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Title: Changes in prostate-specific antigen at time of prostate cancer diagnosis following Medicaid expansion in young men

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Precis

Medicaid expansion under the Affordable Care Act was associated with decreases in the proportion of young men presenting with high-risk prostate-specific antigen at the time of prostate cancer diagnosis. These results suggest Medicaid expansion improved access to PCa screening.

Abstract

Background: We sought to determine the effect of Medicaid expansion under the Affordable Care Act (January 1, 2014) on the epidemiology of high-risk prostate-specific antigen (PSA) levels (≥20 ng/ml) at the time of prostate cancer (PCa) diagnosis. We hypothesized better access to care will result in a reduction of high-risk features at diagnosis.

Methods: We performed a retrospective cohort study on 122,324 men aged <65 years diagnosed with PCa within the National Cancer Database. Difference-in-difference (DID) analyses adjusting for sociodemographics using linear regression compared PSA at diagnosis pre-expansion (2012-2013) and post-expansion (2015-2016) between men residing in states that did or did not expand Medicaid.

Results: From 2012 to 2016, the proportion of men with PSA ≥20 ng/mL increased (18.9% to 19.8%) in non-expansion states and decreased in expansions states (19.9% to 18.2%). Compared to men in non-expansion states, men in expansion states experienced a decline in PSA ≥20 ng/mL (DID -2.33%, 95% CI -3.21% to -1.44%, p<0.001). Accordingly, the proportion of men presenting with high-risk disease decreased in expansion states relative to non-expansion states (DID -1.25% 95% CI -2.26% to 0.25%, p=0.015;). A similar, statistically significant decrease in PSA ≥20ng/mL was noted among black men (DID -3.11%, 95% CI -5.25% to 0.96%, p=0.005).
Conclusions: In Medicaid expansion states, there was an associated decrease in the proportion of young men presenting with PSA ≥20 ng/ml at the time of PCa diagnosis. These results suggest Medicaid expansion improved access to PCa screening. Longer-term data should assess oncologic outcomes.

Key words: prostatic neoplasms; United States; epidemiology; young adult; Medicaid; patient protection and affordable care act

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Introduction

Men without health insurance harbor a greater risk of metastases at time of diagnosis of prostate cancer (PCa) when compared to a general population in the United States[1] and present with higher prostate-specific antigen (PSA; a marker of disease severity).[2] Uninsured patients have been shown to have higher odds of presenting with advanced disease and experience worse cancer-specific survival compared to those with Medicaid[2, 3] Thus increasing health insurance coverage through Medicaid expansion could result in improved cancer-specific outcomes.

The implementation of the Affordable Care Act (ACA) allowed states to expand Medicaid eligibility to cover a larger group of low-income Americans; 24 states and the

District of Columbia had opted to expand by January 1, 2014. Following expansion, states that had "opted in" saw an increase in rates of Medicaid coverage and a subsequent reduction in uninsurance rates relative to states that did not expand.[4] Previous studies have associated Medicaid expansion with an increase in cancer screening and a decrease in late-stage diagnoses for some.[5-7] Due to the prolonged natural history of prostate cancer, it is not surprising there were no decreases in late-stage PCa in the first year of expansion (2014).[6] One manner to detect improvements in PCa care is to assess PCa screening by measuring prostate-specific antigen (PSA) levels prior to diagnosis. As noted in screening trials, PSA values ≥20ng/mL are associated with a poor prognosis and PSA-based PCa screening can reduce the number of men who present with high-risk PSA values prior to diagnosis.[8, 9] Thus, declines in high-risk PSA values at the time of PCa diagnosis may precede a stage migration towards earlier disease and improvements in PCa oncologic outcomes.

In this context, we used a large national cancer registry in the US with data through the third year of Medicaid expansion (2016) to measure the association between Medicaid expansion and PSA at the time of PCa diagnosis. We hypothesized state-wide Medicaid expansion would be associated with improvements in access to PCa screening as determined by decreases in the proportion of men with PCa presenting with high-risk PSA levels (≥20ng/mL) at the time of diagnosis.

