Appendix Exhibit A1: Detailed history of pressure ulcer metrics and value-based policy

Centers for Medicare & Medicaid Services (CMS)-led efforts to measure and improve HAPUs, and HACs more generally, date back to the Institute of Medicine's (IOM) seminal 1999 report, "To Err is Human," which identified a high rate of preventable adverse events and validated a widespread problem of patient safety for Medicare patients.[1] These efforts have led to several different metrics and policy programs aimed at improving patient safety through a reduction in HACs, including HAPUs. **Exhibit 1** summarizes these different programs.

2002: MPSMS Standardized Measurement of Pressure Ulcers Through Chart Review

The Medicare Patient Safety Monitoring System (MPSMS) is a national patient safety surveillance system that had monitored rates of select adverse events since 2002. MPSMS was developed by CMS and the Department of Health and Human Services to better define the magnitude of certain adverse events and patient safety issues in the Medicare fee-for-service population, and to track HAC incidence rates in line with CMS' efforts to improve HAC rates.[2, 3] Hospital-acquired pressure ulcers were added to the collection system in 2004.

MPSMS identifies adverse events using chart review, with trained abstractors identifying events amongst a sample of patients. To minimize cost and burden, sampled records have been drawn from medical records collected for other purposes. Prior to 2007, the MPSMS sample was drawn from the Medicare Hospital Payment Monitoring Program and included a random sample of hospitalized Medicare fee-for-service hospitalized beneficiaries. In 2009, the system was expanded to include hospitalized patients aged 18 and older from all payers hospitalized for congestive heart failure,

acute myocardial infarction, pneumonia, and/or major surgical procedures.[2, 4]

The Agency for Healthcare Quality and Research assumed coordination duties for the MPSMS in 2009, and since 2010, AHRQ's *National Scorecard on Rates of Hospital-Acquired Conditions* has used MPSMS data to track the national rate of HACs,[5] and show progress towards the goal set by the Partnership for Patients to reduce HACs.[6] The *National Scorecard*'s 2015 interim report showed a 21 percent decline in HACs between 2010 and 2015.[7] AHRQ estimates this corresponds to 3.1 million fewer HACs experienced by patients, resulting in nearly 125,000 fewer patient deaths and a reduction of $28.1 billion in associated health care costs. As one of the most common and costly HACs, AHRQ estimates that the observed 10% reduction in HAPUs accounts for nearly one-quarter of this composite reduction, second only to adverse drug events.

AHRQ is also currently developing and implementing the Quality and Safety Review System (QSRS), a successor system to MPSMS designed to capture more than the 21 specific adverse events in the MPSMS.[8] While the QSRS continues to use chart review by trained abstractors, it has also been designed to interface with EHR capabilities and uses the Centers for Disease Control's National Healthcare Safety Network (NHSN) definitions for certain healthcare associated infections.[2, 9]

2008: HACI Stops Additional Payment for Many Types of Pressure Ulcers

The 2008 Hospital-Acquired Condition Initiative (HACI) denies payment for several HACs, including advanced-stage HAPUs, and removes lower-stage pressure ulcers (including both hospital-acquired and present-on-admission) as payable comorbidities when listed as diagnoses in administrative discharge data. Prior to this system, hospitals had received additional reimbursement from CMS for care of patients with any kind of pressure ulcer.

Early examinations of pressure ulcers documented in administrative data for California showed HACI resulting in a negligible effect on pressure ulcer incidence, with rates of HAPUs documented in administrative data declining from 0.29% in 2007 to 0.27% in 2009, present-on-admission pressure ulcers increasing from 2.3% to 3.0%, and payment reduced statewide by 0.21% for all payers. Due to their higher incidence, removal of payment for lower-stage pressure ulcers accounted for 99.5% of the overall payment change, while payment denial for advanced stage HAPUs accounted for the remaining 0.5%.[10] A substantial decline in HAPUs observed at 210 academic medical centers between 2008 and 2012 has been attributed to passage of the HACI, however much of this incidence drop occurred immediately after policy implementation, suggesting that the policy hastened a change in documentation of HAPU claims rather than changes in clinical practice or adoption of new evidence-based practice related to pressure ulcer incidence.[11]

