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A crisis has been rising to a boiling point in our communities, largely overshadowed and partially fueled by the COVID-19 pandemic: the epidemic of substance use. According to the National Institute on Drug Abuse, almost 92,000 Americans died from drug overdoses in 2020, up from 52,404 in 2015. With this October marking National Substance Abuse Prevention Month, the October issue of *The American Journal of Managed Care®* features 2 important studies shedding light on factors that may influence opioid prescribing and keep individuals from receiving substance use disorder treatment.

"THOUGHTFUL BENEFIT DESIGN AND RESPONSIBLE OPIOID PRESCRIBING COULD BE COMPONENTS OF A MULTIFACETED APPROACH TO COMBAT THE EPIDEMIC."

An article by Adeniyi T. Togun, MD, PhD, MS, MPH, and coauthors explores how pharmaceutical companies changed how they market opioids to physicians after release of the 2016 CDC guidelines on prescribing opioids for chronic pain in the primary care setting. They find that the dollar value of food and beverages spent per opioid marketing encounter increased after the release of the guidelines, although the monthly number of marketing encounters per physician decreased. Considering other research findings that show an association between pharmaceutical opioid marketing and increases in opioid prescriptions by physicians who receive these payments, the authors call for further education for physicians on these marketing practices.

Also in this issue, researchers led by Matthew D. Eisenberg, PhD, examine how uptake of high-deductible health plans (HDHPs) affects use of substance use disorder treatment services. They find that enrollees were less likely to use such services after being offered an HDHP and that the burden of spending shifted from health plans to patients. In particular, there was a drop in medication-assisted treatment associated with HDHP uptake, which could signify that financial barriers are keeping patients from accessing these evidence-based, effective therapies. In the context of rising enrollment in HDHPs, the authors highlight the concern that this shift may be exacerbating the undertreatment of substance use disorder, and they call for all plans to include medications for opioid use disorder on their preferred formulary tiers without cost sharing.

We know that our health care system's efforts to prevent and manage substance use disorder must extend beyond a single month and incorporate multiple strategies. The findings in this issue reveal how thoughtful benefit design and responsible opioid prescribing could be components of a multifaceted approach to combat the epidemic, and the journal looks forward to publishing future research on these and other avenues to alleviate the burden of substance use disorder on American families. ■

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SEE ALSO DBT DRUG BENEFIT TRENDS® FOR MEDICAL DIRECTORS, PHARMACY DIRECTORS, AND OTHER MANAGED CARE DECISION MAKERS

NIH Requests Input From Pharmacists on Wide Strategic Plan for Research on Women's Health

The forthcoming strategic plan will be focused on guiding future National Institutes of Health (NIH) research efforts to improve the health of all women throughout the life course.

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COMMENTARY

Scenario Analysis When Conducting Budget Impact Analyses for Rare Diseases

Eric P. Borrelli, PhD, PharmD, MBA; and R. Scott Leslie, PhD, MPH

Pharmacoeconomic analyses are an important and useful guide for understanding a pharmacotherapeutic intervention's financial impact for relevant stakeholders. One type of pharmacoeconomic analysis that assesses a pharmacotherapeutic intervention's short-term financial implications is a budget impact analysis. Although methodology guidelines for budget impact analyses in the United States currently exist, not much guidance is available for analyses that are being conducted of rare or ultrarare disease states. In this article, we propose conducting a scenario analysis for pharmacotherapeutic interventions to treat rare diseases by varying health plan sizes to indicate what the potential plan impact would be if 1 member in said health plan received treatment. We then walk through an illustrative example and discuss the rationale for it.

FULL TEXT AND PDF AT: ajmc.com/link/89252

CLINICAL

Implementing Clinical Informatics Tools for Primary Care–Based Diabetic Retinopathy Screening

Sally L. Baxter, MD, MSc; Quinn Quackenbush, MSN, RN; John Cerda, BA; Chhavi Gregg, BDS, MHA; Marlene Millen, MD; and Christine Thorne, MD, MPH

OBJECTIVES: To improve diabetic retinopathy (DR) screening rates through a primary care–based "teleretina" screening program incorporating clinical informatics tools.

STUDY DESIGN: Quality improvement study at an academic institution.

METHODS: Existing DR screening workflows using in-person eye examinations were analyzed via a needs assessment. We identified gaps, which clarified the need for expanding DR screening to primary care settings. We developed informatics tools and described associated challenges and solutions. We also longitudinally monitored imaging volume and quality.

RESULTS: The needs assessment identified several gaps in baseline DR screening workflows. Health information technology (IT) considerations for the new primary care–based teleretina screening program included integrating the new program with existing information systems, facilitating care coordination, and decreasing barriers to adoption by incorporating automation and other features aimed at decreasing end-user burden. We successfully developed several tools fulfilling these goals, including integration with the ophthalmology picture and archiving communication system, a customized aggregated report in the electronic health record to monitor screenings, automation of billing and health maintenance documentation, and automated results notification to primary care physicians. Of 316 primary care patients screened between October 2020 and July 2021, 73 (23%) were found to have ocular pathology, including DR, glaucoma, age-related macular degeneration, and a range of other eye conditions that were previously undiagnosed.

CONCLUSIONS: New models of health care delivery, including telemedicine workflows, have become increasingly important for complex diabetic care coordination and require substantial health IT engagement. This program illustrates how clinical informatics tools can make substantial contributions to improving diabetes care.

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POLICY

Implementation and Cost Validation of a Real-time Benefit Tool

Shiven Bhardwaj, PharmD, MAS; Steven D. Miller, MD, MBE; Amanda Bertram, MS; Kerry Smith, MS; Jessica Merrey, PharmD, MBA; and Ashwini Davison, MD

OBJECTIVES: To assess the accuracy of a real-time benefit tool (RTBT) that is compliant with the standards of the National Council for Prescription Drug Programs (NCPDP) in a large academic medical center.

STUDY DESIGN: Observational study of electronic health records and pharmacy records from July 14, 2019, through January 14, 2020, across all ambulatory clinics and outpatient pharmacies in the health system.

METHODS: Main assessments included (1) demographic characteristics of patients in whom the RTBT was used and those in whom it was not used, (2) types of changes most frequently made to medication orders upon reviewing the RTBT, and (3) comparison of the out-of-pocket costs for prescriptions vs the RTBT-generated estimates.

RESULTS: The most common modifications made to prescriptions due to RTBT use were changes in days' supply (44%) and the quantity of medication (69%). In more than 98% of prescription orders, patients' out-of-pocket costs were either equivalent to or lower than the estimates generated by the RTBT.

CONCLUSIONS: Current standards established by NCPDP yield accurate patient out-of-pocket estimates and could serve as a national standard for all Part D sponsors.

FULL TEXT AND PDF AT: ajmc.com/link/89254

POLICY

Characteristics, Utilization, and Concentration of Outpatient Care for Dual-Eligible Medicare Beneficiaries

Paula Chatterjee, MD, MPH; Joshua M. Liao, MD, MSc; Erkuan Wang, MA; Danielle Feffer, BA; and Amol S. Navathe, MD, PhD

OBJECTIVES: To characterize the (1) distribution of outpatient care for dual-eligible Medicare beneficiaries ("duals") and (2) intensity of outpatient care utilization of duals vs non–dual-eligible beneficiaries ("nonduals").

STUDY DESIGN: Using data preceding the introduction of several outpatient alternative payment models, as well as Medicaid expansion, we evaluated the distribution of outpatient care across physician practices using a Lorenz curve and compared utilization of different outpatient services between duals and nonduals.

METHODS: We defined practices that did (high dual) and did not (low dual and no dual) account for the large majority of visits based on the Lorenz curve and then performed descriptive statistics between these groups of practices. Practice-level outcomes included patient demographics, practice characteristics, and county measures of structural disadvantage and population health. Patient-level outcomes included number of outpatient visits and unique outpatient physicians, primary vs subspecialty care visits, and expenditures.

RESULTS: Nearly 80% of outpatient visits for duals were provided by 35% of practices. Compared with low-dual and no-dual practices, high-dual practices served more patients (1117.6 patients per high-dual practice vs 683.8 patients per low-dual practice and 447.5 patients per no-dual practice; $P < .001$) with more comorbidities (3.9 mean total Elixhauser comorbidities among patients served by high-dual practices vs 3.6 among low-dual

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practices and 3.3 among no-dual practices; $P < .001$). With regard to utilization, duals had 2 fewer outpatient visits per year compared with nonduals (13.3 vs 15.2; $P < .001$), with particularly fewer subspecialty care visits (6.5 vs 7.9; $P < .001$) despite having more comorbidities (3.5 vs 2.7; $P < .001$).

CONCLUSIONS: Outpatient care for duals was concentrated among a small number of practices. Despite having more chronic conditions, duals had fewer outpatient visits. Duals and the practices that serve them may benefit from targeted policies to promote access and improve outcomes.

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MANAGERIAL

Long-term Medication Adherence and Preventive vs Reactive Care Utilization Among Older Adults With Diabetes

Aliza R. Karpes Matusevich, PhD; Christy Xavier, PharmD; and Rafia S. Rasu, PhD

OBJECTIVES: To assess long-term adherence to oral hypoglycemic agents (OHAs) and determine if adherence affects total health care expenditures of reactive vs preventive services.

STUDY DESIGN: Retrospective cohort study.

METHODS: This study measured adherence to OHAs using Medical Expenditure Panel Survey 2013-2017 data. Adults 65 years and older who had diabetes and were taking at least 1 OHA were included. Respondents with a medication possession ratio (MPR) of at least 80% were considered adherent. Health care utilization and expenditure were compared among adherent and nonadherent respondents for preventive and reactive services. Utilization data were analyzed using negative binomial regression and expenditure data using γ-family generalized linear regression models.

RESULTS: Approximately 67% of the cohort (n = 1279) were adherent. The adherent group had greater health care expenditure overall than nonadherent respondents ($29,985 [95% CI, $27,161-$32,743] vs $24,623 [95% CI, $21,623-$28,122]; $P < .05$). Although expenditure was higher for prescription medications and office visits, mean emergency department expenditures were higher for adherent respondents. The utilization and proportion of expenditure on preventive vs reactive health care services did not differ by adherence as defined by an MPR of at least 80%.

CONCLUSIONS: Increasing adherence provides an opportunity to improve CMS quality ratings. Our finding that adherence does not affect the financial burden of disease might be explained by the increased costs of preventive medication and increased comorbidity burden of these patients. Low adherence to OHAs encourages clinicians to be more proactive in ensuring that prescription medications are refilled regularly. By emphasizing equitable diabetes education and tailoring quality initiatives that minimize racial disparities, adherence can be better achieved.

FULL TEXT AND PDF AT: ajmc.com/link/89255

TRENDS FROM THE FIELD

Evaluating Smoking Cessation Service at an Emergency Department Clinical Observation Unit

Celine Chang Chyi Ng, BPharm; Stefan Kowalski, BPharm, MAppSc; Wei Ling Mu, MNursing (APN); Pei Ting Tan, MSc; Elaine Yin Leng Leong, MHealthAdmin; Pak Liang Goh, MBBS; Ru Peng Mong, MBBS; and Hoon Chin Lim, MBBS, MRCS (EM)

OBJECTIVES: To evaluate the effectiveness of a pilot smoking cessation service in an emergency department (ED) clinical observation unit.

STUDY DESIGN: A descriptive case series review was undertaken of smoking cessation service patients in the short-stay unit of an acute hospital in Singapore from July 1, 2018, to December 31, 2019.

METHODS: Upon admission, ED nurses screen all patients regarding their current smoking status and implement the 5 A's framework, which involves the steps of Ask-Advise-Assess-Assist-Arrange. Patients in the "contemplation" and "preparation" stages were offered the following components: (1) a bedside counseling session by a pharmacist and (2) a follow-up appointment at an outpatient smoking cessation clinic. Postdischarge follow-up telephone calls at 1, 6, and 12 months were carried out as part of the study data collection to obtain abstinence information.

RESULTS: Forty-seven patients were included in the study; the majority were male (n = 41; 87.2%). The median numbers of cigarettes smoked per day at baseline, 1 month, 6 months, and 12 months were 14, 5, 3, and 5, respectively. The overall point-prevalence abstinence rates over the same follow-up time points were 26.5%, 38.7%, and 31.3%, respectively. The proportions of patients lost to follow-up at 1 month, 6 months, and 12 months were 27.7%, 34.0%, and 31.9%, respectively.

CONCLUSIONS: Given the small sample and high number of uncontactable patients, more research is needed to assess whether the trend toward increasing point-prevalence abstinence rate over time and the trend toward decreasing median number of cigarettes smoked are observed in a larger sample.

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Community Health Workers' Critical Role in Trust Building Between the Medical System and Communities of Color

Cristian Capotescu, PhD; Tashi Chodon, MPH, BSN; James Chu, PhD; Elizabeth Cohn, PhD, RN; Gil Eyal, PhD; Rishi Goyal, MD, PhD; Olusimbo Ige, MD, MS, MPH; Jack LaViolette, MSc; Sarah Mallik, MD, MA; Lula Mae Phillips, RN, MEd, MDiv, DMin; Paulette Spencer, MPH, MA; and Danielle Lee Tomson, MPhil

The COVID-19 pandemic has laid bare discriminatory and inequitable health outcomes in communities of color around the country. In New York City, Black and Latino communities experienced significantly greater hospitalization and mortality rates than the White population, with early (prevaccine) fatality estimates suggesting an approximate 3.5-fold disparity for Hispanic adults and 5.4-fold disparity for non-Hispanic Black adults relative to non-Hispanic White adults.[1] This should surprise no one, given the documented economic and racial inequalities in the United States, and indeed, fine-grained analyses suggest that "structural determinants pervasive in Black and Hispanic communities," primarily associated with poverty, are driving these disparities.[2] The pandemic has also drawn attention to a crisis of mistrust in the relations between communities of color and the medical system. Initially, at least, Black and Latino communities had lower vaccination rates than their White counterparts, and this remains true for the former.[3] How can medical institutions regain the trust of local communities, and who might do this trust-building work on the ground?

To explore these questions, the Trust Project at Columbia University partnered with the Bronx Community Health Network, a nonprofit health center system that provides access to affordable, quality services at school- and community-based health centers, to host a town hall conversation and a follow-up roundtable in fall 2021. Together with local advocates, policy makers, community health workers (CHWs), and the public, we sought to better understand the relationship between Bronx residents and the medical field. The following are the lessons we learned from these conversations, which we would like to bring to the attention of medical decision makers.

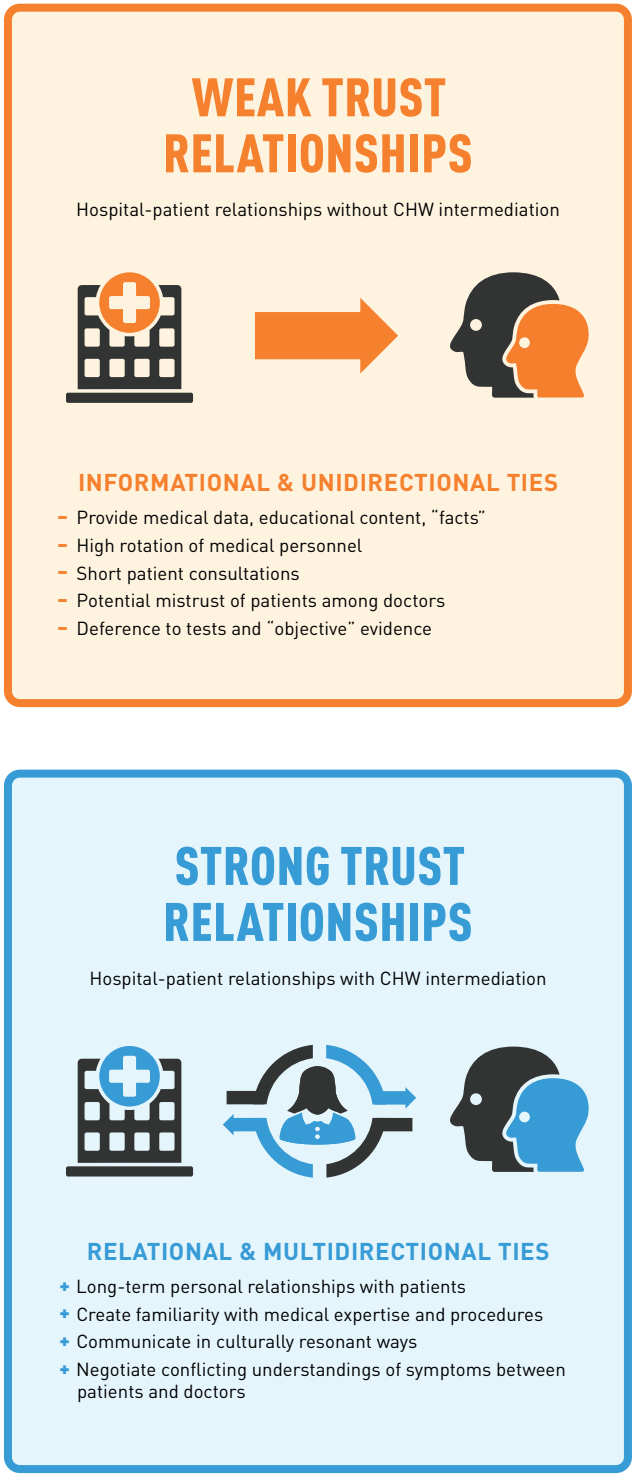
The first point we learned from our participants was that focusing attention on the presumed mistrust of the medical field by communities of color is misguided. Public and academic conversations often begin from the "problem" of mistrust. The unstated premise of beginning in this way is that it is evident that communities of color should trust medical providers and medical institutions. In this reading, the onus is placed on marginalized communities to "unlearn" their distrust toward medical practitioners. Although the academic discussion on mistrust has begun to acknowledge that this premise is wrong,[4] our interlocutors' daily experiences suggest that these assumptions still guide much of the day-to-day, on-the-ground discourse. Put differently, the national conversation should shift from fixing individuals to fixing the system. It is important to recognize that given the history of medical discrimination and medical racism, trust is not the obvious default for patients of color. Before doctors, hospitals, and health care providers decry mistrust, the task at hand should be to heighten patient engagement and make patients want to come into care, share and disclose important information, and be part of care planning. In other words, the medical field must become more trustworthy.[5]

The second point we learned follows from the first. Attempts to build trust in medical treatments and vaccines often assume that "more" or "better" information is needed to educate mistrustful patients. If, however, the problem is one of trustworthiness, a unidirectional, monologic information campaign is likely to backfire. There is little evidence to suggest that a misunderstanding of the benefits and risks associated with vaccination is the primary driver of vaccine hesitancy.[6] Many interventions based on this "deficit" model have not significantly affected vaccination rates, with some research suggesting that they may even increase the perceived risks associated with vaccines.[7] Communicating medical advice is not the simple transmission of information. When it comes to

TAKEAWAY POINTS

- Trust is not the default for patients of color. Asking many patients of color to "unlearn" their mistrust of hospitals should be reversed to: What can hospitals do to earn the trust of their patients?
- Trust in medical treatments and vaccines cannot be heightened through "more" or "better" information. The relational quality of communication deserves as much attention as the content of the information in interventions.
- Trust cannot be earned overnight; it requires time and attention. Community health workers cultivate relationships with patients, provide them with an essential degree of familiarity with medical expertise and procedures, and can do this consistent, long-term labor.

