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Oregon Health & Science University
RESEARCH PROTOCOL

Protocol Title:
Evaluating Community Health Centers' Adoption of a New Global Capitation Payment (eCHANGE)

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Specific Aims:
Aim 1: Assess pre-post Alternative Payment Methodology (APM) changes in internal services utilization and quality of clinical care delivered in intervention sites, as compared with control sites.

Hypothesis 1a: Patterns of internal services utilization (e.g., face-to-face visits, e-mail visits) will change among intervention clinics' patients from pre- to post-APM, while control clinics' patients' rates will not change.
Hypothesis 1b: Intervention site patients will achieve greater pre-post improvements in quality of care delivered internally, as compared to the rates of improvement for patients in control clinics.

Aim 2: Measure pre-post changes in patients' utilization of external services (e.g., emergency department) and overall costs to the Medicaid program among patients from intervention clinics, as compared to patients from control clinics.

Hypothesis 2a: Expenditures attributed to external services will decrease for patients from intervention clinics, but these expenditures will remain the same or increase for patients in the control clinics.
Hypothesis 2b: Total Medicaid expenditures will decrease for patients from intervention clinics, while expenditures for patients from control clinics will remain the same or increase.

Aim 3: Study the change processes associated with APM implementation, including the organizational, workflow, and service delivery changes made in the Community Health Centers (CHCs) during and after APM implementation.

Hypothesis 3a: APM clinics will make fundamental pre-post changes in patterns of clinical care delivery and staff workflow.
Hypothesis 3b: There will be variability among the intervention clinics in what changes are successfully achieved, associated with vision, approach, strategic planning, and other clinic characteristics.

We will utilize a mixed-methods approach, drawing upon both qualitative and quantitative data from clinic site visits, clinic surveys, key informant interviews, follow-up calls, Medicaid administrative claims, and the OCHIN electronic health record (EHR).

Background and Significance:

The common practice of reimbursing primary care providers through a fee-for-service model hampers efforts to develop patient-centered medical homes: it rewards a high volume of face-to-face clinic visits, which does not necessarily lead to value, quality, and patient-centered care. This is especially problematic in Community Health Centers (CHCs), which are currently paid based on the Prospective Payment System (PPS) rate, a fee-for-service model. To reform this payment model in CHCs, Oregon developed an Alternative Payment Methodology (APM) that converts PPS (Medicaid revenue) to a prospective, capitated per-member per-month rate. The Oregon Primary Care Association (OPCA) is providing technical assistance to the APM clinics, with funding from the Robert Wood Johnson Foundation. The APM project seeks to (i) incentivize providing value over volume of visits, (ii) support comprehensive treatment modalities for patients with complex needs, and (iii) allow CHCs to focus more of their resources on population health initiatives.

APM is being implemented in several phases. Three CHC organizations are participating in Phase I of the APM demonstration project, which kicked off on March 1, 2013. Five additional CHC joined Phase II July 1, 2014 or October 1, 2014. Phase III began July 1, 2015 with three additional CHC organizations. Each CHC organization may include several clinics. All but one of the APM CHCs are members of the OCHIN community health information network practice-based research network, with a single, shared EHR. In this study, we propose to evaluate the APM clinics and/or patients matched to an equal number of control clinics and/or patients that are part of the OCHIN network.

Preliminary Studies / Progress Report:

For over a decade, we have worked with policy makers to evaluate the impact of Oregon Health Plan (OHP) policy changes. We learned about problems families experienced when they lost insurance, barriers faced when accessing care, disparities in care, and the importance of health insurance coverage and a usual source of care.[1-24] Once we identified these barriers, we worked with families, community advocacy organizations, and policy makers to improve access to public health insurance in Oregon. State policies to expand and improve coverage programs were informed by this research. Specifically, we found that even small co-payments led to increased uninsurance and unmet care needs.[7,23,25-28] We learned that children with short coverage gaps had disproportionate rates of unmet need,[10] and uninsured children had even higher rates of unmet need.[2,4] Our findings influenced changes, including: the elimination of co-payments for Medicaid beneficiaries, expansions in the OHP, and the passage of a state referendum which expanded Oregon's Children's Health Insurance Program (CHIP). Our work also informed policies that made public insurance more accessible (e.g., shortened waiting periods). Our finding that parents with public insurance were more likely than those with private coverage to have continuously insured children informed initiatives to expand public coverage to more Oregon parents.[11] Many other states requested copies of publications based on these findings, and this work was highlighted in policy briefs at the national level.[29]

Research Design and Methods

Subjects and Experimental Design:

This is a clinic- or patient-level matched prospective study design, coupled with a difference-in-

differences (DID) approach. The sample is Oregon CHCs participating in the APM demonstration project implemented by the state of Oregon (implementation clinics and/or patients) and an equal number of control clinics and/or patients.

