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Study concept and design: Growdon, Sacks, Avorn.
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1. Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States origins and prospects for reform. *JAMA*. 2016;316(8):858-871. doi:10.1001/jama.2016.11237

2. Johansen ME, Richardson C. Estimation of potential savings through therapeutic substitution. *JAMA Intern Med*. 2016;176(6):769-775. doi:10.1001/jamainternmed.2016.1704

3. Centers for Medicare and Medicaid Services. Medicare Part D Drug Spending Dashboard and Data. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html. Published March 14, 2019. Accessed March 20, 2019.

4. Whelton PK, Carey RM, Aronow WS, et al. ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. *Hypertension*. 2018;71(6):1269-1324. doi:10.1161/HYP.0000000000000066

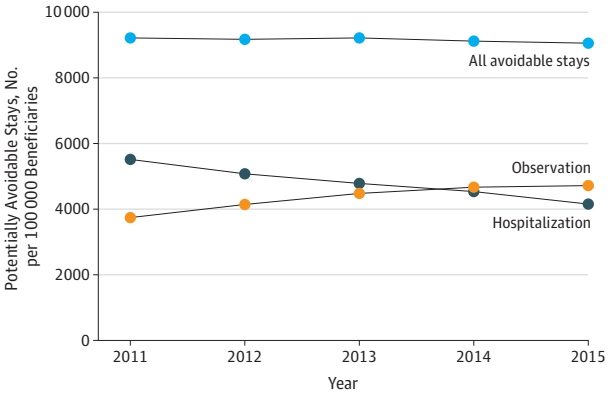
5. Vanderholm T, Klepser D, Adams AJ. State approaches to therapeutic interchange in community pharmacy settings: legislative and regulatory authority. *J Manag Care Spec Pharm*. 2018;24(12):1260-1263.

6. Sacks CA, Lee CC, Kesselheim AS, Avorn J. Medicare spending on brand-name combination medications vs their generic constituents. *JAMA*. 2018;320(7):650-656. doi:10.1001/jama.2018.11439

Trends in Hospitalization vs Observation Stay for Ambulatory Care–Sensitive Conditions

Hospitalizations related to ambulatory care–sensitive conditions (ACSCs) are widely considered a key measure of access to high-quality primary care.[1] The Agency for Healthcare Research and Quality defines ACSCs as conditions, such as urinary tract infection and dehydration, for which hospitalization is generally avoidable if patients have access to effective primary care.[2] In recent years, there has been substantial focus on improving ambulatory care nationally.[3] Therefore, rates of hospital admissions related to ACSCs are used with increasing frequency to assess and incentivize the performance in the ambulatory setting of health care professionals participating in national Medicare alternative payment programs, such as accountable care organizations and alternative quality contracts administered by private payers, which increase pressure on hospitals to admit fewer patients.[4] To date, there is some evidence that rates of avoidable hospitalizations have indeed been falling.[2] However, during this same period, the rates of hospital admissions "for observation," which do not count as inpatient admissions, have been increasing.[5] The degree to which reported drops in avoidable hospitalizations related to ACSCs represent real gains in ambulatory care and not simply an artifact of an increasing shift from inpatient status to observation status is unknown.

Figure. Trends in Potentially Avoidable Hospitalizations and Hospital Observation Stays Related to Ambulatory Care–Sensitive Conditions



Multivariable linear regression models were used to estimate yearly hospitalization rates and observation stays while adjusting for patient demographics and comorbidities, treating time as a categorical variable, and including hospital referral region–fixed effects.