FIGURE. Building Trust? The 2 Models of Patient-Hospital Relationships



CHW, community health worker.

Source: This graphic was created by Nate Lavey, video production manager at INCITE, Columbia University.

eliciting trust, the medium, format, and timing of communication are as crucial—perhaps more crucial—than its informational content, however scientifically correct. An information blitz from above, coming fast on the heels of a moral panic about "mistrust" and "disinformation," is likely to elicit the opposite reaction than intended. In other words, the relational quality of communication deserves as much attention when crafting interventions as the content of the information itself, if not more so.[8,9]

How can such ties be built, where trustworthiness is lacking and will take a long time to rebuild? A third lesson we learned from our conversations is that CHWs already function as essential mediators who perform critical trust-building work (**Figure**). When CHWs are situated at the access points to the medical system, they are uniquely equipped to communicate and negotiate information between both sides (ie, to replace the unidirectional flow of information with a dialogue). Moreover, their training and background, as well as the temporal rhythm of their work, are well suited to remediate some of the aspects of hospital routines that are least conducive to projecting trustworthiness.

Consider that the rapid administrative rotation of medical personnel and 15-minute patient consultations—all hallmarks of overwhelmed hospitals that often serve communities of color—are unfit to establish trust in the medical system. Before even meeting with doctors, racial disparities are present in wait times.[10-12] Trust cannot be earned overnight; it requires time and attention, which are both scarce commodities in the notoriously depersonalized hospital system. Hospitals should introduce human-centered routines (more face time and less screen time[13]) that improve the continuity, quality, and patient experience of care. However, they can do this far more effectively if they draw upon CHWs, who cultivate long-term relationships with patients and provide them with an essential degree of familiarity with medical expertise and procedures.

Consider also that most hospitals and the larger health care system do not provide information in easily digestible, linguistically accessible, or culturally resonant ways,[14] leading to apprehension among patients toward the medical establishment when these encounters result in repeated distressing patient experiences—not necessarily outright mistrust. Because CHWs mirror the demographic makeup of the communities they serve, they possess the requisite linguistic and cultural competency to convey public health knowledge to diverse patient groups. This does not excuse doctors, hospital personnel, or medical leadership from attaining basic cultural awareness and humility themselves, nor from hiring and retaining more representative rosters of medical employees. Medical professionals must also interrogate their own mistrust of patients. Racial prejudice and implicit bias regarding minority groups are widespread in hospitals[15] and can lead hospital employees to dismiss or pathologize patients' reports of their symptoms. Although CHWs can provide critical support for these trust-building efforts, hospitals must cultivate a new culture of patient care.

It should also be noted that the way hospitals communicate medical knowledge often disregards how adults learn. Adults generally

do not appreciate receiving lectures for perceived missteps or being told what to do without explanation. This problem is exacerbated by clinical practices that rely on extensive testing in lieu of listening. The deference to tests, taken to furnish "objective" evidence, serves to end conversations while rendering patients' reports of their symptoms conditional upon test results. In such contexts, the reliance on tests makes doctors appear inattentive or even dismissive, thereby undermining their trustworthiness. As familiar members of the community, CHWs can mediate the often conflicting understandings of symptoms between patients and doctors, building trust among all parties.

Finally, we have learned one more lesson from the CHWs who participated in our town hall conversation. We are not the first to suggest the importance of community voices such as CHWs to building trust. Many others—from public health researchers to leaders of the Biden administration's "trusted messengers" program—have argued for the importance of local intermediaries between the medical profession and the public. Although such efforts are laudable for acknowledging the social context of intervention, they are also sociologically naïve. Trusted messengers programs presume that the messengers themselves would naturally trust the message they are asked to convey, or that they have faith in the medical and governmental elites they are asked to represent (ie, they will form a coalition with the elite to influence the patients). In the context of a pandemic, CHWs and other mediators are asked to convey rapidly changing recommendations without having input into their formulation. Loath to risk their own credibility among community members in the process, they are far more likely to align themselves with the patients, against the elites.[13] This is especially true as they are asked to do all this while cognizant of their own experiences of being sidelined and ignored by medical institutions. We do not believe this is a recipe for success.

Despite their hinge position as trusted mediators between the medical field and patient communities, many CHWs remain underresourced and undervalued. If hospitals want to rebuild trust among communities of color, where the pandemic has revealed it to be frayed or absent, they must invest in CHWs by training more of them, paying them commensurate salaries, and including them in decision-making about the messages they are asked to convey. However, CHWs are only one side of the equation. The other side concerns hospitals themselves. They cannot continue to place the burden on communities and CHWs—often the ones most adversely affected by public health crises—to orchestrate the trust-building process. Although community leadership will play an important role in rebuilding trust in the medical system, their efforts must be mirrored by inward-facing efforts to reform the culture of hospital care. ■

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Changes in Opioid Marketing Practices After Release of the CDC Guidelines

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ABSTRACT

OBJECTIVES: After the release of the CDC guidelines in March 2016, the rate of opioid prescriptions decreased. How or whether pharmaceutical companies changed their opioid marketing practices post release of the CDC guidelines is unknown. Our objectives were to (1) evaluate whether the release of the guidelines was associated with changes in total monthly marketing spending received per physician, monthly marketing encounter frequency per physician, and spending per encounter during opioid marketing; and (2) evaluate whether such changes in marketing differed between specialist physicians and primary care physicians (PCPs) and between urban and rural primary care service areas (PCSAs).

STUDY DESIGN: Retrospective observational cross-sectional study using opioid marketing spending data from the CMS Open Payments database between August 2013 and December 2017.

METHODS: Single-group and multiple-group interrupted time series analyses were used to evaluate differences in the immediate changes in level and trend over time in opioid marketing practices post release of the CDC guidelines.

RESULTS: Post release of the CDC guidelines, the monthly number of marketing encounters per physician and total monthly amount received per physician decreased. However, the amount spent at each marketing encounter increased. The release of the CDC guidelines was associated with an immediate increase in level of opioid marketing spending per encounter by $0.59 (95% CI, $0.51-$0.68; $P < .001$) and an over-time increase in rate of spending per encounter of $0.04 per month (95% CI, $0.03-$0.05; $P < .001$). These changes differed between specialists and PCPs and between urban and rural PCSAs.

CONCLUSIONS: It is important to continue ongoing education for physicians on changes in pharmaceutical opioid marketing practices.

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Death from drug overdose remains an important public health crisis in the United States and is the leading cause of death among those younger than 50 years.[1] Two-thirds of the 63,632 drug overdose deaths in 2016 involved an opioid,[2] and 40% of the 63,632 deaths involved prescription opioids specifically.[3] Prescription opioid overdose deaths increased from 3442 in 1999 to 17,029 in 2017.[4] After the onset of the COVID-19 pandemic in the United States in March 2020, there has been a further spike in drug overdose deaths; 107,270 drug overdose deaths were reported in 2021, with 80,816 of the deaths attributed to all opioids and 13,503 specifically to prescription opioids.[5]

About 20% of US adults reported experiencing chronic pain in 2016,[6] and 20% of noncancer pain is treated with opioids.[7] Although the prevalence of pain reported by Americans has not changed since the 1990s, opioid prescriptions for pain have increased.[8,9] In an effort to reduce the burden of prescription opioid overdose, the CDC in March 2016 issued new guidelines on opioid prescription for chronic pain by primary care physicians (PCPs).[10] The guidelines recommend initiating opioid treatment with immediate-release opioids at doses less than 50 morphine milligram equivalents (MME) per day. One of the guidelines also reads: "Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Physicians should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient." The guidelines have in fact shown to be associated with a reduction in opioid prescription rate,[11] but whether the pharmaceutical companies implemented different opioid marketing strategies to counter the reduction in prescriptions after the release of the CDC guidelines is unknown. Pharmaceutical marketing to physicians has been shown to be associated with increases in physician drug prescriptions and formulary addition requests by physicians for the promoted drugs.[12-20] Pharmaceutical sales representatives meet with physicians to talk about their drugs and encourage prescriptions. They engage in promotional activities with physicians that may involve gifts, food and beverages, dinners, sponsorships for conferences, expense-paid travel and lodging, honoraria, consulting fees, compensation for serving as faculty or speaker, and the like.[21,22]

TAKEAWAY POINTS

- It is unknown how the CDC guidelines on opioid prescribing have been associated with pharmaceutical opioid marketing practices to physicians; the current study sheds light on this.
- The CDC guidelines on opioid prescribing were associated with a decrease in total monthly marketing spending received per physician, a decrease in monthly frequency of opioid marketing encounters per physician, and an increase in spending per physician encounter during opioid marketing.
- Pharmaceutical marketing changes after the release of the CDC guidelines on opioid prescribing differed between specialist and primary care providers and also between rural and urban primary care service areas.
- Physicians who received higher spending per encounter also had higher encounter frequencies.

About 48% of physicians accepted industry-associated payments in 2015.[23] In an article that discussed pharmaceutical marketing tactics, one of the authors, a former pharmaceutical sales representative, wrote, "It's my job to figure out what a physician's price is. For some it's dinner at the finest restaurants..." and "During training, I was told, when you're out to dinner with a doctor, 'The physician is eating with a friend. You are eating with a client.'"[24] Indeed, about 95% of nonresearch opioid marketing encounters involve food and beverages.[25] Simple acts such as providing food enable marketing messages to be more positively received.[26] When people receive gifts they feel indebted and have a tendency to return the favor,[26] and in these cases of pharmaceutical opioid marketing, the return may be more opioid prescriptions.

In 2010, the Sunshine Act was passed into law through the Affordable Care Act and it required that medical product manufacturers report payments made to physicians to CMS, which publishes the data annually in a publicly searchable Open Payments database.[27] Payments for such things as meals, gifts, and speaking fees started being reported in the Open Payments database in August 2013. The American Medical Association recommends that any gifts accepted by physicians should primarily be of benefit to patients and should not be of significant value.[28] Although the majority of internal medicine program directors did not find pharmaceutical support desirable, more than half (56%) of them reported accepting support from the pharmaceutical industry.[29]

Between 2013 and 2015, nonresearch opioid-related marketing to physicians exceeded $46 million.[25] In the Medicare Part D population, it has been shown that physicians who receive opioid-related payments prescribe more opioids than those who do not.[30-33] Another study showed the association between increases in county-level pharmaceutical marketing of opioids and higher overdose mortality.[34] However, to our knowledge, no study has evaluated whether the CDC guidelines have been linked with changes in pharmaceutical opioid marketing spending per encounter, changes in frequency of marketing encounters with physicians, or changes in total marketing amount spent per physician. Therefore, we evaluated whether the dollar value of food and beverages spent per physician encounter during opioid marketing, monthly number of encounters per physician, and total monthly amount received per physician changed post release of the CDC guidelines. We focused on food and beverage gifts because they account for about 95% of the opioid marketing encounters.[25]

Although the CDC guidelines on opioid prescribing were focused on PCPs, clinicians often adopt evidence-based recommendations from outside of their own areas of practice,[35,36] and some specialist providers also adopted the CDC guidelines.[36,37] Hence, we examined whether associated changes in opioid marketing post release of the CDC guidelines differed between PCPs and specialists. To our knowledge, these questions have not been previously examined.

Certain differences between rural and urban areas with regard to opioids have been documented, including rates of opioid prescriptions being higher in rural than urban areas,[38,39] which may in turn influence pharmaceutical opioid marketing practices. However, whether postguideline changes in pharmaceutical marketing practices differed between urban and rural primary care service areas (PCSAs) is unknown. Hence, we also evaluated whether associated changes in postguideline opioid marketing differed between urban and rural PCSAs.

Overall, our study evaluates whether, post release of the CDC guidelines, the dollar value of food and beverage gifts per physician encounter for opioid marketing, monthly number of encounters per physician, and total monthly amount received per physician changed. Also, we evaluated whether these changes in marketing practices post release of the CDC guidelines differed between specialist physicians and PCPs, as well as between urban and rural PCSAs.

METHODS

Study Population

We used the CMS Open Payments database,[22] a database that collects information on financial relationships between physicians and drug or device companies, which are required by the federal government to publicly report payments to provide transparency in the health care system. We extracted all opioid marketing spending on food and beverages for physicians between August 2013 and December 2017.

Outcomes

The outcome variables were the amount spent on each opioid marketing encounter with food and beverages, monthly number of encounters per physician, and total marketing amount spent on each physician per month. All yearly monetary values were converted to 2016 US$ equivalents using the 2016 consumer price index[40] to address inflation during the study period.

Measures

Physicians receiving marketing spending were classified into PCPs and specialist physicians. PCSAs are standardized systems of

geographical units that measure access to primary care resources, utilization, supply, and associated outcomes.[41] Physicians' practice locations were assigned to PCSAs using their zip codes according to the Dartmouth Atlas.[42] A single PCSA is made up of several Census tracts. We calculated the population-weighted proportion of Census tracts classified with a US Department of Agriculture rural-urban commuting area code of 3 or lower.[43] If the weighted proportion was greater than or equal to 0.75, that PCSA was considered to be urban; if less than 0.75, the PCSA was considered to be rural. Other cutoff values for population-weighted proportion of PCSAs different from 0.75 were explored and had no effect on the rural/urban classification or results.

Statistical Analysis

We used single-group interrupted time series analysis (ITSA)[44,45] with a linear probability model clustered on physicians to examine changes in opioid marketing pre- and post release of the CDC guidelines. We clustered SEs on physicians to account for repeated observation of physicians. The ITSA model allows for the evaluation of population-level interventions without case and control groups and is useful for teasing out immediate change in outcome measures, as well as changes in trajectory (slope) over time, following an intervention.[44] We chose a linear probability model over a logit model to produce readily interpretable estimates[46] and show how much opioid marketing practices changed post release of the CDC guidelines.

Changes in amount spent per opioid marketing encounter, monthly number of encounters per physician, and total monthly marketing amount received per physician were analyzed as a one-time change in level (intercept) at the time of exposure to the CDC guidelines and as change in trend over time after release of the CDC guidelines. The single-group ITSA was modeled in the form of equation 1. We used a multiple-group ITSA to evaluate whether changes in opioid marketing practices after release of the CDC guidelines are different when marketing to PCPs compared with specialist physicians, as well as when marketing in urban PCSAs compared with rural PCSAs. The multiple-group ITSA was modeled in the form of equation 2 using interaction terms.

$$y_{ijt} = \beta_0 + \beta_1 * Months\mathrm{t} + \beta_2 * CDC_{guidelinet} + \beta_3 * MonthsSinceCDC_{guidelinet} + \beta_4 * X_j + \varepsilon\mathrm{t}$$

$$y_{ijt} = \beta_0 + \beta_5 * Months\mathrm{t} + \beta_6 * Months\#(group2-group1)\mathrm{t} + \beta_7 * CDC_{guidelinet} + \beta_8 * CDC_{guideline}\#(group2-group1)\mathrm{t} + \beta_9 * MonthsSinceCDC_{guidelinet} + \beta_{10} * MonthsSinceCDC_{guideline}\#(group2-group1)\mathrm{t} + \beta_{11} * X_j + \varepsilon\mathrm{t}$$

where y_{ijt} is the outcome variable for physician *i* from pharmaceutical company *j* at month *t*, *Months* is a linear time trend in months that starts at the beginning of our sample period, $CDC_{guideline}$ is a binary indicator variable that equals 0 prior to the release of the CDC guidelines, and 1 after release of the CDC guidelines, $MonthsSinceCDC_{guideline}$ is a linear time trend that equals 0 prior to the release of the CDC guidelines and starts counting up each month afterward, (*group2 – group1*) is a binary indicator variable that is either equal to group 1 or group 2 (eg, specialist/PCP for physician types or rural/urban for PCSAs), # is an interaction term, X_j is a vector of pharmaceutical marketing company fixed effects entered as a categorical variable, and εt is the random error at observation *t*.

β_0 is the intercept (starting level of the outcome), β_1 is the slope or trajectory of the outcome until the introduction of the CDC guidelines, β_2 represents the one-time change in level of outcome immediately at the time of implementation of the CDC guidelines (immediate treatment effect intercept change), β_3 represents the difference in the post–CDC guidelines trend/slope and pre–CDC guidelines trend/slope of outcome variable (treatment effect over time after the CDC guidelines), β_4 is a vector of the outcome variable by each pharmaceutical company, β_5 is the slope or trajectory of the outcome until the introduction of the CDC guidelines in the reference group, β_6 is the difference in slope or trajectory of outcome until the introduction of the CDC guidelines between groups compared, β_7 represents the one-time change in level of outcome immediately at the time of implementation of the CDC guidelines in the reference group, β_8 represents the difference in immediate one-time change in level of outcome at the time of implementation of the CDC guidelines in March 2016 between groups compared, β_9 represents the difference in the post–CDC guidelines trend/slope and pre–CDC guidelines trend/slope of outcome variable in the reference group, β_{10} represents the difference between the 2 groups' compared change in the post–CDC guidelines and pre–CDC guidelines trend/slope of the outcome variable (difference in treatment effect over time post CDC guidelines), β_{11} is a vector of the outcome variable by each pharmaceutical company, and ε is the error term.

We repeated the analysis using 1-month and 2-month washout periods and our findings remained unchanged (with similar directions and magnitudes of changes in intercept and slope post release of the CDC guidelines). A washout period is a time period that is excluded from the analysis with the aim of allowing for some time for implementation of the intervention. For example, with the release of the CDC guidelines in March 2016, a 1-month washout leaves out the month of March 2016 from the analysis, and a 2-month washout leaves out the months March and April 2016 from the analysis.

Systemic differences in dollar amount spent on food and beverages during marketing across pharmaceutical companies were accounted for by including an indicator variable for each company as controls in all models.

All analyses were performed using DbVisualizer version 10.0.15 (DbVis Software AB) and Stata 14 (StataCorp LLC).

