Medicaid Expansion Association with End-Stage Liver Disease Mortality Depends on Leniency of Medicaid Hepatitis C Virus Coverage

Manuscript ID: LT-21-283

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Key Words
Affordable Care Act
Health insurance
Disparities
Health equity
Liver transplant
End-stage liver disease
Hepatitis C virus

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/LT.26209

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Direct-acting antivirals
**Abbreviations**

ACA- Affordable Care Act  
LT- Liver transplantation  
HCV- Hepatitis C virus  
DAA- Direct-acting antivirals  
ESLD- End-stage liver disease  
LDR- Listing-to-death ratio  
UNOS STAR- United Network for Organ Sharing Standard Transplant Analysis and Research  
CDC WONDER- Center for Disease Control and Prevention Wide-ranging OnLine Data for Epidemiologic Research  
HCV+ALD- Hepatitis C virus and alcohol liver disease co-diagnoses  
APC- Annual percent change

**Grants and financial support**- This manuscript was supported by the Dean’s Diversity and Healthcare Disparity Research Award grant from Weill Cornell Medicine  
**Conflicts of interest**- Dr. Robert S. Brown, Jr. does consulting for and receives grant support from AbbVie and Gilead. None of the other authors have any conflicts of interest to disclose.

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Abstract

Background and Aims

The Affordable Care Act (ACA) expanded Medicaid around the same time that direct-acting antivirals (DAAs) became widely available for the treatment of hepatitis C virus (HCV). However, there is significant variation in Medicaid HCV treatment eligibility criteria between states. We explored the combined effects of Medicaid expansion and leniency of HCV coverage under Medicaid on liver outcomes.

Methods

We assessed state-level end-stage liver disease (ESLD) mortality, listings for liver transplant (LT), and listing-to-death ratio (LDR) for adults 25-64 years old using data from UNOS and CDC WONDER. States were divided into four nonoverlapping groups based on expansion status on January 1, 2014 (expansion versus non-expansion) and leniency of Medicaid HCV coverage (lenient versus restrictive coverage). Joinpoint regression analysis evaluated for significant changes in slope over time (joinpoints) during the pre-expansion (2009-2013) and post-expansion (2014-2018) time periods.

Results

We found significant changes in annual percent change (APC) for population-adjusted ESLD deaths between 2014-2015 in all cohorts except for the non-expansion/restrictive cohort, in which deaths increased at the same APC from 2009-2018 (APC +2.5% [95% CI 1.8, 3.3]). In the expansion/lenient coverage cohort, deaths increased at an APC of +2.6% (95% CI 1.8, 3.5) until 2014 and then tended to decrease at an APC of -0.4% (95% CI -1.5, 0.8). LT listings tended to decrease over time for all cohorts. For LDR, only the expansion/lenient and expansion/restrictive cohorts had statistically significant joinpoints.

Conclusion

Improvements in ESLD mortality and LDR were associated with both Medicaid expansion and leniency of HCV coverage under Medicaid. These findings argue for the implementation of more lenient and widespread public health insurance to improve liver disease outcomes, including mortality.
Introduction
In an effort to expand health insurance coverage, the Affordable Care Act (ACA) was signed into law in 2010 and allowed participating states to expand Medicaid. The first cohort of states to expand Medicaid through the ACA did so on January 1, 2014 with several other states following suit in subsequent years.(1, 2) In addition to increasing Medicaid enrollment,(3) Medicaid expansion has been associated with improvements in socioeconomic disparities throughout a variety of domains in health care.(4-11)

Although liver transplantation (LT) has historically been subject to well-documented disparities in care,(12-14) the impact that ACA Medicaid expansion has had on liver disparities and LT outcomes is understudied. In prior analysis, Medicaid expansion has been associated with worse transplant outcomes,(15) increases in the number of LT patients using Medicaid insurance, and a differential impact on waitlisting rates by race/ethnicity.(16-18) Recently, Kumar et. al found that states expanding Medicaid had 8.3 fewer liver-related deaths per million population than would have been expected if they had not expanded Medicaid,(19) however their associations were not significantly different when states with poor HCV coverage under Medicaid were excluded.

