Impact of the CMS Payment Bundle for Hemodialysis Vascular Access

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Background

- In 2011, CMS implemented the ESRD prospective payment system (PPS, or "the bundle"), creating a single comprehensive payment for dialysis services, including injectable drugs, which were previously separately billable.
- It is unknown how the change in reimbursement for thrombolytic agents has affected the care of dialysis patients.
- We investigated the effect of the PPS on access management in chronic hemodialysis (HD) patients using a tunneled catheter.

Methods

- **Study design**: Retrospective quarterly period prevalent cohorts
- **Data source**: US Renal Data System (USRDS), 2008 to 2015
- **Index date**: First date of quarter (for those already using a catheter) or the first date of HD with a catheter in a quarter
- **Inclusion criteria**:
  - ESRD patient on chronic HD using a catheter
  - Covered by Medicare Parts A/B for 3 months prior to index date (or since ESRD date for incident ESRD patient)
- **Exclusion criteria**:
  - Less than 18 years old on index date
  - Previous kidney transplant
- **Follow-up**: Until earliest of: kidney transplant, access/modality change, loss of Medicare coverage, death, or end of quarter
- **Outcomes**:
  - Claims for thrombolytic use, mechanical clot removal, and catheter replacement, identified using HCPCS/ICD-9 codes
  - Missed/delayed HD sessions among patients on thrice-weekly HD
- **Covariates**: Identified from ESRD Medical Evidence Report and ICD-9-CM codes on claims in 3 months prior to index date.
- **Statistical analysis**:
  - Poisson regression used to estimate quarterly event rates and the association of the PPS with change in trend of outcomes (using a piecewise linear function for quarter-time).
  - Logistic regression used to examine association of location of thrombolytic administration with missed/delayed HD and catheter replacement.
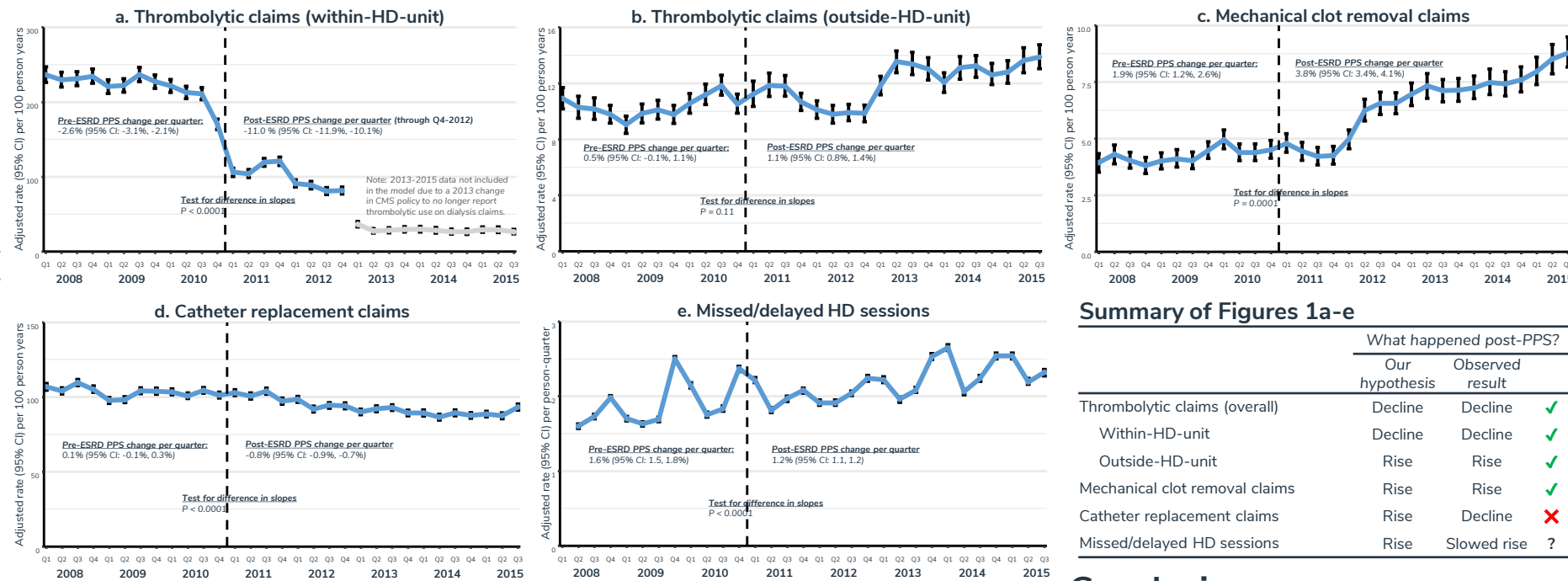
Results