We will interact with approximately 40 clinic staff subjects at each of the Phase I clinic sites, and approximately 10 staff subjects at the OPCA office, aged 18-100 years.

We will also assemble a dataset of EHR data on approximately 400,000 patients aged 2-64 from the implementation clinics and/or patients and control clinics and/or patients. All Phase I study sites have agreed to take part in the initial qualitative data collection portion of this study and have agreed to $1000 compensation at the organization level for their participation. We will select control sites and/or patients based on matching algorithms to ensure selected controls are similar to implementation clinics and/or their patients.

We will conduct up to two site visits to intervention clinics to observe practice changes that occurred post APM-implementation. We will also conduct preliminary qualitative data collection in the APM sites, including a practice survey and key informant interviews. Due to a shortage of funding for the initial baseline data collection, and because the Phase II and III sites have limited involvement in the study, they will not receive reimbursement for study participation.

Baseline qualitative data collection

Box 1: Qualitative Activities, Subjects and Recruitment

Study Site Name	Study Activities	Approximate Number of Clinic Staff Subjects at Each Site	Recruitment Strategy
Phase I APM Sites: Virginia Garcia – Beaverton, Cornelius, Hillsboro, McMinnville (several clinics may be included at each of these locations) Mosaic Medical – Bend, Prineville, Madras (several clinics may be included at each of these locations) OHSU Richmond (several clinics may be included from this location)	Pre-site visit telephone interview	1	Clinic "point-person"
	Phone interview after monthly OPCA meeting, if needed	2	Clinic "point-person"
	Staff interviews	10	Referred by clinic "point-person" and identified by study staff during site visit
	Practice Change Assessment Questionnaire	20	Clinic staff meeting attendees
Oregon Primary Care Association Office	Observe monthly meetings	10	Monthly project meeting attendees
Phase II APM Sites: OHSU Scappoose (several clinics may be included from this location) Coastal Family Health	Telephone interview	1	Clinic "point-person"
	Phone interview after monthly OPCA meeting, if needed	2	Clinic "point-person"
	Practice Change Assessment Questionnaire	20	Clinic staff meeting attendees

Center (several clinics may be included from this location) Benton County Health Department - Benton, East Linn, Monroe, Lincoln (several clinics may be included at each of these locations) Multnomah County Health Department- Northeast, East County, Rockwood, Mid County, Southeast, North Portland (several clinics may be included at each of these locations) Yakima Valley Farmworkers Clinic - Hermiston, Woodburn, Portland, Salem (clinics from this CHC organization who do not have an OCHIN Epic EHR may not be included in this study)			

Site visits. We will conduct a site visit in implementation CHCs to collect data from staff. The visit will collect data to help us observe and understand APM-related processes and workflows, and assess factors unique to each clinic that facilitate or hinder change. Trained study staff will collect data during the site visits, which will last approximately 3-5 days at each of the APM sites. We will use the multi-method assessment process (MAP),[30] as we have successfully done in other studies.[31-33] Using MAP's iterative process, field researchers will gather data, synthesize information and select new avenues to probe in a cycle. As the data expand and lead to deeper insights, new key informants may be tapped and new data sources mined. This iterative process is central to obtaining rapid and substantive knowledge in field research. At each site visit, the team will spend the first 2-3 days intensively observing activities. During the visits, we will focus on areas that clinics targeted for change, observing and describing tasks, workflow and clinical operations; team members will also talk informally with clinic staff, as these opportunistic conversations may elicit different information than what is captured in formal interviews.

In addition, we will conduct semi-structured interviews with a diverse group of clinic staff. These interviews will be designed to explore experiences with the APM model and the change process. We will obtain in-depth information about what they did (or did not do) as a result of APM and why. We will have regular follow-up phone calls with these key informants, roughly once a month, to ask about specific changes. Team members will prepare field notes and debrief to share observations and strategize for additional visits. After the site visit, the field team will debrief with the full team to share findings, get feedback, review the interview list, and refine the interview guide, as needed. If needed, we will continue to conduct interviews and observations with a focus on filling knowledge gaps for 1-2 final days. A total of 8-10 interviews will be conducted per CHC; we will schedule the interviews as convenient for participants.

CHC surveys. At APM sites, we will survey CHC staff using the Practice Change Assessment Questionnaire to assess staff attitudes about change and facilitators and barriers to change at the clinic. The study team will conduct the surveys at a clinic meeting and personally follow-up with non-responders.

Statistical considerations

Inclusion Criteria. Qualitative data collection will target current staff at the APM implementation clinics, aged 18-100.

Data management. Study staff will assemble a database of all data elements. Qualitative data will be catalogued in a spreadsheet. Field notes, hand-written on site, will be expanded and put into electronic form by the researchers. Interviews will be digitally recorded and professionally transcribed. Recordings, field notes, summaries of follow-up phone calls, transcripts and digital copies of all collected artifacts will be kept on a secure network. Access to digital files will be password protected. We will use Atlas.ti™ qualitative software to aid this process. Surveys will be designed to scan electronically into a REDCap database, checked for accuracy by study staff, and exported to statistical software for analysis..