Assessing the impact of ACA Medicaid expansion on liver disease is complicated by the advent of direct-acting antivirals (DAAs) for hepatitis C virus (HCV), which started to become widely available around the same time as Medicaid expansion in 2014.(20, 21) DAAs have been credited with decreasing HCV mortality and decreasing the burden of HCV patients on the LT waitlist.(21, 22) Although Medicaid expansion has been associated with higher numbers of DAA prescriptions,(20) there is widespread state-level variation in access to HCV treatment under Medicaid. Restrictive criteria for HCV coverage under Medicaid vary across states based on fibrosis stage, sobriety period, and prescriber specialty.(20, 23) Nonetheless, the combined effect of expansion status and leniency of HCV coverage under Medicaid has not been fully assessed.

Together, ACA Medicaid expansion and the release of DAAs for HCV were two potential boons to the care of liver patients in the last decade. The impacts of Medicaid expansion and DAA therapy on
the field of hepatology have largely been assessed separately in prior studies, but the two are likely interrelated and their impacts may be synergistic. The need for studies that not only assesses the effects of expanding public insurance but also the leniency of coverage for liver-related treatments is paramount to guide future health policy. We used a state-level ecological design to study two important questions: 1) Did the impact of Medicaid expansion on end-stage liver disease (ESLD) mortality vary by leniency of HCV coverage under Medicaid? 2) What were the impacts of Medicaid expansion and Medicaid HCV coverage on listings for LT relative to ESLD mortality rates?

Methods

Study Cohort and Data Collection

Data were gathered from two separate databases, the United Network for Organ Sharing Standard Transplant Analysis and Research (UNOS STAR) file and the Centers for Disease Control and Prevention Wide-ranging OnLine Data for Epidemiologic Research (CDC WONDER). UNOS STAR includes de-identified information for all liver transplant recipients in the United States. Our study used UNOS STAR data for LT listings annually between 2009-2018. CDC WONDER is a publicly available database that includes mortality data from US death certificates. The CDC WONDER “Multiple Cause of Death” database was queried for patients with any of the following ESLD International Classification of Diseases, Tenth Revision (ICD-10) codes listed on their death certificates as the “underlying cause of death”: end-stage liver disease or cirrhosis (K74.4: secondary biliary cirrhosis, K74.5: biliary cirrhosis unspecified, K74.6: other and unspecified cirrhosis of liver, K70.3: alcoholic cirrhosis of liver, K71.7: toxic liver disease with fibrosis and cirrhosis of liver), hepatic failure (K72: hepatic failure not elsewhere classified, K70.4: alcoholic hepatic failure), and hepatocellular carcinoma (C22.0: liver cell carcinoma - malignant neoplasm). Although we recognized that running analyses strictly for HCV would likely miss many patients because the “underlying cause of death” is usually coded as a broader diagnosis (such as cirrhosis or ESLD),(19) we also assessed ESLD deaths from hepatitis C virus and alcohol liver disease co-diagnoses (HCV+ALD). To do this, we included ICD codes K70 (alcohol liver disease) and either B17.1 (acute hepatitis C) or B18.2 (chronic hepatitis C) as secondary causes of death.
We analyzed the cohort at the level of the state and divided the states into four separate groups based on expansion status (expansion versus non-expansion) and leniency of Medicaid coverage for HCV (lenient coverage versus restrictive coverage). The 18 states with transplant centers that expanded Medicaid on January 1, 2014 were defined as “expansion states,” and the 14 states with transplant centers that did not expand Medicaid between 2014-2018 were defined as “non-expansion states”. States that expanded Medicaid after January 1, 2014 but before December 31, 2018 were excluded and states without a liver transplant center were also excluded. HCV treatment “leniency” was defined based on the *Hepatitis C: State of Medicaid Access 2017 National Summary Report*, which assigns state-specific grades from A-F based on restrictive HCV coverage policies under Medicaid in 2017.(24) Restrictive HCV coverage policies that were factored into grades included fibrosis requirements prior to treatment, sobriety periods prior to treatment, and limitations on prescriber eligibility. States with grades A-B (lenient coverage, n=21 states) were compared to states with grades C-F (restrictive coverage, n=11 states) in both expansion states and non-expansion states (*Figure 1*).