RESULTS

During the study period, 94.8% of all opioid marketing encounter payments involved food and beverages and a total of 86,101 unique physicians received opioid marketing spending with food and beverages; 35.5% of the physicians were PCPs. A total of 684,343 opioid marketing encounters occurred during the study period. Of the total encounters, 89.9% occurred in urban PCSAs compared with

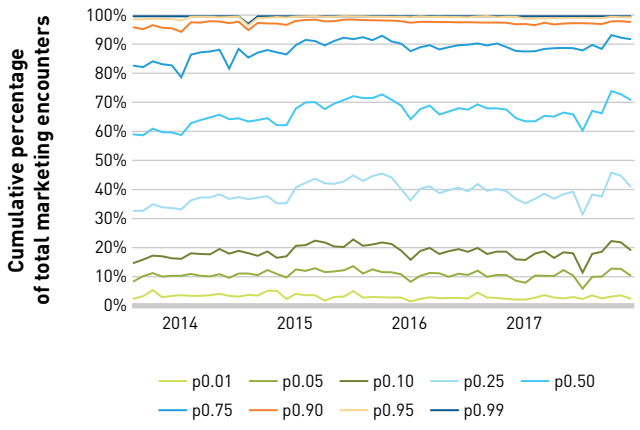
TABLE. Changes in Monthly Pharmaceutical Opioid Marketing Spending per Physician, Number of Monthly Opioid Marketing Encounters per Physician, and Opioid Marketing Spending per Encounter After Release of the CDC Guidelines[a]

	Total monthly spending per physician (95% CI)	Monthly number of encounters per physician (95% CI)	Spending per encounter (95% CI)
Pre–CDC guidelines slope	0.32 (0.14-0.49) $P < .001$	0.03 (0.02-0.04) $P < .001$	−0.03 (−0.03 to −0.02) $P < .001$
Immediate level change post CDC guidelines	−11.75 (−25.02 to 1.52) $P = .083$	−0.89 (−1.61 to −0.17) $P = .017$	0.58 (0.49-0.67) $P < .001$
Post–CDC guidelines change in slope	−1.07 (−2.09 to −0.05) $P = .040$	−0.08 (−0.14 to −0.02) $P = .008$	0.04 (0.03-0.05) $P < .001$
Urban PCSAs	5.04 (3.16-6.92) $P < .001$	0.41 (0.30-0.52) $P < .001$	0.23 (0.14-0.33) $P < .001$
Specialist providers	10.25 (8.43-12.08) $P < .001$	0.87 (0.76-0.99) $P < .001$	0.23 (0.15-0.30) $P < .001$
Constant	8.18 (2.67-13.69) $P = .004$	0.80 (0.28-1.33) $P = .003$	13.80 (12.83-14.77) $P < .001$

PCSA, primary care service area.

[a]Regressions included pharmaceutical company fixed effects (indicator variables for each pharmaceutical company). SEs are clustered at the physician level.

FIGURE 1. Trends in Total Opioid Marketing Encounters[a]



[a]Lines represent a percentile of physicians based on their mean payment per encounter; for example, the light green/lowest line represents the top 1% of physicians who receive the highest payment per encounter. To interpret: In January 2014, the top 1% of physicians who receive the highest payment per encounter accounted for 3.5% of all opioid marketing encounters. The top 5% accounted for 10.4% of all opioid marketing encounters, and so on.

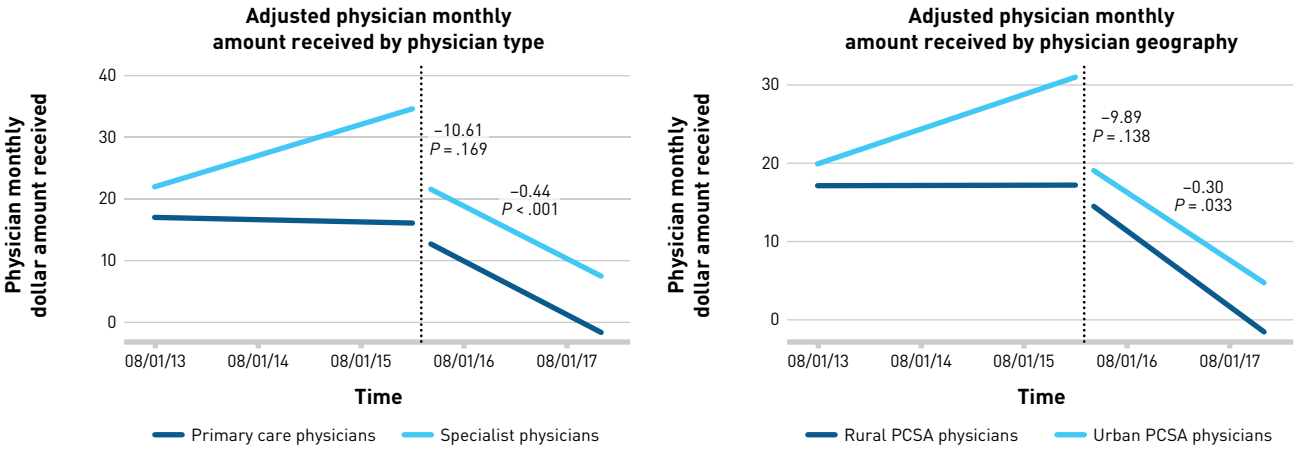
10.1% in rural PCSAs (**eAppendix Table 1** [eAppendix available at **ajmc.com**]). Seven pharmaceutical companies accounted for 91% of all opioid marketing encounters. The mean (SD) amount spent on meals and beverages on each encounter was $16.6 ($25.7), the mean (SD) monthly number of encounters per physician was 1.5 (3.9), and the mean (SD) total monthly spending per physician per month was $25.3 ($75.5).

The **Table** shows the association of total monthly opioid marketing spending per physician, monthly number of encounters per physician, and spending per opioid marketing encounter with the release of the CDC guidelines. Prior to the release of the CDC guidelines, the total monthly opioid marketing spending and monthly number of encounters per physician were increasing at a rate of $0.32 (95% CI, $0.14-$0.49; $P < .001$) and 0.03 (95% CI, 0.02-0.04; $P < .001$), respectively. Post release of the CDC guidelines, the change in total monthly opioid marketing spending and monthly number of encounters per physician decreased over time by $1.07 per month (95% CI, −$2.09 to $0.05; $P = .040$) and 0.08 encounters (95% CI, −0.14 to −0.02; $P = .008$) per month, respectively. The direction of the change remained the same using 1-month and 2-month washout periods post release of the CDC guidelines (eAppendix Table 1 and **eAppendix Table 2**). In contrast, before the release of the CDC guidelines, the amount spent per opioid marketing encounter on food and beverage was declining at a rate of $0.03 per month (95% CI, −$0.03 to −$0.02; $P < .001$). Post release of the CDC guidelines, there was an immediate increase in level of spending per encounter by $0.58 (95% CI, $0.49-$0.67; $P < .001$) and the change in amount of spending per encounter increased at a rate of $0.04 per month (95% CI, $0.03-$0.05; $P < .001$). The direction of the change remained the same using 1-month and 2-month washout periods post release of the CDC guidelines, even though the magnitudes of increase in spending were slightly higher (eAppendix Tables 1 and 2).

Also, physicians who received higher marketing spending per encounter also received more encounters (**Figure 1**). For example, in January 2014, the top 1% of physicians who received the highest payment per encounter accounted for 3.5% of all opioid marketing encounters. The top 5% accounted for 10.4% of all opioid marketing encounters (Figure 1).

We also found variations in the changes in opioid marketing practices post release of the CDC guidelines by physician specialty and geographic locations. The decline in total monthly opioid marketing spending and number of encounters per physician post release of the CDC guidelines was greater among specialist physicians than PCPs and in urban PCSAs than rural PCSAs (**Figure 2** and **Figure 3**). Post release of the CDC guidelines, the immediate increase in level of spending per encounter was greater among specialist physicians than PCPs by $0.32 (95% CI, $0.16-$0.48; $P < .001$); however, the rate of increase in amount of spending per encounter was lower among specialist physicians compared with PCPs by $0.02 per month (95% CI, −$0.03 to −$0.01; $P = .005$) (**Figure 4**). Likewise, post release of the CDC guidelines, the immediate increase in level of spending per encounter was greater in urban than rural areas by $0.26 (95% CI, $0.05-$0.46; $P = .014$); however, the rate of increase was lower in urban PCSAs compared with rural PCSAs by $0.02 per month (95% CI, −$0.04 to −$0.01; $P = .039$) (Figure 4).

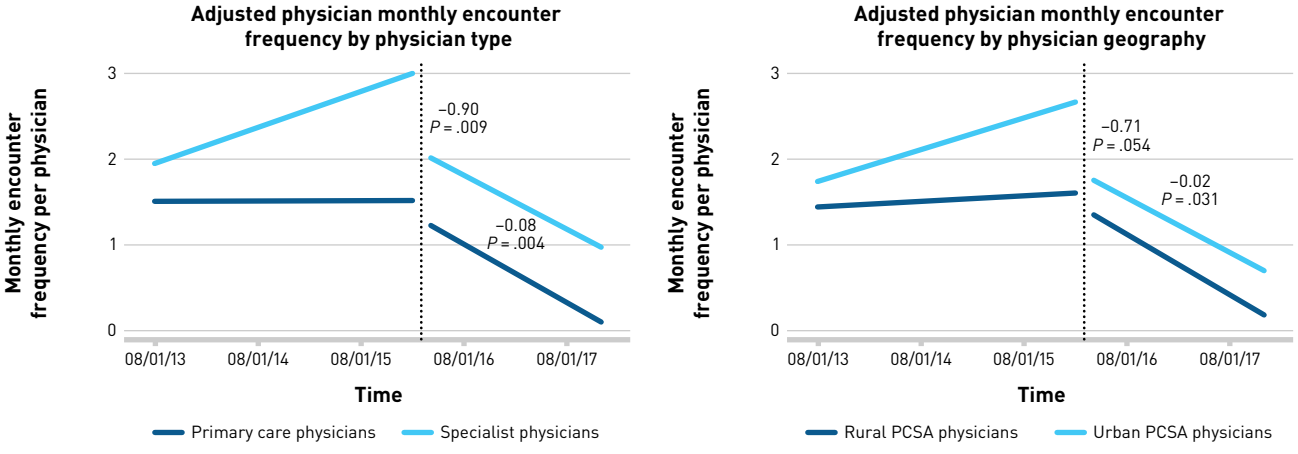
FIGURE 2. Differences in the Change in Physician Monthly Opioid Marketing Amount Received After Release of the CDC Guidelines: Primary Care vs Specialist Physicians, and Urban vs Rural PCSA Physicians[a]



PCSA, primary care service area.

[a]The release of the CDC guidelines in March 2016 is indicated by the dotted vertical line; differences in the change in intercept and changes in slope with corresponding *P* values after the CDC guidelines release are reported between groups.

FIGURE 3. Differences in the Change in Number of Physician Monthly Opioid Marketing Encounters After Release of the CDC Guidelines: Primary Care vs Specialist Physicians, and Urban vs Rural PCSA Physicians[a]



PCSA, primary care service area.

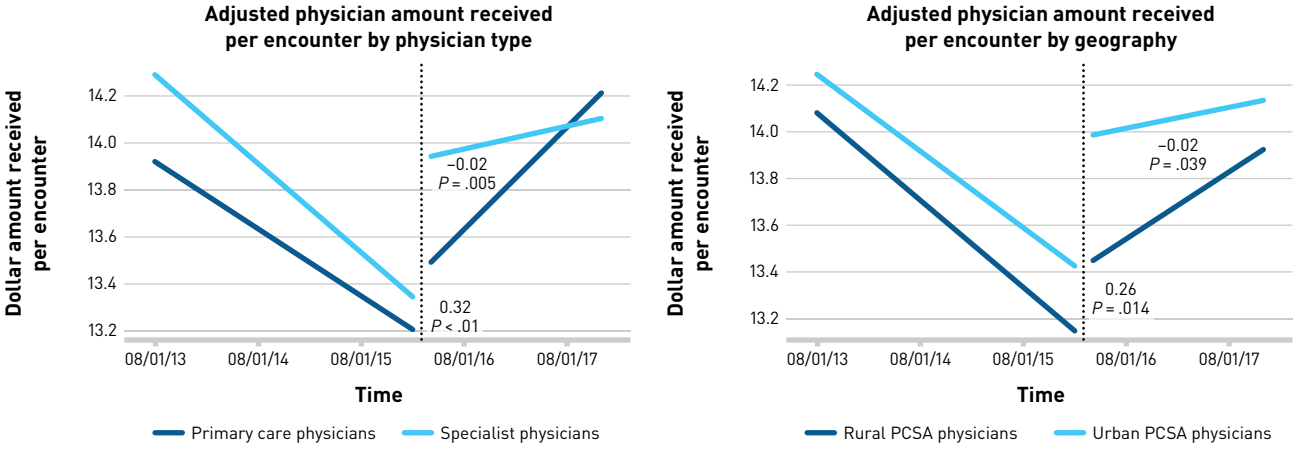
[a]The release of the CDC guidelines in March 2016 is indicated by the dotted vertical line; differences in the change in intercept and changes in slope with corresponding *P* values after the CDC guidelines release are reported between groups.

DISCUSSION

In this study that examined 684,343 non–research-related opioid marketing encounters involving food and beverages between August 2013 and December 2017, we found that post release of the CDC guidelines pharmaceutical companies reduced the total monthly amount spent on opioid marketing per physician and monthly number of opioid marketing encounters per physician. However, the amount spent on food and beverage per encounter increased. We also noted a shift in trend in prescription opioid marketing practices; before the release of the CDC guidelines, the amount spent per encounter on opioid marketing was declining, but post release of the guidelines, it started to increase.

In addition, we found that physicians who received higher marketing spending per encounter accounted for a disproportionately larger share of all encounters. This finding may be consistent with more focused marketing targeting of high-volume prescribers. For

FIGURE 4. Differences in the Change in Physician Amount Received per Opioid Marketing Encounter After Release of the CDC Guidelines: Primary Care vs Specialist Physicians, and Urban vs Rural PCSA Physicians[a]



PCSA, primary care service area.

[a]The release of the CDC guidelines in March 2016 is indicated by the dotted vertical line; differences in the change in intercept and changes in slope with corresponding *P* values after the CDC guidelines release are reported between groups.

example, in February 2021, a charge was brought against a large consulting company, alleging that it advised "opioid manufacturers to target prescribers who write the most prescriptions, for the most patients, and thereby make the most money."[47]

We also observed that the rate of change in spending per encounter post release of the CDC guidelines compared with before the release of the guidelines was significantly higher among PCPs than specialist physicians. The CDC guidelines targeted PCPs, and PCPs prescribe about half of all prescription opioids,[48,49] which may explain why they were more heavily targeted with a higher rate of opioid marketing spending per encounter post release of the CDC guidelines.

The rate of increase in marketing spending per encounter post release of the CDC guidelines was also significantly higher in rural than in urban PCSAs. Perhaps this is because rural areas have a higher rate of opioid prescriptions,[38,39] potentially making them more attractive for marketing spending per encounter.

Several studies' findings have shown that pharmaceutical opioid marketing targeted to physicians is associated with increases in opioid prescriptions by physicians receiving these payments.[30-33] It is important to continue ongoing education for physicians to increase their awareness of changes in pharmaceutical opioid marketing practices. Study findings have shown and suggested that educational interventions for physicians, as well as legislation that limits the value of gifts received by physicians, may be beneficial in addressing the potential influence of pharmaceutical opioid marketing on physician prescribing.[16,50,51]

Limitations

Our study focused on food and beverage encounters and did not evaluate other forms of pharmaceutical opioid marketing, such as spending on education, consulting fees, honoraria, and grants. Also, our analysis evaluates response to the CDC opioid guidelines at the national level and may not have accounted for some state-level policy changes on opioid prescribing during the study period. For example, in 2016, Massachusetts limited first-time opioid prescriptions to 7 days, and in 2017, Utah recommended that alternatives to opioid treatment should be tried before initiating opioid treatment.[52,53]

CONCLUSIONS

After the release of the CDC guidelines on opioid prescribing, total monthly amount spent per physician and monthly frequency of marketing encounters per physician decreased and instead the value of food and beverage gift items during each encounter increased. It is important to continue to educate physicians to maintain awareness of pharmaceutical opioid marketing practices. ■

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Authorship Information: Concept and design (ATT, PK-M, RW, MMJ, TB); acquisition of data (PK-M, TB); analysis and interpretation of data (ATT, PK-M, MMJ, TB); drafting of the manuscript (ATT, RW, MMJ, TB); critical revision of the manuscript for important intellectual content (ATT, PK-M, RW, MMJ, TB); statistical

analysis (ATT); obtaining funding (PK-M, TB); administrative, technical, or logistic support (PK-M, RW, MMJ, TB); and supervision (PK-M, TB).

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Practice Radiation Patterns Among Oncologists in the Oncology Care Model

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ABSTRACT

OBJECTIVES: CMS created the Oncology Care Model (OCM) to increase the delivery of cost-efficient cancer care, but in linking medical oncologist compensation to total costs of care, the model also prompted concerns about reductions in radiation therapy utilization. We compare practices that participated in the model with those that did not through its launch to estimate whether radiation therapy utilization was reduced under the OCM.

STUDY DESIGN: Retrospective analysis of a secondary claims-based data set.

METHODS: We used 5 years of reimbursement claims data from a large community oncology network in which approximately half of the practices participated in the OCM to measure the relative change in utilization following OCM participation compared with practices that did not participate in the OCM. We evaluated use of radiation therapy for all cancer diagnoses and, more specifically, bone metastases, lung cancer, and breast cancer to assess whether effects varied by setting using 3 quasi-experimental estimation techniques (difference-in-differences, event study, and triple differences regressions).

RESULTS: We found no evidence of reductions in radiation therapy utilization associated with the OCM between participant and nonparticipant practices in any of the specifications or subpopulations analyzed.

CONCLUSIONS: Despite the potential incentives for medical oncologists to reduce radiation therapy utilization, we found no evidence that such reduction occurred.

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CMS created the Oncology Care Model (OCM) under the Patient Protection and Affordable Care Act given the trajectory of Medicare cancer spending.[1,2] The model sought to drive care quality under the traditional fee-for-service system by adding an additional $160 Monthly Enhanced Oncology Services payment per chemotherapy-initiated episode to drive care coordination and an additional Performance-Based Payment (PBP) to drive cost efficiency within each episode.[3]

Although total-cost-of-care models such as the OCM have the appeal of cost predictability and containment through active utilization management, they also raise the possibility that medical oncologist gatekeepers may view the services of other specialists as a source of costs needing containment. The PBP incentives in the model underscore this concern. There is limited research concerning the OCM and radiation therapy, but episodes that involve radiation therapy within the OCM have been found to be generally more costly than those not involving radiation therapy.[4] The emerging literature on the OCM also suggests that the model led to modest reductions in care and costs. These effects include relative reductions in office-based care,[5] emergency department visits, intensive care unit episodes, end-of-life care,[6] and hospitalizations.[7-16] These reductions are consistent with similar models such as the Medicare Shared Savings Program,[17-19] the 2-sided Pioneer program,[20] the accountable care organization (ACO) Investment Model,[21] and other ACO models.[22,23]

In this study, we assess the extent to which radiation oncology referrals were affected by whether medical oncologists were participating in the OCM.