Analysis Plan. We will begin qualitative analyses shortly after data collection commences. The study team will meet regularly to review all data, and listen to and discuss key segments of the recorded interviews. Analyzing qualitative data as it is collected is crucial to monitoring data quality, refining observation and interview guides, and monitoring theme saturation. This ongoing process will be used to track emerging themes and create a coding template to be used for more in-depth analysis. We will follow the 5-phase analysis strategy described by Miller and Crabtree (describing, organizing, connecting, corroborating/ legitimizing, representing).[34,35] We will use an immersion-crystallization approach in which the team reads and discusses the data for each clinic (immersion) to identify key findings (crystallization);[35,36] we will do this twice, first to identify key themes within each "case" CHC, and then to identify cross-case finding.

The survey data and interview transcripts will be coded using the 5-phase analysis strategy explained above. We will also analyze differences between the Phase I and Phase II clinics' experiences with APM implementation.

Quantitative data collection

We will compile EHR and Medicaid claims datasets that include data from up to 3 years pre-APM implementation, during implementation, and ≥3 years post.

Aims 1 and 2 Evaluation Summary				
Evaluate effect of APM intervention on:	**Study Time Periods**	**Data Sources**	**Inclusion Criteria**	**Analyses**
Aim 1. Internal services utilization and quality of care delivered; Aims 2 & 3. Utilization of and spending on services outside of the CHC,	Up to 3 years pre-APM implementation ; ≥3-years post-APM implementation ;	1. Internal services: OCHIN EHR data 2. External services and expenditures:	1. Total clinic population: established patients at intervention and control clinics aged 2-64 2. Medicaid	Clinic level analysis using the DID analysis and patient level analysis using Generalized Estimating Equation models, to accommodate serial and intra-clinic correlations, categorical and continuous covariates, fixed and time-dependent covariates. Two-part models will be used to accommodate distributions

total Medicaid spending.	(We will assess how long implementation takes and include it as transition time to our analyses)	OCHIN EHR data; Medicaid administrative data (including intervention CHCs' per-member per-month capitated payment rates)	Population: Medicaid-enrolled patients at intervention and control clinics aged 2-64	of healthcare spending. Matching methods will be utilized to reduce the observed bias and to adjust for imbalances between intervention and control clinics and/or patients.

Data Sources

EHR data. We will assemble a dataset of EHR data elements including all demographics, healthcare utilization, diagnoses, treatment, and health insurance coverage start and stop dates for all established patients age 2-64 for patients of APM clinics and their matched controls. We will include data from the following dates: no earlier than January 1, 2010 – December 31, 2018. The EHR is **centrally hosted and managed** at OCHIN and shared across all study CHC clinics. OCHIN maintains this central data warehouse, and the data are standardized across all OCHIN CHCs and regularly checked for accuracy.

Medicaid administrative data. These data will provide information on external services received and costs incurred. Oregon's Medicaid recipients are assigned unique individual identification (ID) numbers, facilitating data linkages across multiple databases, including the OCHIN EHR data. We will use claims and cost data from Medicaid.

Linkage between EHR and Medicaid administrative data. Project staff will use state ID numbers to create individual-level linkages between OCHIN EHR and Medicaid data..[37-39] **All transfers will be done securely.** A de-identified dataset will be transferred to OHSU. The lead research analyst at OHSU has obtained security clearances to work with OCHIN's data team to assist with preparing the dataset to transfer to OHSU.

This study is being conducted in collaboration with OCHIN. The State of Oregon data will be shared with OCHIN under a Data Access Agreement. OCHIN will then share Medicaid and OCHIN EHR data with OHSU under a Data Use Agreement.

Data included in the datasets Once the Medicaid-OCHIN EHR link is created, names, addresses, social security numbers and ID #s will be removed by the OCHIN analysts and a study ID will be given to the records that does not stem from any identifiers prior to sending the datasets to OHSU. OCHIN will maintain, but not share with OHSU the crosswalk that links the study ID to the identified data.

Inclusion criteria. OCHIN's EHR data includes internal services utilization and care quality on all patients seen, regardless of insurance type (Aim 1). We will assess the APM's impact on the entire clinic population (aged 2-64) as well as relevant subpopulations (e.g., Medicaid-insured, uninsured, APM patients). For some comparisons, the denominator will be patients with clinic contact. Patients in a clinic's panel will not necessarily be the same individuals in the pre- vs. post-APM period. Because APM might result in fewer face-to-face visits, we will work with our expert advisors to determine what "counts" as contact with the clinic. For some comparisons, we will create a longitudinal cohort of the *same patients* over time. Assessment of external services utilization and overall costs will focus on the Medicaid-insured (Aim 2).