Methods

Datasets

The National Cancer Database (NCDB) is comprised of over 1,500 hospitals accredited by the American College of Surgeons Commission on Cancer with data through 2016.[10] Based on estimates from the American Cancer Society,[11] the NCDB captured about 68% of all new PCa cases diagnosed in the United States in 2016 (oliver.facs.org/BMPub/index.cfm). Information on our analysis of Census data can be found in our **Supplemental methods.**

Patients

We included all men diagnosed with PCa from 2012 (two years prior to Medicaid expansion) through 2016, excluding men diagnosed in 2014 as a washout year. Additionally, we included men age 64 and younger who resided in a state that either expanded Medicaid on January 1, 2014, expanded Medicaid after the study period (after December 31, 2016), or never expanded Medicaid (n=132,976, 100%; **Figure 1**). We excluded men with unknown data on regional education (n=1,677, 1.3%) or income (n=268, 0.2%). An additional 2,847 men (2.1%) were excluded due to missing data on insurance type (insured or non-insured). Finally, a total of 5,860 (4.4%) were excluded due to missing data on cancer grade, stage, or PSA at diagnosis. Thus, in total 10,652 (8.0%) of patients who met inclusion criteria were excluded from our primary analyses.

Primary exposures

Our main exposures of interest were year of diagnosis - pre-expansion (2012-2013) versus post-expansion (2015-2016) - and residing in states that expanded Medicaid on January 1, 2014 versus expanded Medicaid after the study period or never expanded Medicaid never expanded Medicaid during the study period (**Figure 1**). Other exposures considered in multivariable analyses are discussed in the **Supplemental methods.**

Outcomes

Our outcomes were based on changes in the annual proportion of measurements relative to 2012-2013 in states that expanded Medicaid. Our primary outcome was changes in the proportion of men presenting with PSA ≥20 ng/mL at the time of diagnosis. A cutoff of 20 ng/mL was chosen for three reasons: **1)** PSA ≥20 ng/mL is considered by the National Comprehensive Cancer Network criteria and clinical series to be high-risk and associated with high-grade disease and high likelihood of disease recurrence following optimal local treatment.[12-14] Additionally, in a large PCa screening trial, in the earlier years of screening, there were higher proportions of men being diagnosed with a PSA ≥20 ng/mL which was associated with worse survival.[8] **2)** Second, in that same screening trial, declines in the percentage of men being diagnosed with PSA ≥20 ng/mL were noted within only two screening rounds,

suggesting it can serve as a marker of screening access in the few years following Medicaid expansion.[8] **3)** Finally, the NCDB codes PSA values greater than 99 ng/mL only as such and thus assessment of PSA as a continuous variable would not be possible.[12]

Secondary outcomes included changes in proportion of men diagnosed with intermediate- or low-risk disease (biopsy Gleason grade groups 1-3, PSA < 20 ng/mL, and cT1-2 stage) and high-risk disease (biopsy Gleason grade groups 4-5, PSA ≥ 20 ng/mL, or cT3-4 stage) as defined by the National Comprehensive Cancer Network (NCCN).[12] Additionally, metastatic disease at diagnosis (AJCC edition 7 cM1 or cN1[15]) and insurance coverage (yes vs no) for men with PCa was assessed.

Statistical analyses

We compared median age between patients from expansion and non-expansion states using the Mann-Whitney U test and compared categorical variables using Chi-squared tests.

Analyses simply comparing outcomes pre- and post-intervention would not account for temporal trend prior to the intervention or other external factors. Thus, our primary and secondary outcomes were assessed using a difference-in-difference (DID) analysis[16] with patients residing in Medicaid expansion states serving as the intervention group and those residing in non-expansion states serving as controls. DID were calculated as percentage by performing linear regression analyses with an interaction term between Medicaid expansion and time and multiplying by 100. Two separate dummy variables were created to represent time pre- and post-intervention: 1) 2012-2013 vs 2015-2016 and 2) 2012-2013 vs 2015 or 2016. To test our hypothesis and avoid multiple testing, we would reject the null hypothesis if there was statistical significance ($p<0.05$) only when comparing 2012-2013 to 2015-2016. Additional information on the use of the DID analysis can be found in our **Supplemental methods.** Unadjusted annual rates for each outcome were displayed as percentages.