Methods | We obtained a national 20% sample of the Medicare Fee-for-Service Inpatient and Outpatient Claim Files from 2011 to 2015 and used the Agency for Healthcare Research and Quality Prevention Quality Indicators software to identify avoidable hospitalizations and observation stays related to ACSCs.[6] These included all hospital stays related to both acute conditions (dehydration, bacterial pneumonia, urinary tract infection, and perforated appendix) and chronic conditions (including diabetes short-term complications, diabetes long-term complications, uncontrolled diabetes, lower extremity amputation related to diabetes, asthma in adults, chronic obstructive pulmonary disease, hypertension, heart failure, and angina without procedure). The Harvard T. H. Chan School of Public Health institutional review board's Committee on the Use of Human Subjects approved this study and waived the need for informed patient consent because all data were retrospective and deidentified. We used multivariable linear regression models to estimate yearly rates of avoidable hospitalizations and observation stays within each hospital referral region (HRR), the geographic territory representing each regional tertiary care market. The models included adjustments for patient age, sex, race, dual Medicare and Medicaid status, and comorbidities (using comorbidities data obtained from the Chronic Conditions Data Warehouse) and treated time as a categorical variable. We then estimated yearly slopes, similarly adjusting for patient demographics and comorbidities and using time as a continuous variable. Statistical analyses were performed from November 2018 to March 2019 using SAS software, version 9.4 (SAS Institute Inc). A 2-sided $P < .05$ was considered statistically significant.

Table. Change in Rates of Hospitalization and Observation Stays Related to Overall, Acute, and Chronic ACSCs[a]

Admission Status by ACSC Category	Year		Yearly Change, Slope (95% CI)	*P* Value for Trend
	2011	2015		
All ACSCs, No. per 100 000 Medicare beneficiaries				
Hospitalization	5517	4158	−326.2 (−332.8 to −319.7)	<.001
Observation	3743	4718	245.6 (233.4 to 257.7)	<.001
Chronic ACSCs, No. per 100 000 Medicare beneficiaries[b]				
Hospitalization	3055	2340	−167.8 (−172.9 to −162.7)	<.001
Observation	2617	3350	188.6 (178.5 to 198.7)	.001
Acute ACSCs, No. per 100 000 Medicare beneficiaries[c]				
Hospitalization	2463	1819	−158.4 (−162.4 to −154.4)	<.001
Observation	1126	1368	57.0 (51.7 to 62.3)	<.001

Abbreviation: ACSCs, ambulatory care–sensitive conditions.

[a] Multivariable linear regression models were used to estimate yearly hospitalization rates and observation stays by using a 20% national sample of Medicare inpatient and outpatient data for 2011 to 2015 after adjusting for patient demographics and comorbidities, and treating time as a categorical variable. Yearly slopes were estimated by treating time as a continuous variable. All models included HRR fixed effects. The study baseline was 2011, and 2015 was the latest year for which relevant national data were available.

[b] Chronic ACSCs included short-term and long-term complications of diabetes, uncontrolled diabetes, lower extremity amputation related to diabetes, asthma in adults, chronic obstructive pulmonary disease, hypertension, heart failure, and angina without procedure.

[c] Acute ACSCs included dehydration, bacterial pneumonia, urinary tract infection, and perforated appendix.

Results | In 2011, there were 5517 ACSC-related, potentially avoidable inpatient hospitalizations and 3743 similarly avoidable observation stays per 100 000 Medicare beneficiaries (**Figure**). By 2015, the rate of potentially avoidable inpatient hospitalizations had decreased to 4158 and the rate of potentially avoidable hospital observation stays had increased to 4718 per 100 000 beneficiaries. The risk-adjusted slopes were −326.2 per 100 000 beneficiaries per year (95% CI, −332.8 to −319.7; $P < .001$) for avoidable inpatient hospitalizations and 245.6 per 100 000 beneficiaries per year (95% CI, 233.4 to 257.7; $P < .001$) for avoidable observation stays (**Table**). Approximately 75.2% of the decrease in national avoidable hospitalizations from 2011 to 2015 was offset by the increase in hospital stays under observation status. A greater shift from inpatient to observation stays was seen for chronic ACSCs than for acute ACSCs.