Study variables. We adapted Aday and Andersen's model of health care utilization to help us understand the interplay between *predisposing factors*, *enabling / hindering factors*, and *need for care,* their impact

on utilization of CHC services and other recommended care, and the resulting effect on external services utilization and overall cost of care. The primary independent variable is whether or not the patient was exposed to the APM by being a patient at an intervention vs. control site (an *enabling / hindering factor*). The *primary dependent variables* of utilization of internal / external services and quality of care delivered are based on (i) the Medicaid initial core sets of health quality measures for adults,[43,44] and (ii) pediatric care quality measures developed by AHRQ's National Advisory Council Subcommittee on Children's Healthcare Quality Measures for Medicaid and CHIP Programs, pursuant to the Children's Health Insurance Program Reauthorization Act. We will select measures that are: 1) identified by Oregon's Medicaid program and/or those on the list of Clinical Quality Measures and other EHR incentive programs;[45,46] 2) feasibly measured with EHR or Medicaid claims data (**our team has created methods for adapting quality measures based on claims data for use in OCHIN's EHR data[47,48]**); 3) representative across age groups and gender; 4) representative of treatment levels (e.g., prevention, acute and chronic condition care); and 5) relevant to CHC populations. With guidance from an expert advisory group, we will select and define final specifications and modify them to accommodate calculation over the pre-post periods. Assessment of internal services utilization and quality can be done using OCHIN's EHR data; assessment of external services utilization will use EHR data linked with Medicaid administrative data.

Statistical analyses. We will conduct analyses at the clinic- and patient-level. The clinic-level analyses are typically performed in cluster-randomized trials, and the individual-level analyses are typically performed in observational studies in order to account for socio-demographic differences among clinics.

Clinic-level: We will summarize baseline measures using descriptive statistics and data visualization methods (e.g., histograms, scatter plots) to assess how baseline data differs. To compare pre- and post-APM rates, we will assess data in pre- and post-APM time periods, using regression methods to estimate pre- vs. post-intervention change for each clinic. We will use a Generalized Estimating Equation (GEE) approach to adjust for serial correlation and other potential confounders. The pre- vs. post-APM changes will be calculated with GEE logit regression between intervention and control CHCs (DID analysis). Additional analyses to account for differences among APM phases and temporal inclusion may be used.

Patient-level: The primary independent variable is whether a patient belongs to an intervention or control CHC. Other covariates include predisposing factors and need for services. We will use GEE models[49,50] which offer flexible regression modeling to accommodate different sources of correlations (serial, intra-clinic, and intra-family), 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 quality rates, a GEE logistic regression model can analyze quality of care received in pre- and post-APM periods as a function of whether a patient belongs to an intervention or control CHC and other possible confounders (e.g., predisposing factors; need for services). Serial, and intra-clinic correlations will be modeled, and empirical robust standard errors will be applied, to provide valid inference.[51] As an exploratory secondary analysis, we will evaluate the impact of the APM intervention on total number of recommended services received. The distribution of the total services received will be examined first before selecting a specific model to use for the analysis. Analytic models will be refined through an iterative process, guided by the hypotheses, conceptual model, and preliminary analyses. If there are significant patient differences between the intervention and control sites, we may use propensity score methods in the analysis phase to reduce the observed bias and adjust for imbalances between intervention and control clinics.[52]

Econometric analyses. Using difference-in-differences methods, we will calculate the average pre-post APM difference in spending of patients in APM intervention clinics, subtracted by the average difference among patients in comparison clinics. Changes in spending after APM implementation in the intervention

clinics vs. spending changes in the control clinics will "net out" any secular changes not related to APM. Any remaining significant differences in outcome – the DID – are attributed to the APM intervention. These findings will help to assess whether the APM intervention can help reduce costs, and if so, whether the reduction comes from lower spending at the CHC level or through reductions in potentially unnecessary or inefficient use of specialty and hospital services. We note that CHCs are not financially at risk for services outside of the CHC and thus do not have incentives to act as gatekeepers to care. Thus, reductions in spending for specialty services and other external services would most likely reflect improvements in internal care delivery.

Analytically, the difference-in-differences estimate is represented by the marginal effect on the interaction between a dummy variable indicating that the observations occur in the post-APM period and a dummy variable indicating the individual's attribution to an APM intervention clinic. We will also include patient-level variables to account for predisposing factors and need for services. A variety of issues must be addressed in our DID estimation:

Definition of external services. External services will be defined as any care occurring outside of the CHC, e.g., emergency department visits, hospitalizations, and other ambulatory care that takes place in settings other than the CHC.

