

Access to effective smoking cessation medications in patients with medicare, medicaid and private insurance

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ARTICLE INFO

Keywords:

Medicare
Smoking-cessation
Varenicline
Insurance
Affordable-care-Act

ABSTRACT

Objectives: Compare financial barriers to the most effective smoking cessation medications - varenicline and combination nicotine replacement therapy (CNRT) across major insurance categories and determine whether these financial barriers impact smoking cessation outcomes.

Study design: Longitudinal retrospective observational cohort study.

Methods: Patients seen at Duke Smoking Cessation Program 05/2016 through 07/2021 were studied. Those prescribed varenicline or CNRT were determined to have financial barriers to access if they could not purchase the medication using insurance or their own funds. Outcomes were compared between Medicare, Medicaid, and private insurers. Abstinence was defined as self-reported 7-day smoking abstinence.

Results: Patients with Medicare were 5.08 times more likely to face a financial barrier to highly effective smoking cessation medications compared to patients with private insurance ($p < 0.00001$) and 2.81 times more likely compared to Medicaid ($p < 0.00001$). Patients able to access these highly effective medications achieved a smoking abstinence rate that was 1.58 times higher than those who could not ($p = 0.01$)

Conclusions: Findings suggest Medicare coverage of the most effective smoking cessation medications is considerably worse than Medicaid or private insurance; inability to access these medications may lead to lower rates of smoking abstinence.

1. Introduction

Smoking is the leading cause of preventable morbidity and mortality in the United States (US), causing roughly 480,000 preventable deaths and costing \$157 billion in health-related economic losses annually [1]. In 2019 14% of US adults smoked, with 68% expressing a desire to quit and 55% making a quit attempt [2–5]. Evidence has repeatedly confirmed that use of Food and Drug Administration (FDA) approved smoking cessation medications (nicotine patch, gum, lozenge, inhaler, nasal spray, bupropion and varenicline) increase abstinence rates amongst those attempting to quit [6]. More recently, large meta-analyses have demonstrated that combination nicotine replacement therapy (CNRT) (patch combined with gum, lozenge, inhaler or spray) is 2.3 times and varenicline is 2.4 times as effective as placebo, while therapies such as patch alone or bupropion are 1.6–1.8 times as effective: a statistically significant difference reflecting roughly double the efficacy [2]. This finding has led expert panels to recommend

varenicline and CNRT as “standard-of-care” smoking cessation pharmacotherapy [7–10].

Consensus in public health research is that reducing out-of-pocket costs for smoking cessation aids promotes more quit attempts and higher quit rates on a population level [11,12]. Projections by Baker et al. have estimated that for every dollar invested into full coverage without cost sharing for smoking cessation pharmacotherapy, savings are \$1.18 for private insurers, \$2.50 for Medicaid and \$3.22 for Medicare over 10 years due to reduction in smoking-related medical expenditures [13]. In alignment with this knowledge, federal policy requires that Medicare, Medicaid, and most private insurers cover smoking cessation pharmacotherapy, but exact requirements differ [14].

Under 2013 Patient Protection and Affordable Care Act (ACA) most market-based (i.e., private) insurers must impose no cost-sharing for United States Preventative Services Task Force (USPSTF) “Grade A” preventative services, which include all seven FDA approved smoking cessation medications [1,15–17].

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<https://doi.org/10.1016/j.puhip.2023.100427>

Received 6 March 2023; Received in revised form 28 July 2023; Accepted 5 September 2023

Available online 10 September 2023

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Medicaid is likewise required by the ACA to provide coverage for smoking cessation medications but without restrictions on cost-sharing seen for private insurers [18]. Because Medicaid is managed by state government agencies, policies vary from state to state. In North Carolina where this study was conducted, varenicline, nicotine patch, gum and lozenges are included on the Medicaid “preferred drug list” and could be purchased for three dollars, with limits on yearly quit attempts [20,22]. The large majority of state Medicaid plans provide smoking cessation medications with a low co-payment (i.e. \$5 or less) [19–22].