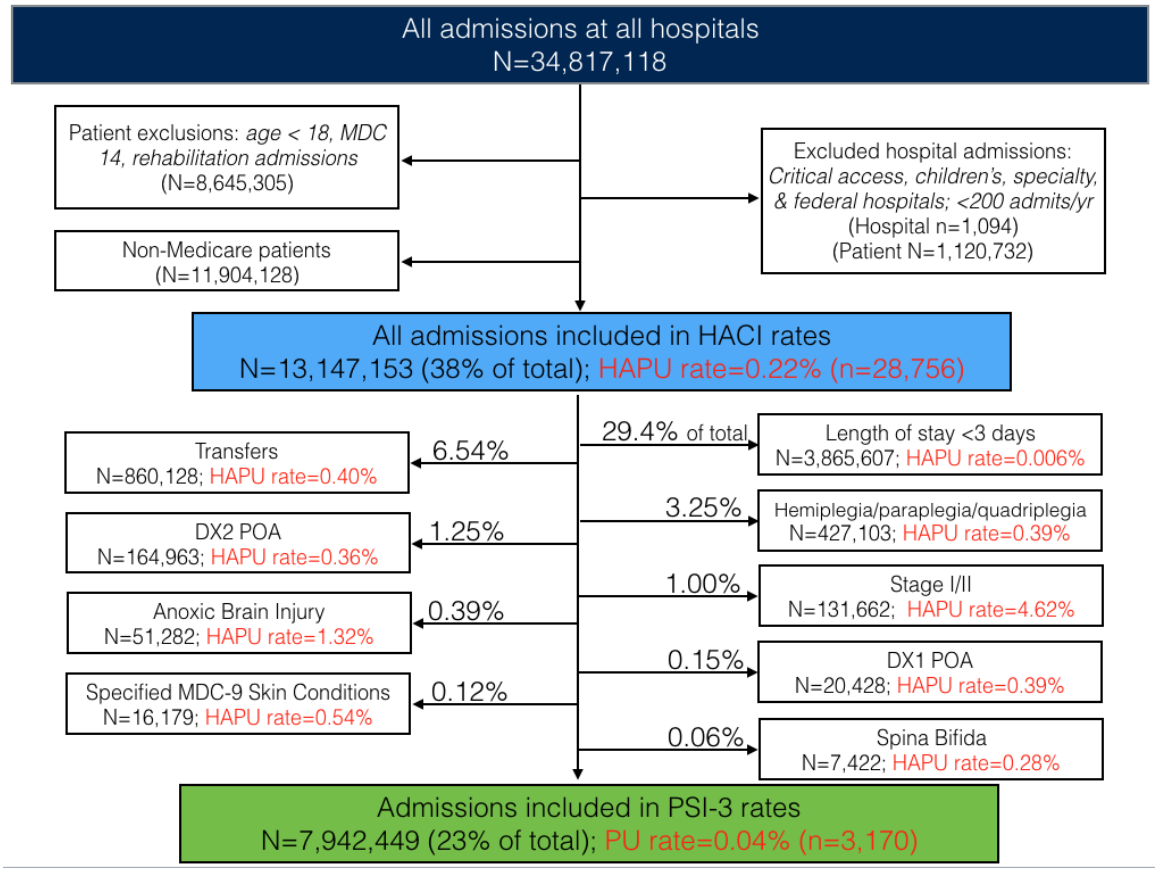
2014: PSI-3-Measured Pressure Ulcers Included in HACRP Penalty Program

CMS's HAC Reduction Program (HACRP), first implemented for Fiscal Year 2015, subjects hospitals to penalties for having high rates of HACs, including Advanced HAPUs. HACRP penalized hospitals whose 'Total HAC score' falls into the bottom quartile with a one percent reduction in total Medicare reimbursement.[12] The Total HAC score includes two domains: (1) ARHQ Patient Safety Indicator (PSI) 90 Composite, which includes the PSI-3 measure of HAPUs, accounting for 15% of the total HAC score; and (2) NHSN Healthcare-Associated Infection rates, which accounts for the remaining 85%.[12]

The PSI-3 HAPU measure, released by AHRQ in 2003, is currently included as one of 10 measures in the composite PSI-90 and accounts for 5.9841% of the PSI-90

