

Antiobesity Medication Use in 2.2 Million Adults Across Eight Large Health Care Organizations: 2009-2015

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Objective: The aim of this study was to examine the prescribing patterns and use of antiobesity medications in a large cohort of patients using data from electronic health records.

Methods: Pharmacy- and patient-level electronic health record data were obtained on 2,248,407 adults eligible for weight-loss medications from eight geographically dispersed health care organizations.

Results: A total of 29,964 patients (1.3% of total cohort) filled at least one weight-loss medication prescription. This cohort was 82.3% female, with median age 44.9 years and median BMI 37.2 kg/m². Phentermine accounted for 76.6% of all prescriptions, with 51.7% of prescriptions being filled for ≥ 120 days and 33.8% filled for ≥ 360 days. There was an increase of 32.9% in medication days for all medications in 2015 compared with 2009. Higher prescription rates were observed in women, black patients, and patients in higher BMI classes. Of 3,919 providers who wrote at least one filled prescription, 23.8% ($n=863$) were “frequent prescribers” who wrote 89.6% of all filled prescriptions.

Conclusions: Weight-loss medications are rarely prescribed to eligible patients. Phentermine accounted for $>75\%$ of all medication days, with a majority of patients filling it for more than 4 months. Less than one-quarter of prescribing providers accounted for approximately 90% of all prescriptions.

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Introduction

Obesity is widely acknowledged to be a serious public health problem, with 39.6% of Americans having BMI ≥ 30 kg/m², and 7.7% having BMI ≥ 40 (1). Currently available treatment options for weight reduction include lifestyle changes, weight-loss medications, and bariatric surgery. These three options vary both in the degree of weight loss that they typically produce and their relative cost, risk, and side effects. Weight-loss medications are the intermediate choice between lifestyle programs and bariatric surgery in both effectiveness and cost. The NIH guidelines on the treatment of obesity published in 1998 advocated consideration of weight-loss medications for the treatment of adults with BMI >30 or those with BMI >27 with a weight-related comorbidity, such as diabetes, hypertension, hyperlipidemia, or

degenerative arthritis (2). This approach to management was affirmed in the updated 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity in Adults and the more recent Endocrine Society clinical practice guideline on the pharmacological management of obesity published in 2015 (3,4). This strategy was also advocated in recent guidelines from both the American Diabetes Association (5) and the American Association of Clinical Endocrinologists guideline on the management of type 2 diabetes mellitus (6). Research has also suggested that satisfaction with weight loss may be higher when weight-loss medications are used compared with lifestyle approaches, including dietary modification, exercise, and use of weight-loss supplements, and that use of a weight-loss medication is associated with greater weight loss (7,8).

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Despite support from guidelines and interest from patients, weight-loss medications are seldom prescribed, and prescribing habits of health care providers vary greatly. While little data on this topic currently exist, a study of patients cared for by the Veterans Health Administration (VHA) showed that only 0.2% of more than 2 million patients who met NIH criteria for consideration of a weight-loss medication filled a prescription for one of these agents (9). In this study, facility-level prescribing rates for those who met VHA criteria for eligibility varied from 0% to 21% across the 140 facilities studied. Another study examining pharmacy claims of more than 80 million patients between 2008 and 2011 showed that despite increasing concern over obesity as a clinical problem, the use of weight-loss medications over this time period actually declined from 45 to 24/100,000 enrollees (10). These low rates of weight-loss medication use may reflect provider or patient concerns over the safety and efficacy of these agents, providers' lack of experience with this class of medications, Food and Drug Administration (FDA) restrictions on long-term use of older agents, lack of insurance coverage, or bias that weight is primarily a behavioral problem that should be treated with behavioral measures (11,12).

PCORnet, the National Patient-Centered Clinical Research Network, an initiative of the Patient-Centered Outcomes Research Institute (PCORI), provides a unique opportunity to examine the prescribing of weight-loss medications in a large cohort of patients cared for in representative practices around the country. The Kaiser Permanente and Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL) network is one of the clinical data research networks within PCORnet. PORTAL uses a common data model to aggregate data on a racially, ethnically, and geographically diverse group of about 17 million people who receive their care at one of 11 affiliated research centers, including several Kaiser Permanente regions, HealthPartners, and Denver Health. Clinical data, provider characteristics, and pharmacy records were available from 2009 to 2015 on patients at these sites with BMI > 25 ($n=4.9$ million) during this period.