METHODS AND MATERIALS

Overall Research Approach

We combined reimbursement claims data from a large community oncology network in which approximately half of the practices participated in the OCM with 3 quasi-experimental regression specifications (difference-in-differences [DID], event study, and triple differences [DDD] methods) to evaluate whether the OCM

TAKEAWAY POINTS

- CMS created the Oncology Care Model (OCM) to increase the delivery of cost-efficient cancer care.
- However, the model prompted concerns about reductions in radiation therapy utilization because medical oncologist compensation was linked to total costs of care.
- We compared practices that participated in the model with those that did not through its launch to estimate whether radiation therapy utilization was reduced under the OCM.
- Despite the potential incentives for medical oncologists to reduce radiation therapy utilization, we find no evidence that such reduction occurred.

was associated with relative reductions in radiation therapy use. This allowed us to measure relative changes in care patterns before and after the OCM between contemporaneous participant and nonparticipant practices while accounting for changes common to all providers (eg, scientific advances, practice guideline changes) that are unrelated to the OCM. In each specification, we controlled for mean differences between OCM and non-OCM practices and individual providers (which controls for any group differences in behaviors such as referral patterns), the month of care, mean patient characteristics such as age and sex, mean share of patients treated with chemotherapy, number of Medicare patients and overall patients treated, and the number of physicians at a given practice. We also included practice-level trends.

Many oncologists follow accepted guidelines concerning radiation therapy,[24] but some cancers have less clear guidance, which allows for more individual provider discretion in whether to refer patients for radiation therapy.[25] Therefore, in addition to measuring potential effects of the OCM across all patients with cancer, we also looked at specific subgroups with relatively higher levels of discretion: those with bone metastases, lung cancer, and breast cancer. Cancer with bone metastases is a setting with relatively higher radiation therapy utilization, whereas breast cancer and lung cancer are settings in which radiation can be considered discretionary. For example, in an older woman with early breast cancer who is a candidate for breast conservation, radiation can be omitted.

Data and Study Population

The reimbursement claims data used in this study provide utilization measures from a large community oncology network that includes 14 practices that participated in the OCM and 16 practices that did not. In this setting, patients with advanced disease are largely under the primary care of a medical oncologist across the sample. As part of the same national network, these practices also share other similarities, such as financial integration between medical and radiation specialties, purchasing, staffing, pathways, and electronic health record and decision support systems. The data contain provider-by-month totals or means and span 5 years for care given between July 1, 2014, and June 30, 2019. One large outlier practice was excluded because of distinct preperiod patterns that would render the pre-OCM samples incomparable. This study was approved by the governing institutional review board under the exemption criteria.

Data Construction

The key outcome measure is utilization of radiation therapy services. This variable was defined by the presence of any 1 of the following Current Procedural Terminology codes: 77261, 77262, 77263. These codes identify treatment planning and represent a 1-time charge per course of therapy for varying levels of planning difficulty (ie, simple or "clearly defined," intermediate or "moderate level of planning difficulty," and complex treatment planning, respectively).[26] The unit for this outcome variable is the monthly mean number of unique billed radiation therapy services for a given physician. This is not whether a patient has ever received radiation care but rather the share of a physician's patients who received radiation care planning services in each month.

We analyzed potential changes in care patterns associated with the OCM on 4 subpopulations: all cancer diagnoses, bone metastases (defined as any of the following *International Classification of Diseases, Ninth Revision* [*ICD-9*] or *Tenth Revision* [*ICD-10*] codes: 198.5, C79.50-C79.52), lung cancer (defined as any of the following *ICD-9* or *ICD-10* codes: 162.3-162.9, C34.0-C34.9), and breast cancer (defined as any of the following *ICD-9* or *ICD-10* codes: 174.0-174.9, C50.0-C50.9). All cancers were included to provide visibility into the overall effects of the model, acknowledging that the OCM may lead to participants selecting different patients and biasing the comparison.[7] We then assessed potential care differences within the bone metastases, lung cancer, and breast cancer subpopulations both to avoid this potential selection bias and to identify potentially stronger effects given the relatively higher levels of discretion for radiation therapy among these subpopulations.

Statistical Analyses

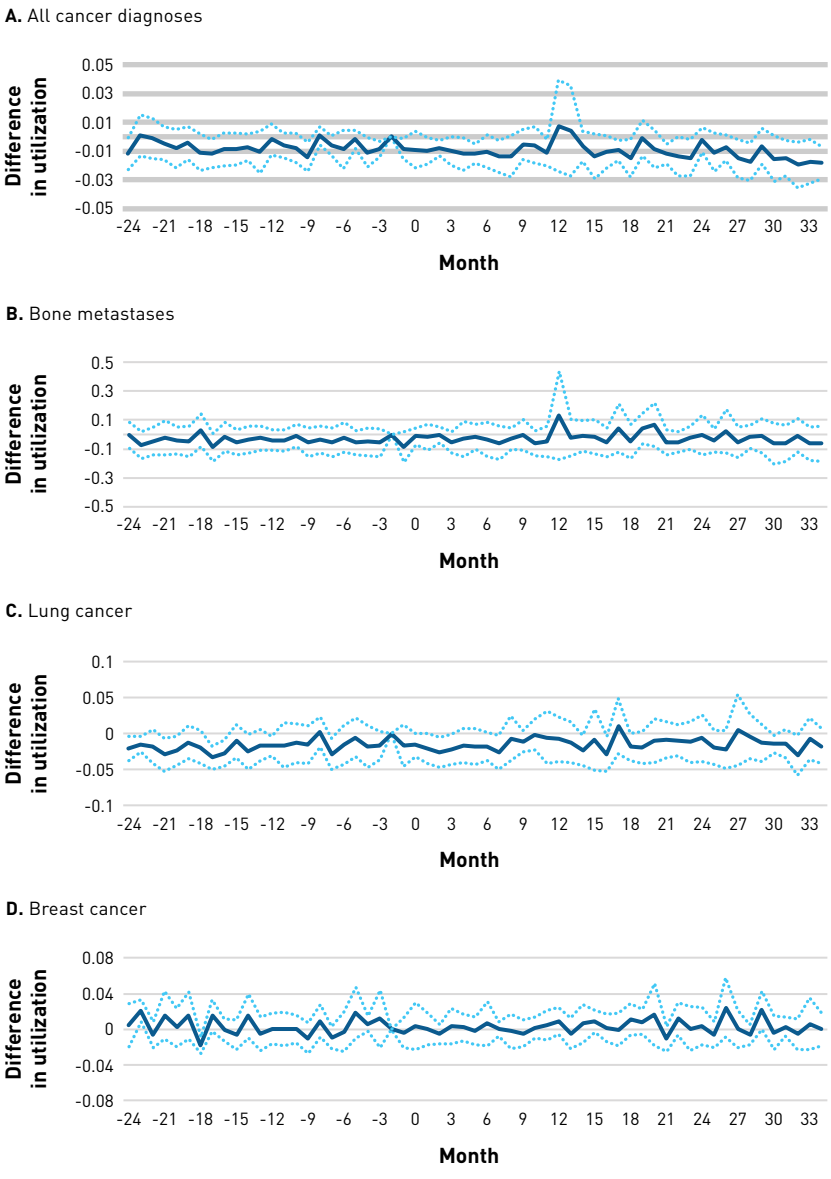
We utilized a DID model to estimate the average association of providing care at OCM-participating practices compared with nonparticipating practices across 2 years of preimplementation and 3 years of postimplementation periods. We also included 2 variations to the DID model: (1) an event study and (2) a DDD model. In all specifications, we controlled for mean differences between practices, providers, month, and monthly mean values for average patient age and age squared, mean share of female patients, mean share of chemotherapy-treated patients, total monthly number of patients and Medicare patients, and total number of physicians at a given practice. DID regressions also included group-specific linear time trends. Exact specifications are specified in the **eAppendix** (available at **ajmc.com**).

Whereas a DID model considers the average relative postlaunch vs prelaunch differences between OCM and non-OCM practices, an event study considers the relative monthly differences between OCM and non-OCM practices. Intuitively, the event study improves upon a simple plot of means by subtracting the non-OCM value from the OCM value for each period and controlling for potential

confounders through a multivariate regression. The estimates are then plotted with 95% CIs (as in the **Figure**) where statistically significant differences between OCM and non-OCM practices can be seen when a point estimate for a given period, along with its CI lower and upper limit values, are either all positive (for statistically significant positive estimates) or all negative (for statistically significant negative estimates). This allows us to assess 2 important considerations: (1) whether the OCM and non-OCM practices trended similarly in the preperiod (and thus may be suitable comparators) and (2) whether the OCM took time to induce practice pattern differences. In contrast, our DDD specification alters the DID model to assess the degree to which providers who see more Medicare patients may experience greater effects compared with providers with fewer Medicare patients. It is analogous to a dose-effect response in which more Medicare exposure corresponds with more OCM incentive exposure and induces stronger effects.

Finally, while the event study provides insights into potential differences in preperiod trends, we also assessed the extent to which the OCM is associated with different preperiod levels in the observable control characteristics listed above through a simple linear regression model (also specified in the eAppendix).

FIGURE. Event Study Plot for Radiation Therapy Use, by OCM Status[a]



OCM, Oncology Care Model.

[a]Dark lines are the connected estimates on OCM for each month. Dotted lines are connected 95% CIs. See Equation 2 in the eAppendix for exact specification.

RESULTS

Selection Bias Considerations

For each specific event study analysis of the cancer subgroups (ie, bone metastases, lung cancer, and breast cancer), most preperiod estimates are not statistically significant at the 90% confidence level and the plotted estimates are relatively flat, suggesting similar preperiod trends when accounting for mean patient characteristic differences (Figure). For the analysis of all cancer types, 7 of the 23 preperiod estimates are negative and statistically significant. However, this is driven by noise in the month prior to OCM launch in which the OCM mean plot increases and the non-OCM mean plot decreases from preperiod values. By instead omitting the preperiod variable for 2 months prior to the OCM where the OCM and non-OCM plots do not uncharacteristically diverge, only 3 preperiod (and 3 postperiod) estimates are statistically significant, supporting this noisy data concern. A similar pattern occurs for lung cancer that again disappears with changing the omitted period to 2 months prelaunch. These results are available upon request but can also be visualized by their flat plots in the Figure.

Finally, among the 11 observable control variables included in the regression, 2 estimates are statistically significant (OCM-participating providers saw patients who were on average 0.024 years older [95% CI, 0.001-0.046; $P = .04$] and provided 0.263 more units of radiation therapy services [95% CI, −0.010 to 0.536; $P = .06$]) (**Table 1**). At a 90% confidence level, one would expect slightly more than (but approximately) 1 statistically significant estimate.

TABLE 1. Preperiod Practice Attributes, by OCM Status[a]

Variable	Non-OCM (SD)	OCM (SD)	Estimate for OCM (95% CI)	*P*
Radiation	0.020 (0.085)	0.028 (0.114)	0.263* (−0.010 to 0.536)	.06
Age	70.8 (4.0)	71.2 (3.0)	0.024** (0.001-0.046)	.04
Female	0.577 (0.228)	0.562 (0.204)	−0.048 (−0.296 to 0.200)	.69
Chemotherapy treated	0.298 (0.248)	0.365 (0.239)	0.249 (−0.097 to 0.595)	.15
Number of patients	81.9 (58.5)	84.1 (53.4)	−0.001 (−0.005 to 0.003)	.63
Number of Medicare patients	26.4 (21.6)	30.7 (22.9)	0.002 (−0.007 to 0.012)	.63
Number of physicians	51.0 (30.7)	39.7 (16.2)	−0.004 (−0.014 to 0.006)	.43
Age squared	5028 (536)	5072 (403)	<0.001 (<0.001-<0.001)	.16
Breast cancer	0.144 (0.176)	0.156 (0.172)	0.103 (−0.176 to 0.382)	.45
Lung cancer	0.100 (0.132)	0.096 (0.105)	−0.089 (−0.413 to 0.236)	.58
Bone metastases	0.010 (0.043)	0.015 (0.046)	0.478 (−0.132 to 1.088)	.12
Observations	5086	8232	13,318	

OCM, Oncology Care Model.

*$P < .10$; **$P < .05$.

[a]An indicator variable for OCM participation was regressed against each variable under a single linear regression model. See Equation 4 in the eAppendix for exact specification.

TABLE 2. DD and DDD Estimates[a]

	All cancer diagnoses		Bone metastases		Lung cancer		Breast cancer	
Estimates	(1) DID	(2) DDD	(3) DID	(4) DDD	(5) DID	(6) DDD	(7) DID	(8) DDD
Treatment effect	<0.001	−0.009	0.031	−0.083	−0.006	−0.083	<0.001	0.034
95% CI	−0.008 to 0.009	−0.102 to 0.085	−0.051 to 0.113	−0.639 to 0.474	−0.016 to 0.004	−0.192 to 0.026	−0.010 to 0.010	−0.050 to 0.118
P	.87	.85	.45	.76	.21	.13	1.00	.42
Trends?	✓		✓		✓		✓	
N	39,781	39,781	10,946	10,946	28,316	28,316	29,727	29,727
Mean	0.024	0.024	0.098	0.098	0.024	0.024	0.023	0.023
Effect / mean	2.7%	−37.5%	31.7%	−84.7%	−25.4%	−346%	−0.1%	148%

DID, difference-in-differences; DDD, triple differences; OCM, Oncology Care Model.

[a]See equations 1 and 3 in the eAppendix for exact specification. For the DD estimates, the treatment effect is the estimate on the OCM*Post variable; for the DDD estimates, it is the estimate on the OCM*Post*Medicare variable.

Event Study

Given the 4 regression populations (including the populations with all cancer and lung cancer with 2 months prior to launch as the omitted reference variable), each with 36 postlaunch estimates (eg, a total of 144 estimates), only 7 estimates are statistically significant. This is about what one expects at random given a 95% confidence level. Although the practices themselves decided whether to participate in the OCM, their preperiod characteristics and trends appear to be comparable and the plots of these estimates also show little meaningful relative deviations from their respective comparison practices after OCM launch (Figure).

DID

Given that there are few statistically significant estimates in the event study specification, and that the DID model estimates average prelaunch vs postlaunch differences, there are no statistically significant estimates at the 90% confidence level. These results again hold when focusing only on observations with at least 1 unit of radiation therapy billed (results available upon request).

DDD

There are no statistically significant estimates in the DDD specification at the 90% confidence level—for full samples and samples only with at least 1 unit of radiation therapy billed—suggesting that variation in shares of Medicare patients (and thus OCM exposure) is not associated with different levels of radiation therapy use (**Table 2**).

DISCUSSION

Across all 4 patient populations, we found no evidence of relative reductions in radiation therapy use among participants in comparison with nonparticipant practices, suggesting that the OCM had little effect on in-network referred radiation therapy care. These results provide timely insights for providers and policy makers who continue to evaluate participation in and design of these models. Following the COVID-19 public health emergency, the Center for Medicare & Medicaid Innovation extended the model through June 2022 and included several flexibilities (eg, providing the option to forgo 2-sided risk arrangements, removal of COVID-19 episodes from PBP calculations, relaxed quality reporting).[27] CMS has further decided to indefinitely delay implementation of the Radiation Oncology Model, following stakeholder feedback.[28] This model sought to assess whether various payment models (ie, prospective, bundled, site-neutral, modality agnostic, or episodic models) reduce Medicare radiation therapy costs.[29-31] Other models that involve PBPs for both medical and radiation oncologists within the same model may yield different utilization patterns. However, our results suggest that medical oncologists in the OCM did not meaningfully alter their referral patterns.

Limitations

This research has several limitations. For one, we were unable to precisely identify more specific subpopulations with cancer in which

discretion over radiation therapy is at its highest or in which radiation therapy is most prevalent (eg, we assess breast cancer generally rather than stage I-III disease specifically). Thus, we relied upon the *ICD-9* and *ICD-10* systems to identify our subpopulations but recognize their shortcomings as coding systems. We attempted to identify the margins in which these effects would be most pronounced (eg, by assessing providers who see relatively more Medicare patients; by focusing on bone metastases, lung cancer, and breast cancer subpopulations; and by conditioning our analyses only on observations with at least 1 unit of radiation therapy billed). In all scenarios, we found no statistically significant effects. However, we recognize that there may be smaller subpopulations inaccessible to us in which the effects are most pronounced and measurable but otherwise muted among all other observations. Finally, we were unable to identify referrals occurring outside of the network. If this was the case most of the time or was more subject to reductions due to in-network vs out-of-network referral preferences, then our empirical approach would miss these important effects due to data limitations.

CONCLUSIONS

Overall, despite the potential incentives for medical oncologists to cut back on radiation therapy services, we found no evidence suggesting that the OCM was associated with reduced levels of radiation therapy. These estimates hold across several model specifications, and our results suggest that medical oncologists did not meaningfully alter radiation oncology services during the first few years of the OCM. ■

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Formulary Restrictions and Stroke Risk in Patients With Atrial Fibrillation

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ABSTRACT

OBJECTIVES: To determine the use of formulary restrictions (prior authorization and step therapy) on the use of non–vitamin K antagonist oral anticoagulants (NOACs) and their effect on health outcomes.

STUDY DESIGN: Longitudinal cohort study. We identified a sample of Medicare beneficiaries with an incident diagnosis of atrial fibrillation (AF) in 2011 to 2015 and followed them until the end of 2016 or death. We compared anticoagulant use and health outcomes associated with Medicare Part D plan coverage of NOACs.

METHODS: The primary outcomes were composite rates of death, stroke, transient ischemic attack, and systemic embolism. We used Cox proportional hazards models to estimate the association between formulary restrictions and adverse health outcomes.

RESULTS: Beneficiaries enrolled in Part D plans that restricted access to NOACs had a lower probability of NOAC use (30.2% vs 32.2%), worse adherence conditional on NOAC use (32.1% vs 34.3% adherent), and longer delays in filling an initial prescription (46% vs 55% filled within 30 days of AF diagnosis). Beneficiaries in restricted plans had higher aggregate risk of mortality/stroke/transient ischemic attack (adjusted HR, 1.098; 95% CI, 1.079-1.118).

CONCLUSIONS: Limiting access to NOACs may exacerbate current underuse of anticoagulants and increase the risk of stroke among patients with newly diagnosed AF. Pharmacy benefit managers and Part D plans need to continuously review the appropriateness of formulary policies to ensure patient access to effective medications.