Medicare coverage, for those >65 years old is divided into four parts (Part A –inpatient care, Part B – outpatient care, Part D – medication coverage, and Part C – Medicare Advantage –which provides a comprehensive package of benefits, serving the role of A, B and D) [23]. All Medicare recipients are automatically enrolled in parts A and B and may enroll in either in C or D for additional out of pocket costs [28]. Medicare Part D drug plans do not cover over-the-counter (OTC) medications and thus do not cover OCT products: nicotine patches, gum or lozenges [24,24,25]. Medicare Part C also does not typically cover OTC medications, with a few plans occasionally providing some scope of OTC coverage [24,26] As a prescription drug, varenicline is covered by both Medicare C and D but is classified as Tier 3 or 4 medication under part D, resulting in high copays, as much as \$469 per month, or \$1407 for standard 12 weeks of treatment [26].

Currently there is little to no outcomes data comparing Medicare, Medicaid, and private insurers’ facilitation of access to the most effective smoking cessation medications. One reason for this is that coverage criteria within individual plans can be complex, employing varying payment schedules for different medical conditions, incorporating factors such as previous out of pocket spending (contributing to a deductible) and considering previous quit attempts [23]. Differences in patient incomes, provider prescribing practices and legal requirements for state and federal plans also add variability. Certain individuals also have hybrid plans such as “special needs plans” that combine Medicare and Medicaid [27]. One helpful study by Jarlenski et al. assessed utilization of smoking cessation medications in patients with Medicare Part D, finding that purchase rates were lower compared to the general population, but it did not assess financial barriers.2 [8].

With new data showing that two specific pharmacotherapy regimens (varenicline and CNRT) are significantly more effective than others, the goal of our study was to characterize patients’ ability to obtain prescribed varenicline or CNRT across three general categories - Medicare, Medicaid and private.

2. Methods

2.1. Setting

Confounding complexities such as state policy differences, provider prescribing differences, and demographic variability across treatment populations needed to be minimized, thus exclusively patients within the Duke Smoking Cessation Program were compared. The program treats patients with nicotine dependence, and providers uniformly prioritize highly effective pharmacotherapy (varenicline or CNRT) when possible. Additionally, the program collects data on self-reported 7-day smoking abstinence.

2.2. Data collection

The sample was derived from electronic records between 05/26/2016 (program inception) and 07/21/2021 (when analysis began). Selected patients were adult (≥ 18 -year-old) smokers, with Medicare, Medicaid, or private insurance with sufficient EHR data to determine whether they could acquire prescribed medications (e.g., documented medication orders, notes describing outcomes) (Fig. 1). Because patients needed at least 2 visits to evaluate access, only patients with >1 visit were included (Fig. 1). Patients were excluded if medication access could not be verified through manual review of chart data (Fig. 1).

2.3. Data management and analysis - access

For each patient, all notes from the Smoking Cessation Program were manually reviewed and systematically coded to denote if the patient faced financial barriers to medication including unaffordable co-pay, unaffordable OTC cost, or necessity of patient assistance programs. A

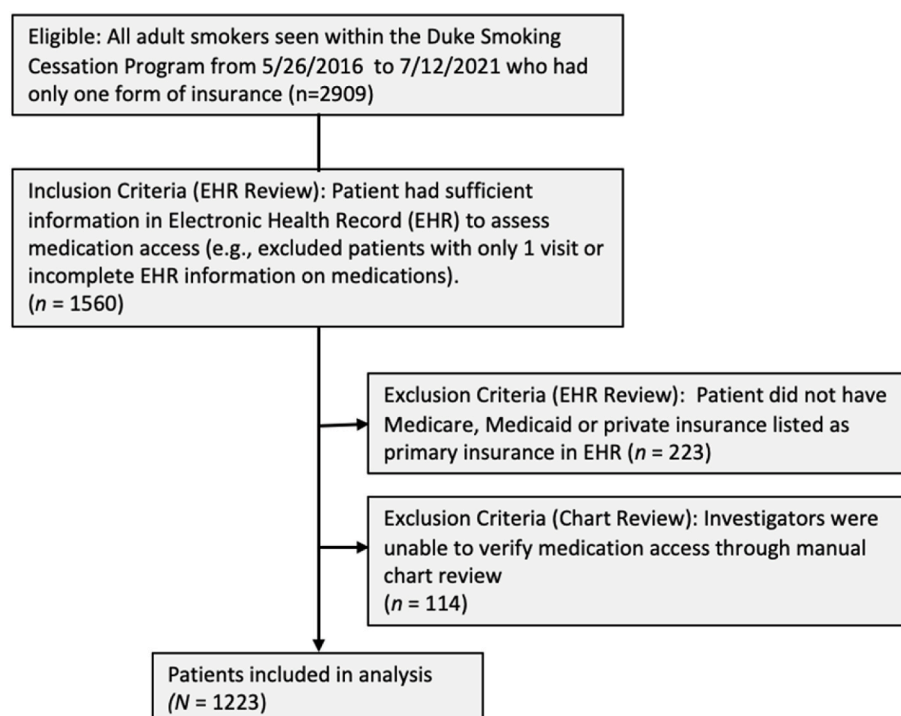


Fig. 1. Consort diagram.