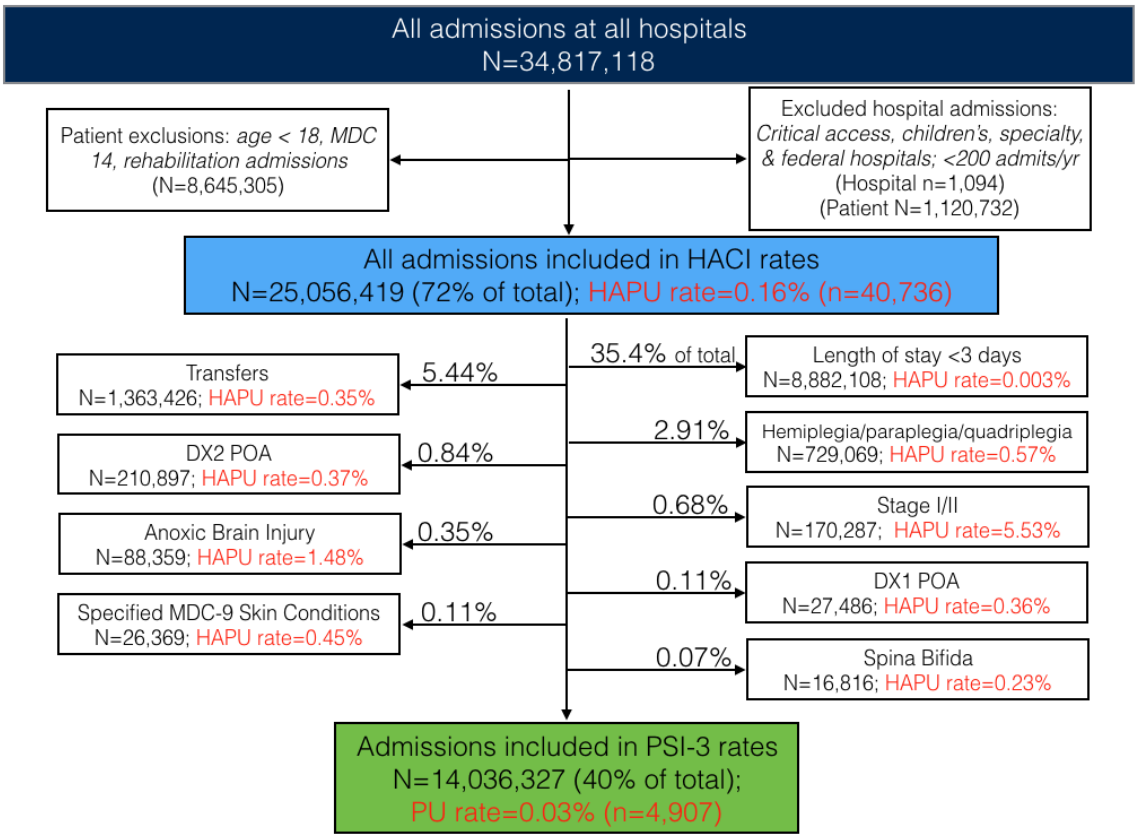
score.[13, 14] Unlike the HACI pressure ulcer measures, which capture all stages of hospital-acquired and present-on-admission pressure ulcers, the PSI-3 measures only advanced stage (Stage III, IV or Unstageable) HAPUs. Further, the PSI-3 excludes several cohorts of patients with conditions that put them at higher risk for pressure ulcer development, including spina bifida, paralysis, anoxic brain injuries, and certain skin conditions, as well as transfers and patients with a length of stay less than 3 days (down from 5 days in 2016).[15, 16] ARHQ reported PSI-3 HAPU rates nationwide of 0.027% in July 2017.[15]

Appendix Exhibit A2: HACI and PSI-3 Hospital and Patient Exclusions (Medicare Patients) for all states and all years (Medicare)



Source: Authors' analysis of administrative data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases for Florida (FL), New York (NY) and Washington (WA), 2009-2014

Appendix Exhibit A3: HACI and PSI-3 Hospital and Patient Exclusions (All Payer) for all states and all years (All Payer)



Source: Authors' analysis of administrative data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases for Florida (FL), New York (NY) and Washington (WA), 2009-2014

Appendix Exhibit A4: Full model results from negative binomial models (Medicare and all payer); incidence rate ratio (IRR) and 95% confidence intervals

