



Clinical trial insurance coverage for cancer patients under the Affordable Care Act



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ARTICLE INFO

Article history:

Received 16 September 2015

Received in revised form

23 November 2015

Accepted 10 December 2015

Available online 17 December 2015

Keywords:

Cancer clinical trial

Insurance denial

Affordable Care Act

Barrier

Grandfathered policy

ABSTRACT

Background: Participation in cancer clinical trials has been shown to increase overall survival with minimal increase in cost, but enrollment in adult cancer clinical trials remains low. One factor limiting enrollment is lack of insurance coverage, but this barrier should be reduced under the 2010 Patient Protection and Affordable Care Act (ACA), which includes a provision requiring coverage for clinical trial participation as of 2014.

Methods: To assess the number of Kansas adults aged 19–64, newly covered with health insurance for participation in oncology clinical trials as a result of the ACA, a cross sectional design using extracted data from the 2012 American Community Survey, Public Use Microdata Sample to estimate the number of individuals covered by insurance and data from the 2014 Department of Health and Human Services Health Insurance Marketplace enrollment to estimate those newly enrolled through ACA.

Results: In 2014, there was an estimated increase of 3% (54,397; 95% CI: 44,149–64,244) for a total of 72% (1,171,041) of Kansans aged 19 to 64 with health insurance coverage for clinical trial participation.

Conclusion: Three main factors limit the effectiveness of the ACA provisions in expanding clinical trial coverage: 1) 'grandfathered' self-funded employer plans not subject to state Employee Retirement Income Security Act (ERISA) regulations, 2) Medicaid coverage limits not addressed under the ACA, 3) populations that remain uninsured. Kansas saw a negligible increase in insurance coverage as a result of the ACA thus lack of insurance coverage is likely to remain a concern for cancer patients.

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1. Introduction

An estimated 37 million individuals will be newly insured with health insurance coverage due to the ACA over the next 10 years; many of whom may have been without access to high-quality cancer prevention, early detection and treatment services [1]. Cancer is the second leading cause of death in the United States and in 2014, it was estimated that 1,665,540 new cancer cases would be diagnosed and about 585,720 Americans would die from cancer [2]. The development of investigational compounds is crucial in the quest for advancing treatment options and discovering the cure for cancer. Participants in clinical trials have access to cutting edge

approaches to treatment and technology and trial participation has been shown to be associated with a higher survival rate [3,4]. However, less than 5% of cancer patients participate in clinical trials despite nearly one-third of Americans indicating a willingness to participate if asked [5,6].

The reasons affecting low accrual are varied and complex, but include cost-related hurdles, specifically lack of insurance coverage, especially those with private insurance compared to government-funded insurance [3,7,8]. Potential denial of coverage was reported as the reason for declining participation for 8–20% and as high as 85% of eligible patients [9,10].

Removing the insurance coverage barrier is addressed in section 2709 of the 2010 Patient Protection and Affordable Care Act (ACA) as new policies are required to cover routine costs for participation in all phases of qualified clinical trials as of January 1, 2014. This study examines how effective the ACA provisions have been for increasing the number of Kansans with insurance coverage for cancer clinical trials.

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2. PRE-ACA attempts to address coverage

Third party payers of health care costs have been covering routine care procedures for patients participating in clinical trials for decades, but this coverage has been steadily declining despite evidence suggesting the incremental costs of receiving treatment through a clinical trial is not significantly different than receiving treatment outside of the trial [11–14]. Prior to the ACA, the federal government and many states attempted to address the issue of clinical trial coverage by enacting legislation or adopting cooperative agreements with insurance companies to ensure coverage for cancer patients' routine procedures while participating in a clinical trial [15]. Several factors limited the comprehensive nature of these efforts including inconsistent state legislation and regulations that do not apply to self-insured plans often offered by large employers, and varying Medicaid coverage rules set by each state. Research suggests these laws had varying effects on overall clinical trial accrual rates [9,16–18]. Nearly one in five individuals aged 19–64 were not covered for trial participation based solely on not having health insurance coverage in 2012 [19].

3. ACA addresses coverage for trial participation

As of January 1, 2014, the ACA requires insurance providers offering new policies as qualified health plans, to cover routine patient costs defined as “all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial, including hospital visits, imaging, laboratory tests and medications” and excludes any procedures or tests specifically related to the research project and data collection [20]. However, absence of regulations to enforce this mandate and exemptions for grandfathered plans, group plans and health insurance coverage with enrollees prior to March 23, 2010, may significantly impact the outcome of this mandate on clinical trial coverage [21–23].

