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Assessing Community Cancer care after insurance ExpanSionS (ACCESS) study protocol

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ABSTRACT

Background: Cancer is the second most common cause of mortality in the United States. Cancer screening and prevention services have contributed to improved overall cancer survival rates in the past 40 years. Vulnerable populations (i.e., uninsured, low-income, and racial/ethnic minorities) are disproportionately affected by cancer, receive significantly fewer cancer prevention services, poorer healthcare, and subsequently lower survival rates than insured, white, non-Hispanic populations. The Affordable Care Act (ACA) aims to provide health insurance to all low-income citizens and legal residents, including an expansion of Medicaid eligibility for those earning ≤138% of federal poverty level. As of 2012, Medicaid was expanded in 32 states and the District of Columbia, while 18 states did not expand, creating a 'natural experiment' to assess the impact of Medicaid expansion on cancer prevention and care.

Methods: We will use electronic health record data from up to 990 community health centers available up to 24-months before and at least one year after Medicaid expansion. Primary outcomes include health insurance and coverage status, and type of insurance. Additional outcomes include healthcare delivery, number and types of encounters, and receipt of cancer prevention and screening for all patients and preventive care and screening services for cancer survivors.

Discussion: Cancer morbidity and mortality is greatly reduced through screening and prevention, but uninsured patients are much less likely than insured patients to receive these services as recommended. This natural policy experiment will provide valuable information about cancer-related healthcare services as the US tackles the distribution of healthcare resources and future health reform.

Trial Registration: Clinicaltrails.gov identifier NCT02936609.

1. Introduction

Cancer is the second leading cause of mortality in the United States (US), accounting for one in four deaths [1]. Five-year cancer survival rates have increased over the past 40 years from 49% in 1975–77 to 68% in 2004–2011 due, in part, to improved cancer screening and prevention services [1,2]. Vulnerable populations (*i.e.*, uninsured, low-income, and racial/ethnic minorities) are disproportionately affected by cancer, receive significantly fewer cancer prevention services and poorer quality healthcare, and subsequently experience lower survival rates compared to insured, white, non-Hispanic populations [3–6]. Thus, it is hypothesized that the Affordable Care Act (ACA) will reduce insurance-related disparities. The ACA aimed to provide health insurance to all low-income citizens and legal residents, including an expansion of Medicaid eligibility to those earning ≤138% of the federal poverty level [7]. In 2012, however, the US Supreme Court ruled that states were not legally required to implement the Medicaid expansions [8]. As of April 2016, 32 states and the District of Columbia implemented Medicaid expansions while 18 states did not [9], creating a 'natural experiment' to learn whether and to what extent Medicaid expansion can affect recommended cancer prevention and screening for all patients and preventive care and screening services for cancer survivors.

Using electronic health record (EHR) data from the ADVANCE (Accelerating Data Value Across a National Community Health Center Network) clinical data research network of PCORNnet [10] will allow us to study the impact of ACA Medicaid expansion on cancer prevention and survivor care in a vulnerable population, as this dataset includes patients seen in community health centers. Community health centers comprise much of our nation's healthcare 'safety net' meaning they see

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patients regardless of their ability to pay. Patients seen in the safety net are vulnerable populations consisting of low-income, Medicaid-insured or uninsured, and underserved racial/ethnic minorities. This is particularly important for Medicaid research as many people directly affected by states' decisions to expand or not expand Medicaid are seen at community health centers and these centers are experiencing an influx of patients who gained insurance post-ACA [11–14]. Evidence suggests that cancer survivors receive most of their general and preventive care from primary care providers rather than oncologists once they complete active cancer treatment.[15, 16] ADVANCE data allow for evaluation of services received when uninsured and insured and for comparisons between expansion and non-expansion states. EHR data is a novel way to assess receipt of healthcare as compared to self-report, which has inherent biases [17, 18].