We performed an exploratory analysis by limiting our analyses to Black men, a racial group with previously documented higher risk of PCa death and presentation with later stage disease.[17] Additional univariable comparisons were made between patients

who did and did not meet exclusion criteria and we also performed a sensitivity analysis of our primary outcome including excluded patients with “unknown” dummy variables for all missing data. All analyses were conducted using Stata 13.0 (College station, TX).

Results

Cohort characteristics

The cohort consisted of 65,954 men from non-expansion states and 56,370 men from expansion states (Supplemental **table 1**). Over the entire study period, patients from expansion states were more likely to be White (74% vs 67%, p<0.001) and more likely to have no comorbidities (84.4% vs 82.6%, p<0.001). More patients in expansion states lived in regions of high median house-hold income ($64,000 annually; 47% vs 29%, p<0.001). About 19% of the cohort presented with PSA ≥20 ng/mL at the time of diagnosis and high PSA was associated with high grade disease at biopsy **(Supplemental table 2).**

Medicaid expansion and PSA at diagnosis

The unadjusted proportion of men with PSA ≥20 ng/mL increased from 18.9% to 19.8% from 2012 to 2016 in non-expansion state while this proportion decreased in expansions states from 19.9% to 18.2% (**Figure 2A** and **Supplemental table 3**). Based on the multivariable DID analysis, Medicaid expansion was associated with a 2.33% decrease (95% confidence interval [CI] 3.21% to 1.44%, p<0.001) in the proportion of men presenting with PSA ≥20ng/mL in expansion states relative to non-expansion states from the pre-expansion era (2012-2013) to the post-expansion era (2015-2016; **Table 1**). The adjusted DID comparing year 3 of expansion (2016) to the pre-expansion era showed a decrease of 2.95% (95% CI 4.03% to 1.86%, p<0.001) in expansion states relative to non-expansion states.

Similarly, adjusted DID analyses limited to Black men showed expansion was associated with a decrease of 3.11% (95% CI 5.25% to 0.96%, p=0.005) in expansion states relative to non-expansion states from the pre-expansion era to the post-expansion era (**Table 2**). The adjusted DID comparing year 3 of expansion alone to the pre-expansion era showed a decrease of 4.51% (95% CI 7.13% to 1.88%, p=0.001) in expansion states relative to non-expansion states.

Medicaid expansion and risk group at diagnosis

We then sought to determine if decreases in the proportion of men presenting with PSA ≥20 ng/mL resulted in decreases in men categorized as having a high risk of disease progression based on NCCN high-risk localized disease criteria at diagnosis.[12] In adjusted DID analysis, expansion was associated with a significant decrease in the proportion of high-risk disease at diagnosis in expansion states relative to non-expansion states from the pre- to post-expansion era (-1.25% [95% CI -2.26% to 0.25%], p=0.015; **Figure 2A, Table 1,** and **Supplemental table 3**). Among black men, the overall DID was not statistically significant (p=0.083; **Table 2**). However, the adjusted DID comparing year 3 of expansion alone to the pre-expansion era did demonstrate a significant decrease of 3.42% (95% CI -6.25% to -0.59%, p=0.018) in expansion states relative to non-expansion states among black men.