MEDICARE RESULTS

	HACI All-Stage	HACI Early-Stage	HACI Advanced-Stage	PSI-3	PSI-3 excluded (all) All-Stage	PSI-3 excluded (all) Early	PSI-3 excluded (all) Advanced	PSI-3 excluded (no LOS) Early	PSI-3 excluded (no LOS) Advanced
Time	**0.92 (0.90,0.94)**	**0.92 (0.90,0.94)**	**0.97 (0.94,0.99)**	0.98 (0.95,1.01)	**0.92 (0.88,0.95)**	**0.91 (0.87,0.94)**	0.97 (0.92,1.03)	**0.92 (0.88,0.96)**	0.99 (0.93,1.04)
State									
FL	REF	REF	REF	REF	REF	REF	REF	REF	REF
NY	**1.11 (1.03,1.20)**	1.02 (0.94,1.11)	**1.66 (1.50,1.85)**	**1.36 (1.20,1.54)**	**1.49 (1.33,1.67)**	**1.34 (1.19,1.51)**	**2.15 (1.82,2.54)**	0.95 (0.85,1.08)	**1.52 (1.28,1.80)**
WA	**0.77 (0.68,0.87)**	**0.76 (0.67,0.86)**	**0.81 (0.68,0.98)**	0.92 (0.74,1.13)	**0.80 (0.67,0.97)**	**0.81 (0.67,0.98)**	0.76 (0.56,1.04)	**0.66 (0.54,0.80)**	**0.60 (0.43,0.82)**
Constant	**$6.38x10^{66}$ ($1.04x10^{48}$, $3.90x10^{85}$)**	**$4.73x10^{72}$ ($2.28x10^{53}$, $9.79x10^{91}$)**	**$9.64x10^{23}$ ($1.07x10^{3}$, $8.72x10^{48}$)**	$4.74x10^{13}$ ($1.11x10^{-16}$, $2.02x10^{43}$)	**$1.77x10^{74}$ ($1.94x10^{40}$, $1.60x10^{108}$)**	**$6.47x10^{83}$ ($4.49x10^{47}$, $9.30x10^{119}$)**	$5.42x10^{18}$ ($5.37x10^{-32}$, $5.48x10^{68}$)	**$2.52x10^{70}$ ($2.98x10^{34}$, $2.10x10^{106}$)**	$7.66x10^{9}$ ($1.64x10^{-41}$, $3.58x10^{60}$)
Hospital-level Random Effect	**0.71 (0.66, 0.76)**	**0.73 (0.68,0.78)**	1.01 (0.91,1.12)	**1.15 (1.02,1.29)**	0.96 (0.87,1.07)	1.02 (0.91,1.15)	**1.30 (1.08,1.57)**	**0.86 (0.76,0.97)**	1.15 (0.95,1.39)

Excluded cohorts:

	Anoxic brain injury	Hemi/para/ quadriplegia	Spina bifida	Skin conditions	Transfers	LOS < 3 days
Time	0.95 (0.90,0.99)	0.94 (0.91, 0.97)	0.93 (0.72, 1.21)	1.11 (0.98, 1.26)	0.91 (0.87, 0.94)	0.89 (0.82, 0.97)
State						
FL	REF	REF	REF	REF	REF	REF
NY	1.28 (1.07, 1.54)	0.99 (0.89, 1.11)	0.27 (0.08, 0.95)	0.66 (0.43, 1.01)	0.93 (0.82, 1.06)	0.95 (0.68, 1.31)
WA	0.41 (0.27, 0.63)	0.66 (0.54, 0.80)	1.22 (0.38, 3.92)	0.19 (0.06, 0.62)	0.65 (0.52, 0.80)	1.70 (1.12, 2.59)
Constant	$2.12x10^{45}$ (5.66, $7.97x10^{90}$)	$2.23x10^{51}$ ($8.18x10^{23}$, $6.10x10^{78}$)	$6.16x10^{58}$ ($2.70x10^{-167}$, $1.40x10^{284}$)	$6.28x10^{-96}$ ($3.90x10^{-206}$, $1.01x10^{15}$)	$1.42x10^{82}$ ($4.21x10^{49}$, $4.80x10^{114}$)	$4.67x10^{95}$ ($2.78x10^{18}$, $7.90x10^{172}$)
Hospital-level Random Effect	0.72 (0.50, 1.04)	0.59 (0.50, 0.70)	2.90 (0.36, 23.09)	0.04 ($1.89x10^{-13}$, $9.05x10^{9}$)	0.87 (0.76, 0.99)	2.12 (1.29, 3.48)

Note: All models include variables for time trend (year), state, and hospital level random effects. IRR represents multiplicative effect on count of outcome. 95% confidence intervals shown in parentheses. Bold coefficients represent significant effects of time at the p<0.05-level.

