Out-of-Pocket Costs and Initiation of HCV Treatment among U.S. Medicare Beneficiaries Receiving Low-income Subsidy

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MAIN FINDINGS

A small increase in out-of-pocket costs was associated with modest-to-moderate reduction in the rate of initiating Direct-Acting Antivirals for HCV among low-income Medicare beneficiaries in the U.S.

Background

- Low-income Medicare beneficiaries face disproportionate burden of Hepatitis C Virus (HCV)
- Low-income beneficiaries may be especially vulnerable to high out-of-pocket (OOP) cost of Direct-Acting Antivirals (DAAs) for HCV
- Low-income subsidy (LIS) provided in Medicare Part D may not be adequate to mitigate the OOP burden
- OOP costs are not observed for patients who did not initiate DAA, posing methodological challenges of estimating the effects of OOP

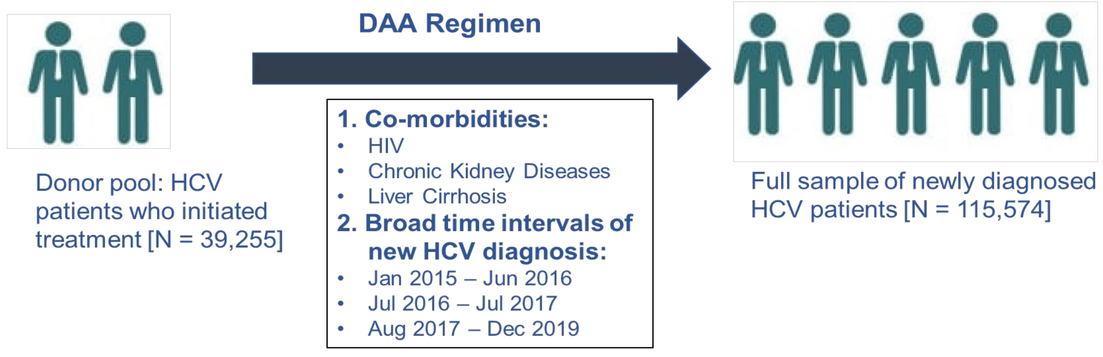
Data and Population

- 2014-19 fee-for-service Medicare data
- Medicare beneficiaries aged 18 or older with a new diagnosis of HCV based on RNA test followed by ICD-9/10 dx within 180 days
- Further restrict to beneficiaries in the LIS cost-share groups
  - Low – Medium – High cost-sharing
  - Excluding beneficiaries in the "very low" group because 99% had 0 OOP

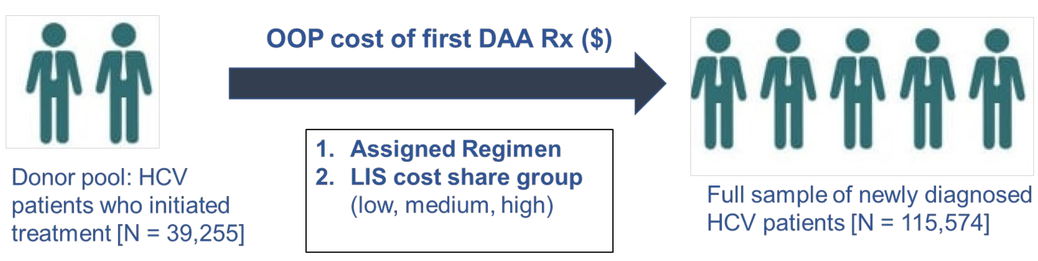
Analytical Strategies

- Assign hypothetical OOP cost to all low-income subsidy patients with a new HCV diagnosis, with a two-step approach

Step 1: Assign a DAA regimen



Step 2: Assign hypothetical OOP cost



- Linear regression of 0/1 indicator of DAA initiation as a function of
  - Log(hypothetical OOP)
  - Patient demographics (sex, race/ethnicity, age at diagnosis)
  - Medicare-Medicaid dually eligibility
  - Comorbid conditions (HIV, CKD, Cirrhosis)
  - 0/1 indicators of state and year of diagnosis

Results

Variable	Full sample (N= 115,574)	Subsample, initiated DAA (N= 39,255)	Subsample, did not initiate DAA (N=76,319)
Demographics			
Female (vs. male)	43%	41%	44%
65 or above (vs. younger than 65)	26%	28%	26%
Non-Hispanic White	60%	59%	60%
Non-Hispanic Black	25%	29%	24%
Hispanic	10%	9%	11%
Asian/Pacific Islander	2%	2%	3%
American Indian/ Alaska Native	1%	1%	1%
Unknown/Other Race	1%	1%	1%
Medicare-Medicaid Dually Eligible	89%	88%	89%
Co-morbidities			
HIV	7%	6%	7%
Chronic Kidney Disease (CKD)	15%	13%	16%
Cirrhosis	14%	17%	12%
DAA initiation within 6 months	30%	100%	0%

LIS cost-share group	N	Rate of DAA Initiation	Actual OOP Cost (from Donor Pool) Mean [SD]	Hypothetical/Assigned OOP Cost Mean [SD]
Low	74,667	29%	$3.04 [1.3]	$3.07 [1.3]
Medium	38,968	33%	$6.32 [2.4]	$6.45 [2.6]
High	1,938	36%	$848.78 [504.5]	$868.76 [449.9]

Estimated change in rate of initiation with incremental changes in OOP cost

	Low cost-share	Medium Cost-share	High Cost-share
Mean OOP cost (A)	0.2874	0.3293	0.3565
Mean OOP cost + 1 SD (B)	0.2801	0.3137	0.3287
Absolute difference (B-A)	-0.0073	-0.0156	-0.0278
Relative difference (B-A)/A	-2.5%	-4.7%	-7.8%
P-value of difference	<0.001	<0.001	<0.001

Conclusions

- OOP cost varied substantially among Medicare patients receiving low-income subsidy for their pharmacy benefits.
- In all three cost-share groups of LIS beneficiaries, an increase in (expected) OOP cost was associated with reductions in the likelihood of DAA initiation.
- Such reductions were modest among low- and medium- cost-share groups and greatest among high-cost-share group.
- Further reduction in OOP costs may be necessary but not sufficient to achieve high treatment rates among low-income Medicare beneficiaries.

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