patient was defined as having a “financial barrier” if they were unable to purchase the prescribed medication with insurance coverage or personal funds. Scenarios not categorized as financial barriers included extensive delays in access (e.g., due to requirement for prior authorization), or limits on quit attempts per year. Patients who did not attempt to purchase prescribed medications were excluded. For comparisons between insurance groups, patients covered by hybrid Medicare-Medicaid plans were excluded. Chi square tests evaluated differences in financial barriers with logistic regression to analyze covariates.

2.4. Data management and analysis – effectiveness

Evaluation of treatment response required consideration of which patients successfully took their medications. Actual exposure to prescribed medication was determined from clinical notes, defined as use for at least 2 weeks; patients who did not adhere to medications or who could never access prescribed medications were considered to have no exposure. Only patients who attempted to pick up prescribed medications were considered. Secondary analyses were conducted to determine if exposure to effective smoking cessation medications (either varenicline or CNRT) was associated with abstinence, defined as self-reported 7-day smoking abstinence over the duration of care. Chi square tests were employed; covariate analysis assessed confounding.

3. Results

3.1. Participants

The study sample included 1223 smokers (Table 1). Relative to the population eligible for review, no significant differences were seen in sex or race, and the sampled population was slightly older (57.0 vs. 55.8; p = 0.006). Across insurance groups: there were no significant differences in gender. Medicare patients had a mean age of 63.7; (SD 9.27) years, significantly higher than Medicaid (age 49.2; SD 11.18, p<0.001) and private insurance recipients (age 50.9; SD 10.89 p<0.001; Table 1). Medicaid recipients were significantly more likely to be African American (61.0%) compared to Medicare (41.4%; p<0.001) and private insurance recipients (33.3%; p<0.001; Table 1). Of 607 Medicare recipients, 477 (78.6%) had Medicare alone without a supplemental Medicaid plan (i.e., special needs plan). (Fig. 2, Table 2).

3.2. Participants – medication prescribing

The following proportions of eligible patients were prescribed varenicline or CNRT (i.e., most effective medications): 1087/1223 (88.9%) overall, 426/477 (89.3%) Medicare-without-Medicaid, 422/457 (92.3%) privately insured and 134/159 (84.3%) Medicaid patients. The following portions of those patients attempted to pick up these medications 1000/1087 (91.2%) overall, 397/426 (83.2%) Medicare-without-Medicaid, 383/422 (90.8%) privately insured and 125/134 (93.3%) Medicaid patients (Fig. 2, Table 2).

Table 1 Sample demographics.

	Eligible for Inclusion	Sample	Medicare	Private	Medicaid
N	2909	1223	607	457	159
%Male	44.4%	43.0%	42.3%	44.6%	40.9%
%African American	42.8%	40.9%	41.4%**	33.3%	61.0%
Mean Age	55.8***	57	63.7	50.9*	49.2*

Demographic differences between insurance groups; Chi Square Test: Sex, Race. Two tailed T-test: Age.

*p<0.05, relative to Medicare, **p<0.05, relative to Medicaid, ***p<0.05 relative to sample population.