Here, we present the project aims, methods, and planned analyses for the Assessing Community Cancer care after insurance ExpanSionS (ACCESS) Study (R01CA204267).

2. Study aims and hypotheses

We will use EHR data to explore the following specific aims:

2.1. Aim 1. Compare pre-post receipt of cancer prevention and screening among vulnerable community health center patients in medicaid expansion versus non-expansion states

Hypothesis 1a. Cancer prevention and screening will significantly increase among community health center patients in expansion states, compared to those in non-expansion states.

Hypothesis 1b. Racial/ethnic disparities in cancer prevention and screening will be significantly reduced in expansion states versus no change in non-expansion states.

2.2. Aim 2. Compare pre-post insurance status, visits, and receipt of routine, recommended primary and preventive care among cancer survivors seen in community health centers in expansion versus non-expansion states

Hypothesis 2a. A higher percentage of uninsured cancer survivors will have gained insurance coverage in expansion states, compared to those in non-expansion states.

Hypothesis 2b. Cancer survivors who are community health center patients in expansion states will have a significant increase in visits, visits paid by Medicaid, and survivor care relative to no change among patients in non-expansion states.

3. Methods

3.1. Data sources

We will use EHR data from the ADVANCE clinical data research network, described elsewhere [10]. Briefly, the ADVANCE data integrates longitudinal, outpatient EHR data from the OCHIN (not an acronym) community health information network, Health Choice Network, and Fenway Health in a research-ready data warehouse of 990 community health centers with > 3.1 million active patients [10].

3.1.1. Aim 1. Eligibility criteria

From the ADVANCE dataset, we will include all patients with ≥1 primary care visit anytime during the pre- or post-period to ensure that the patient was in the system during this time. Patients aged 19–64 years at the visit, residing in a state with ≥1 eligible community health center in the ADVANCE data using the EHR by 1/1/2013 from 20 states (14 states that implemented Medicaid expansion as of 10/1/2016: AK, CA, HI, MA, MD, MN, MT, NM, NV, OH, OR, RI, and WA and 6 states that did not: FL, KS, MO, NC, WI, and TX) [9]. We set these age criteria to exclude patients < 19 and ≥65, since patients 65 and older are eligible for Medicare (not Medicaid), and most states have more generous public coverage eligibility for children than adults.

Table 1
Potential patients from the ADVANCE data for inclusion in the study.

Total N = 950,304	Expansion states[a] (n = 584,282)		Non-expansion states[b] (n = 366,022)	
	All patients (n = 576,711)	Cancer survivors (n = 7571)	All patients (n = 361,421)	Cancer survivors (n = 4601)
	%	%	%	%
Sex				
Men	39.9	35.1	35.5	33.4
Women	60.1	64.9	64.5	66.6
Age in years				
20–44	61.0	21.5	57.7	28.0
45–64	39.0	78.5	42.3	72.0
Race/ethnicity				
White	55.3	65.7	29.2	42.8
Black	10.0	6.3	30.7	24.5
Other	4.5	3.6	2.1	1.6
Hispanic	26.8	21.0	35.8	29.5
Missing	3.4	3.4	2.1	1.6
Insurance Type				
Medicaid	23.3	31.0	13.0	22.0
Private	21.2	25.7	14.5	18.1
Insurance Status				
Uninsured	50.2	29.2	69.7	51.8

Data from 2012-2015.

[a] Expanded Medicaid as of 10/1/2016 14 states (AK, CA, HI, IN, MA, MD, MN, MT, NM, NV, OH, OR, RI, and WA) and 374 community health centers.

[b] Did not expand Medicaid as of 10/1/2016 6 states (FL, KS, MO, NC, TX, and WI) and 299 community health centers.

3.1.2. Aim 2. Eligibility criteria

Using the National Cancer Institute definition, cancer survivors will be defined as anyone who has had a cancer diagnosis recorded in the EHR at any time [19]. We will use cancer-related International Classification of Diseases, Ninth Revision codes [20, 21] and the problem list to identify cancer survivors. The ADVANCE population is similar to national community health center patients (see Table 1 for potential patients for inclusion) [11].