ALL PAYER RESULTS

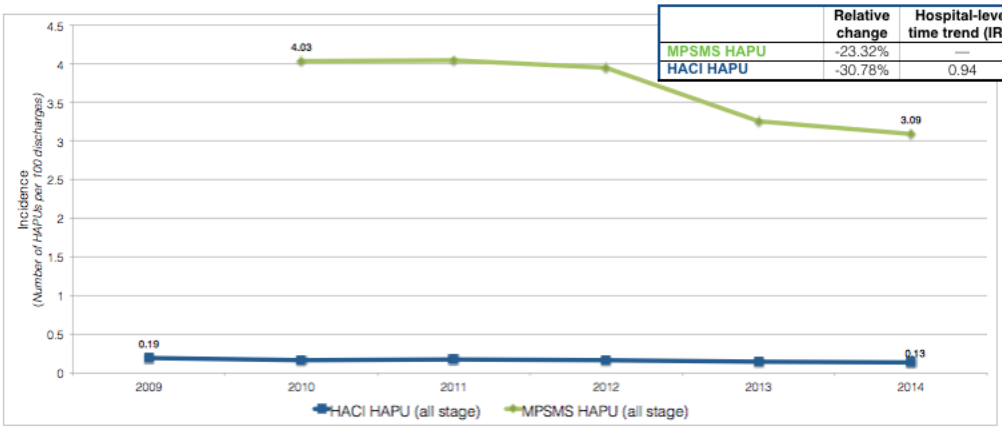
	HACI All-Stage	HACI Early-Stage	HACI Advanced-Stage	PSI-3	PSI-3 excluded (all) All-Stage	PSI-3 excluded (all) Early	PSI-3 excluded (all) Advanced	PSI-3 excluded (no LOS) Early	PSI-3 excluded (no LOS) Advanced
Time	**0.94 (0.92,0.96)**	**0.93 (0.91,0.95)**	0.99 (0.96,1.02)	0.99 (0.96,1.02)	**0.96 (0.94,0.99)**	**0.95 (0.92,0.98)**	1.02 (0.98,1.06)	**0.94 (0.91,0.96)**	1.00 (0.97,1.04)
State									
FL	REF	REF	REF	REF	REF	REF	REF	REF	REF
NY	0.97 (0.90,1.05)	**0.91 (0.84,0.98)**	**1.35 (1.22,1.49)**	**1.26 (1.13,1.40)**	**1.17 (1.06,1.29)**	1.08 (0.97,1.19)	**1.52 (1.33,1.75)**	**0.83 (0.75,0.92)**	**1.18 (1.03,1.35)**
WA	**0.76 (0.68,0.86)**	**0.77 (0.69,0.87)**	**0.81 (0.69,0.95)**	0.95 (0.80,1.13)	**0.78 (0.67,0.91)**	**0.78 (0.66,0.91)**	0.82 (0.65,1.02)	**0.58 (0.49,0.68)**	**0.62 (0.49,0.78)**
Constant	**$6.66x10^{50}$ ($2.05x10^{32}$, $2.17x10^{69}$)**	**$1.42x10^{57}$ ($4.69x10^{38}$, $2.50x10^{76}$)**	$2.01x10^{4}$ ($1.4x10^{-20}$, $2.91x10^{28}$)	$6.41x10^{6}$ ($7.9x10^{-20}$, $5.19x10^{32}$)	**$7.72x10^{30}$ ($4.66x10^{6}$, $1.32x10^{55}$)**	**$3.54x10^{41}$ ($2.36x10^{16}$, $5.30x10^{66}$)**	$7.43x10^{-20}$ ($1.1x10^{-53}$, $5.19x10^{14}$)	**$2.15x10^{54}$ ($7.70x10^{29}$, $5.98x10^{78}$)**	$2.92x10^{-7}$ ($5.3x10^{-41}$, $1.62x10^{27}$)
Hospital-level Random Effect	**0.74 (0.69,0.77)**	**0.75 (0.70,0.80)**	1.01 (0.92,1.10)	0.98 (0.89,1.09)	0.98 (0.90,1.07)	0.99 (0.90,1.09)	**1.37 (1.20,1.56)**	**0.80 (0.72,0.88)**	1.13 (0.98,1.30)