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Historically, stroke risk in patients with atrial fibrillation (AF) has been lowered by treatment with warfarin sodium. First approved for use in humans in 1954, warfarin is both efficacious—it has been shown to reduce the risk of stroke by up to 70% in patients with AF—and inexpensive.[1,2] However, its use can be burdensome to patients because of numerous food and drug interactions requiring dietary and treatment restrictions and the need for ongoing laboratory testing and dose adjustment to achieve anticoagulant control. Consequently, patients taking warfarin are in the target therapeutic international normalized ratio range only about half of the time.[3,4]

Recently introduced non–vitamin K antagonist oral anticoagulants (NOACs)—including dabigatran, rivaroxaban, and apixaban—provide more convenient therapeutic options and have demonstrated equivalent or superior efficacy compared with warfarin.[5-9] However, NOACs are considerably more expensive and, until recently, lacked a reversal agent to mitigate the risk of life-threatening bleeding. Some health plans initially excluded NOACs from coverage or chose to restrict access to them through the use of prior authorization (PA) and step therapy (ST) requirements. Under PA, the health plan or pharmacy benefit manager must authorize a particular prescription before it can be covered. Under ST, also called "fail first," patients must try and fail to reach therapeutic target on a lower-cost alternative, in this case warfarin, before receiving authorization for the originally requested medication. Both PA and ST are designed to promote formulary compliance, reduce unnecessary prescription drug use, and lower costs, but if not used judiciously, they can induce patients to delay treatment, switch to less effective medications, or become nonadherent and, as a result, experience adverse health effects.[10-20]

Herein we examine the effect of the use of PA and ST on the utilization of NOACs among patients with newly diagnosed AF enrolled in Medicare Part D. We linked detailed, plan-level information on the coverage of NOACs in Part D plans to beneficiaries' medical and prescription drug claims. We tested the association between coverage restrictions and NOAC use, including initiation and adherence, and whether coverage restrictions were associated with elevated risk of stroke and bleeding.

TAKEAWAY POINTS

Non–vitamin K antagonist oral anticoagulants (NOACs) were documented to be equivalent or superior to warfarin at reducing stroke risk in patients with atrial fibrillation. Mixed findings have been reported on the impact of step therapy and prior authorization on patients' medication use and health outcomes across various drug classes.

- Step therapy and prior authorization policies were associated with reduced NOAC use and higher stroke rates among patients with new atrial fibrillation in Medicare.
- Pharmacy benefit managers and Medicare Part D plans need to continuously review the appropriateness of formulary policies to ensure patients' access to effective medications.

METHODS

Data

Through a reuse agreement with the National Bureau of Economic Research, we used data for a 20% random sample of fee-for-service Medicare beneficiaries. We linked data on enrollment, demographics, and parts A (inpatient), B (outpatient), and D (pharmacy) claims for patients with newly diagnosed AF from 2010 to 2016. Inpatient and outpatient medical claims provided information on *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) diagnosis codes (*International Classification of Diseases, Tenth Revision, Clinical Modification* [*ICD-10-CM*] codes were included beginning October 2015) and Current Procedural Terminology procedure codes, dates of service, and spending. Part D claims provided information related to prescription drug claims, including National Drug Code, fill dates, and days supplied. Enrollment and claims data were supplemented with claim histories from the Chronic Conditions Data Warehouse, which identifies incident dates of diagnosed chronic health conditions and cardiovascular risk factors.

We linked the Part D claims to the plan characteristics file, which provided detailed information on each plan's formulary, benefit design, and utilization management policies, including PA and ST. We used this information to identify the formulary restrictions and cost-sharing requirements for each NOAC in the plan-year. To adjust for other aspects of plan quality, we linked the plan characteristic file with the annual Part D star performance rating provided by CMS.[21] Star ratings, which range from 1 to 5, were designed to provide summary measures of how well Part D plans perform in terms of customer service, member experience, drug pricing, and patient safety.

Study Sample

The study sample consisted of beneficiaries with an incident diagnosis of AF (*ICD-9-CM* diagnosis code 427.31 or *ICD-10-CM* codes I48.0-I48.2, I48.91) between 2010 and 2015, based on at least 1 inpatient or 2 outpatient or carrier claims (**eAppendix Table 1** [eAppendix available at **ajmc.com**]). We excluded patients who died or had a stroke within 30 days of the index AF diagnosis and defined the index date as the date of the first AF medical claim (inpatient or outpatient). We required at least 1 year of follow-up data unless the patient died within 364 days of the index AF diagnosis. We also required enrollment in a fee-for-service Medicare plan for at least 1 year before the incidence date to capture the health history. We excluded beneficiaries enrolled in Medicare Advantage plans due to incomplete capture of medical claims and those enrolled in a Part D plan through an employer because CMS waives Part D formulary submission requirements for these plans. Finally, we excluded patients with valvular heart disease, end-stage chronic kidney disease, kidney transplant, dialysis, or hip or knee replacement surgery with a diagnosis of deep vein thrombosis or pulmonary embolism at any point during the study sample (**eAppendix Table 2**).

We categorized Part D plans into 2 groups based on their coverage of NOACs. Plans were defined as unrestricted if 1 or more NOACs were available without PA/ST and as restricted if all NOACs were subject to PA/ST or not covered by the plan (by 2013, all prescription drug plans covered at least 1 NOAC). We excluded a small number of beneficiaries who switched from an unrestricted to a restricted plan or vice versa after their AF diagnosis. The final study sample included 139,041 patients with incident AF, 36% of whom (n = 50,596) were enrolled in restricted plans.

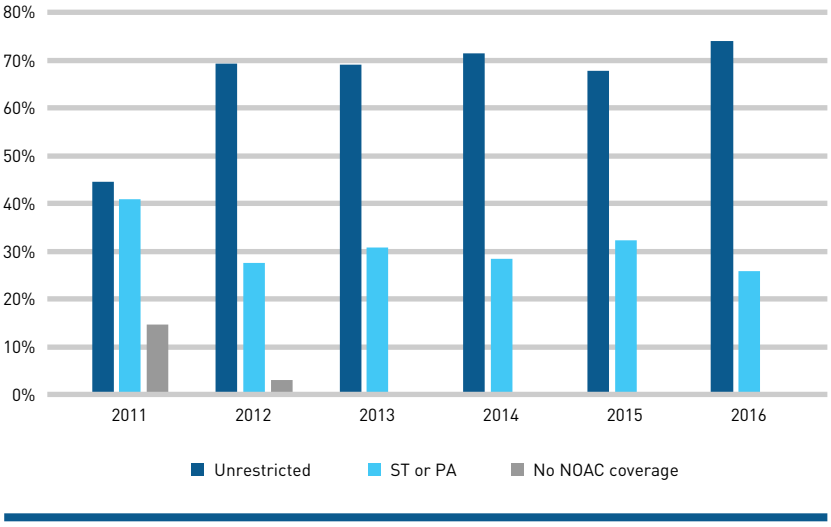
Statistical Analyses

To estimate the direct impact of PA/ST on medication use, we counted the number of anticoagulant prescription fills (30-day equivalent) 1 year before the index date and after diagnosis for patients in restricted and nonrestricted plans. To control for differences in beneficiaries' cardiovascular risk and other characteristics that may influence anticoagulant use, we compared the medication adherence of patients in restricted plans vs those in unrestricted plans using multivariate logistic regression. The key independent variable was a binary indicator for a restricted plan as defined earlier. Other independent variables included beneficiary demographics (age, sex, race/ethnicity) and binary indicators for AF incidence year to control for time trends. Race/ethnicity was determined using the beneficiary race code in enrollment data from CMS and by applying an algorithm developed by the Research Triangle Institute that improves identification of Hispanic and Asian individuals based on name. To adjust for patients' socioeconomic status, we linked enrollment and claims data from their AF incidence year to zip code–level data on household income and education from the American Community Survey. We also controlled for 27 comorbid conditions identified in the Chronic Conditions Data Warehouse (**eAppendix Table 3**). These included binary indicators for previous diagnosis of stroke, acute myocardial infarction, congestive heart failure, hypertension, and diabetes (full model results are available from the corresponding author). To control for plan quality, we calculated the beneficiary-level mean star rating since incident diagnosis and created a binary variable indicating mean star rating above the median.

We also examined the association between formulary restrictions and clinical outcomes. The primary outcome was the composite risk of death or stroke, including ischemic stroke, hemorrhagic stroke, and transient ischemic attack (TIA). The secondary outcome was major bleeding, including gastrointestinal bleeding, intracranial bleeding, and bleeding from other sites. To focus on acute events, outcomes were identified using only inpatient or emergency department medical claims (see eAppendix Table 1 for associated *ICD-9-CM* and *ICD-10-CM* codes). We plotted unadjusted Kaplan-Meier curves of unadjusted rates of all-cause mortality, stroke, or TIA for patients in restricted vs unrestricted plans. We grouped patients into 3 subgroups based on their CHA_2DS_2-VASc (congestive heart failure, hypertension, age ≥ 75 years, diabetes, stroke, vascular disease, age 65-74 years, sex category) scores at AF incidence date (≤ 3, 4-5, or ≥ 6), and we used Cox proportional hazards models to test the association between PA/ST and all-cause mortality, stroke, and bleeding for each subgroup. Cox regressions included the same set of covariates as the logistic regression models for medication use.

We ran several additional analyses to assess whether patients at higher cardiovascular risk differentially enrolled in less restrictive plans and whether the magnitude of effects we observed were consistent with clinical trial data. First, we predicted rates of NOAC use and stroke by plan type (**eAppendix Table 4**). Second, we estimated the association between anticoagulant use and adverse health outcomes for a subsample of patients without a history of anticoagulant use before their incident AF date (**eAppendix Table 5**). Finally, we compared predicted stroke rates using observed differences in NOAC use in the present sample with the effect sizes reported from clinical trial data (**eAppendix Table 6**).

FIGURE 1. Use of Formulary Restrictions on NOACs in Stand-alone Medicare Part D Plans, 2011-2016, Weighted by Enrollment



NOAC, non–vitamin K antagonist oral anticoagulant; PA, prior authorization; ST, step therapy.

TABLE 1. Summary Characteristics of Medicare Part D Plans With and Without Restrictions on NOACs[a]

Characteristic	Unrestricted plans (n = 5002)	Restricted plans (n = 1344)
Unique medications on plan formulary, n	1139	1234
Covered medications subject to ST or PA, %	21.1	21.2
Enhanced alternative plans, %	30.1	43.4
Mean star rating	3.34	3.26
Plans rated ≤ 2.5 stars, %	15.8	9.7
Plans rated 3-3.5 stars, %	62.7	77.1
Plans rated ≥ 4 stars, %	20.7	13.3

NOAC, non–vitamin K antagonist oral anticoagulant; PA, prior authorization; ST, step therapy.
[a]Stand-alone Part D plans, 2011-2016, weighted by enrollment.

RESULTS

Coverage of NOACs

Figure 1 reports the prevalence of formulary restrictions in our sample of Part D plans. Warfarin accounted for 94% of anticoagulant prescriptions for patients with AF in 2011 and remained the most frequently prescribed anticoagulant throughout the study period, although its share of use fell to 62% by 2016 (**eAppendix Figure 1**). The steady increase in NOAC prescriptions coincided with a decline in formulary restrictions. In 2011, 44% of plans covered NOACs without restrictions, 41% imposed PA or ST, and the remaining 15% excluded NOACs from the formulary altogether. However, by 2013 all the plans in the sample covered at least 1 NOAC, and the percentage of Part D plans imposing PA or ST decreased to 31% in 2013 and to 26% by 2016.

Importantly, unrestricted plans were similar to restricted plans in their coverage of all other medications (**Table 1**). The number of unique medications included in the formulary of restricted plans was similar to that in unrestricted plans (1234 and 1139, respectively), as was the fraction of formulary drugs subject to PA or ST (21% in both plan types). Unrestricted plans had slightly higher mean star ratings (3.34 vs 3.26, respectively) and were more likely to receive a star rating of 4 or higher (20.7% vs 13.3%, respectively) than restricted plans.

Anticoagulant Use

A primary concern when using observational claims data to assess health outcomes is that plan choice may be correlated with

TABLE 2. Sample Characteristics of Medicare Beneficiaries Enrolled in Restricted and Unrestricted Plans, 2011-2015

Characteristic	Plan-year coverage of NOACs		
	Unrestricted (n = 88,445)	Restricted or off formulary (n = 50,596)	*T* test for equal means (*P*)
Demographics			
Mean age in years at incidence date	76.5	77.8	<.001
Male sex, %	43.0	42.0	<.001
Race/ethnicity, %			
White	85.8	89.1	<.001
Black	6.31	4.72	<.001
Asian	1.71	1.37	<.001
Hispanic	4.21	3.30	<.001
Other	1.96	1.56	<.001
Socioeconomic status (zip code–level mean)			
Household income, median, $	54,598	58,359	<.001
High school graduate, %	78.5	79.8	<.001
Bachelor's degree, %	20.9	23.2	<.001
Mean star rating (1-5 stars)	3.44	3.30	<.001
Mean CHA_2DS_2-VASc score	4.39	4.49	<.001
CCW history of cardiovascular risks, %			
Acute myocardial infarction	8.56	8.52	.796
Heart failure	46.5	46.1	.199
Ischemic heart disease	65.1	66.9	<.001
Stroke/transient ischemic attack	21.7	22.2	.029
Hypertension	90.9	91.9	<.001
CCW history of other comorbidities, %			
AD	8.51	8.42	.561
AD-related disorders, senile dementia	20.4	20.0	.027
Anemia	62.5	65.4	<.001
Asthma	18.1	18.2	.815
Benign prostate hyperplasia	19.6	21.3	<.001
Cancer, breast	5.95	7.09	<.001
Cancer, colorectal	3.88	4.18	.007
Cancer, endometrial	1.16	1.19	.723
Cancer, lung	2.70	3.13	<.001
Cancer, prostate	5.74	6.67	<.001
Cataract	70.5	73.7	<.001
Chronic kidney disease	34.2	33.9	.287
Chronic obstructive pulmonary disease	38.4	38.2	.352
Depression	37.8	35.6	<.001
Hip/pelvic fracture	5.29	5.65	.004
Hyperlipidemia	82.2	84.8	<.001
Hypothyroidism	27.6	29.4	<.001
Osteoporosis	25.1	27.6	<.001
Rheumatoid arthritis/osteoarthritis	62.5	64.2	<.001

(continued)

unobserved factors that affect medication use and outcomes, including health status. Given the similarities in restricted and unrestricted plans aside from their coverage of NOACs, it is not surprising that we found little evidence that beneficiaries differentially enrolled in the 2 plan types (Table 2). Beneficiaries in restricted plans were slightly older (1 year) at the time of their incident AF diagnosis and were less likely to be male and non-White, but they had similar rates of acute myocardial infarction, heart failure, heart disease, stroke, and TIA before their AF diagnosis.

Beneficiaries enrolled in unrestricted plans had modestly higher rates of NOAC use (32.2% vs 30.2% in restricted plans) and lower, but not statistically significantly different, use of warfarin (32.9% vs 33.3%, respectively). Conditional on NOAC use, beneficiaries in unrestricted plans had higher adherence rates (34.3% vs 32.1%) and shorter delays in filling an initial prescription. More than 55% of those in unrestricted plans filled their first NOAC within 30 days of AF diagnosis compared with 46% in restricted plans.

Regression results shown in Table 3 indicate that patients in restricted plans had lower use of NOACs. They had lower odds of receiving a NOAC (odds ratio [OR], 0.961; 95% CI, 0.937-0.986) after an initial AF diagnosis but no statistically significant difference in warfarin use. Plan-level differences in NOAC use varied markedly by race/ethnicity, with lower use among Black (OR, 0.786; 95% CI, 0.695-0.890), Hispanic (OR, 0.864; 95% CI, 0.753-0.993), and Asian (OR, 0.772; 95% CI, 0.625-0.955) individuals in restricted plans compared with White individuals. The association between formulary restrictions and NOAC use was more pronounced for those at higher risk of stroke, with lower use of NOACs among those at intermediate (CHA_2DS_2-VASc score of 4 or 5: OR, 0.942; 95% CI, 0.907-0.978) and high (CHA_2DS_2-VASc score ≥6: OR, 0.926; 95% CI, 0.879-0.977) stroke risk.

Health Outcomes

Figure 2 plots the cumulative incidence of mortality/stroke/TIA by plan type. Kaplan-Meier estimates of the composite risk of death, stroke, and TIA within 500, 1000, 1500, and 2000 days after the index date (defined as 30 days after the AF incidence date) were 21.9%, 37.7%, 51.0%,

and 62.4%, respectively, for beneficiaries in restricted plans compared with 20.2%, 34.9%, 46.4%, and 55.4%, respectively, for beneficiaries in unrestricted plans. In multivariate Cox regression analyses, patients in restricted plans also had higher risk of mortality/stroke/TIA (adjusted HR, 1.098; 95% CI, 1.079-1.118) (Table 3). Bleed rates were also higher, with an adjusted HR of 1.046 (95% CI, 1.014-1.079).

Table 3 reports adjusted HRs of adverse outcomes by sex, race, and CHA_2DS_2-VASc subgroups over a range of clinical end points (ischemic and hemorrhagic strokes, TIAs, and bleeding). The association between formulary restrictions and composite risk of death, stroke, and TIA was slightly stronger for women (OR, 1.102; 95% CI, 1.078-1.128) compared with men (OR, 1.091; 95% CI, 1.060-1.122) and for Black patients (OR, 1.139; 95% CI, 1.062-1.222) compared with White patients (OR, 1.091; 95% CI, 1.071-1.112). We also found that the impact of PA/ST was greater for hemorrhagic stroke (OR, 1.109; 95% CI, 1.020-1.206) relative to ischemic stroke (OR, 1.082; 95% CI, 1.026-1.142) and for intracranial bleeds (OR, 1.103; 95% CI, 1.011-1.203) relative to gastrointestinal bleeding (OR, 1.030; 95% CI, 0.994-1.068) in the full sample.

TABLE 2. (*Continued*) Sample Characteristics of Medicare Beneficiaries Enrolled in Restricted and Unrestricted Plans, 2011-2015

Characteristic	Plan-year coverage of NOACs		
	Unrestricted (n = 88,445)	Restricted or off formulary (n = 50,596)	*T* test for equal means (*P*)
Use of anticoagulants: since AF incidence date, %			
NOACs	32.2	30.2	<.001
Proportion of days covered	57.2	56.9	.278
Proportion of adherent anticoagulant use	34.3	32.1	<.001
Filled first NOAC claim in ≤30 days[a]	55.5	46.1	<.001
Warfarin only	25.3	26.0	.004
Proportion of days covered	59.6	57.4	<.001
Proportion of adherent users	33.7	30.3	<.001
Filled first claim in ≤30 days[b]	60.2	58.9	.105
Use of anticoagulants: 1 year before AF incidence date, %			
NOACs	8.05	6.09	<.001
Proportion of days covered	19.2	21.7	<.001
Warfarin only	0.17	0.16	.062
Proportion of days covered	34.7	32.4	<.001
All-cause mortality rate, %	34.4	39.9	<.001
Stroke and bleeding, %			
Stroke	5.17	5.88	<.001
Ischemic	3.99	4.54	<.001
Hemorrhagic	1.61	1.88	<.001
Transient ischemic attack	4.59	5.23	<.001
Major bleeding	15.2	16.2	<.001
Intracranial	1.70	1.93	.003
Gastrointestinal	11.8	12.4	.001
Other	2.73	2.97	.011

AD, Alzheimer disease; AF, atrial fibrillation; CCW, Chronic Conditions Data Warehouse; CHA_2DS_2-VASc, congestive heart failure, hypertension, age ≥ 75 years, diabetes, stroke, vascular disease, age 65-74 years, sex category; NOAC, non–vitamin K antagonist oral anticoagulant.