Based on the above results, we surmised decreases in high-risk localized disease would accompany increases in the proportion of men presenting with NCCN intermediate- or low-risk PCa – which is associated with a greater likelihood of cure with local treatment.[12] In adjusted DID analysis, expansion was associated with a non-significant increase in the proportion of intermediate- or low-risk disease in expansion states relative to non-expansion states from the pre- to post-expansion era (0.99% [95% CI -0.07% to 2.05%], p=0.067; **Figure 2B** and **Table 1**). However, the adjusted DID comparing year 3 of expansion alone to the pre-expansion era showed a significant increase of 1.60% (95% CI 0.30% to 2.91%, p=0.016) in expansion states relative to non-expansion states. Similarly among Black men, the DID analysis showed an increase in intermediate- or low-risk disease when comparing all pre- and post-expansion years for changes that approached significance (2.44% [95% CI -0.05% to 4.48%], p=0.055; **Table 2**). The adjusted DID comparing year 3 of expansion alone to the pre-expansion era showed a significant increase of 3.31% (95% CI 0.32% to 6.30%, p=0.016) in expansion states relative to non-expansion states.

Finally, we assessed trends in the presentation of metastatic disease at diagnosis. From the pre- to post- expansion era, the unadjusted proportion of men presenting with metastatic disease at diagnosis increased in both expansion (4.2% to 6.9%) and non-expansion states (4.5% to 6.9%) from 2012 to 2016 (**Figure 2D**). There was no significant DID when comparing pre-expansion years to all post-era years

(p=0.4) or pre-expansion years to year 3 of expansion (p=0.4; **Table 1**). These results were similar among Black men (p=0.3 and p=0.9, respectively; **Table 2**).

Sensitivity analyses

Men excluded from the primary analysis differed only marginally in terms of sociodemographics from those who were included **(Supplemental table 4).** A sensitivity analyses including these excluded men demonstrated similar DIDs for PSA ≥20ng/mL for the entire cohort (-1.76%, 95% CI -2.65% to -0.89%, p<0.001) and Black men (-2.30%, 95% CI -4.37% to -0.823%, p=0.030; **Supplemental table 5**).

Trends in insurance coverage

From Census data we found a similar magnitude change in insurance coverage for men age 18 to 64 years in expansion states relative to non-expansion states over our study period (Crude DID: -1.1%; **Supplemental figure 1**)**.** A similar trend was noted among men with PCa in the NCDB (Adjusted DID: -0.38%, 95% CI -0.78 to 0.01, p=0.061; **Supplemental figure 2**).

Discussion

We sought to measure the correlation between Medicaid expansion on access to PCa screening by assessing the proportion of men presenting with high-risk PSA (≥20 ng/mL) at the time of PCa diagnosis, which is associated with a greater risk of disease recurrence following PCa treatment and worse survival following a PCa diagnosis.[8, 13] Using a multivariable DID approach comparing PSA values between men in expansion and non-expansion states, we found Medicaid expansion was associated with decreases in the proportion of men presenting with PSA ≥ 20 ng/mL, a surrogate for disease with a high-risk of recurrence following treatment.[12-14] Similarly, we also noted a decrease in the proportion of men presenting with high-risk disease in expansion states relative to non-expansion states.

These results are encouraging given the multitude of studies demonstrating sociodemographic disparities in PCa outcomes.[18-21] Previous work from population-based data in the US noted men with any insurance were much less likely than men

without any insurance to present with metastatic disease at the time of PCa diagnosis.[21] Additional prior work from the NCDB showed men age <65 years with Medicaid insurance were more likely to present with metastatic disease compared to men with private insurance.[20] In the NCDB, Medicaid expansion was not associated with changes in the proportion of men with newly diagnosed PCa presenting with metastatic disease. However, this was not surprising based on large screening trials which showed reductions in metastatic disease at diagnosis took four to six years following randomization.[22, 23] Meanwhile, reductions in the number of men presenting with high-risk PSA ≥20 ng/mL were seen after only 2 rounds of screening[8] and significant increases in intermediate- or low-risk disease were seen within 3 years of randomization.[23]