Excluded cohorts:

	Anoxic brain injury	Hemi/para/ quadriplegia	Spina bifida	Skin conditions	Transfers	LOS < 3 days
Time	0.98 (0.94, 1.02)	**0.96 (0.93,0.99)**	0.88 (0.73,1.06)	**1.13 (1.02,1.26)**	**0.93 (0.90,0.96)**	**0.89 (0.82,0.97)**
State						
FL	REF	REF	REF	REF	REF	REF
NY	**1.16 (1.00, 1.35)**	**0.91 (0.82,0.99)**	**0.47 (0.22,0.99)**	**0.68 (0.47,0.99)**	0.90 (0.79,1.01)	0.88 (0.65,1.19)
WA	**0.45 (0.33, 0.60)**	**0.64 (0.55,0.76)**	0.68 (0.23,1.99)	0.37 (0.18,0.77)	0.61 (0.50,0.74)	**1.57 (1.06,2.32)**
Constant	$3.54x10^{16}$ ($4.16x10^{-21}$, $3.01x10^{53}$)	**$1.72x10^{34}$ ($1.44x10^{10}$, $2.06x10^{58}$)**	$2.30x10^{109}$ ($3.14x10^{-57}$, $1.70x10^{275}$)	**$5.60x10^{-112}$ ($3.0x10^{-207}$ $1.06x10^{-16}$)**	**$1.36x10^{62}$ ($1.35x10^{31}$ $1.37x10^{93}$)**	**$2.08x10^{97}$ ($5.62x10^{25}$ $7.70x10^{168}$)**
Hospital-level Random Effect	0.86 (0.69,1.06)	**0.57 (0.49,0.65)**	1.43 (0.22,9.21)	$3.5x10^{-5}$ (N/A)	0.94 (0.84,1.06)	**2.56 (1.75,3.74)**

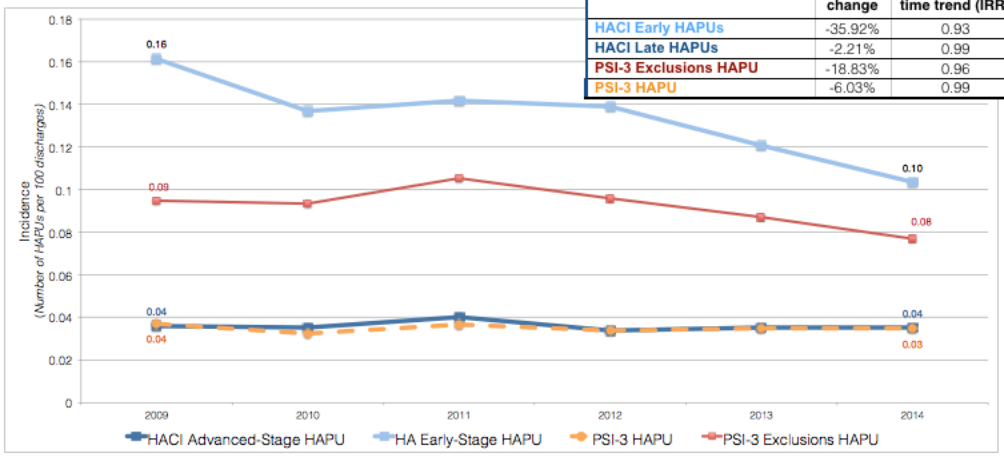
Note: All models include variables for time trend (year), state, and hospital level random effects IRR represents multiplicative effect on count of outcome. 95% confidence intervals shown in parentheses. Bold coefficients represent significant effects of time at the p<0.05-level.