Lack of health insurance coverage for clinical trial participation does not necessarily preclude a patient from participating in the trial, but likely means the patient must assume responsibility for all cancer treatment-related care while on the trial and risk denial of coverage for other health services if the insurance company determines that the cost is related to trial participation. As individuals consider trial participation, they weigh their perceived benefits, including broader societal benefits from cancer research, with monetary and non-monetary costs of participation [24]. Although research suggests patients are more likely to decline being a research participant due to preferring the standard therapy or not wanting to be on a trial, financial and insurance issues were frequently cited as reasons for non-enrollment when patients desired treatment through a clinical trial [8].

4. Methods

We used current population survey data from the 2012 American Community Survey, Public Use Microdata Sample (PUMS) and adjusted insurance coverage using estimates from the literature and ACA marketplace enrollment numbers to estimate post-ACA cancer clinical trial coverage [25]. ACA health insurance marketplace data was obtained from the United States (US) Census Bureau and the United States Department of Health and Human Services (HHS) report dated May 1, 2014 [26]. PUMS includes individual and household-level data for a one percent sample of the US population and is meant to be nationally representative of the US civilian, non-institutionalized population. PUMS data are gathered through interview and mail questionnaires on an ongoing basis and made public yearly. The HHS report derives its numbers from the ACA

health insurance open enrollment period from October 1, 2013 to March 31, 2014, and includes the special enrollment period activity through April 19, 2014.

PUMS data are used to estimate the number of Kansans covered by type of health insurance in 2012. Estimates are adjusted for sampling and response bias using the available weights. The HHS report is used to estimate post-ACA insurance status. Note that we use 2012 insurance status as the baseline to isolate the effects of ACA coverage. Specifically, we apply percent changes in the uninsured to calculate 2014 estimated coverage assuming that the underlying distribution in insurance status remains steady. This allows us to capture ACA-related changes separate from trends in insurance coverage between 2012 and 2014. State laws and regulations and results from the literature are used to estimate the proportion of individuals with each insurance coverage type (i.e. employer, government, uninsured) who are covered for clinical trial participation. Individual and household-level data for Kansas adults aged 19 to 64 was chosen because older Americans were generally covered prior to the ACA through Medicare, which began covering trial participation in 2000 with the enactment of the clinical trial policy national coverage determination (NCD) by the Centers for Medicare and Medicaid Services [27]. Children up to the age of 19 were generally covered through Medicaid or the Children's Health Insurance Program and were not expected to have significant changes in coverage rates due to the ACA.

The seven insurance types collected in PUMS were grouped into three categories: commercial payer (employer or union sponsored, purchased directly from insurance company); government payer (Medicare, Medicaid, TriCare, Veterans Health Administration (VA))¹; and no coverage². When an individual was covered by more than one insurance plan, they were assigned to the category with the highest cancer trial coverage rates (e.g. Medicare first, employer coverage second, Medicaid third). Once these categories were developed, the proportion of individuals with insurance coverage for clinical trial participation was estimated.

Point estimates from national survey data and the literature were used to calculate the approximation of the newly insured. Ninety-five percent confidence intervals are used to calculate lower and upper bound estimates of the newly insured. The results are based on a study of Kansas and provide a framework for identifying the policy areas fundamental to determining the ACA's impact nationally. In Kansas, it was estimated that 14,630 new cancer cases would be diagnosed and 5460 Kansans would die from cancer in 2014 [2].

Using the PUMS data as a baseline, changes in coverage type were estimated using: ACA enrollment through the Marketplaces; changes in employer coverage; changes in government coverage; and changes in uninsured rates. PUMS data estimation and confidence intervals were calculated using Stata version 12.0. Estimates of coverage changes were developed using Microsoft Office Excel.

5. Results

The 2012 population of Kansans aged 19–64 was 1,627,427 (95% CI: 1,602,848–1,652,007). Insurance coverage by category for these individuals is represented in Fig. 1. Pre-ACA, eighty-four percent of

¹ Medicare is federal health insurance coverage for individuals 65 years and older and for those younger than 65 deemed disabled. Medicaid is a government health insurance program for low-income households operated by states with federal matching funds. TriCare is a health insurance program for active duty military members, reserve members, military retirees and their families. The VA is an integrated health insurance and health care system for Veterans.

² Indian Health Service (IHS) access was included in the no insurance tabulation as IHS is not an insurance provider.

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