In the US, decreases in the proportion of men with PCa presenting with PSA ≥20 ng/mL and high-risk PCa in Medicaid expansion states may reflect improvements in access to healthcare and PCa screening. Thus, lower PSAs and less high-risk disease at diagnosis in the first few years following expansion may precede decreases in incident *de novo* metastatic disease in expansion states and decreases in death due to PCa. Importantly, however, the greatest impact of Medicaid expansion would likely take place in states with the highest incidence of PCa-related deaths. As demonstrated in Mokad et al., the states with the highest incidence of PCa-related deaths are concentrated in the southeast United States and include Mississippi, Alabama, Georgia, and South Carolina.[24] Notably, these states have still not expanded Medicaid (**Figure 1**). This suggests our findings may actually underestimate the potential positive impact of Medicaid expansion on PCa outcomes since states with the worst outcomes did not expand.

Additionally, during the study period, PCa screening practice patterns were likely influenced by the United States Preventive Services Task Force (USPSTF) 2012 guidelines, which recommended against any routine PCa screening.[25, 26] Since then, the USPSTF has assigned a grade “C” recommendation to PCa screening for men age 55 to 69 after a shared decision making conversation between patients and clinicians.[27] With potentially increased acceptance of PCa screening related to these new guidelines and increases in young men with health insurance in expansion states as demonstrated

by our analysis of Census data, Medicaid expansion states may continue to see improvements in PSA, and potentially stage, at PCa diagnosis.

In subgroup analyses, PSA and high-risk disease at diagnosis also decreased among Black men residing in expansion states relative to those in non-expansion states. This indicates Medicaid expansion may help reduce PCa outcome disparities among vulnerable racial groups, consistent with previous work.[17, 28, 29] Previous work has noted that men with PCa and insurance more often receive definitive treatment and have improved cancer-specific survival.[21, 30] However, even among men with health insurance, those with Medicaid are less likely than those with private insurance to receive definitive treatment for PCa.[20] Thus, future work should assess the association between Medicaid expansion and access to PCa treatment for men of vulnerable populations. Notably, however, Medicaid expansion only applies to men younger than age 65, which suggests further work and interventions will be needed to reduce racial outcome disparities following a PCa diagnosis which may be largely due to differences in healthcare access.[31]

Our study is not without limitations. The NCDB is not a population-based dataset and thus its trends are reflective of the hospital patient population within the database and most hospitals within this dataset are academic or comprehensive treatment centers (**Supplemental table 1**). Comparisons to non-NCDB cohorts have shown hospitals included in the NCDB comprise different proportions of hospitals by state, are less likely to represent critical access hospitals or rural hospitals, and may offer more cancer-related services**.**[32] The NCDB is also limited by the variables it captures and thus we cannot account for any unmeasured relevant factors. Follow-up for this study was relatively short following Medicaid expansion and ongoing study is warranted to discern the downstream effects on PCa outcomes, including survival and incidence rates. In data from a large screening trial in Europe, up to 6 years were required to see reductions in incident metastatic disease and up to 8 years prior to reductions in death due to PCa.[23, 33] While our data suggests Medicaid expansion improved access to optimal PCa care as measured by disease risk at the time of diagnosis, it did not assess actual screening rates in expansion states. Previous work has suggested screening did not change in expansion states by 2015, but these data require longer follow-up.[34]

Finally, while our analysis of insurance coverage does suggest Medicaid expansion resulted in more men with health insurance, our analysis of Census data included all men age 18 to 64 years regardless of cancer diagnosis and our analysis within the NCDB included men who were already diagnosed with PCa. A more thorough insurance analysis on the subject of PCa screening would assess men in the screening age range without a prior diagnosis of PCa.

In the context of these limitations, our study is the first to assess changes in PSA values at the time of PCa diagnosis following state-wide Medicaid expansion on January 1, 2014. In the years following Medicaid expansion there was a decrease in men presenting with high-risk PSA values at diagnosis, suggesting an increase in access to PCa screening in expansion states. However, we suspect with longer follow-up, Medicaid expansion may result in decreases in the diagnosis of metastatic disease and PCa death as seen in PCa screening trials with improved access to screening.[23] Additionally, future work should be directed at assessing the effects of Medicaid expansion on vulnerable populations such men of African heritage.