Appendix Exhibit A5: Trends in MPSMS, HACI & PSI-3 Pressure Ulcer Incidence, 2009-2014 (All Payer)



	Relative change	Hospital-level time trend (IRR)	95% CI for time trend
MPSMS HAPU	-23.32%	—	—
HACI HAPU	-30.78%	0.94	0.92, 0.96

Panel A: **Incidence of HACI-defined HAPUs (all stages, 2009-2014) and MPSMS-defined HAPUs (all stages, 2010-2014)**



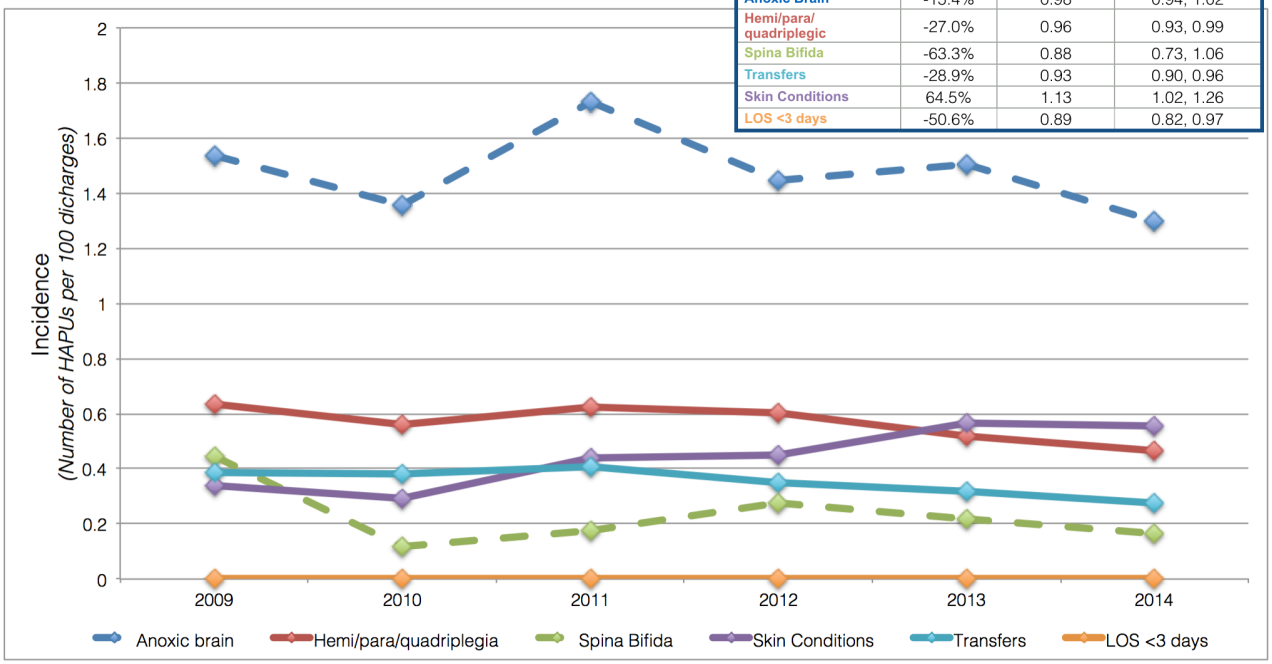
	Relative change	Hospital-level time trend (IRR)	95% CI for time trend
HACI Early HAPUs	-35.92%	0.93	0.91, 0.95
HACI Late HAPUs	-2.21%	0.99	0.96, 1.02
PSI-3 Exclusions HAPU	-18.83%	0.96	0.94, 0.99
PSI-3 HAPU	-6.03%	0.99	0.96, 1.02

Panel B: **Incidence of HACI-defined HAPUs (Early and Advanced Stage), PSI-3-defined HAPUs (i.e., Advanced Stage) and PSI-3-defined HAPUs among discharges excluded from PSI-3 measurement (2009-2014)**

Source: Authors' analysis of administrative data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases for Florida (FL), New York (NY) and Washington (WA), 2009-2014

Appendix Exhibit A6: Trends in PSI-3-defined (Advanced Stage) Hospital Acquired Pressure Ulcer Incidence for PSI-3 Excluded Cohorts (Medicare), 2009-2014