Accounting for clinic-level effects. Our study will focus on the "treatment-effect" of the APM: how does the transition to a capitated payment system affect health care spending? Since this is our main focus, our approach may include use of clinic-level fixed effects to net out any time-invariant differences in clinic-level cost 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 costs. As in many analyses of a patient's health care costs, in any given year, many patients will have no visits or expenditures. 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.[53] 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.[54,55]

Accounting for all expenditures. Estimates of changes in spending must account for all expenditures, including capitated and fee-for-service (FFS) payments. Of note, Oregon's Medicaid managed care organizations (MCOs) provide encounter data to the state Medicaid agencies in lieu of FFS claims, a common practice in many states. These data are assessed for general accuracy and consistency and have been used by states to set managed care payment rates. In order to attach "paid" amounts to these encounter claims, we will impute a "paid" amount across all FFS and MCO claims (that is, any external services for which there would be payment outside of the APM capitation rate) based on the median FFS payment. The study team has used this approach previously and has extensive experience in the data structures, elements, values, means of combining records and methods for aggregating and measuring service dimensions.[25,56] In summary, creation of the expenditure variable will be based on a blend of actual FFS payments, recorded capitation rates, and, where necessary, imputed expenditures that have served as the actuarial basis for rate setting in Oregon.

Modeling interaction terms. In non-linear models (e.g., the 2-part model) the interpretation of the interaction effect cannot be directly calculated from the coefficient on the interaction term.[57] Our approach will be to estimate the 2-part model, save those coefficients, and use empirical simulation (also known as "recycled predictions") methods to determine the APM's average effect using bootstrapping to derive 95% confidence intervals.

Accounting for repeated observations. We will observe outcomes for each individual in the pre- and post-APM periods. We will consider several options for modeling the error component, including random effects and generalized estimating equations, and the block bootstrap.

Human Subjects Considerations:

Potential Risks, Protection from Risks, and Risk/Benefit Discussion

Site Visits: Conducted at CHC practices. No personally identifiable information will be collected during these visits.

Staff Interviews: Interviews will be recorded. Research team members will follow IRB consent and privacy protocols at all times. Transcripts from completed interviews will be coded with a unique identifier and kept secure in a locked file cabinet when not in use. All computer files containing unique identifier links will be password protected, accessible only to relevant study team personnel.

Research team members will follow IRB privacy protocols at all times. All recordings will be kept secure in a locked file cabinet when not in use and destroyed once the study is complete. All computer files will be password protected, accessible only to relevant study team personnel. All electronic files will be maintained for 2 years after the conclusion of the study, including all data analyses. After this time period, all paper and computer data files will be destroyed or will be used for ongoing research. In the latter instance, the principal investigator will obtain IRB approval.

Follow Up Phone Calls with Key Informants: Interviews will be recorded. Research team members will follow IRB consent and privacy protocols at all times. Summaries and transcripts of these calls will be coded with a unique identifier and kept secure in a locked file cabinet when not in use. All computer files containing unique identifier links will be password protected, accessible only to relevant study team personnel.

Research team members will follow IRB privacy protocols at all times. All recordings, transcripts, and computer files will be stored on a password protected drive, accessible only to relevant study team personnel. All electronic files will be maintained for 2 years after the conclusion of the study, including all data analyses. After this time period, all paper and computer data files will be destroyed or will be used for ongoing research. The principal investigator will obtain IRB approval before using data from this study for other research.

Observation of Project Meetings: Conducted with project leads from each clinic organization and the Oregon Primary Care Association. No personally identifiable information will be collected during monthly meetings.

EHR Abstraction: Conducted with the records of patients aged 2-64 who receive health care at intervention and control CHCs. All EHR data from the OCHIN member clinics are stored securely at OCHIN, each clinic has business use agreements with OCHIN to handle and manage PHI from their clinical data. OCHIN data analysts will be responsible for secure transfer of data. When all data linkages have been completed, the data will be de-identified (OCHIN will maintain a crosswalk of identifiers, but it will not be shared with OHSU).

Potential Risks

Potential risk to Practices: For practices, this is a low risk study. We will be observing practice operations and implementation of the APM. This observation does not pose a risk to the practice, as all of the data we collect, via survey and fieldnotes, is immediately de-identified.

Potential risk to CHC staff: The CHC staff interviews and CHC staff survey pose minimal risk to practice members because the survey itself does not contain any personal information about the practice members. It is possible that someone in the practice could use information about a respondent's role (e.g., Office Manager) to identify that person and his or her responses. For this reason, our study team collects these data personally, and the data we collect is completely confidential, and only used by the study team. If data is reported to practices, we only report these data in aggregate so that it is not possible to link an individual and his or her responses.

Potential Risk to Patients: Our protocol and procedures for collecting data and conducting record abstraction ensure that we are not collecting any information that could be used to identify patients that participate in this study. The EHR data collection holds a minimal risk of the small possibility of disclosure of legally protected health information (PHI) or personal information. We will ensure proper protections are in place to prevent any disclosure.