Notes: The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society. The data used in the study are derived from a de-identified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology employed, or the conclusions drawn from these data by the investigators.

Study Presentations: A poster presentation of these data was presented at the 2019 annual meeting of the Society of Urologic Oncology on December 4, 2019 (Washington, DC).

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485

Table 1: Adjusted difference-in-difference analysis for all men with prostate cancer

Outcome at diagnosis	Post-Medicaid expansion years combined (2015-2016)		Post-Medicaid expansion year 2 (2015)		Post-Medicaid expansion year 3 (2016)	
	DID,% (95% CI)	p	DID,% (95% CI)	p	DID,% (95% CI)	p
PSA >20 ng/mL	-2.33 (-3.21 to -1.44)	**<0.001**	-1.73 (-2.81 to -0.65)	**0.002**	-2.95 (-4.03 to -1.86)	**<0.001**
Intermediate- or low-risk	0.99 (-0.07 to 2.05)	0.067	0.38 (-0.91 to 1.67)	0.6	1.60 (0.30 to 2.91)	**0.016**
High-risk	-1.25 (-2.26 to -0.25)	**0.015**	-0.63 (-1.86 to 0.59)	0.3	-1.88 (-3.12 to -0.64)	**0.003**
Metastatic	0.26 (-0.26 to 0.78)	0.3	0.26 (-0.38 to 0.90)	0.4	0.26 (-0.38 to 0.90)	0.4

Difference-in-differences were calculated using multivariable linear regression with an interaction term between a time variable for pre-expansion and post-expansion and patient residence in a state that did or did not expand Medicaid. All covariates in **Supplemental table 1** from age to regional high-school attainment were included in each regression. Bold indicates statistical significance. Abbreviation: DID, difference-in-difference

Table 2: Adjusted difference-in-difference analysis for black men with prostate cancer

Outcome at diagnosis	Post-Medicaid expansion years	Post-Medicaid expansion year 2	Post-Medicaid expansion year 3

	combined (2015-2016)		(2015)		(2016)	
	DID,% (95% CI)	p	DID,% (95% CI)	p	DID,% (95% CI)	p
PSA >20 ng/mL	-3.11 (-5.25 to -0.96)	**0.005**	-1.76 (-4.36 to 0.85)	0.186	-4.51 (-7.13 to -1.88)	**0.001**
Intermediate- or low-risk	2.40 (-0.05 to 4.84)	0.055	1.52 (-1.44 to 4.48)	0.3	3.31 (0.32 to 6.30)	**0.030**
High-risk	-2.05 (-4.36 to 0.27)	0.083	-0.73 (-3.53 to 2.07)	0.6	-3.42 (-6.25 to -0.59)	**0.018**
Metastatic	-0.36 (-1.69 to 0.98)	0.6	-0.79 (-2.41 to 0.82)	0.3	0.10 (-1.54 to 1.73)	0.9

Difference-in-differences were calculated using multivariable linear regression with an interaction term between a time variable for pre-expansion and post-expansion and patient residence in a state that did or did not expand Medicaid. All covariates in **Supplemental table 1** from age to regional high-school attainment were included in each regression. Bold indicates statistical significance. Abbreviation: DID, difference-in-difference