[a]New NOAC users only (n = 18,332).

[b]New warfarin users only (n = 15,865).

DISCUSSION

We studied the association between formulary restrictions on the use of NOACs and associated clinical outcomes among Medicare beneficiaries with an incident diagnosis of AF. Although formulary restrictions have been shown to reduce use of the targeted drug or medical service, there is some concern that substitution to an alternative therapy is often incomplete.[11-16] The present results seem to validate this concern in the case of AF, as we found that restricting access to NOACs by either requiring PA/ST or not covering them at all reduced the likelihood of using these medications by approximately 2 percentage points (PP) and lowered overall anticoagulant use by 1.3 PP among Medicare beneficiaries with incident AF. In addition, formulary restrictions reduced mean adherence rates by 2.2 PP among NOAC users and reduced the probability of filling a first prescription within 30 days of AF incidence by 9.1 PP among new NOAC users. Lower use and delayed initiation of NOACs were associated with elevated risks of stroke and bleeding, consistent with data from clinical trials and other observational studies.

These findings are particularly concerning given that anticoagulants are substantially underused in community practice.[22] A recent initiative to improve outpatient cardiac care in the United States found that only 60% of patients at high thromboembolic risk ($CHADS_2$ [congestive heart failure, hypertension, age ≥ 75 years, diabetes, stroke] score ≥ 2) were treated with warfarin or NOACs.[23] A retrospective analysis of more than 94,000 patients with an acute ischemic stroke who had a known history of AF found that 84% did not receive guideline-recommended therapeutic anticoagulation preceding the stroke or had anticoagulation levels that were not in the therapeutic range.[4] Our results suggest that limiting access to NOACs may exacerbate the underuse of anticoagulants and increase the risk of stroke and bleeding for those at high thromboembolic risk. These findings are particularly germane to women with AF, who are at greater risk when taking warfarin, and minority groups, for whom NOACs are relatively underprescribed.[24-26]

Although common, the use of PA, ST, and other utilization management strategies is controversial. Health plans and pharmacy

TABLE 3. Associations Between Restricted Access to NOACs and Anticoagulant Use and Clinical Outcomes, Overall and by Patient Subgroup[a]

Access to NOACs: ST/PA vs unrestricted	Medication use		Clinical outcomes							
	Any NOAC use	Any warfarin use	Any of: died, stroke, or TIA	All-cause mortality	Ischemic stroke	Hemorrhagic stroke	TIA	Major bleeding	Intracranial	Gastrointestinal
All patients										
	0.961*** (0.937-0.986)	0.988 (0.963-1.013)	1.098*** (1.079-1.118)	1.115*** (1.095-1.137)	1.082*** (1.026-1.142)	1.109** (1.020-1.206)	1.081*** (1.028-1.136)	1.046*** (1.014-1.079)	1.103** (1.011-1.203)	1.030 (0.994-1.068)
Patient subgroups										
Male sex (n = 59,273)	0.983 (0.946-1.022)	1.002 (0.963-1.042)	1.091*** (1.060-1.122)	1.110*** (1.078-1.144)	1.087* (0.994-1.190)	1.125* (0.987-1.282)	1.094** (1.007-1.188)	1.037 (0.989-1.087)	1.157** (1.016-1.316)	1.003 (0.948-1.062)
Female sex (n = 79,769)	0.943*** (0.912-0.975)	0.977 (0.944-1.010)	1.102*** (1.078-1.128)	1.119*** (1.092-1.146)	1.080** (1.011-1.155)	1.097* (0.983-1.224)	1.073** (1.008-1.142)	1.051** (1.008-1.095)	1.055 (0.938-1.187)	1.048** (1.001-1.097)
White (n = 120,958)	0.983 (0.957-1.009)	0.977* (0.950-1.004)	1.091*** (1.071-1.112)	1.106*** (1.084-1.128)	1.077** (1.016-1.142)	1.116** (1.019-1.222)	1.088*** (1.031-1.147)	1.040** (1.006-1.076)	1.118** (1.017-1.229)	1.022 (0.983-1.062)
Black (n = 7970)	0.786*** (0.695-0.890)	1.139** (1.021-1.271)	1.139*** (1.062-1.222)	1.170*** (1.087-1.260)	0.999 (0.827-1.207)	0.988 (0.701-1.394)	1.113 (0.910-1.363)	1.067 (0.948-1.202)	0.988 (0.689-1.418)	1.067 (0.935-1.218)
Hispanic (n = 2202)	0.864** (0.753-0.993)	1.093 (0.949-1.258)	1.084* (0.987-1.191)	1.124** (1.017-1.242)	1.101 (0.854-1.418)	1.019 (0.675-1.539)	1.022 (0.789-1.322)	1.150* (0.984-1.345)	1.196 (0.808-1.771)	1.159 (0.968-1.388)
Asian (n = 2520)	0.772** (0.625-0.955)	1.003 (0.785-1.281)	1.265*** (1.088-1.470)	1.351*** (1.150-1.588)	1.17 (0.801-1.708)	1.171 (0.649-2.115)	0.829 (0.512-1.340)	1.101 (0.853-1.421)	0.892 (0.483-1.647)	1.047 (0.782-1.401)
CHA_2DS_2-VASc score ≤3 (n = 42,154)	0.998 (0.954-1.044)	0.986 (0.938-1.036)	1.146*** (1.098-1.195)	1.169*** (1.118-1.224)	1.125* (0.984-1.285)	1.104 (0.917-1.330)	1.094 (0.969-1.234)	1.037 (0.971-1.108)	1.149 (0.950-1.390)	1.021 (0.945-1.103)
CHA_2DS_2-VASc score of 4 or 5 (n = 60,960)	0.942*** (0.907-0.978)	0.976 (0.940-1.014)	1.083*** (1.055-1.112)	1.110*** (1.079-1.141)	1.04 (0.959-1.128)	1.092 (0.965-1.235)	1.022 (0.946-1.103)	1.044* (0.997-1.093)	1.064 (0.936-1.209)	1.033 (0.979-1.089)
CHA_2DS_2-VASc score ≥6 (n = 35,927)	0.926*** (0.879-0.977)	0.992 (0.944-1.043)	1.090*** (1.059-1.123)	1.094*** (1.061-1.129)	1.100** (1.011-1.197)	1.128 (0.976-1.304)	1.130*** (1.045-1.223)	1.052* (0.995-1.112)	1.122 (0.964-1.306)	1.032 (0.970-1.099)

AF, atrial fibrillation; CHA_2DS_2-VASc, congestive heart failure, hypertension, age ≥75 years, diabetes, stroke, vascular disease, age 65-74 years, sex category; NOAC, non–vitamin K antagonist oral anticoagulant; PA, prior authorization; ST, step therapy; TIA, transient ischemic attack.

*P < .10; **P < .05; ***P < .01.

[a]Models adjust for patient demographics, comorbidities, zip code–level income and education, mean plan star rating, and year of AF diagnosis. The key independent variable is a binary indicator for continuous enrollment in a restricted plan since incident AF diagnosis. Table displays odds ratios of anticoagulant use and HRs of clinical outcomes, with 95% CIs in parentheses.

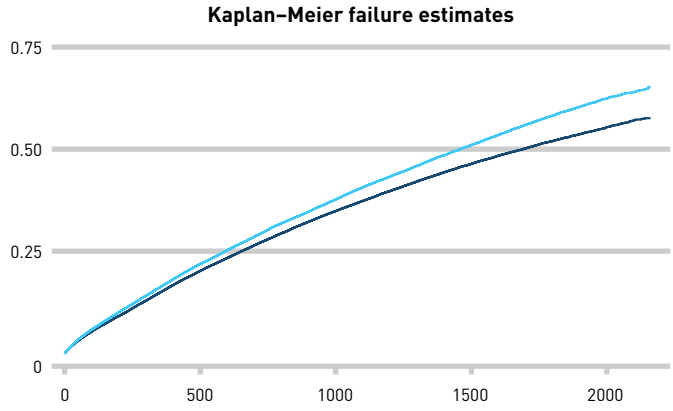
benefit managers contend that the PA process reduces waste and unnecessary use. However, physicians often object that these policies are overused, impose administrative burden, and undermine their clinical decision-making.[27] In addition, physicians, pharmaceutical manufacturers, and patient advocates argue that these policies can induce patients to delay treatment, switch to less effective medications, or become nonadherent in some cases and, as a result, experience adverse health effects. The evidence on this is mixed; some studies find that PA, ST, and other restrictions lead to nonadherence and worse health outcomes,[9-14] whereas others find no effects.[15-17] Although encouraging the use of less expensive alternatives in a therapeutic class may be warranted in many contexts, our study highlights a particular class in which PA/ST may be harmful to patients.

A recent economic analysis comparing apixaban with warfarin found that apixaban was clinically superior for patients with AF and was cost-effective by current US norms but not cost-saving.[28] This exemplifies the near-universal trade-off between cost and quality resulting from medical innovation. Medicare and most commercial health insurance plans typically base coverage decisions of new medical technologies on evidence of effectiveness rather than on cost-effectiveness or any other direct measure of value.[29] Yet the continued growth in health care spending heightens pressure on manufacturers to demonstrate the clinical and economic value of their products. Broad and increasing use of formulary restrictions raises concern that there are other therapies besides NOACs for which restricting access may be clinically and/or economically counterproductive.

Limitations

This study has several limitations. Because Part D is a voluntary program, these results may be biased if beneficiaries at higher

FIGURE 2. Cumulative Failure Rate of the Composite Outcome of Death, Stroke, and Transient Ischemic Attack by Formulary Restriction on NOACs[a]



Number at risk					
Unrestricted	88,445	62,624	31,389	12,455	2151
Restricted	50,596	35,359	18,447	7966	1635

NOAC, non–vitamin K antagonist oral anticoagulant; PA, prior authorization; ST, step therapy.
[a]The index date is 30 days after incident diagnosis of atrial fibrillation.

cardiovascular risk are more likely to enroll in plans that restrict access to potentially more effective, higher-cost therapies. We found no evidence that Medicare beneficiaries differentially enrolled in Part D plans based on the coverage of NOACs. Furthermore, the goal of this study was not to evaluate the efficacy of the medications, which has been well established in clinical trials, but rather to assess how plan-level policies designed to restrict access to these drugs affected medication use and clinical outcomes in real-world populations. These questions can be answered only by observational studies.

Because we relied on medical claims, we lacked clinical detail such as the type of AF, ejection fraction, and smoking histories. Observational studies using registries and single-center electronic medical records typically provide more clinical detail than those relying on administrative data. In addition, we restricted the analyses to stand-alone Part D prescription drug plans due to the lack of medical claims for Medicare Advantage and Part D plans. The latter may have stronger financial incentives to provide generous drug coverage if keeping enrollees healthy leads to savings in medical costs.

CONCLUSIONS

PA and ST policies are most effective when there is clear evidence that a service is being overused or misused and when patient safety and cost implications indicate that it is helpful or appropriate. Nonetheless, their use can be costly for payers, manufacturers, physicians, and patients. A recent study estimated that drug utilization management costs $93.3 billion annually in the United States.[30] Given the administrative and economic burden on providers and the risk to patients, it may be more effective to identify and educate outlier physicians rather than impose these policies on all providers and their patients. All payers, not just Part D sponsors, need to continuously review the use and appropriateness of formulary policies to ensure that beneficiaries have access to clinically beneficial medications. ■

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The Impact of HDHPs on Service Use and Spending for Substance Use Disorders

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ABSTRACT

OBJECTIVES: Although high-deductible health plans (HDHPs) reduce health care spending, higher deductibles may lead to forgone care. Our goal was to determine the effects of HDHPs on the use of and spending on substance use disorder (SUD) services.

STUDY DESIGN: We used difference-in-differences models to compare service use and spending for treating SUD among enrollees who were newly offered an HDHP relative to enrollees offered only traditional plan options throughout the study period.

METHODS: We used deidentified commercial claims data from OptumLabs (2007-2017) to identify a sample of 28,717,236 person-years (2.2% with a diagnosed SUD). The main independent measure was an indicator for being offered an HDHP. The main dependent measures were the probability of (and spending associated with) using SUD services and specific treatment types.

RESULTS: Enrollees were 6.6% ($P < .001$) less likely to use SUD services after being offered an HDHP relative to the comparison group. Reductions were concentrated in inpatient, intermediate, and ambulatory care, as well as medication use. Being offered an HDHP was associated with a decrease of 21% ($P < .001$) on health plan spending and an increase of 14% ($P < .01$) on out-of-pocket spending.

CONCLUSIONS: Offering an HDHP was associated with a reduction in SUD service use and a shift in spending from the plan to the enrollee. In the context of the US drug epidemic, these study findings highlight a concern that the movement toward HDHPs may be exacerbating undertreatment of SUD.

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Enrollment in high-deductible health plans (HDHPs) is increasing rapidly, with 22% of covered workers enrolled in a plan with an annual deductible exceeding $2000 in 2019.[1] Proponents of HDHPs argue that higher cost sharing incentivizes enrollees to "shop" for care. Detractors argue that cost sharing is a blunt instrument and reduces utilization across the board. Indeed, HDHPs have been shown to reduce health care spending,[2,3] but higher deductibles encourage consumers to forgo care in the short term,[4-6] leading to adverse outcomes in the long term. Previous research on HDHPs suggests that vulnerable populations, including those with chronic conditions whose health outcomes are tied to continuing, uninterrupted care, are at the greatest risk of negative consequences in response to higher cost sharing.[7]

This evidence on HDHPs raises concerns about potential negative effects for individuals with substance use disorders (SUDs) because these conditions are most effectively managed as chronic conditions with longer time in treatment leading to better outcomes,[7,8] often co-occur with mental illness and other chronic medical conditions,[9] and can be costly.[10] Furthermore, given that SUD is vastly undertreated,[11] that only about 10% of individuals with SUD treatment needs receive treatment,[12] and that access to evidence-based SUD treatments (eg, medications for opioid use disorder) is severely limited in many communities,[13-15] the shift toward HDHPs might be creating further barriers to SUD diagnosis and treatment. Prior descriptive work has found suggestive evidence that HDHPs are associated with lower rates of emergency department and hospital use, as well as higher out-of-pocket (OOP) costs for individuals with SUD.[16,17] However, selection bias makes it difficult to draw causal inferences from comparisons of individuals enrolling in HDHPs with enrollees of traditional, low-deductible plan choices because the decision to enroll may be nonrandom: HDHP enrollees are known to be, on average, younger and healthier.[18]

Importantly, increases in drug- and alcohol-related mortality have made connecting individuals with evidence-based SUD treatment a national priority. From 1999 to 2017, more than 700,000 Americans died from drug overdoses,[19] and drug-related deaths have contributed to declines in life expectancy over the past 3 years.[20,21]

In this context, it is critical to understand how health insurance design choices may be facilitating or deterring access to lifesaving treatments for SUD. We aimed to evaluate whether the decision of an employer to offer an HDHP was associated with use of health care services to treat SUD and spending on these services. Our use of an intent-to-treat design to examine how a firm's decision to offer an HDHP affects SUD service use and spending (rather than directly examining outcomes for those choosing to enroll in HDHPs) minimizes concerns about individual nonrandom selection into HDHPs vs traditional health plans. We also examine whether any changes in SUD spending attributable to HDHPs are borne primarily by the health plan or by enrollees in the form of OOP payments.

TAKEAWAY POINTS

- Although high-deductible health plans (HDHPs) reduce health care spending, higher deductibles may lead to forgone care.
- This is of concern for individuals with substance use disorders (SUDs) because these conditions are undertreated and often co-occur with other chronic conditions.
- We find that enrollees were 6.6% less likely to use SUD services after being offered an HDHP relative to the comparison group. Reductions were concentrated in intermediate care, ambulatory care, and medication use.
- Being offered an HDHP was associated with a decrease of 21% on health plan spending and an increase of 14% on out-of-pocket spending.
- In the context of the US drug epidemic, these study findings highlight a concern that the national movement toward HDHPs may be exacerbating undertreatment of SUD.

METHODS

Data

We used deidentified administrative claims data from the OptumLabs Data Warehouse from 2007 to 2017. The database includes enrollment records for commercial enrollees, medical (including behavioral health) and pharmacy claims, benefit design information, and a blinded firm identifier. Each firm identifier distinguished groups within a firm with a shared plan offering. Firms that offered the same choice set of plans to all employees had a single identifier, whereas firms that offered different choice sets to different groups of employees were assigned different identifiers for each group.

Sample Identification

We constructed our sample in several steps. First, we began with individuals with a valid deductible and medical, pharmacy, and mental health coverage (ie, behavioral health coverage falls under the same deductible). We required enrollees to be enrolled for at least 11 months of their plan year and limited enrollees to be aged between 12 and 64 years. Next, we selected continuous spans of time for each firm, eliminating firms with large changes in firm size (ie, changed by ± 50% between consecutive years; this resulted in an exclusion of 2% person-years) given that large swings in enrollment from year to year might indicate that many enrollees switched to a different insurance carrier that is unobserved in our data.

To define the treatment group, we categorized 369,239 firms as those offering HDHPs by calculating the percentage of enrollees at that firm enrolled in an HDHP in that year. Treatment firms were characterized by having at least 2 years with less than 5% HDHP enrollment immediately followed by having greater than 5% HDHP enrollment in all subsequent years (11% of firms). This threshold is arbitrary by nature but has support in prior literature.[2,5] We chose it as a number that would be high enough to signal that a nontrivial number of enrollees actually had the opportunity to enroll, but low enough not to exclude firms with low uptake. This threshold allows us to identify a more plausibly generalizable treatment group, with enrollment in an HDHP in the postperiod treatment group ranging from 5% enrolled to 100% enrolled. Comparison firms were defined as those having 0% HDHP enrollment for all years in which the firm is found in the data (35% of firms). We omitted enrollees affiliated with other types of firms, such as those always offering an HDHP (**eAppendix A** [eAppendices available at **ajmc.com**]).