Adequacy of Protection Against Risks

a. Recruitment and Informed Consent
IRB and HIPAA approval will be obtained for all study steps.

Full explanation of the study will be given to practice leaders. We will ask practice leaders to explain the study to practice staff. An information sheet will be used to provide information about the study to potential subjects prior to qualitative data collection.

We are applying for a Waiver of Authorization for the EHR abstraction.

b. Protection Against Risk In the Study
All researchers are trained and follow federal HIPAA regulations, which require specific protocols for the transferring, storage, and reporting of protected health information. The data we analyze at OHSU will not contain any personal identifiers. In the manner described above, each patient whose EHR data we use will be assigned a unique subject identification. All data will be stored on secure servers as well as secure, password protected computers in the locked offices. Any signed consent forms will be stored in a locked office.

All of the data we collect will be securely exported under the direct supervision of the investigator and co-investigators. Secure communications by electronic mail are also provided using secure messaging software. In addition, all data will be computerized and managed on OCHIN HIPAA-compliant computers. All data will be stored and backed up password-protected secure servers. The research team will meet at regular intervals to identify and discuss any data collection and management issues that may arise.

Potential Benefits of the Proposed Research to Subjects and Others

This study will greatly enhance our understanding of how to improve primary care delivery and readiness to change in primary care clinics. Participating clinics will benefit from study findings that help identify barriers and facilitators of successful APM implementation.

Importance of the Knowledge to be Gained

This study has the potential to greatly improve primary care delivery and patient health in CHCs by:

- Filling a critical knowledge gap: traditional fee-for-service reimbursement models are not achieving improvements in population health at reduced cost, so testing alternative payment methods is imperative;
- Measuring the *real-time* effects of health policy changes on care delivery in vulnerable populations;
- Using mixed methods to evaluate an APM "natural experiment" in CHCs, including using CHCs' electronic health record (EHR) data to assess process and outcomes of a policy reform;
- Engaging CHCs in a study that will inform ongoing / future policy and practice changes;
- Informing the potential dissemination of alternative payment methods to more CHCs and other primary care settings; and
- Determining what types of practice change can be affected with payment reforms – information crucial to future efforts to combine payment reform with other forms of technical assistance.

Inclusion of Children

Data from children and adults aged 2-64 from CHCs will be utilized for the quantitative portion of this study. CHCs care for a large proportion of racial/ethnic minority and low-income populations. We will also involve adults who are CHC staff in study site visits and interviews; we will not be interacting directly with children.

Literature Cited:

1. Angier H, DeVoe JE, Tillotson CJ, Wallace LS. Changes in US Family Health Insurance Coverage Patterns: Comparing 2003 to 2008. *Family Medicine.* 2013;45(1):26-32.

2. Gold R, Nichols G, Muench J, et al. Implementing an Integrated Care Setting's Diabetes QI Initiative in Safety Net Clinics: A Practice-Based Randomized Trial. Paper presented at: 5th Annual NIH conference on the Science of Dissemination and implementation: Science at the Crossroads2012; Bethesda, MD.

3. Gold R, Muench J, Hill C, et al. Collaborative development of a randomized study to adapt a diabetes quality improvement initiative for federally qualified health centers. *Journal of Health Care for the Poor & Underserved.* Aug 2012;23(3 Suppl):236-246.

4. DeVoe JE, Petering R, Krois L. A Usual Source of Care: Supplement or Substitute for Health Insurance Among Low-Income Children? Recent Findings from Oregon. *Med Care.* 2008;46(10):1041-1048.

5. Angus L, Devoe J. Evidence that the citizenship mandate curtailed participation in Oregon's Medicaid family planning program. *Health Aff.* Apr 2010;29(4):690-698.

6. Bauer J, Angus L, Fischler N, Rosenberg KD, Gipson TF, Devoe J. The impact of citizenship documentation requirements on access to medicaid for pregnant women in Oregon. *Maternal and child health journal.* Aug 2011;15(6):753-758.

7. Carlson M, DeVoe J, Wright B. Short-term impacts of coverage loss in a Medicaid population: early results from a prospective cohort study of the Oregon Health Plan (OHP) *Annals of family medicine.* 2006;4(4):391-398.

8. DeVoe J, Fryer G, Phillips R, Green L. Receipt of preventive care among adults: insurance status and usual source of care. *American journal of public health.* 2003;93:786-791.

9. DeVoe J. The unsustainable US health care system: a blueprint for change. *Annals of family medicine.* May-Jun 2008;6(3):263-266.

10. DeVoe JE, Graham A, Krois L, Smith J, Fairbrother GL. "Mind the gap" in children's health insurance coverage: does the length of a child's coverage gap matter? *Ambulatory Pediatrics.* 2008;8(2):129-134.