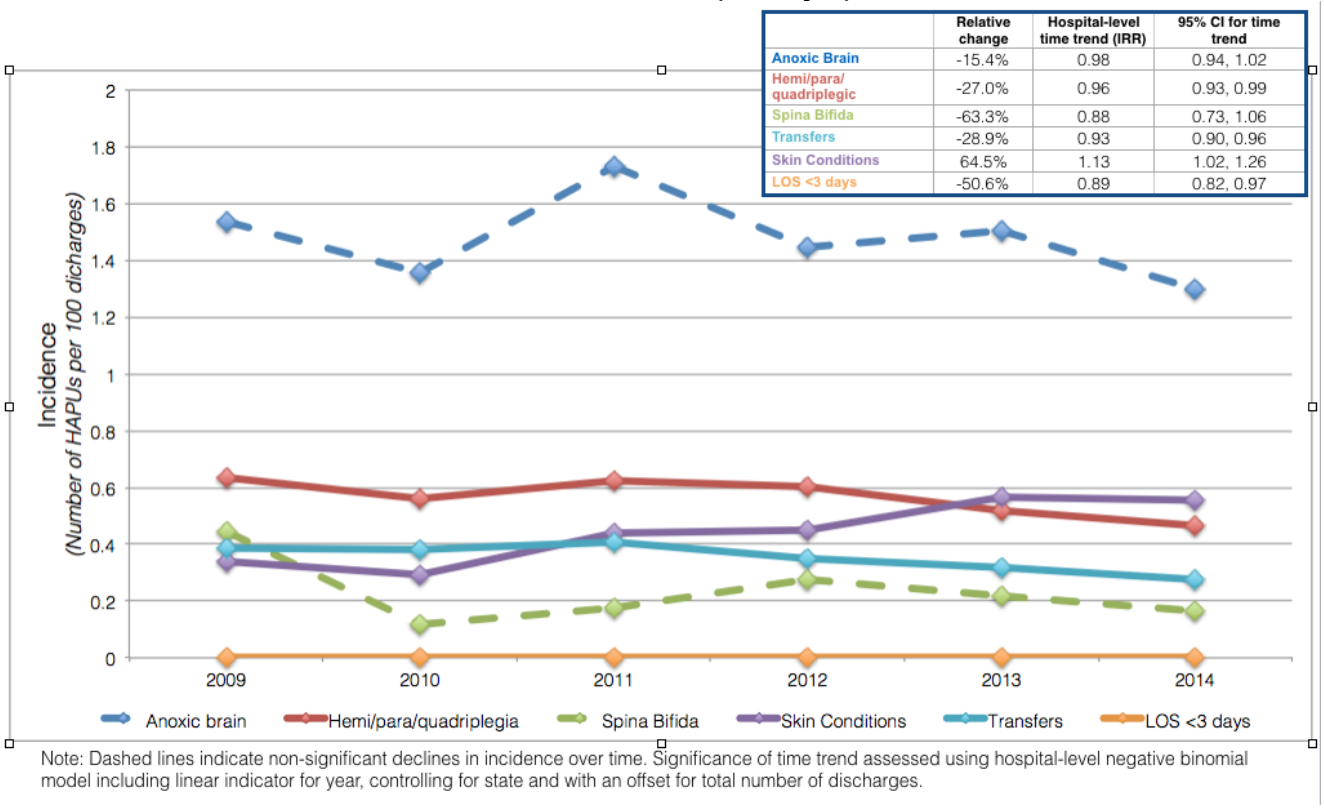
	Relative change	Hospital-level time trend (IRR)	95% CI for time trend
Anoxic Brain	-15.4%	0.98	0.94, 1.02
Hemi/para/ quadriplegic	-27.0%	0.96	0.93, 0.99
Spina Bifida	-63.3%	0.88	0.73, 1.06
Transfers	-28.9%	0.93	0.90, 0.96
Skin Conditions	64.5%	1.13	1.02, 1.26
LOS <3 days	-50.6%	0.89	0.82, 0.97



Note: Dashed lines indicate non-significant declines in incidence over time. Significance of time trend assessed using hospital-level negative binomial model including linear indicator for year, controlling for state and with an offset for total number of discharges.

Source: Authors' analysis of administrative data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases for Florida (FL), New York (NY) and Washington (WA), 2009-2014

Appendix Exhibit A7: Trends in PSI-3-defined (Advanced Stage) Hospital Acquired Pressure Ulcer Incidence for PSI-3 Excluded Cohorts (All-Payer), 2009-2014



Note: Dashed lines indicate non-significant declines in incidence over time. Significance of time trend assessed using hospital-level negative binomial model including linear indicator for year, controlling for state and with an offset for total number of discharges.

Source: Authors' analysis of administrative data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases for Florida (FL), New York (NY) and Washington (WA), 2009-2014

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