- Our analysis includes 31 quarterly cohorts of HD patients using a catheter as the vascular access.
- On average, there were 69,428 patients per quarter.
- Patient characteristics are summarized below (data is shown for only the first quarter for each year).
- With few exceptions, the prevalence of covariates were generally similar across the quarterly cohorts.
- All subsequent models adjust for patient characteristics to account for shifts in patient case-mix over time.

Table 1. Patient characteristics across the quarterly cohorts.

	Q1-2008	Q1-2009	Q1-2010	Q1-2011	Q1-2012	Q1-2013	Q1-2014	Q1-2015
Cohort size, N	71,215	72,262	70,861	70,046	69,689	71,442	68,693	66,502
Age category, %								
18 to 54 years	24.7	25.7	26.2	26.0	25.3	24.0	23.5	22.4
55 to 64 years	20.6	21.5	22.3	22.9	22.9	22.5	22.5	22.5
65 to 74 years	26.5	25.8	25.3	25.5	25.9	26.7	27.6	28.7
75+ years	28.2	27.0	26.2	25.5	25.9	26.8	26.4	26.4
Female, %	49.1	49.4	49.3	48.8	48.5	48.3	47.9	47.4
Race, %								
White	58.0	56.9	56.7	56.4	56.9	58.0	58.3	59.0
Black	37.4	38.4	38.5	38.7	38.1	36.9	36.5	35.6
Other	4.6	4.7	4.8	4.9	5.0	5.1	5.3	5.3
Dual eligibility, %	46.2	46.9	47.3	48.7	48.5	45.7	49.1	48.4
Primary cause of ESRD, %								
Diabetes	47.5	47.3	47.3	47.3	47.1	47.2	47.5	47.8
Hypertension	29.6	29.6	29.8	30.0	30.1	30.7	31.0	31.0
GN or cystic kidney disease	9.7	10.1	10.0	9.7	9.6	9.1	8.8	8.4
Other	13.2	12.9	12.9	13.0	13.2	13.0	12.7	12.8
Time since start of ESRD, %								
≤ 90 days	16.8	16.4	16.9	16.7	19.7	21.6	21.5	22.5
91 to < 365 days	20.4	19.6	19.5	18.7	17.5	20.0	20.1	20.5
1 to <3 years	37.7	31.0	27.0	27.2	25.5	22.6	22.7	23.0
3+ years	25.1	33.0	36.5	37.5	37.4	35.8	35.6	34.0
Liu comorbidity index, %								
0	9.3	9.7	9.7	9.2	8.9	8.3	8.4	8.1
1-4	35.5	35.4	35.4	34.3	34.4	34.5	34.9	34.6
5-7	25.6	25.3	24.9	24.3	24.1	24.3	24.2	24.3
8+	29.6	29.6	30.0	32.3	32.7	32.9	32.4	33.0
Comorbid conditions, %								
Atherosclerotic heart disease	39.9	39.3	39.4	40.6	41.3	41.6	40.8	41.0
Congestive heart failure	51.3	50.7	50.2	50.7	50.5	50.3	49.5	50.5
Cerebrovascular disease	18.1	18.2	18.1	18.5	18.4	18.1	18.2	17.9
Peripheral vascular disease	33.6	33.4	33.5	34.8	34.3	33.9	33.9	34.1
Other cardiac disease	26.7	26.9	27.7	29.4	30.4	30.5	30.5	31.4
COPD	22.5	22.6	23.0	24.8	25.3	25.7	25.4	26.0
Gastrointestinal bleeding	5.9	5.7	5.6	6.1	6.4	6.0	5.9	5.8
Liver disease	5.6	5.7	5.4	6.2	6.5	6.2	5.8	5.2
Dysrhythmia	21.8	21.7	22.2	24.9	25.4	26.8	26.9	27.9
Cancer	9.5	9.4	9.5	9.6	9.8	9.7	9.8	9.8
Diabetes	64.6	64.4	65.0	66.5	67.3	67.9	67.7	68.1