Identification of Enrollees With SUD

For our spending analyses, we focused on a population coded as having an SUD based on having at least 1 medical claim with an SUD diagnosis in any of the diagnosis code positions, following prior research.[22,23] Enrollees having claims meeting this criterion during the time in which they were at a treatment or comparison firm were designated as having an SUD for the remainder of the study period. This particularly sensitive SUD sample selection criterion was intended to minimize potential bias due to reduced use of services associated with HDHPs.[2,24] We identified SUD diagnosis codes with *International Classification of Diseases, Ninth Revision, Clinical Modification* codes 291, 292, 303, 304, and 305 (excluding 305.1 [tobacco use disorder] and 305.8 [antidepressant abuse]) and *Tenth Revision* codes F10-F19 (excluding F17.2x [tobacco use disorder]).

Measures

The key independent variable in our analysis was a binary indicator of whether an enrollee was associated with a firm that *offered* an HDHP. For this measure, we defined a plan as an HDHP if its shared medical and pharmacy deductible (or sum of medical and pharmacy deductible) met the Internal Revenue Service definition in that calendar year. This cutoff changes by calendar year but averaged $1232 over the study period for individual plans and $2427 for family plans.[25] Traditional plans were defined as plans that did not meet this threshold.

The main dependent variables were measures of SUD service use and spending conditional on use overall and disaggregated into specific treatment types including inpatient, emergency department, intermediate (inclusive of residential, partial

hospitalization, and intensive outpatient), ambulatory, and medication. Nonmedication services were identified using procedure (Current Procedural Terminology and Healthcare Common Procedure Coding System), revenue, and American Medical Association place-of-service codes having an SUD diagnosis code (defined above) as the primary diagnosis on the medical claim. SUD emergency department use also included overdoses. SUD inpatient use required 50% or more of hospital facility claims to have a primary diagnosis of SUD or a diagnosis of an overdose. Intermediate and ambulatory SUD services were identified if the SUD diagnosis was the primary diagnosis or the second diagnosis when accompanied by a primary diagnosis for a mental health condition. Ambulatory SUD services also included Screening, Brief Intervention, Referral to Treatment and medication administration procedure claims, agnostic of diagnosis codes. Medication use was identified from pharmacy claims for alcohol use disorder (AUD) and opioid use disorder (OUD) medications and medical claims for administration of AUD and OUD medications.

To avoid double-counting, nonmedication services occurring on the same day were attributed to the highest level of care on that day (eg, claims meeting criteria for an ambulatory SUD service but occurring on the day of SUD intensive outpatient treatment were attributed to the intermediate category). Medication administration spending was attributed to the highest level of care on that day, whereas pharmacy spending was captured separately (**eAppendix B**).

Spending was categorized by OOP, health plan, and total spending (the sum of OOP and health plan spending) by aggregating values within an enrollee-year. Negative dollar amounts were coded as zeroes (0.001% of enrollee-years) and spending was top-coded at the 99.9th percentile in each calendar year. Spending was examined conditional on use in the associated category.

Enrollee-level covariates included age, sex, race/ethnicity (Asian, Black, Hispanic, White, or unknown), family size, Census block household income (ie, < $40,000; ≥ $40,000 and < $75,000; ≥ $75,000 and < $125,000; ≥ $125,000 and < $200,000; > $200,000; or unknown), Census block–level education (ie, less than high school, high school, some college, bachelor's or more, or unknown), and Census division. Income, race/ethnicity, and education were estimated based on personal identifying information linked to a mix of proprietary sources for OptumLabs. The Chronic Conditions Warehouse was used to construct 47 condition indicators included as covariates.[26]

Statistical Analyses

We analyzed the effects of offering an HDHP on SUD service use and spending outcomes using a 2-way fixed effects difference-in-differences study design. We included preperiod data before a firm began offering an HDHP to control for differences in individual characteristics that varied across firms but might be correlated with our outcome measures. To control for secular trends, we also included, as a comparison group, enrollees at firms that never offered an HDHP. Our empirical approach compared changes in SUD service use and spending over time between treatment group enrollees who are offered an HDHP and comparison group enrollees who have not yet been offered an HDHP. The unit of analysis was the person-year. The HDHP variable indicated whether the enrollee's firm offered an HDHP in a given calendar year and was coded as zero for all years in firms that never offered an HDHP. Models included the individual-level covariates listed above and calendar year and firm fixed effects. For probability of service use outcomes (entire sample), we estimated ordinary least squares (OLS) regressions. For spending outcomes (SUD sample), we estimated OLS regressions on a logged dependent variable, to account for skew. In all models, SEs were clustered at the firm level to account for unobservable correlations within each firm. All analyses were conducted in Stata 16 MP (StataCorp LLC). This study was approved by the institutional review board of the Johns Hopkins Bloomberg School of Public Health.

The key assumption for our analyses was that, absent the firm offering an HDHP, enrollees at firms in the treatment group would have had trends in SUD service use and spending consistent with the trends seen in enrollees at firms in the comparison group. Although this assumption is ultimately untestable, 3 pieces of evidence gave us confidence in this assumption. First, we evaluated differences across treatment and comparison groups and across study year trends using standardized mean differences (SMDs) and found that 98% of covariate SMDs fell below 0.1, a commonly used threshold for evaluating covariate balance (**eAppendix C**).[27] Firm-level characteristics were also similar across groups (**eAppendix D**), and we observed no differential selection into the sample (**eAppendix E**). Second, unadjusted rates of our outcome variable (SUD service use) had fairly similar levels and trends across groups in the preperiod (**eAppendix F.1**). Third, when we explicitly tested for preperiod differences in trends prior to HDHP offer, we found no statistically significant differences (**eAppendix F.2**). Given new advances in difference-in-differences methodology, we also estimated stratification models analyzing treatment heterogeneity over time (**eAppendix G**).

Our analytic approach relied on discrete changes in the fraction of a firm's enrollees enrolled in an HDHP, requiring a sharp cutoff to identify when a firm began offering an HDHP. As described above, we used a 5% threshold in our main analyses based on prior research.[2,5] In sensitivity analyses, alternative thresholds were used. As noted above, we restricted our analysis to firms that had a stable size year to year, using a greater than 50% turnover cutoff. In sensitivity analyses, alternative cutoffs were used.

RESULTS

Table 1 displays unadjusted enrollee characteristics in the treatment and comparison groups across the pre- and post periods. **Table 2** shows unadjusted rates of SUD use and spending across service type. Overall, unadjusted rates of SUD use and spending increased from the preperiod to the post period but at a slower rate in the treatment group relative to the comparison group. This is consistent with prior evidence showing that HDHPs do not decrease spending but, instead, slow the growth in spending.[2,3] Mean annual deductibles

TABLE 1. Unadjusted Descriptive Characteristics of Enrollees Offered and Not Offered an HDHP Across Person-Years, 2007-2017[a]

	Full sample				Diagnosed with substance use disorder			
	Offered HDHP		Not offered HDHP		Offered HDHP		Not offered HDHP	
Characteristic	Preperiod	Post period	Preperiod	Post period	Preperiod	Post period	Preperiod	Post period
Age in years, mean (SD)	38.3 (14.5)	38.2 (14.7)	38.0 (14.3)	38.0 (14.6)	38.0 (14.1)	38.9 (14.3)	38.0 (14.1)	38.6 (14.3)
Sex, %								
Male	47.7	49.0	49.9	50.7	61.1	60.1	62.4	61.8
Female	52.3	51.0	50.1	49.3	38.9	39.9	37.6	38.2
Race/ethnicity, %								
White	63.5	60.9	63.1	59.2	67.3	65.5	67.7	63.4
Black	12.1	11.2	9.5	9.6	10.2	10.1	9.2	9.9
Hispanic	9.0	8.8	11.0	11.2	8.2	7.8	8.7	9.3
Asian	4.7	5.5	4.4	5.1	1.7	1.8	1.7	1.8
Missing/unknown	10.7	13.6	12.0	14.9	12.5	14.9	12.7	15.6
Count of chronic conditions, mean (SD)	0.6 (1.1)	0.5 (1.1)	0.5 (1.1)	0.6 (1.1)	1.0 (1.6)	1.0 (1.6)	1.0 (1.6)	1.0 (1.6)
Full sample, n	6,343,122	8,188,748	8,154,427	6,030,939	109,506	232,125	160,794	142,031

HDHP, high-deductible health plan.

[a]Includes selected sample characteristics for the treatment group (offered HDHP) and comparison group (not offered HDHP), before and after HDHP offer. To construct comparison group means, we took the weighted average of comparison group characteristics across calendar years and weighted by how often those calendar years appear in the treatment sample during the pre- and post periods. Chronic conditions are derived from the Chronic Conditions Warehouse. Count includes number of chronic conditions, ranging from 0 to 21. Full sample characteristics and covariate balance statistics are available in the eAppendix C Table.

TABLE 2. Unadjusted SUD Service Use and Spending Among Enrollees Offered and Not Offered an HDHP Across Person-Years, 2007-2017[a]

	Offered HDHP		Not offered HDHP	
Use and spending	Preperiod	Post period	Preperiod	Post period
Probability of SUD service use				
Any SUD inpatient use, %	3.9	3.6	3.7	3.9
Any SUD emergency department use, %	7.9	5.3	8.7	6.7
Any SUD intermediate use, %	6.7	4.9	6.7	5.6
Any SUD ambulatory use, %	23.2	15.6	22.2	18.0
Any SUD medication, %	8.8	7.0	8.8	8.0
Annual spending on SUD services conditional on use in $, mean (SD)				
SUD spending	4689 (13,058)	6955 (20,136)	4658 (11,444)	6425 (17,618)
SUD inpatient spending	10,740 (15,212)	12,573 (18,447)	10,783 (15,917)	11,661 (16,729)
SUD emergency department spending	1501 (2507)	1960 (2712)	1407 (2116)	1794 (2501)
SUD intermediate spending	6323 (11,786)	10,472 (17,284)	5901 (8557)	9216 (14,674)
SUD ambulatory use spending	619 (1217)	680 (1592)	606 (1289)	678 (1555)
SUD pharmacy spending	1516 (2128)	1736 (2485)	1581 (2073)	1891 (2486)
Diagnosed with SUD, n	109,506	232,125	160,794	142,031

HDHP, high-deductible health plan; SUD, substance use disorder.

[a]Includes outcome measures for probability of SUD service use and average annual spending on SUD services, conditional on use for the treatment group (offered HDHP) and comparison group (not offered HDHP), before and after HDHP offer. To construct comparison group means, we took the weighted average of comparison group characteristics across calendar years and weighted by how often those calendar years appear in the treatment sample during the pre- and post periods.

showed similar trends prior to HDHP offer, with a large, expected increase in the treatment group after HDHP offer (**eAppendix H**).

Table 3 indicates that the adjusted probability of using any SUD services increased after treatment group enrollees were offered an HDHP; however, this increase was smaller relative to the change in the comparison group (–0.04 percentage points [PP]; $P < .001$), implying a 6.6% reduction in the probability of using SUD services after the treatment group is offered an HDHP relative to otherwise similar enrollees who continued to be offered only traditional health plan choices by their employer (full model results in **eAppendix I**).

Among the study population with an SUD diagnosis, we found no differences in mean total spending on SUD services among

TABLE 3. Adjusted Probability of SUD Service Use and Spending Conditional on Use Among Enrollees With SUD Offered and Not Offered an HDHP[a]

Probability and spending	Preperiod	Post period	Change in value attributable to HDHP offer
Probability of SUD service use (n = 28,724,702)	**%**		**Percentage points (95% CI)**
Probability of use			
Employer offered an HDHP	0.65	0.76	−0.04 (−0.07 to −0.02)
Employer did not offer an HDHP	0.68	0.83	
SUD spending conditional on use (n = 197,155)	**$**		**$ (95% CI)**
Total spending			
Employer offered an HDHP	1052	1258	13 (−52 to 82)
Employer did not offer an HDHP	1060	1249	
Out-of-pocket spending			
Employer offered an HDHP	168	215	24 (9-41)
Employer did not offer an HDHP	169	190	
Health plan spending			
Employer offered an HDHP	655	588	−138 (−178 to −96)
Employer did not offer an HDHP	662	746	

HDHP, high-deductible health plan; OLS, ordinary least squares; SUD, substance use disorder.

[a]Results from the first model (probability of use of SUD services) estimated from an OLS regression model and results from the spending models are from an OLS regression model with a logged dependent outcome variable. Changes in spending are computed using percent changes acquired from the OLS model multiplied by the adjusted preperiod mean. Plans were defined as HDHPs if their deductible met the Internal Revenue Service definition of an HDHP (varies by year; ~$1200). Control firms had 0% of enrollees having an HDHP in all years. Treatment firms had less than 5% HDHP take-up in the preperiod years and greater than 5% HDHP take-up in the postperiod years. SUD treatment service spending was based on medical (including behavioral) and pharmacy claims. Covariates include age, gender, family size, 9-level Census division, race/ethnicity indicators, household income, median education at the Census block level, non–behavioral health co-occurring conditions, calendar year fixed effects, and firm fixed effects. Data are for years 2007-2017. Full model results are available in eAppendix I.

treatment group enrollees offered an HDHP relative to comparison group enrollees who continued to be offered only traditional health plan options. However, enrollees in the treatment group had larger increases in OOP spending on SUD services ($168 to $215, pre- to post) relative to the comparison group ($169 to $190, pre- to post), resulting in higher annual OOP spending averaging $24 ($P < .01$). In contrast, mean spending on SUD services paid for by health plans decreased for treatment group enrollees ($655 to $588, pre- to post) relative to comparison group enrollees ($662 to $746, pre- to post), resulting in $138 ($P < .001$) lower mean annual per-enrollee spending by HDHPs (full model results in eAppendix I).

Figure 1 shows that there was a decrease in the probability of enrollees with SUD diagnoses using inpatient SUD services (−0.30 PP; $P = .01$), intermediate SUD services (−0.50 PP; $P = .006$), ambulatory SUD services (−1.70 PP; $P < .001$), and guideline-recommended medications to treat SUD (−0.38 PP; $P = .029$) attributable to being offered an HDHP.

Similarly, as shown in **Figure 2** (focused on the population with SUD diagnoses), both emergency department spending and ambulatory SUD spending by health plans decreased by annual means of $137 and $23, respectively, in HDHPs relative to traditional plans.

Our key robustness checks found no qualitative changes when we varied the HDHP enrollment threshold used to identify the treatment group or when we varied the maximum allowed change in year-to-year firm size (**eAppendix J**).

DISCUSSION

Offering an HDHP was associated with a 0.04-percentage-point lower probability of using SUD services, implying a 6.6% reduction from baseline service use. These reductions were driven by reductions in use of intermediate and ambulatory services and medication treatment for SUD. Overall, we did not find differences in total spending among SUD service users but did find a shift in costs from the insurer to the patient. These changes in SUD treatment rates and spending were consistent with prior literature on HDHPs in other clinical contexts.[2-6] Although small in magnitude, these estimates are clinically relevant because SUD is vastly undertreated.[11]

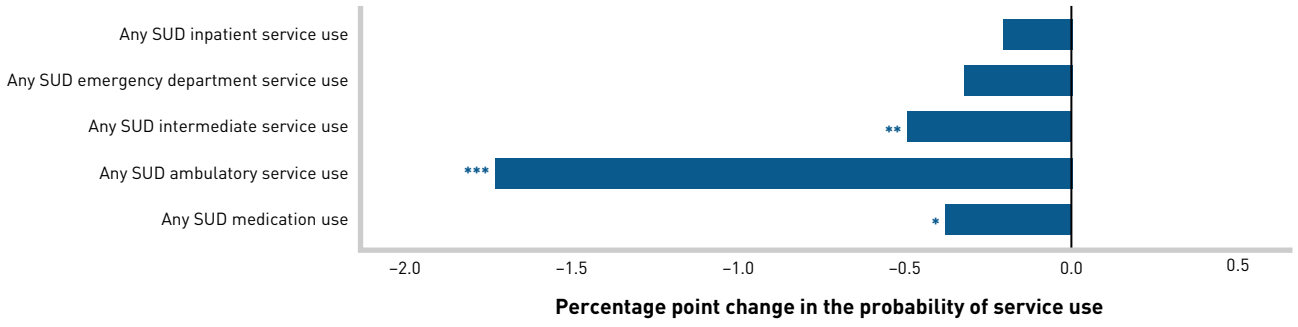
Our results have several important implications. First, the financial barriers imposed by HDHPs were associated with lowered SUD treatment rates. This is especially concerning given the already low rates of treatment in this population and the high morbidity and mortality associated with SUD. When evaluating the costs and benefits associated with switching employees to an HDHP, individuals should consider the potential increased costs for SUD treatment, and plan benefit managers should be cognizant of the financial implications for their enrollees with SUD.

Second, our results suggest that the effects are driven by reductions in inpatient, intermediate, ambulatory, and medication use, with no effects on emergency department use. This is not surprising, as demand for emergency care is more inelastic than intermediate, ambulatory, or medication use. However, these findings are in contrast to the public health policy goal for improving SUD care—that is, more robust use of ambulatory care (rather than just receiving episodic inpatient or emergency care) and also of evidence-based AUD and OUD medication.[15,28] Thus, even in the context of HDHPs, financial and administrative barriers to accessing ambulatory care and SUD medications should be as low as possible. For OUD, for example, all 3 FDA-approved medications should be offered and be included in preferred formulary tiers without prior authorization or cost sharing.[29-31]

Limitations

This study is subject to several important limitations. First, although our analysis uses a rigorous analytic approach, our results are still based on observational data and not a randomized controlled trial. We took steps to mitigate this concern, including taking advantage of the exogenous HDHP offer (rather than relying on individual selection decisions) and by carefully analyzing preperiod trends

FIGURE 1. Percentage-Point Change in the Probability of Use of Different Types of SUD Services Attributable to Being Offered an HDHP[a]

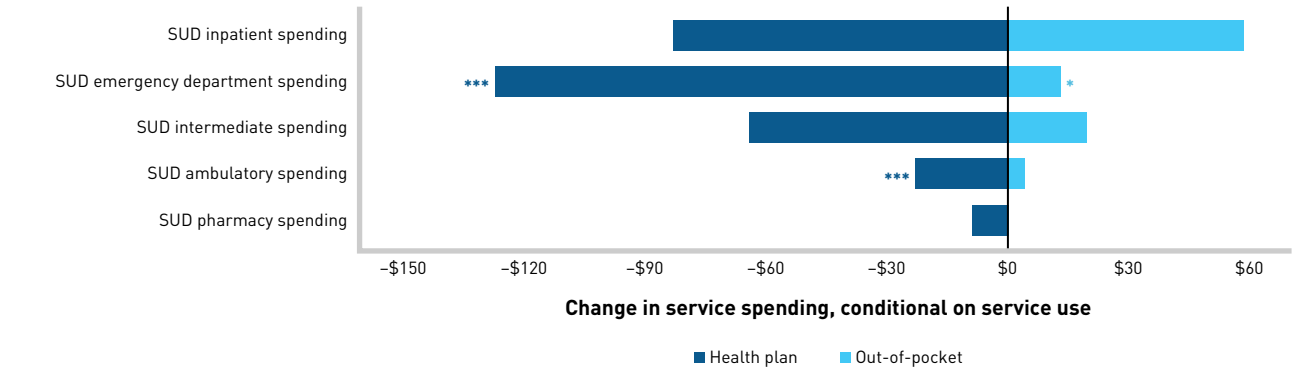


HDHP, high-deductible health plan; OLS, ordinary least squares; SUD, substance use disorder.