Discussion | The rates of avoidable hospitalizations related to ACSCs have declined over time in the Medicare population. However, there has been a concomitant increase in the rates of avoidable observation stays for the same types of conditions, especially for chronic ACSCs. Our study results suggest that the major part of the improvement in hospitalization rates for ACSCs is likely related to increased designation of patients for observation status. Although the observational nature of this study limits our ability to establish a definitive causal relationship between these trends, the findings have important policy implications. First, they call into question how much progress is being made in improving ambulatory care, particularly for chronic conditions such as diabetes and heart failure. Second, they suggest that any alternative payment model that uses avoidable hospitalizations as a quality measure to assess performance in the primary care setting should also account for potentially avoidable observation stays.

Jose F. Figueroa, MD, MPH
Laura G. Burke, MD, MPH
Jie Zheng, PhD
E. John Orav, PhD
Ashish K. Jha, MD, MPH

Author Affiliations: Department of Health Policy and Management, Harvard T. H. Chan School of Public Health, Boston, Massachusetts (Figueroa, Burke, Zheng, Orav, Jha); Division of General Internal Medicine, Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts (Figueroa, Orav); Department of Medicine, Harvard Medical School, Boston, Massachusetts (Figueroa, Burke, Jha); Department of Emergency Medicine, Beth Israel Deaconess Medical Center, Boston, Massachusetts (Burke); Harvard Global Health Institute, Harvard University, Cambridge, Massachusetts (Jha).

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Corresponding Author: Jose F. Figueroa, MD, MPH, Department of Health Policy and Management, Harvard T. H. Chan School of Public Health, 42 Church St, Cambridge, MA 02138 (jfigueroa@hsph.harvard.edu).

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Concept and design: Figueroa, Burke, Jha.
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Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Zheng, Orav.
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1. Gao J, Moran E, Li YF, Almenoff PL. Predicting potentially avoidable hospitalizations. *Med Care*. 2014;52(2):164-171. doi:10.1097/MLR.0000000000000041

2. Agency for Healthcare Research and Quality (AHRQ). Potentially avoidable hospitalizations. http://www.ahrq.gov/research/findings/nhqrdr/chartbooks/carecoordination/measure3.html. Published 2016. Accessed April 3, 2019.

3. Blumenthal D, Abrams M, Nuzum R. The Affordable Care Act at 5 years. *N Engl J Med*. 2015;373(16):1580.

4. CMS Medicare Shared Savings Program. *Accountable Care Organization (ACO) 2018 Quality Measures: Narrative Specifications Document*. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2018-reporting-year-narrative-specifications.pdf. Published January 20, 2018. Accessed July 1, 2019.

5. Dharmarajan K, Qin L, Bierlein M, et al. Outcomes after observation stays among older adult Medicare beneficiaries in the USA: retrospective cohort study. *BMJ*. 2017;357:j2616. doi:10.1136/bmj.j2616

6. Agency for Healthcare Research and Quality (AHRQ). QI modules. https://www.qualityindicators.ahrq.gov/Archive/default.aspx#. Accessed March 12, 2019.

Inclusion of Clinical Trial Registration Numbers in Conference Abstracts and Conformance of Abstracts to CONSORT Guidelines

Clinical trial registration facilitates identification, tracking, and assessment of clinical trials and limits publication bias caused by the selective reporting of trial results.[1] Inclusion of trial registration numbers in conference abstracts, as recommended by the Consolidated Standards of Reporting Trials (CONSORT) guidelines for abstracts[2] is particularly important because many conference presentations of trials remain unpublished.[3] In the present study, we reviewed abstracts presented at 8 major medical and surgical conferences held in 2017 to assess the extent to which conference abstracts reporting randomized clinical trial (RCT) results cite trial registration numbers and conform to other key CONSORT guidelines.

Methods | For this cross-sectional study, 8 major conferences held in 2017 in the fields of cardiology, endocrinology, gastroenterology, hepatology, nephrology, and urology (medical specialties of special interest to the authors) and with readily available abstracts were selected for review (**Table**). Abstracts were identified by searching for the word *randomized* (or *randomised*). Abstracts that reported primary results of an RCT were then examined for inclusion of a trial registration number, and the following 5 additional key elements of the CONSORT guidelines for abstracts[2]: the word *randomized* or *randomised* or RCT in the title, statement of a primary outcome, number of participants randomized in each group, and number of participants analyzed in each group, and dates of recruitment and follow-up. Inclusion of a trial registration number and the additional 5 CONSORT reporting items in the abstract were each given a score of 1 if present and 0 if absent and then combined to obtain a summary score with a range of 0 to 6.