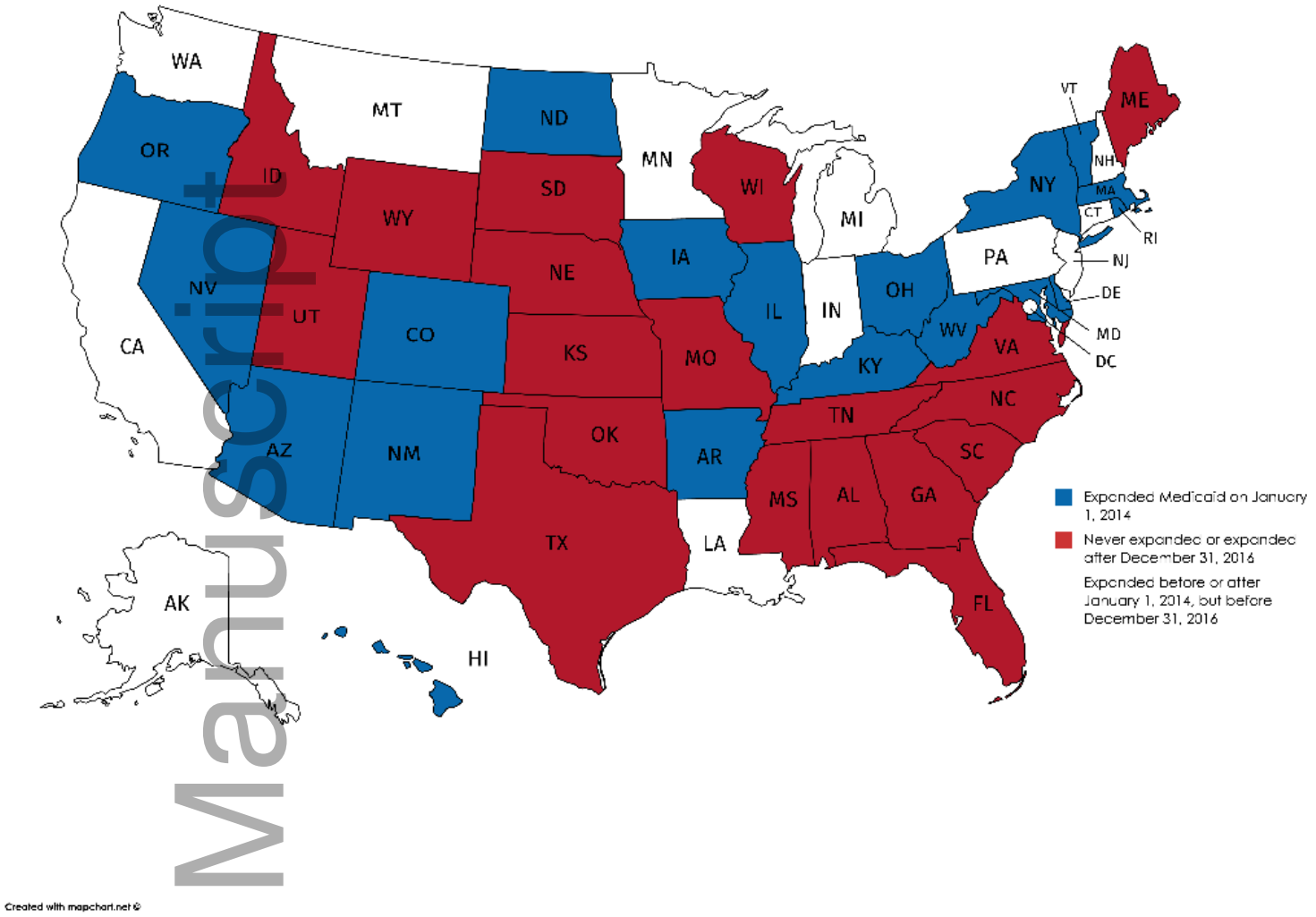
Figure legends

Figure 1: Medicaid expansion by state

Only states that expanded Medicaid on January 1, 2014 (expansion states), expanded Medicaid after December 31, 2016, or never expanded Medicaid (non-expansion states) were included in this study. Map generated with information on Medicaid expansion timing from the National Cancer Database data dictionary as well as https://www.healthinsurance.org/medicaid/ (Accessed October, 9, 2019). The following states will expand or have expanded Medicaid since December 31, 2016: ID, ME, NE, VA, UT.