The purpose of this study was to identify patterns of prescribing and usage rates of FDA-approved weight-loss medications in a large cohort of eligible patients cared for in a variety of typical care environments between 2009 and 2015 using data from electronic health records (EHRs). The time period examined constitutes a period when sibutramine was removed from the market (October 2010) and the FDA granted approval of several new weight-loss medications (lorcaserin in May 2012, phentermine/topiramate extended release in July 2012, naltrexone/bupropion sustained release in September 2014, and liraglutide 3.0 mg in December 2014). We also sought to characterize the providers who prescribed these medications as well as look for variations in local prescribing practices. The overall goal was to examine whether data from EHRs support the notion that prescribing rates for weight-loss medications to eligible patients are low and to lay a foundation for future studies using data from EHRs that could help understand the factors leading to low rates of prescribing of weight-loss medications.

Methods

Study setting

The PORTAL network is a clinical data research network funded by the PCORI to promote collaboration across several large health systems with EHRs (13). For purposes of this analysis, the following eight health networks were studied: Kaiser Permanente regions (Northwest

[Oregon], Southern California, Mid-Atlantic [Virginia, Maryland, and District of Columbia], Hawaii, Colorado, and Washington state), HealthPartners, and Denver Health. From these sites, a cohort of adults with overweight and obesity was constructed to enable large-scale observational research across diverse clinical care settings. The development and description of this cohort have been previously published (14). For all sites except Denver Health, plan members aged > 18 years with at least 12 months of continuous membership between January 1, 2009, and December 31, 2015, who were not pregnant, and who had a weight and height recorded in the EHR during the inclusion period were identified. Denver Health is a safety-net institution and does not enroll members. Therefore, eligibility criteria at this site included all adults who had any medical encounter with a weight and height during the specified period.

The Kaiser Permanente Southern California Institutional Review Board approved the research. The institutional review boards at the other sites reviewed the protocol and subsequently ceded review.

Study population

Patients within the PORTAL Obesity Cohort who were identified as having received a weight-loss medication between 2009 and 2015 or who were eligible for a weight-loss medication during this period were selected for this study. Eligibility criteria included patients with BMI ≥ 30 or patients with BMI between 27 and 29.9 who also had a diagnosis of at least one weight-related comorbidity (based on *International Classification of Diseases, Ninth Revision* codes) recorded in the EHR. Providers who prescribed weight-loss medications that were filled by an Obesity Cohort patient between 2009 and 2015 were also identified. Care providers were classified as being primary care providers if they practiced general internal medicine, family medicine, or obstetrics and gynecology. All other care providers were classified as specialists. We were not able to determine whether a provider had special training in obesity treatment (e.g., American Board of Obesity Medicine certification) or a focused practice in treating patients with obesity. Medication days were determined by the number of prescriptions written for a specific patient times the number of pills in the prescription during the period specified.

Data analysis

BMI was calculated as weight (kilograms) divided by height (meters squared). If more than one weight, height, or BMI was available during the study period, the first recorded BMI that met medication eligibility criteria was used.

SAS Enterprise Guide 5.2 (SAS Institute, Inc., Cary, North Carolina) was used to calculate descriptive statistics. Demographic and socio-demographic characteristics of those receiving at least one fill for a weight-loss medication were compared with the overall cohort of eligible individuals.

Results

From 2009 to 2015, a cohort of 3,306,484 patients who had overweight or obesity was identified, of which 2,248,407 (68.4%) were considered to be eligible for weight-loss medications based on the NIH criteria. Of the medication-eligible cohort, 76.7% had obesity (BMI ≥ 30) and 23.3% had a BMI 27 to 29.9 with at least one

weight-related comorbidity. Medication-eligible patients varied across sites, from the smallest site having 35,941 patients to the largest site with 1,335,734 patients.

Table 1 describes demographic characteristics of patients eligible for a weight-loss medication and those who received at least one prescription for one of these drugs. Overall, 1.3% ($n=29,964$) of eligible patients received a weight-loss medication prescription. Rates of prescription receipt varied across the eight sites, ranging from 0.6% in the region with the lowest rate of prescribing to 2.9% of eligible patients in the region with the highest rate of prescribing. Of those receiving a prescription, 83.7% were female, 45.1% were non-Hispanic white, and the mean BMI was 37.2. Those receiving a prescription for a weight-loss medication had a median age of 44.9 years. Overall, 0.5% of medication-eligible men and 2.1% of medication-eligible women received a prescription for a weight-loss medication. Rates of prescribing rose as BMI increased and varied depending on race and ethnicity (Figure 1).