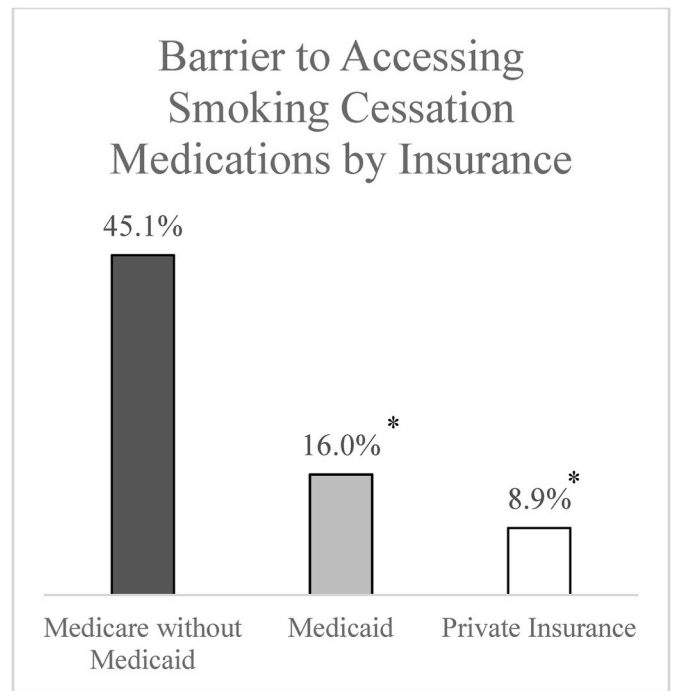


Fig. 2. Financial barrier to acquiring prescribed smoking cessation medication by insurance group *p<0.001 relative to Medicare.

4. Access to most effective medications (primary outcome)

45.1% of Medicare-without-Medicaid recipients had financial barriers to the most effective pharmacotherapies. Financial barriers for Medicare-without-Medicaid patients were significantly more frequent than Medicaid (16.0%; p<0.001, RR = 2.82, 95% CI 1.86-4.27) or privately insured patients (8.9%; p<0.001, RR = 5.08, 95% CI 3.62-7.13; Fig. 2). Patients with Medicare-without-Medicaid faced more frequent financial barriers to varenicline (51%) compared to Medicaid (5.1%; p<0.001, RR = 9.17, 95% CI 3.50-23.98; Table 2) and private insurance recipients (9.2%; p<0.001, RR = 5.58, 95% CI 3.85-8.08; Table 2). Patients with private insurance experienced fewer financial barriers to CNRT (14.8%) compared to Medicaid (34.4%, p = 0.008, RR = 2.33, 95% CI 1.33-4.07) and Medicare-without-Medicaid patients (46.9%; p<0.001, RR = 3.12, 95% CI 1.99-5.07) (Table 2).

4.1. Access- covariates

Age>64 was associated with more frequent financial barriers to the most effective medications but was confounded by Medicare insurance status. Within Medicare, age did not predict financial barriers (p = 0.67). African American race had a significant positive correlation with financial barriers to highly effective medication (32.8% vs. 21.8%, p<0.001, RR = 1.51, 95% CI 1.22-1.86). However, insurance with Medicaid, the insurance group with a significantly higher African American population did not; insurance with Medicaid predicted reduced financial barriers compared to African American patients overall (32.8% vs. 16.0%, p = 0.002, RR = 2.05, 95% CI 1.34-3.14).

4.2. Differences between medicare drug plans

Medicare Part C and Medicare Part D supplemental plans are intended to provide more effective coverage than Parts A and B alone. However, while incidence of financial barriers was numerically higher (54.1%) amongst A-and-B-only patients compared to Part C (49.8%) or part D (36.5%) patients, differences were non-significant (Table 2).

Table 2
Barrier to most effective smoking cessation medications by insurance type.

	Medicare without Medicaid	Medicaid	Private Insurance	Medicare A and B	Medicare Part C	Medicare Part D
Most effective Medication***	45.1% (179/397)	16.0%* (20/125)	8.9%* (34/383)	54.1% (20/37)	49.8% (105/211)	36.5% (27/74)
Varenicline	51.0% (146/286)	5.1%* (4/78)	9.2%* (28/306)	53.6% (15/28)	53.7% (88/164)	50% (26/52)
CNRT	46.9% (76/162)	34.4% (21/61)	14.8%* (17/115)	76.9% (10/13)	56% (42/75)	27.3%** (9/33)

***Most Effective Medications: Percentage of patients who were prescribed varenicline, CNRT or both who could not access any form of highly effective smoking cessation medication after making an attempt to purchase them. *p<0.001 relative to Medicare without Medicaid, **p<0.05 relative to patients without any supplemental drug plan (i.e., Medicare A and B only).

4.3. Medication effectiveness and smoking abstinence

Of the 1000 patients who attempted to pick up their medications, 784 (78.4%) accessed them and used them for at least 2 weeks (Table 3). 312/397 (78.6%) of Medicare-without-Medicaid patients achieved this as did 334/383 (87.2%) of privately insured and 109/125 (87.2%) of Medicaid patients (Table 3).

Patients exposed to the most effective smoking cessation medications were significantly more likely to reach abstinence. The abstinence rate for those exposed to the most effective medications was 26.3% compared to 16.7% for those taking other treatments who had initially been prescribed varenicline or CNRT (p<0.001, RR = 1.58, 95% CI 1.14,2.17) (Table 3). Covariate analysis revealed that neither age, sex nor race significantly predicted abstinence.