The study period was January 1, 2009 to December 31, 2013 (pre-expansion period) and January 1, 2014 to December 31, 2018 (post-expansion period). We included all individuals between the ages of 25-64 years. Individuals over 64 years old were excluded because many of these individuals were already Medicare beneficiaries prior to ACA Medicaid expansion. Individuals under 25 years old were excluded because many were covered under other insurance programs such as by the Children’s Health Insurance Program or parental insurance plans. As such, this analysis was not designed to assess children or older adults.

This protocol was approved as exempt from consent by the Weill Cornell Medical College Institutional Review Board.

**Outcomes**

Our primary outcome in this study was state-level ESLD mortality. Secondary outcomes included LT listings and listing-to-death ratio (LDR). LDR is a metric that was recently reported by our group and reflects access to transplantation—measuring how effectively states listed patients for LT relative to
their mortality rate from ESLD. (25) That is, higher LDR may reflect higher relative access to LT listing. LT listings and ESLD mortality data were derived from the UNOS STAR dataset and CDC WONDER dataset, respectively.

**Statistical Analysis**

Primary and secondary outcomes were calculated annually. Raw numbers were then adjusted for the states’ total population using annual population estimates from the National Center for Health Statistics, which releases postcensus bridged-race population estimates on July 1st of each year. Difference in primary and secondary outcomes between pre- and post-expansion was tested using Wilcoxon rank-sum test.

Although Medicaid expansion occurred on January 1, 2014 for our cohort of expansion states, we expected that some impacts of Medicaid expansion would be delayed by a year or longer until after patients had time to enroll in the plan, complete transplant evaluations, and be listed. Therefore, we conducted joinpoint regression analysis, which has been used previously to assess the impact of the ACA (26, 27) to determine years in which significant changes in slopes occurred over time in the primary and secondary outcomes. Unlike a traditional difference-in-difference model where a pre-specified change point is used to model the difference between two time periods (before and after the change point), joinpoint regression analysis uses linear regression modeling to calculate statistically significant changes in the slopes (annual percent change; APC) when compared to the average APC over the entire study period. (28, 29)

To assess changes over time, we calculated the APC in our outcomes, comparing expansion versus non-expansion states with lenient versus restrictive policies, as four separate cohorts. The study period was segmented by points where there was a trend change in APC for each outcome (‘‘joinpoints’’), and a separate APC was calculated for the segments between joinpoints. The maximum number of joinpoints was set as 1 to model if and when the effect of Medicaid expansion occurred.
The Joinpoint Regression Program (Software version 4.8.0.1) was used to conduct the joinpoint regression analysis. A two-sided p-value of less than 0.05 was considered statistically significant.

**Results**

**State Cohort Characteristics**

Of the 18 included expansion states, 15 states (83%) had lenient HCV coverage under Medicaid and 3 states (17%) had restrictive coverage. 14 states were included as non-expansion states, of which 6 (43%) had lenient coverage and 8 (57%) had restrictive coverage (*Figure 1*). Expansion states tended to be in the Northeast, upper Midwest, and West regions, whereas non-expansion states tended to be in the South, lower Midwest, and Southwest regions.

**ESLD Deaths by Cohort**

ESLD deaths increased significantly in all cohorts over the study period. Between the pre- and post-expansion time periods, population-adjusted ESLD deaths increased from 71.9 to 77.6 deaths/100,000 population (+8.0%, p<0.01) in expansion states and from 84.2 to 94.6 (+12.4%, p<0.01) in non-expansion states (*Table 1*). Expansion states with lenient Medicaid HCV coverage had the smallest increase in population-adjusted ESLD deaths (+7.1%, p<0.01). In contrast, expansion states with restrictive Medicaid HCV coverage had the largest increase in population-adjusted ESLD deaths (+15.7%, p<0.01). Among non-expansion states, those with restrictive coverage had larger increases in adjusted ESLD deaths than those with lenient coverage (+12.8% vs. +11.9%, respectively, both p<0.01).