11. DeVoe JE, Krois L, Edlund C, Smith J, Carlson NE. Uninsured but Eligible Children: Are Their Parents Insured? Recent Findings From Oregon. *Med Care.* 2008;46(1):3.

12. DeVoe JE, Krois L, Edlund T, Smith J, Carlson NE. Uninsurance among children whose parents are losing Medicaid coverage: Results from a statewide survey of Oregon families. *Health Serv Res.* Feb 2008;43(1 Pt 2):401-418.

13. DeVoe JE, Krois L, Stenger R. Do children in rural areas still have different access to health care? Results from a statewide survey of Oregon's food stamp population. *The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association.* Winter 2009;25(1):1-7.

14. DeVoe JE, Tillotson CJ, Wallace LS, Selph S, Graham A, Angier H. Comparing types of health insurance for children: a public option versus a private option. *Med Care.* Sep 2011;49(9):818-827.

15. DeVoe JE, Ray M, Krois L, Carlson MJ. Uncertain health insurance coverage and unmet children's health care needs. *Fam Med.* Feb 2010;42(2):121-132.

16. DeVoe JE, Tillotson C, Wallace L. Uninsured children with insured parents. *Journal of the American Medical Association.* 2008;300(16):1904-1913.

17. Angier H, Wiggins N, Gregg J, Gold R, Devoe JE. Engagement of Community Health Workers In a Health Policy Research Project Through a Novel Technique: The Community Retreat. Paper presented at: North American Primary Care Research Group2011; Banff, Alberta.

18. Willson JM, Wallace LS, DeVoe JE. Are State Medicaid Application Enrollment Forms Readable? *Journal of Healthcare for the Poor and Underserved.* 2009;20(423-431).

19. Hansen JS, Wallace LS, DeVoe JE. How readable are Spanish-language Medicaid applications? *Journal of immigrant and minority health / Center for Minority Public Health.* Apr 2011;13(2):293-298.

20. DeVoe JE, Tillotson CJ, Wallace LS, Lesko SE, Pandhi N. Is health insurance enough? A usual source of care may be more important to ensure a child receives preventive health counseling. *Maternal and child health journal.* Feb 2012;16(2):306-315.

21. Wallace LS, DeVoe JE, Hansen JS. Assessment of Children's Public Health Insurance Program enrollment applications: a health literacy perspective. *Journal of pediatric health care : official publication of National Association of Pediatric Nurse Associates & Practitioners.* Mar-Apr 2011;25(2):133-137.

22. DeVoe JE, Westfall N, Crocker S, et al. Why Do Some Eligible Families Forego Public Insurance for Their Children? A Qualitative Analysis. *Family Medicine.* 2012;44(1):39-46.

23. Wright B, Carlson M, Edlund C, DeVoe J, Gallia C, Smith J. The impact of increased cost sharing on Medicaid enrollees. *Health Affairs.* 2005;24(4):1106-1116.

24. Yamauchi M, Carlson MJ, Wright BJ, Angier H, Devoe JE. Does Health Insurance Continuity Among Low-income Adults Impact Their Children's Insurance Coverage? *Maternal and child health journal.* Feb 23 2012.

25. Wallace N, McConnell KJ, Gallia C, Smith J. How Effective are Co-Payments in Reducing Expenditures for Low-Income Adult Medicaid Beneficiaries? Experience from the Oregon Health Plan. *Health services research.* 2008;43(2):515-530.

26. Handel DA, McConnell KJ, Wallace N, Gallia C. How Much Does Emergency Department Use Affect the Cost of Medicaid Programs? *Annals of Emergency Medicine.* 2008;51(5):614-621.

27. Lowe RA, McConnell KJ, Vogt ME, Smith JA. Impact of Medicaid cutbacks on emergency department use: the Oregon experience. *Annals of Emergency Medicine.* Dec 2008;52(6):626-634.

28. Wallace NT, McConnell KJ, Gallia CA, Edlund TD. Benefit policy and disenrollment of adult Medicaid beneficiaries from the Oregon health plan. *Journal of Health Care for the Poor & Underserved.* Nov 2010;21(4):1382-1394.

29. Ku L. *Collateral Damage: Children Lose Coverage When Their Parents Lose Health Insurance.* Washington DC: Center on Budget and Policy Priorities;2007.

30. Crabtree BF, Miller WL, Stange KC. Understanding practice from the ground up. *J Fam Pract.* Oct 2001;50(10):881-887.

31. Cohen D, McDaniel RR, Jr., Crabtree BF, et al. A practice change model for quality improvement in primary care practice. *J Healthc Manag.* May-Jun 2004;49(3):155-168; discussion 169-170.

32. Cohen DJ, Balasubramanian BA, Isaacson NF, Clark EC, Etz RS, Crabtree BF. Coordination of health behavior counseling in primary care. *Annals of family medicine.* 2011;July(9):5.