Figure 2 depicts the time course of the total number of weight-loss medication treatment days between 2009 and 2015. During this period, there was a 32.9% increase in the total number of weight-loss medication treatment days because of an increase in the number of unique patients who received a prescription for one of these medications. Overall, phentermine was the most commonly used medication, accounting for 76.6% of medication treatment days in 25,637 unique patients. This was followed by diethylpropion, orlistat, sibutramine, and lorcaserin at 12.2%, 4.3%, 2.8%, and 2.0% of medication treatment days, respectively. In 2015, 2.7% (248 of 9,184) of all patients

prescribed a weight-loss medication received one of the newer agents (lorcaserin, phentermine/topiramate, naltrexone/bupropion, and liraglutide 3.0 mg).

There was marked regional variation in the rate of prescribing individual medications. Table 2 depicts the fraction of total medication days accounted for by each weight-loss medication in the overall sample as well as the rates of use in regions that had the highest and lowest rates of prescribing for each individual agent. There was a 12% increase in phentermine use from 2011 to 2012, which corresponded to the period when sibutramine was removed from the market. Sibutramine accounted for 6.0% of treatment days in 2010, the year it was withdrawn from the market in October.

Figure 3 depicts the duration of therapy for those individuals who received a prescription for phentermine. The mean number of medication days per patient during the period of observation was 178.3 ± 236.3 days. In total, 51.7% filled for ≥ 120 days and 33.8% filled for ≥ 360 days.

Of those providers who ever prescribed a weight-loss medication ($n=3,902$), 72.9% ($n=2,856$) prescribed to five or fewer patients. These prescribers were responsible for only 3.25% of all prescriptions written. On the other hand, 8.3% of prescribers ($n=376$) prescribed to 21 or more patients. These frequently prescribing care providers wrote 89.6% of all filled prescriptions. Overall, 84.4% ($n=3,308$) of providers were identified as primary care providers, and 92.5% ($n=863$) of clinicians who prescribed to 21 or more patients were primary care providers.

TABLE 1 Demographics and characteristics of those eligible for and prescribed weight-loss medications

	Eligible ($n=2,248,407$)	Prescribed ($n=29,964$)
Race and ethnicity, number of patients (%)		
White	1,061,429 (47.2)	13,519 (45.1)
Hispanic	625,045 (27.8)	7,560 (25.2)
Black or African American	287,397 (12.8)	6,049 (20.2)
Asian	129,366 (5.8)	916 (3.1)
Native Hawaiian or Pacific Islander	42,091 (1.9)	730 (2.4)
American Indian or Alaska Native	14,247 (0.6)	215 (0.7)
Other or unknown	88,832 (4.0)	975 (3.3)
Gender, number of patients (%)		
Male	1,070,126 (47.6)	4,878 (16.3)
Female	1,178,132 (52.4)	25,086 (83.7)
Unknown	149	
Initial BMI group, number of patients (%)		
Less than 27	92 (0)	0
27-29.9	523,662 (23.3)	1,940 (6.5)
30-34.9	1,156,479 (51.4)	12,960 (43.3)
35-39.9	341,177 (15.2)	7,399 (24.7)
40 or greater	226,997 (10.1)	7,665 (25.6)

Discussion

In this study, data from EHRs from eight geographically dispersed clinical sites providing care to >11 million patients demonstrate that only 1.3% of patients who were eligible for treatment with weight-loss medications received a prescription for one of these medicines over a 6-year period. As has been seen in other studies, phentermine was the most commonly prescribed weight-loss medication. It was prescribed for greater than the FDA-approved 3-month period in more than 50% of those receiving a prescription. Patients with higher BMIs were more likely to receive a prescription for a weight-loss medication, and 84% of patients receiving prescriptions were women. Finally, a small number of clinicians wrote a vast majority of these prescriptions, and there was marked practice variation between sites in the rate of prescribing and the frequency of prescribing specific agents.