Figure 2: Unadjusted temporal trends in outcomes at diagnosis among states that expanded and did not expand Medicaid

Error bars represent 95% confidence intervals. Vertical dotted lines demarcate the division between pre- and post-Medicaid expansion. Abbreviation: PSA, prostate-specific antigen



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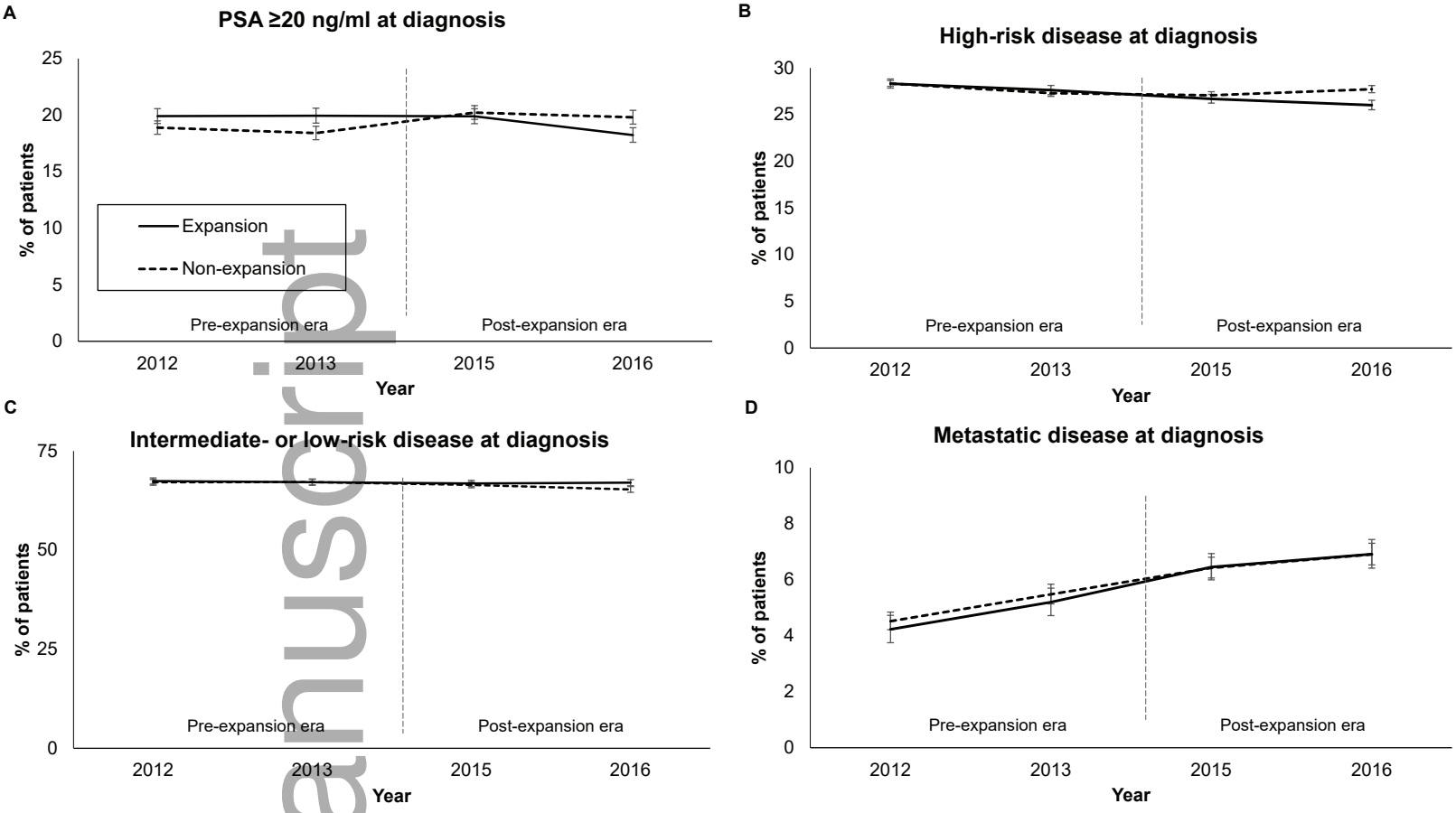

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