3.2. Pre- and post-periods

We will include a 12- or 24-month pre-period for all states depending on the analysis conducted and the date of Medicaid expansion (which varies by state). The majority of included states expanded Medicaid on 1/1/14; 3 states expanded later (IN on 2/1/2015, AK on 9/1/2015, and MT on 1/1/2016) [9]. The post-period will be 24-months or longer for those that expanded Medicaid on 1/1/14 and at least 12 months for states that expanded after that date.

3.3. Measures

The independent variable is Medicaid expansion status (i.e., whether or not a state expanded Medicaid due to the ACA and when).

Covariates (i.e. potential confounders) will include: patient-level variables such as sociodemographic variables (age, gender, race, ethnicity, poverty level, language, and urbanicity), number of chronic conditions, and frequency of healthcare visits; and clinic-level variables such as urban/rural status. As expansion versus non-expansion states may have inherent differences unrelated to expansion status, we may adjust for potential state-level economic covariates, including minimum wage data and unemployment rates from the US department of Labor statistics [22] and overall state rates of uninsured adults derived from the US Census Bureau's Current Population Survey [23].

3.3.1. Aim 1. Outcome measures for community health center patients

Health insurance refers to patient's health insurance including coverage status (insured or uninsured), type of health insurance (Medicaid or private), changes in coverage (gain or loss of coverage), and percent of insured visits.

Healthcare delivery includes number and types of all billed encounters overall and yearly, the services received at each visit, and receipt of recommended cancer prevention and screening:

- Cervical cancer screening- females 21–64 years of age: cytology (pap test) every 3–5 years, depends on age and concurrent human papillomavirus (HPV) testing;
- Colorectal cancer screening- adults 50–64 years of age: annual fecal occult blood test, or Sigmoidoscopy every 5 years combined with fecal occult blood test every 3 years, or colonoscopy every 10 years;
- HPV vaccination – females 18–26 years of age; 3 doses of HPV2 or HPV4 within 1 year;
- Smoking screening - adults 19–64 years: assess smoking status; intervention for current smoker: counseled to quit; prescriptions for smoking cessation medications;
- Obesity screening - adults 19–64 years: body mass index measured; intervention for those with body mass index ≥30 kg/m2: counseled or referred to intervention; and
- EHR measureable US Preventive Services Task Force A and B Recommendations [24].

3.3.2. Aim 2. Outcome measures for community health center cancer survivors

Health insurance, as defined above.

Healthcare includes number and types of all billed encounters overall and yearly, the services received at each visit, and receipt of recommended cancer preventive care and screening services for cancer survivors:

- Survivor-specific cancer screenings [25]; and
- EHR measureable US Preventive Services Task Force A and B Recommendations [24].

Additional outcome variables may be added as data becomes available.

3.4. Statistical analysis for both aims

Analyses will be conducted at both the patient- and clinic-levels. Our primary approach to address study aims will utilize difference-in-differences (DID) methodology.[26, 27] For Aims 1 and 2, our primary criteria for studying Medicaid expansion will be estimating differences in outcomes among individual patients and/or clinics in expansion versus non-expansion states over the pre- and post-Medicaid expansion time periods. We will use General Linear or Non-Linear Mixed Effects Models (GLMM) [28], 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). An interaction term for Medicaid expansion (or insurance status) and a post-expansion indicator variable will be included in the model to determine the DID in the outcomes. Where appropriate, to account for nonlinear DID settings, we will utilize a more general version of DID termed the ‘changes-in-changes’ model which does not rely on functional form assumptions [29]. We will stratify the models by insurance type (defined above) because healthcare delivery may vary by types. We will implement state-level random effects in clinic-level analyses and both clinic- and state-level 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 it is possible that Medicaid expansion will vary across clinics and states. However, we recognize that the assumption for random effects may not be met; we will also assess the robustness of our assumptions by running models that treat clinics and states as fixed effects.