COPD: chronic obstructive pulmonary disease, GN: glomerulonephritis

Figures 1a-e. Quarterly event rates and 95% confidence intervals (CI), per 100 patients per year, standardized for age, gender, race, dual eligibility, primary cause of ESRD, ESRD vintage, and Liu comorbidity index (using Q1-2011 as the reference).

a. Thrombolytic claims (within-HD-unit)

Pre-ESRD PPS change per quarter: -2.6% (95% CI: -3.1%, -2.1%)

Post-ESRD PPS change per quarter (through Q4-2012) -11.0 % (95% CI: -11.9%, -10.1%)

Note: 2013-2015 data not included in the model due to a 2013 change in CMS policy to no longer report thrombolytic use on dialysis claims.

Test for difference in slopes P < 0.0001

b. Thrombolytic claims (outside-HD-unit)

Pre-ESRD PPS change per quarter: 0.5% (95% CI: -0.1%, 1.1%)

Post-ESRD PPS change per quarter 1.1% (95% CI: 0.8%, 1.4%)

Test for difference in slopes P = 0.11

c. Mechanical clot removal claims

Pre-ESRD PPS change per quarter: 1.9% (95% CI: 1.2%, 2.6%)

Post-ESRD PPS change per quarter 3.8% (95% CI: 3.4%, 4.1%)

Test for difference in slopes P = 0.0001

d. Catheter replacement claims

Pre-ESRD PPS change per quarter: 0.1% (95% CI: -0.1%, 0.3%)

Post-ESRD PPS change per quarter -0.8% (95% CI: -0.9%, -0.7%)

Test for difference in slopes P < 0.0001

e. Missed/delayed HD sessions

Pre-ESRD PPS change per quarter: 1.6% (95% CI: 1.5, 1.8%)

Post-ESRD PPS change per quarter 1.2% (95% CI: 1.1, 1.2)

Test for difference in slopes P < 0.0001

Summary of Figures 1a-e

	What happened post-PPS?	
	Our hypothesis	Observed result
Thrombolytic claims (overall)	Decline	Decline ✓
Within-HD-unit	Decline	Decline ✓
Outside-HD-unit	Rise	Rise ✓
Mechanical clot removal claims	Rise	Rise ✓
Catheter replacement claims	Rise	Decline ✗
Missed/delayed HD sessions	Rise	Slowed rise ?

Conclusion

- Thrombolytic use outside (vs within) the HD unit was associated with:
  - Missed/delayed HD sessions
  - Catheter replacement (but only in the pre-PPS period)
- It remains unclear whether these associations are explained by delays in care resulting from referral outside the HD unit vs confounding by thrombosis severity.
- Post-PPS, there have been shifts in care for HD patients using a catheter: within-HD-unit thrombolytic use and catheter replacement have fallen, while outside-HD-unit thrombolytic use and mechanical clot removal have risen.
- Future work should explore determinants of missed/delayed HD and whether the rising trend continued beyond 2015.

Table 2. Odds ratios (OR) and 95% confidence intervals (CI) for the association of location of first thrombolytic use with (a) missed/delayed HD and (b) catheter replacement.

	a. Any missed/delayed HD						b. Catheter replacement			
	In 7 days before* thrombolytic use			In 7 days after thrombolytic use			In 7 days after* thrombolytic use			
Location of thrombolytic administration	N patients	N events	%	OR (95% CI)	N events	%	OR (95% CI)	N patients	N events	%	OR (95% CI)
Pre-PPS (2008-2010)											
Within-HD-unit	39567	2417	6.1	1 (Ref)	2359	6.0	1 (Ref)	55924	6466	11.6	1 (Ref)
Outside-HD-unit	4467	587	13.1	2.11 (1.91, 2.32)	353	7.9	1.30 (1.16, 1.47)	7740	998	12.9	1.17 (1.09, 1.26)
Post-PPS (2011-2012)											
Within-HD-unit	18509	1284	6.9	1 (Ref)	1252	6.8	1 (Ref)	25843	3528	13.7	1 (Ref)
Outside-HD-unit	4071	579	14.2	2.02 (1.82, 2.26)	340	8.4	1.21 (1.07, 1.38)	6566	861	13.1	0.94 (0.87, 1.03)

Models are adjusted for age, gender, race, dual eligibility, primary cause of ESRD, ESRD vintage, and Liu comorbidity index.
*This 7-day period includes the date of thrombolytic administration