*$P < .05$; **$P < .01$; ***$P < .001$.

[a]Results from OLS regression models. Plans were defined as HDHPs if their deductible met the Internal Revenue Service definition of an HDHP (varies by year; ~$1200). Control firms had 0% of enrollees having an HDHP in all years. Treatment firms had less than 5% HDHP take-up in the preperiod years and greater than 5% HDHP take-up in the postperiod years. Spending was based on medical (including behavioral) and pharmacy claims. Covariates include age, gender, family size, 9-level Census division, race/ethnicity indicators, household income, median education at the Census block level, non–behavioral health co-occurring conditions, calendar year fixed effects, and firm fixed effects. Data are for years 2007-2017.

FIGURE 2. Change in SUD Spending Conditional on Use of Specific Types of Services Attributable to Being Offered an HDHP[a]



HDHP, high-deductible health plan; OLS, ordinary least squares; SUD, substance use disorder.

*$P < .05$; ***$P < .001$.

[a]Results from OLS regression models with a logged dependent outcome variable. Plans were defined as HDHPs if their deductible met the Internal Revenue Service definition of an HDHP (varies by year; ~$1200). Control firms had 0% of enrollees having an HDHP in all years. Treatment firms had less than 5% HDHP take-up in the preperiod years and greater than 5% HDHP take-up in the postperiod years. Spending was based on medical (including behavioral) and pharmacy claims. Covariates include age, gender, family size, 9-level Census division, race/ethnicity indicators, household income, median education at the Census block level, non–behavioral health co-occurring conditions, calendar year fixed effects, and firm fixed effects. Data are for years 2007-2017.

(eAppendix F). Second, although the data have broad national coverage, they have a higher proportion of enrollees in the South and Central regions and thus our results may not be generalizable to the broader employer-sponsored market. Although prior studies have used similar data to evaluate the effects of HDHPs, this remains a limitation.[32,33] Our analysis focuses on stable employers with stable enrollment over time, but we are unable to observe what happens to employees who switch to a plan offered by a different insurer and may be missing important variation. Third, our data do not include important information about networks or consumer-facing tools that may have been rolled out to employees at the same time as HDHP adoption. Some studies on the effects of HDHPs have had more institutional knowledge about other tools, but the fact that they analyze a single employer may limit generalizability.[24]

CONCLUSIONS

Offering an HDHP led to a 6.6% reduction in the probability of using SUD services and a shift in spending from the plan to the enrollee. In the context of the US drug epidemic, our findings highlight a

concern that the national movement toward enrollment in HDHPs may be exacerbating the undertreatment of SUD. ■

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Turnover Among New Medicare Advantage Enrollees May Be Greater Than Perceived

Jeffrey Dong, MD; Alan M. Zaslavsky, PhD; John Z. Ayanian, MD, MPP; and Bruce E. Landon, MD, MBA

ABSTRACT

OBJECTIVES: To characterize the proportion of Medicare Advantage (MA) enrollees who switched insurers or disenrolled to traditional Medicare (TM) in the years immediately after first choosing to join an MA health plan.

STUDY DESIGN: Retrospective analysis using 2012-2017 Medicare enrollment data.

METHODS: We studied enrollees who joined MA between 2012 and 2016 and identified all enrollees who changed insurers (switched insurance or disenrolled to TM) at least once between the start of enrollment and the end of the study period. We categorized each change as switching insurers or disenrollment to TM, and by whether the previous insurer had exited the market.

RESULTS: Among 6,520,169 new MA enrollees, 15.6% had changed insurance within 1 year after enrollment in MA and 49.2% had changed insurance by 5 years. More enrollees switched insurers rather than disenrolled, and most enrollees who changed insurers did not do so as a result of insurer exits.

CONCLUSIONS: New MA enrollees change insurers at a substantial rate when followed across multiple years. These changes may disincentivize insurers from investing in preventive care and chronic disease management and, as shown in several non-MA populations, may lead to discontinuities in care, increased expenditures, and inferior health outcomes.

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Turnover among enrollees of health plans is a well-studied topic in the commercial,[1] Medicaid,[1-3] and Affordable Care Act marketplaces.[4] Higher rates of insurance switching and disenrollment within these markets have been linked to adverse health outcomes, including delays in seeking medical care,[5] lower adherence to medications,[2] and increased utilization of higher-cost services such as the emergency department or hospital.[2,6] Furthermore, high enrollee turnover may reduce the incentive for health plans to invest in the delivery of certain preventive health services and the management of some chronic medical conditions, as it may take years of continued enrollment before these benefits justify the up-front investment by health plans or other risk-bearing organizations such as accountable care organizations.

Although some research has found increased turnover in Medicare Advantage (MA) patients with high health care needs,[7-10] turnover among the general MA population has received less attention. One study that examined rates of plan switching and disenrollment concluded that only a small percentage of MA enrollees switch plans each year.[11] Other research has largely focused on the problems that older persons may face when trying to switch plans, such as difficulty interpreting plan information, low awareness of quality ratings, and overall frustration with the plan selection process.[12-14] Overall, MA enrollees are often presumed to be "sticky," tending to stay with the same insurer once enrolled.[15]

Differences in health outcomes can become magnified over several years, and insurers may account for enrollment changes over multiple years when planning for future expenditures. The cumulative rate of insurance change after a period of enrollment, rather than yearly rates of change, may better characterize the degree of turnover within MA plans. Thus, we performed a longitudinal analysis of MA enrollment outcomes to measure rates of turnover across multiple years.

METHODS

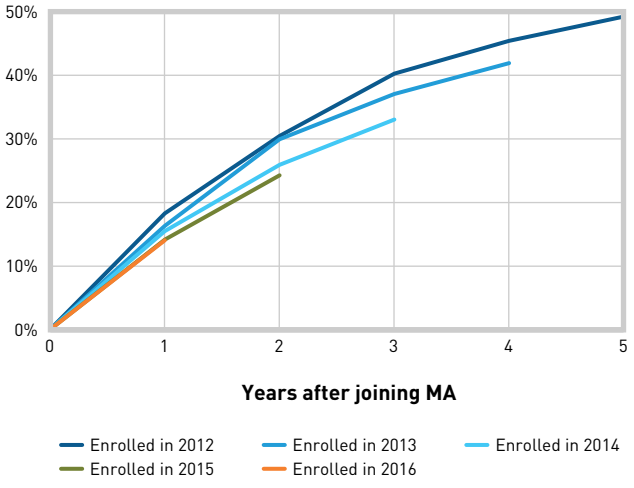
Using data from the CMS Master Beneficiary Summary File (MBSF),[16] we tracked the enrollment status between 2012 and 2017 of new

TAKEAWAY POINTS

We performed a longitudinal analysis of enrollment turnover among new Medicare Advantage (MA) enrollees. We found the following:

- A significant proportion of MA enrollees change insurers within a few years of enrolling in MA.
- Contrary to conventional wisdom, the rate of turnover of new MA enrollees was comparable with that of enrollees in certain commercial and Medicaid markets.
- High turnover among MA enrollees may cause disruptions in care, increase utilization of high-cost services, and create incentives against investments in improved care delivery.

FIGURE 1. Proportion of Enrollees Who Changed Insurance After Newly Enrolling in MA[a]



MA, Medicare Advantage.

[a]Insurance change is defined as either a switch from the enrollee's original insurer to a different MA insurer or disenrollment to traditional Medicare. See eAppendix Table 1 for exact values.

MA enrollees, defined as individuals of any age not enrolled in MA the prior year who then choose to enroll. We focused on these enrollees both to reduce confounding by duration of MA enrollment prior to the study and because recent enrollees comprise a significant portion of the MA population[17]; we verified the latter with data from the MBSF.

We followed each enrollee over time until either a change in insurance, defined as switching insurers or disenrolling to traditional Medicare (TM), or death occurred. Because insurers, otherwise known as parent organizations, can offer multiple plans to enrollees in the same geographic area, we measured switching among insurers, rather than between plans, to better assess the financial impact of turnover on insurers.

We grouped enrollees into cohorts based on year of enrollment and tracked each cohort's enrollment outcomes annually. For each period, we calculated the percentage of enrollees who had changed insurance at least once since the start of enrollment. Each insurance change was further subcategorized as involuntary if the original insurer exited the enrollee's county of residence, voluntary if the insurer did not, or because of a move if the enrollee's county of residence changed; we then calculated trends for each type. Enrollees who left their original insurer due to death were distinguished from those who switched or disenrolled and were included in the denominator but not the numerator when calculating rates of insurance change.

We excluded enrollees in plans that are not available for individual enrollment, such as employer-sponsored plans, Special Needs Plans, Program of All-Inclusive Care for the Elderly plans, Medicare cost plans, Medicare-Medicaid plans, and demonstration plans, because findings for enrollees in these plans are less applicable to the general Medicare population. We used CMS crosswalk files to identify insurer acquisitions and treated these events as if enrollees remained with their original insurer, as the acquiring insurer would be financially responsible for the acquired enrollees.[18] In our supplemental analysis, we stratified by dual-eligibility status and whether the beneficiary was new to Medicare (comparing new Medicare beneficiaries with those who switched from TM). We also compared select demographic characteristics of beneficiaries who changed insurance with those of beneficiaries who did not.

RESULTS

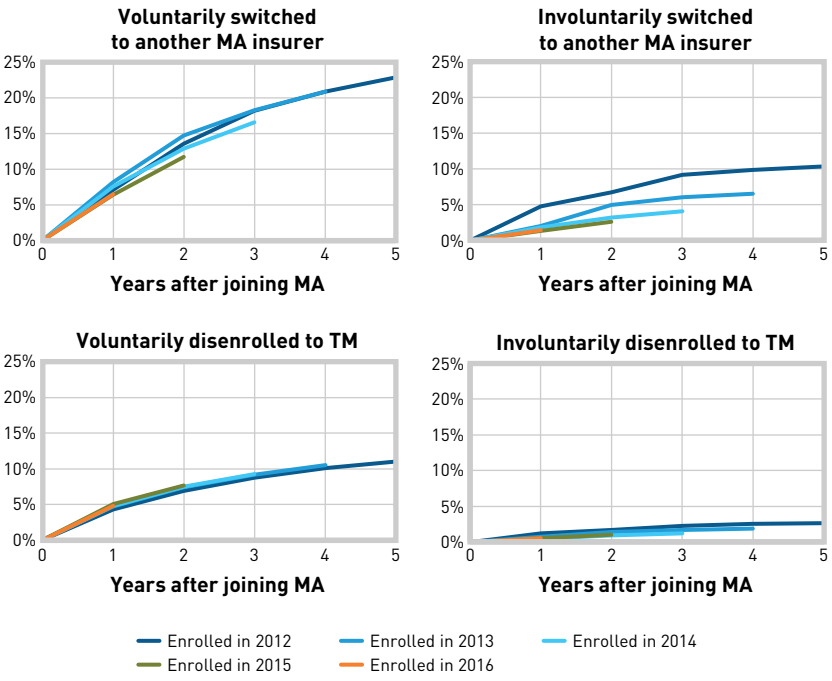
We studied 6,520,169 new MA enrollees who joined between 2012 and 2016, representing approximately 40% of the 16.2 million unique Medicare beneficiaries who were enrolled in individual MA plans between 2012 and 2017. Overall, 15.6% of new MA enrollees had changed insurance 1 or more times by the 1-year mark, 27.7% by 2 years, 37.0% by 3 years, 43.7% by 4 years, and 49.2% by 5 years (**Figure 1** and **eAppendix** [available at **ajmc.com**]). Rates decreased somewhat across subsequent cohorts, with 1-year rates falling from 18.3% in the 2012 cohort to 14.0% in the 2016 cohort and 3-year rates falling from 40.3% in the 2012 cohort to 33.1% in the 2014 cohort.

When stratified by type of insurance change, voluntary switching was the most common, averaging 7.1% by 1 year and 22.9% by 5 years of enrollment, although rates declined somewhat across later cohorts (**Figure 2** and eAppendix). The rate of voluntary disenrollment to TM was approximately half that of voluntary switching and remained stable across successive cohorts. In contrast, the rate of involuntary switching decreased sharply between the 2012 and 2014 cohorts before stabilizing thereafter, whereas involuntary disenrollment to TM saw a smaller decrease across the same time frame. When accounting for the size of each subgroup, the decrease in the overall rate of insurance change appears largely driven by decreases in voluntary and involuntary switching prior to the 2015 cohort.

Dual-eligible enrollees changed insurance at a higher rate than that of the general population, although restricting the analysis to non–dual-eligible enrollees, new Medicare beneficiaries, or

enrollees who switched from TM changed our results by just 1% to 2% each year (full results in eAppendix). Enrollees who changed insurance, especially those who voluntarily disenrolled, were more likely to have switched from TM when joining MA, to be dual-eligible, and to have more chronic conditions on average (eAppendix).

FIGURE 2. Proportion of Enrollees Who Changed Insurance After Newly Enrolling in MA, Stratified by Type of Change[a]



MA, Medicare Advantage; TM, traditional Medicare.
[a]Insurance change is defined as either a switch from the enrollee's original insurer to a different MA insurer or disenrollment to TM. See eAppendix Table 1 for exact values.

DISCUSSION

We show that after initial enrollment, MA enrollees continue to change insurance over the next several years, and that insurance changes are driven predominantly by voluntary choices. Relative to other systems, one may naturally expect lower rates of turnover within MA given that enrollment is not affected by changes in employment, as with commercial and ACA plans, or income, as with Medicaid, and because most MA enrollees can only change insurance only during open enrollment periods. Remarkably, the rates we report are comparable with rates found in certain non-Medicare populations; for example, 26% of enrollees in a mixed commercial and Medicaid population switched insurers within 2 years, and 13.7% of Medicaid enrollees in expansion states changed or lost coverage within 1 year.[1,3]

In an earlier report, Jacobson et al followed MA enrollees across 1-year intervals and found that only a small proportion of enrollees change plans each year.[11] Although our conclusion may appear different because of Jacobson et al measuring plan-level insurance change, focusing on voluntary switching, and including existing MA enrollees, our 1-year switching rates are similar to theirs after accounting for the above (eAppendix). The main reason for the difference appears to be the longer time frame we used, as changes that are perceived as small on a year-to-year basis can add up significantly over time. Our results complement those of prior research by highlighting that the cumulative effect of turnover may have significant downstream effects on both insurers and enrollees.

A key underlying principle of managed care is that investments in preventive health and improved management of chronic conditions will lead to better long-term patient outcomes and, potentially, lower utilization over time. Insurers, however, are more likely to make such investments if they stand to benefit from the future decreased expenditures. Because Medicare provides coverage for almost all individuals 65 years and older, the Medicare program itself should benefit from efforts to prevent future disease. This does not mean, however, that MA plans, which patients can elect to join and leave on a yearly basis, will benefit in the same way. Our data suggest, in fact, that the turnover in MA enrollment may reduce incentives for MA insurers to invest in better management of chronic medical conditions.

One may assume that if enrollees switch insurers frequently, a significant portion of those who switched would eventually reenroll with their original insurer, thus obviating the financial disincentive toward future investment. However, insurers who do not invest in these services may be able to "free ride" from those who do, creating an incentive against future investment. This effect has been observed empirically in other health insurance markets where reenrollment could also occur.[19] Furthermore, discontinuities in enrollment could make the implementation of programs to improve prevention or delay disease progression more difficult—for example, an intervention for enrollees with poorly controlled diabetes may be hindered by spotty data on the frequency of hemoglobin A_{1c} checks—and potentially not as cost-effective.

High turnover rates may also lead to inferior health outcomes among MA enrollees, as has been observed in other insured populations. Discontinuities in medical care have been shown to increase older Americans' usage of emergency care and hospital length of stay,[20] and in non-Medicare populations changes in insurance have also been linked with delays in seeking care, skipping doses of medications, and overall declines in health.[1,2] Some enrollees may change insurance to keep access to an existing provider or medication, but a switch may still introduce discontinuities of care

elsewhere in their care. Although these effects have been studied predominantly in non-MA populations, the negative effects of high turnover could be magnified in MA as both medical complexity and health care utilization generally increase with age.

Our work also highlights several areas for further research. Our data, like those of prior work,[7-10] suggest that high-need enrollees disenroll at higher rates. It would be important to both understand their reasons for disenrollment and assess whether any barriers, such as coverage gaps in Medigap plans for preexisting conditions, affect subsequent outcomes. Trends in insurance change could also be of interest to policy makers. For example, the decrease in involuntary switching and disenrollment over successive cohorts may reflect the greater financial attractiveness for insurers of MA compared with other insurance markets,[21] whereas the decrease in voluntary switching could be suggestive of increased satisfaction among MA enrollees. We caution that the policy implications of these findings are not clear without further investigation.

Limitations

Our study has several limitations. Because we focused on new enrollees, our results may overestimate the overall rate of insurance change within MA as older enrollees tend to change insurance at lower rates, although our study population did include around 40% of all MA enrollees in individual plans. Rates at 4 and 5 years after initial enrollment may become lower with more follow-up data given that there was less insurance change in the 2015 and 2016 cohorts. Because we did not track enrollee outcomes after an insurance change, we do not know what fraction of enrollees eventually reenroll with their original insurer, although these enrollees are still exposed to multiple insurance transitions as described above. Our definition of new enrollees also does allow those who were previously enrolled in MA but disenrolled for multiple years before rejoining to be included. Finally, although we attempted to estimate the fraction of insurance change due to insurer exits, we note that enrollees labeled with an involuntary change may have had other reasons for switching insurance or disenrolling.

CONCLUSIONS

In this study of longitudinal turnover in MA, we show that insurance change among new MA enrollees may be more substantial than previously portrayed, with rates comparable with those of commercial and Medicaid populations. Consequently, turnover in MA may lead to inferior health outcomes through disjointed care and decreased investment in improved care delivery. Future research could help assess the extent to which turnover affects the care that MA enrollees receive. ■

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Authorship Information: Concept and design (JD, AMZ, JZA, BEL); acquisition of data (JD, BEL); analysis and interpretation of data (JD, AMZ, JZA, BEL); drafting of the manuscript (JD); critical revision of the manuscript for important intellectual content (JD, AMZ, JZA, BEL); statistical analysis (AMZ); obtaining funding (BEL); and supervision (BEL).

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