5. Discussion

To our knowledge this is the first study exploring insurance status’s impact on practical access to the most effective smoking cessation medications. The consideration is important given new data showing that varenicline and CNRT, compared to placebo yield roughly double the abstinence likelihood compared to other monotherapies. This study provides two important observations: compared to Medicaid and private insurance, Medicare appears to provide insufficient coverage of highly effective medications, and lower use of these medications appears to be associated with lower smoking abstinence rates. These suggest that Medicare policies should be re-evaluated to provide more comprehensive coverage. Interestingly, 49.8% of Medicare Advantage (Part C) recipients had financial barriers for the most effective pharmacotherapies, despite it typically being considered a premium option.

In this study, use of intensive chart reviews allowed for exploration of each patient’s “treatment story” and a more granular understanding of financial barriers. Among Medicare recipients, the most common barriers were high copays for varenicline. As mentioned above, it was common for Medicare to “cover” varenicline but charge a co-pay of up to \$1407 for 12 weeks.

For next steps to evaluate these disparities, prescribing and cost data from Centers for Medicare and Medicaid Services could better characterize trends nationally. While Jarlenski et al. was able to characterize Medicare patients’ eventual purchase of smoking cessation medications, it could not assess how costs influenced uptake [28].

Table 3
Smoking abstinence rates in patients exposed or not exposed to most effective smoking cessation medications.

	Exposed	Unexposed
All Patients	26.3% (206/784)	17.6%* (36/205)
Medicare without Medicaid	30.6% (81/265)	22.0% (29/132)
Medicaid	21.1% (23/109)	12.5% (2/16)
Private Insurance	26.0% (87/334)	6.1%** (3/49)

Self-reported 7-day abstinence comparing patients exposed or not exposed to prescribed varenicline or CNRT who had attempted to purchase prescribed medication Patients who were unable to acquire varenicline or CNRT, most acquired another FDA approved monotherapy (e.g., bupropion) to quit smoking. *p<0.05, **p<0.001.

To close this Medicare coverage gap, ACA requirements which apply to private insurers could be instituted for Medicare Part D and C (which are managed by private companies) with explicit coverage for over-the-counter nicotine replacement. Given the known benefits of smoking cessation, it may be reasonable to include coverage of highly effective smoking cessation medications in Medicare part B to cover all enrollees [13].

6. Limitations

Several limitations come from the study’s basis in observational data. Some patients had longer follow-up periods, making assessment dependent upon each patient’s engagement in care, and comparative groups were not randomized.

Findings from a single specialized program may not apply uniformly to a general clinical population. In regard to policy implications: Medicare applies nationally, Medicaid coverage for these medications varies minimally from state to state, and while private insurance policies may vary significantly, the vast majority are subject to ACA requirements [14,18,19]

Seven-day self-reported abstinence was used as a proxy for cessation which does not capture the complexities of relapse inherent to smoking cessation; it is however notable that amongst self-quitters, most relapses occur within the first 8 days [29]. Relapse frequencies have been modeled elsewhere [30].

Confounders considered included: age, gender, and race. While age >64 years did predict financial barriers, age was confounded by Medicare insurance status, which provides a more plausible explanation for differences in medication affordability given explicit policy differences. Across the entire study population, African American race predicted poorer medication access. However, given that Medicaid insurance status, a status with significantly more African American patients predicted improved access, it is likely that an intersection between race, insurance status and other uncaptured variables such as income and education drove this disparity.

This study did not account for variations in behavioral interventions. At baseline, behavioral treatment across all program patients is evidence-based counseling provided by clinicians.

Ethical approval

Duke University Health System Institutional Review Board.

Funding

Luisa Masclans is supported through the Duke University School of Medicine. James M. Davis MD is supported by the Duke Cancer Institute and the Duke University Department of Medicine. Grant funding was not used to support this research.

Declaration of competing interest

Luisa Masclans: nothing to disclose. James Davis MD has been supported through NIH funding sources (NCI P30 and NIDA P50) and provides consulting services to Predictably Human Inc. and Currax

Pharmaceuticals LLC.

Acknowledgements

The authors wish to thank the patients and providers at the Duke Smoking Cessation Program for their contribution to the research. The authors would specifically like to thank Jillian Dirkes and Theresa Curington for their research and administrative assistance.

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