Results | We identified 1546 abstracts with the word *randomized* (or *randomised*), representing approximately 7.0% of more than 22 000 abstracts accepted for poster or oral presentations at the 8 conferences examined. Of these, 1124 abstracts (72.7%) reported RCT results, of which 720 (64.1%) reported primary results (**Figure**). Of these 720 abstracts, only 97 (13.5%)

Table. Abstracts Reporting Primary Clinical Trial Results

	Conference Abstracts, No. (%)								
Criteria	AASLD	ACC	ADA	AUA	DDW	EASL	KW	OW	All
Primary abstracts, No.	62	34	198	122	107	70	90	37	720
CONSORT criteria									
Registration number in abstract	20 (32.3)	4 (11.8)	20 (10.1)	16 (13.1)	13 (12.1)	10 (14.3)	14 (15.6)	0	97 (13.5)
Word *randomized* or *randomised* or *RCT* in title	33 (53.2)	10 (29.4)	42 (21.2)	93 (76.2)	92 (86.0)	30 (42.9)	45 (50.0)	8 (21.6)	353 (49.0)
Primary outcome specified	30 (48.4)	14 (41.2)	57 (28.8)	44 (36.1)	58 (54.2)	35 (50.0)	41 (45.6)	4 (10.8)	283 (39.3)
Participants randomized in each group provided	43 (69.4)	17 (50.0)	118 (59.6)	82 (67.2)	78 (72.9)	40 (57.1)	46 (51.1)	18 (48.6)	442 (61.4)
Participants analyzed in each group provided	21 (33.9)	8 (23.5)	41 (20.7)	26 (21.3)	46 (43.0)	18 (25.7)	16 (17.8)	5 (13.5)	181 (25.1)
Trial dates included	8 (12.9)	4 (11.8)	5 (2.5)	38 (31.1)	28 (26.2)	6 (8.6)	11 (12.2)	1 (2.7)	101 (14.0)
≥3 of 6 CONSORT items	30 (48.4)	6 (17.6)	29 (14.6)	57 (46.7)	71 (66.4)	25 (35.7)	29 (32.2)	2 (5.4)	249 (34.6)
Trial registration									
Trial registered	47 (75.8)	18 (52.9)	145 (73.2)	45 (36.9)	79 (73.8)	54 (77.1)	67 (74.4)	22 (59.5)	477 (66.3)
Registered prospectively[a]	29 (46.8)	10 (29.4)	79 (39.9)	21 (17.2)	34 (31.8)	31 (44.3)	34 (37.8)	10 (27.0)	248 (34.4)

Abbreviations: AASLD, American Association for the Study of Liver Diseases, The Liver Meeting, October 20-24, 2017, Washington, DC; ACC, American College of Cardiology, Annual Scientific Session, March 17-19, 2017, Washington, DC; ADA, American Diabetes Association, Scientific Sessions, June 9-17, 2017, San Diego, California; AUA, American Urological Association, Annual Meeting, May 12-16. 2017, Boston, Massachusetts; DDW, American Gastroenterological Association, Digestive Disease Week, May 6-9, 2017, Chicago, Illinois; CONSORT, Consolidated Standards of Reporting Trials; EASL, European Association for the Study of the Liver, Annual Meeting, April 19-23, 2017, Amsterdam, the Netherlands; KW, American Society of Nephrology, Kidney Week, October 31 to November 5, 2017, New Orleans, Louisiana; OW, Obesity Society and American Society for Metabolic & Bariatric Surgery, Obesity Week, October 29 to November 2, 2017.

[a] For trials registered at ClinicalTrials.gov, the number of days from the receipt of the registration information to the start date was used to determine prospective registration. For other trials, the classification was obtained from the World Health Organization International Clinical Trials Registry Platform.[4]