierarchical (mixed) models to more

specifically model (i) clinic-level variation and (ii) patient-level variation. *Modeling health care expenditures.* As in many analyses of a patient's healthcare expenditures, in any given year, many patients will have no visits. Thus, our dependent variable will have a cluster of observations at zero. We will use a well-validated approach for modeling this phenomenon: the 2-part model.[161] Part 1 will use a logistic regression to estimate the probability of any expenditure. Part 2 will focus on individuals with non-zero expenditures. We will use recent literature to guide the appropriate estimation approach, taking into account the potentially skewed distribution of the dependent variable.[162,163]

For **Aim 1**, the primary dependent variables are insurance coverage, utilization of services, and receipt of preventive services in the pre- and post-expansion periods, in expansions versus non-expansion states. To assess service utilization, we will ask questions such as: Has the overall number of CHC services (e.g., visits, immunizations, referrals) increased? To assess preventive services, we will use clinical quality metrics for process (*e.g.,* blood pressure screening rates in the clinic). The primary independent variable is whether a CHC is in a state that expanded Medicaid or not. For **Aim 2**, the primary dependent variables are utilization of services and receipt of preventive services among cohorts of individual patients in expansion states. To assess service utilization, we will ask questions such as: Has the number of primary care visits, per patient, increased? To assess preventive services, we will use clinical quality metrics for process (*e.g.,* breast cancer screening rates among patient cohorts). The primary independent variable is whether a patient is newly insured, already insured, or uninsured. For **Aim 3**, the primary dependent variables are utilization of services in CHCs and external to CHCs and Medicaid expenditures in Oregon. To assess service utilization, we will ask questions such as: What is the rate of hospitalizations in newly versus already insured patients? To assess Medicaid expenditures, we will ask: Are there differences in Medicaid expenditures between newly insured versus already insured patients? Do expenditures plateau over time for newly insured patients? The primary independent variable is whether an Oregon patient is newly insured or already insured. Other covariates for patient- and clinic-level analyses in the three aims include predisposing factors and need for services as described in Box 6, above.

Methods to account for non-users in the post-period. The available data do not indicate whether patients without clinic contact in the post-period are true non-users, or drop-outs (*i.e.,* left the clinic permanently to seek care elsewhere), potentially leading to underestimated utilization rates. A dropout rate that is similar across groups will not impact the comparison between clinics in expansion versus non-expansion states or between patients with different coverage status, but differential dropout poses a threat to the generalizability of the findings. As a sensitivity analysis, we will use pre-expansion data to model the probability that a patient has a visit in year t based on demographic information and the number of visits to the clinic in year t-1 and t-2. Parameters from this model will be used to attach a weight to all patients across all years. This method provides a measure of the contribution of each patient on utilization measures and avoids bias that may arise from defining patient attribution according to utilization patterns that occur because of the Medicaid expansion.

Standard errors adjustments. Depending on the distribution of the outcomes of interest, standard errors may be difficult to estimate using standard regression variance output. Thus, we plan to implement bootstrapping to obtain reliable standard errors when appropriate. Additionally, as a sensitivity analysis, we plan to bootstrap all analytic models simultaneously to allow estimating covariances among parameter estimators across models.

Power calculations. For **Aim 1,** our total sample size includes 761,840 patients distributed over