33. Cohen DJ, Flocke SA, Lawson P, Casucci B. How teachable moments are co-constructed to delivery health behavior advice during primary care visits. *American Academy of Communication in Health Care International Conference*. South Carolina2007.

34. Crabtree BF, Miller WL. *Doing Qualitative Research, 2nd Ed*. Thousand Oaks, CA: Sage Publications, Inc.; 1999.

35. Miller WL, Crabtree BF. The dance of interpretation. *Doing Qualitative Research, 2nd Ed*. Thousand Oaks, CA: Sage Publications, Inc.; 1999:127-143.

36. Borkan J. Immersion/crystallization. In: Crabtree BF, Miller WL, eds. *Doing qualitative research*. 2nd ed. Thousand Oaks, CA: Sage Publications, Inc.; 1999:179-194.

37. Gold R. *The Guide to Conducting Research in the OCHIN Practice Management Data.* Portland, OR: Kaiser Permanente Center for Health Research;2007.

38. Gold R, DeVoe J, Shah A, Chauvie S. Insurance continuity and receipt of diabetes preventive care in Oregon's CHCs. *Med Care.* 2008;47(4):431-439.

39. DeVoe JE, Gold R, McIntire P, Puro J, Chauvie S, Gallia CA. Electronic health records vs Medicaid claims: completeness of diabetes preventive care data in community health centers. *Annals of family medicine.* Jul-Aug 2011;9(4):351-358.

40. Hayes RJ, Alexander NDE, Bennett S, Cousens SN. Design and analysis issues in cluster-randomized trials of

interventions against infectious diseases. *Statistical Methods in Medical Research.* 2000;9:95-116.
41. US Department of Health & Human Services. Community Health Centers and the Affordable Care Act in 2011: Increasing Access to Affordable, Cost Effective, High Quality Care. 2011; http://www.healthcare.gov/news/factsheets/2011/08/communityhealthcenters08092011a.html. Accessed July 20, 2012.
42. The White House. *The Obama Administration and Community Health Centers.* Washington, D.C.2012.
43. US Department of Health and Human Services. Initial core set of health care quality measures for Medicaid-eligible adults. *Federal Register.* 2012;77(2):286-291.
44. Centers for Medicare & Medicaid Services. Initial Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid (Medicaid Core Set): Technical Specifications and Resource Manual for Fiscal Year 2013. 2013; http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/Medicaid-Adult-Core-Set-Manual.pdf. Accessed March 8, 2013.
45. Centers for Medicare & Medicaid Services. Eligible Professional Clinical Quality Measures (CQMs). 2011-2012; http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CQM_Through_2013.html. Accessed March 8, 2013.
46. Oregon Metrics and Steering Committee. Oregon Metrics and Scoring Committee. 2013; http://www.oregon.gov/oha/Documents/MetricsScoringCommitteeMaterials020113.pdf. Accessed March 4, 2013.
47. Gold R, Angier H, Mangione-Smith R, et al. Feasibility of Evaluating the CHIPRA Care Quality Measures in Electronic Health Record Data. *Pediatrics.* Jul 2012;130(1):139-149.
48. Casciato A, Angier H, Milano C, Gideonse N, Gold R, DeVoe JE. A practice-based approach to demonstrate the use of pediatric quality measures in outpatient electronic health record data. *Journal of the American Board of Family Medicine.* 2012;25(5):686-693.
49. Dean C, Nielsen J. Generalized linear mixed models: a review and some extensions. *Lifetime Data Analysis.* 2007;13(4):497-512.
50. Lipsitz SR, Laird NM, Harrington DP. Generalized estimating equations for correlated binary data: using the odds ratio as a measure of association. *Biometrika.* 1991;78(1):153-160.
51. Kauermann G, Carroll RJ. A note on the efficiency of sandwich covariance matrix estimation. *Journal of the American Statistical Association.* 2001;95(456):1387-1396.
52. Luo Z, Gardiner JC, Bradley CJ. Applying propensity score methods in medical research: pitfalls and prospects. *Medical Care Research and Review.* 2010;67(5):528-554.
53. Duan NH, Manning WG, Morris CN, Newhouse JP. A Comparison of Alternative Models for Demand for Medical Care. *Journal of Business & Economic Statistics.* 1983;1(2):115-126.
54. Manning WG. The logged dependent variable, heteroscedasticity, and the retransformation problem. *J Health Econ.* Jun 1998;17(3):283-295.
55. Manning WG, Mullahy J. Estimating log models: to transform or not to transform? *J Health Econ.* Jul 2001;20(4):461-494.
56. McConnell KJ, Wallace NT, Gallia CA, Smith JA. Effect of Eliminating Behavioral Health Benefits for Selected Medicaid Enrollees. *Health services research.* 2008;43(4):1348-1365.
57. Ai CR, Norton EC. Interaction terms in logit an probit models. *Economics Letters.* 2003;80(1):123-129.