Population-adjusted ESLD deaths were the lowest in the expansion/lenient coverage cohort and highest in non-expansion/restrictive coverage cohort throughout the study period (*Figure 2a*). Pre-expansion (before 2014), deaths tended to increase in all cohorts. However, post-expansion in the expansion/lenient coverage cohort, deaths plateaued and then slowly declined after 2015 (*Figure 2a*).
In joinpoint regression analysis for the expansion/lenient coverage cohort, deaths increased at an APC of +2.6% (95% CI 1.8, 3.5) until 2014 and then decreased at an APC of -0.4% (95% CI -1.5, 0.8) (Figure 3a). Similarly, the expansion/restrictive and non-expansion/lenient cohorts had a joinpoint in 2015 (one year after expansion) after which point deaths continued to increase, but at a lower rate than prior to 2015 (Figure 3b-c). In contrast to all of the other cohorts, no joinpoint was seen in the non-expansion/restrictive cohort—deaths in this cohort rose annually throughout the study period at an APC of +2.5% (95% CI 1.8, 3.3) (Figure 3d). The APC in the non-expansion/restrictive cohort (+2.5%) was similar to the pre-2014 APC (+2.6%) in the expansion/lenient cohort but significantly different than its post-2014 APC (-0.4% [95% CI -1.5, 0.8]) (Figure 3a, 3d).

To estimate deaths from HCV+ALD, ICD codes for HCV and ALD were included as secondary causes of death (Supplemental Table 1). Population-adjusted ESLD deaths from HCV+ALD increased significantly in the non-expansion cohorts (p<0.05) after expansion but not in the expansion cohorts. There were no significant differences between the lenient and strict HCV coverage cohorts.

**Listings by Cohort**

Over the study period, population-adjusted listings remained stable or decreased in all of the cohorts (Table 1). In expansion states, listings decreased from 28.7 to 27.6 listings/100k population pre-expansion to post-expansion (-4.2% difference, p<0.01). Listings in non-expansion states also tended to decrease though this was not statistically significant (27.2 to 26.3 listings/100k population pre-expansion to post-expansion (-3.6% difference, p=0.15)) (Table 1). The decrease in listings between the two time periods was not significant for the two restrictive cohorts (p=0.55-1.0) but was significant for the non-expansion/lenient and expansion/lenient cohorts (p<0.01 and p<0.05, respectively) (Table 1). Throughout the entire study period, population-adjusted listings for liver transplant were the lowest in the expansion/lenient cohort (Figure 2b).

There were no joinpoints for population-adjusted LT listings seen in any of the cohorts (Figure 4). Among expansion states, APC in population-adjusted listings was -0.6% (95% CI -1.3, 0.0) in states with lenient coverage and -1.0% (95% CI -2.4, 0.5) in states with restrictive coverage (Figure 4a-b).

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In non-expansion states, APC was -0.9% (95% CI -1.6, -0.2) and -0.3% (95% CI -1.4, 0.9) in lenient and restrictive states, respectively (Figure 4c-d). Between the four cohorts, none of the APCs were significantly different from each other.

**LDR by Cohort**

LDR in expansion states decreased from 0.40 to 0.35 (-11.3% difference, p<0.01) while LDR in non-expansion states decreased from 0.32 to 0.28, pre- to post-expansion (-14.1% difference, p<0.01) (Table 1). Although LDR decreased in all cohorts between the two time periods, the expansion/lenient cohort had the smallest decrease in LDR (-10.5%, p<0.01). The expansion/restrictive cohort had the largest decrease in LDR (-18.6%, p<0.05) (Table 1).

LDR was the highest in the expansion/lenient cohort and the lowest in the non-expansion/lenient cohort throughout the entire study period (Figure 2c). Both of the expansion cohorts (lenient and restrictive) had a joinpoint in 2015, but there was no joinpoint seen in the two non-expansion cohorts (Figure 5). Prior to expansion, LDR tended to decrease at a relatively similar rate in all cohorts except for the expansion/restrictive cohort in which LDR tended to decrease annually at a higher rate (APC -2.9% to -3.1% versus -6.4%). After the 2015 joinpoint in both expansion cohorts, LDR tended to increase. The post-2015 APCs in the expansion/lenient cohort (APC +1.1% [95% CI -3.7, 6.1]) and expansion/restrictive cohort (APC+3.1 [95% CI -6.3, 13.5]) were significantly different than the pre-2015 APC in all of the cohorts (Figure 5).