442 clinics in 16 states. We estimated power accounting for the clustering of patients within clinics and clinics within states. This sample size will provide 90% power in patient-level analyses to detect a minimum of 1.9% difference in changes in binary outcomes before and after Medicaid expansion, when intra-cluster correlation (ICC) is set to 0.10.[175] For example, this corresponds to a scenario where the pre- and post-expansion change of percent of covered visits is +6.0% in the Medicaid expansion group and +4.1% in the non-Medicaid expansion group assuming an ICC=0.10. As most studies show an ICC<0.001,[175] the proposed study will have sufficient power to detect differences of health policy importance. We will also have 90% power to detect a 2.7% difference in changes of binary outcomes, assuming an even more conservative ICC=0.20. For clinic-level analyses, this sample size will provide 90% to detect a minimum of 2.3% difference in binary outcomes before and after Medicaid expansion with an ICC=0.10. For continuous outcomes, the study sample will provide 90% to detect a 0.26 difference in change in mean before and after Medicaid expansion (ICC=0.10). This corresponds to a scenario where the pre- and post-expansion change is +0.30 for clinics in expansion state and +0.04 for clinics in non-expansion state. For **Aim 2**, with a sample size of 447,488 patients, the comparisons of newly insured compared to already insured and uninsured will have 90% power to detect a difference of 3.35%. For example, this corresponds to a scenario where newly insured patients increased covered visits +4.55% (pre vs. post) and only +1.2% increase in covered visits for already insured from pre to post. For **Aim 3** (sample size of 187,684), a comparison of newly insured versus already insured will have 90% power to detect difference in changes in binary outcomes before and after Medicaid expansion of 2.8% assuming an ICC=0.10. Estimates of parameters for all of these power calculations were obtained from a preliminary pull of OCHIN EHR data. **We note that power calculations estimate the minimum numbers needed to detect changes. In reality, the impact of Medicaid expansion could be much greater than these minimums.** Although these calculations are simplistic and do not account for all differences among clinics or propensity score matching, we expect our actual analyses will have a similar or greater power as regression adjustment results in increased precision for certain outcomes and thus increased statistical power.[176]

B.4.5 Dissemination. This study is extremely timely as many states are still deliberating on whether to expand their Medicaid programs, and other states are eager to learn about the impact of their expansions. Our study findings will need to be rapidly disseminated to inform these policy discussions. We have expertise in working with community partners, healthcare practitioners in OCHIN, and state and national policymakers to rapidly and widely disseminate policy-relevant research findings.[177] In addition, our approach to use OCHIN EHR data to study natural policy experiments has broad relevance to the study of national and local healthcare reform efforts. Thus, we will also endeavor to disseminate methods for using and further validating this dataset as we have done successfully with previous studies.[33,36,56,58,59] Finally, as the results of this project unfold rapidly, we recognize the importance of sharing real-time lessons and implementation experiences to a broad national audience. We will leverage our previously launched and supported blog, funded by the Robert Wood Johnson Foundation, to provide information and opportunities for blog readers to dialogue about the implications of health policy reforms[178] (see more specific information in the attachment describing our Data Sharing Plan).

B.4.6 Study considerations. (1) We will use EHR data or Oregon EHR-Medicaid data; EHR data alone have inherent limitations, but as noted above, outperform claims data and/or self-reported data. EHR data sources are not developed for research purposes; however, we have conducted multiple data validation studies, built EHR research datasets, and successfully conducted policy-relevant research in the past.[22,33,34,53,59,61] The combination of EHR and claims

data addresses some of the limitations reported when these individual data sources have been used alone.[29] **(2)** We anticipate missing data, either from services documented in inaccessible parts of the EHR (likely random) or from patients who went outside the OCHIN network to receive services (perhaps not random). Our analyses can accommodate missing data resulting from attrition of patients. We will explicitly model missingness by including variables that are related to missingness in the analysis as covariates.[179] If non-trivial levels of missing data are observed, we will use a method such as multiple imputation to include these patients in analyses.[180] We will conduct a sensitivity analysis comparing parameter values for models using completers only, all patients without multiple imputation, and all patients with multiple imputation, to understand any biases introduced by differential attrition and/or missing not at random.[181] **(3)** As with any 'real-world' study, unobserved changes might occur over time, making it difficult to isolate the effect of the ACA. Patients from expansion and non-expansion states may prove to be very different on average. If so, we plan to perform a propensity score matching of patients to identify the most closely matched patients in expansion and non-expansion states. This propensity score matching along with the use of both clinic- and patient-level analyses, and the use of a DID approach will help minimize these biases.