We will test three-way interaction terms of demographic indicators (*e.g.*, race/ethnicity, gender, and age), time, and Medicaid expansion indicator to address our research questions on disparities. We will compare the potential effect of gaining insurance on cancer prevention and screening for all patients and preventive care and screening services for cancer survivors by demographic characteristics because of the differential prevalence of cancer among different sociodemographic groups.

We will use propensity score weighting methods to reduce observed bias, help minimize external threats to the validity of results, and adjust for imbalances between expansion and non-expansion groups.[30, 31] Clinic- and patient-panel characteristics that remain unbalanced between expansion and non-expansion states after propensity score adjustment will be included as covariates in statistical models to control for residual confounding. We can account for correlation within matched clinic site pairs and within community health centers through random effects using GLMM models.

This study was reviewed and approved by the Oregon Health & Science University Institutional Review Board. It is registered with ClinicalTrials.gov #NCT02936609.

4. Discussion

Cancer morbidity and mortality is greatly reduced through screening and prevention, but uninsured patients are much less likely than insured patients to receive these evidence-based services. Similarly, uninsured cancer survivors receive fewer primary and preventive care services than those with health insurance.[5, 6] The ACA's Medicaid expansion could substantially improve access to essential cancer prevention and screening for previously uninsured patients and facilitate better access to routine healthcare among cancer survivors who gain new health insurance. This natural policy experiment will inform national and state policy decisions as states grapple with how to equitably distribute healthcare resources post-ACA. Evaluations of the ACA must be timely in order to uncover the real-time impacts of this major health reform. The growth of EHR use in community health centers allows us to assess these changes quickly.

This project will provide unique and novel results about the impact of ACA on cancer prevention and screening because it focuses on vulnerable populations receiving care in community health centers from both expansion and non-expansion states (Table 1). Community health center patients are six times more likely to be poor, more than two times as likely to be uninsured, and three times more likely to be Medicaid-insured than the general US population [13]. Evidence suggests that primary care providers outside of community health centers are not accepting new patients with Medicaid or are significantly limiting the number of Medicaid-insured patients in their panels.[32, 33] In other words, despite gaining insurance via Medicaid-expansion, patients may experience difficulties accessing care. This is not the case in community health centers. In fact, studies have already shown a large increase in Medicaid-paid visits in community health centers in the year after implementation of the ACA [34, 35].

4.1. Limitations

EHR data are created for clinical care and not developed for research. Our team; however, has conducted many data validation studies with EHR data [36–38]. Also, we anticipate missing data, both random and not random. Our analyses will accommodate missing data by either including related variables in the analysis as covariates [39] or using methods such as multiple imputation to include these patients in analyses [40]. Lastly, unobserved changes may occur over time, making it difficult to isolate the effect of the ACA. We will use propensity score matching to account for differences between expansion and non-expansion states to minimize biases.

5. Conclusion

This important study will illuminate changes in receipt of cancer prevention and screening for all patients and preventive care and screening services for cancer survivors comparing states that expanded Medicaid to those that did not. Findings will allow for better understanding of health insurance's impact on receipt of cancer care and other healthcare services. Our findings will also inform further improvements in the US healthcare system to mitigate disparities in cancer prevention and survivor care for vulnerable populations.

Ethics approval and consent to participate

Ethics approval from Institutional Review Board at Oregon Health & Science University.

Human Subject consent not necessary as the research presents no more than minimal risk of harm to participants and involves no procedure for which written consent is normally required outside of the research context.

Consent for publication

Not applicable.

Research data

Data sharing not applicable to this article as no datasets were generated or analyzed for the current article.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

HA, NH, MMarino, MMori, KWS, JS, LR, JED made substantial contributions to conception and design of study, and drafting and approving the final manuscript.

HH made significant contributions to drafting and approving the final manuscript.

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