**Discussion**

Medicaid expansion has resulted in millions of newly insured Americans, but its impact on liver disease has been underreported. Prior studies have shown an association between Medicaid expansion and changes in the insurance makeup of the LT waitlist, differences in waitlisting rates by race/ethnicity, and improvements in ESLD mortality.(16-19) Outside of liver disease, Medicaid expansion has been associated with improvements in all-cause mortality, cardiovascular mortality,
and mortality for patients with certain malignancies. Our study adds to the literature by conducting a uniquely designed 2x2 cohort analysis allowing us to analyze the combined impacts of the two most substantial changes in healthcare to impact liver disease over the last decade—Medicaid expansion and the availability of DAAs for HCV. We found that improvements in ESLD mortality and LDR were associated with both Medicaid expansion and leniency of HCV coverage under Medicaid.

Not surprisingly, expansion states with lenient HCV coverage experienced the best outcomes, as evidenced by declining ESLD deaths after expansion, while non-expansion states with restrictive coverage had the worst outcomes without any significant improvement in ESLD deaths. The other two cohorts (expansion/restrictive and non-expansion/lenient) both also had joinpoints in 2014 followed by relative improvements in the APC of ESLD deaths. Although ESLD deaths from HCV+ALD were small, only non-expansion states had significant increases in deaths between the two time intervals. Taken together, our findings support the possibility that Medicaid expansion and leniency of HCV coverage under Medicaid each impacted ESLD mortality and may have acted synergistically.

Although we suspect that leniency of Medicaid HCV coverage is a surrogate for the overall quality of Medicaid coverage in each state, DAA coverage is likely a key contributor to the improvements noted in ESLD mortality. DAAs have been previously shown to improve mortality in patients with HCV and as such, the number of individuals registering on the LT waitlist with HCV has decreased dramatically since 2014. Nephew et al. found decreases in waitlisting rates for Black patients with HCV within expansion states after ACA Medicaid expansion. This was postulated to be from increased access to DAAs in expansion states compared to non-expansion states, resulting in fewer decompensation events necessitating LT. Although we assessed different outcomes, our results suggest that incorporating state-specific Medicaid coverage leniency for DAAs is important in assessing the clinical impacts of Medicaid expansion.
Our study also assesses the association between Medicaid expansion/HCV coverage leniency with listings for LT relative to deaths from ESLD (LDR). As recently reported by our group, the advantage of using LDR is that it incorporates both listings for transplantation and mortality from ESLD into a single metric with a higher LDR suggesting more favorable listing rates relative to the number of liver disease deaths (as a measure of need). (25) In our analysis of LDR, states that expanded Medicaid had improvements in the APC of LDR after expansion while the two cohorts of states that did not expand Medicaid (either with lenient or restrictive coverage) failed to have improvements. Notably, the relative improvements seen in ESLD mortality and LDR within expansion states did not occur due to increased listings for LT. Rather, listings for LT tended to remain relatively steady or decrease over the entire study period in all cohorts. Thus, the relative improvements in APC of LDR within expansion states after 2015 are due to improvements in ESLD deaths (lower denominator) rather than increasing listings (higher numerator). We postulate, therefore, that the mortality improvements in expansion states occurred because increased insurance coverage through Medicaid allowed for more access to essential treatments to prevent the progression of liver disease and mitigated the need for transplant. Such treatments include DAA therapy for HCV (particularly in states with lenient HCV coverage) but also treatment of comorbidities such as diabetes, obesity, and mental health coverage such as alcohol cessation therapy.

Interestingly, states that expanded Medicaid with lenient coverage also had the lowest annual population-adjusted ESLD deaths and highest annual LDR throughout the study period (including before expansion), suggesting an association between better baseline liver disease care and a greater likelihood of enacting Medicaid expansion and having lenient Medicaid coverage. Prior studies have found that Medicaid non-expansion states have populations with lower average income, more comorbidities, and a higher proportion of obese patients than expansion states. (36) Thus, the impact that Medicaid expansion had on liver disease may have been greater in states with relatively less medical and socioeconomic need. As such, both Medicaid expansion and more lenient DAA therapy could have enormous benefits in the states that need it most but have not yet adopted such policies.
Although initial Medicaid expansion occurred on January 1, 2014, the majority of the joinpoints in our study occurred one year after expansion (2015), suggesting a one-year delay in accruing the impact of early ACA Medicaid expansion on ESLD deaths and LDR. The exhibited one-year delay is not surprising given that there should be an expected lag between policy implementation and its effect on clinical outcomes, including mortality. The clinical effect of ACA Medicaid expansion is not immediate and future studies assessing the impact Medicaid expansion on clinical outcomes should factor in this delay into their analysis rather than setting the year that states expanded as a preset changepoint.

Limitations of our study include its state-level design, which may be prone to ecological fallacies. We also lacked detailed information beyond ICD codes in the CDC WONDER database for assessing causes of death. As such, we aimed to capture deaths from ESLD overall but could not capture deaths from specific etiologies of liver disease (other than alcohol and hepatocellular carcinoma) as the “underlying causes of death” and thus could not robustly estimate how many deaths were due to HCV directly. We did attempt to parse out deaths from HCV+ALD, but these values are likely underestimated because we only included one out of multiple overlapping ways that that HCV+ALD may be coded on death certificates. Additionally, we based state-by-state HCV coverage on “The Hepatitis C: State of Medicaid Access National Summary Report”, which assessed HCV restrictions in 2017, but our analysis does not account for changes in state-specific HCV restrictions during our post-expansion period. Unfortunately, many states did not report publicly available data regarding HCV coverage under Medicaid in 2014, so no report card was published until 2017 when all states reported criteria. Our study used the most comprehensive reported data for HCV Medicaid access available during our post-expansion period.

In conclusion, our uniquely designed 2x2 cohort analysis showed an association between ACA Medicaid expansion and ESLD mortality that varied depending on leniency of Medicaid HCV coverage. States that expanded Medicaid and had more lenient coverage tended to have the most relative improvements in ESLD mortality and LDR. Our results add to a growing body of evidence
suggesting that the implementation of lenient and widespread public health insurance policies may improve liver-related outcomes.
References:


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Figure Legends:

**Figure 1:** Summary of states by Medicaid expansion status and leniency of Medicaid coverage for hepatitis C virus treatment

**Figure 2:** Annual outcomes by cohort for (a) end-stage liver disease deaths/100,000 population, (b) liver transplant listings/100,000 population, and (c) listing-to-death ratio (LDR)

**Figure 3:** Joinpoint regression for annual end-stage liver disease deaths per 100,000 population by Medicaid expansion status and leniency of Medicaid hepatitis C virus coverage

**Figure 4:** Joinpoint regression for annual listings for liver transplantation per 100,000 population by Medicaid expansion status and leniency of Medicaid hepatitis C virus coverage

**Figure 5:** Joinpoint regression for listing-to-death ratio by Medicaid expansion status and leniency of Medicaid hepatitis C virus coverage
Table 1: Overview of study cohorts

<table>
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<tr>
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**ESLD**, end-stage liver disease; **LDR**, listing-to-death ratio; Wilcoxon rank-sum test p-value

*p<0.05, **p<0.01
Figure 4:

(a) expansion, lenient

(b) expansion, restrictive

(c) non-expansion, lenient

(d) non-expansion, restrictive

Listings per 100,000 population

APC -0.6%

[-1.3, 0.0]

APC -1.0%

[-2.4, 0.5]

APC: -0.9%

[-1.6, -0.2]

APC -0.3%

[-1.4, 0.9]
Figure 5:

(a) expansion, lenient

(b) expansion, restrictive

(c) non-expansion, lenient

(d) non-expansion, restrictive

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