Low weight-loss medication utilization rates have previously been noted, with several studies showing uptake in 2% to 3% of eligible individuals (15,16). A study that used data from a national electronic prescription database in 2015 showed that despite obesity being substantially more common than type 2 diabetes, the total number of prescriptions for glucose-lowering medications was 15 times higher than those for weight-loss medications (17). These data suggest that providers view obesity and diabetes differently regarding the appropriateness of using pharmacotherapy. This same study found that 74% of all prescriptions for weight-loss medications were for phentermine and that the adoption of sodium-glucose cotransporter-2 inhibitors (a newer class of glucose-lowering medications) was nearly exponential, while adoption of new weight-loss medications was linear over time (17). This finding suggests that providers are more open to prescribing

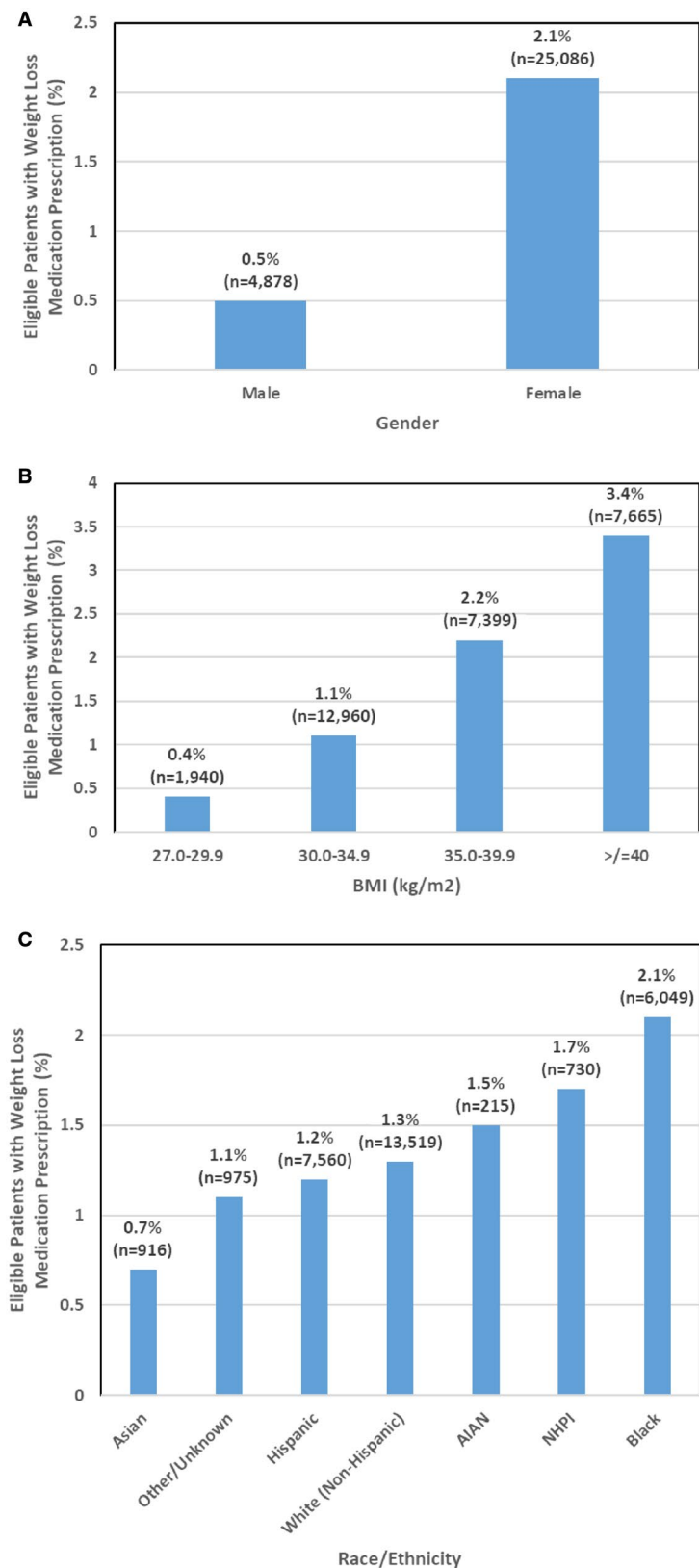


Figure 1 Weight-loss medication prescriptions by sex, BMI, and race/ethnicity. Percentage of eligible patients who received a weight-loss medication prescription by (A) gender, (B) BMI (kg/m²), and (C) race/ethnicity. AIAN, American Indian or Alaskan Native; NHPI, Native Hawaiian or Pacific Islander. [Color figure can be viewed at wileyonlinelibrary.com]

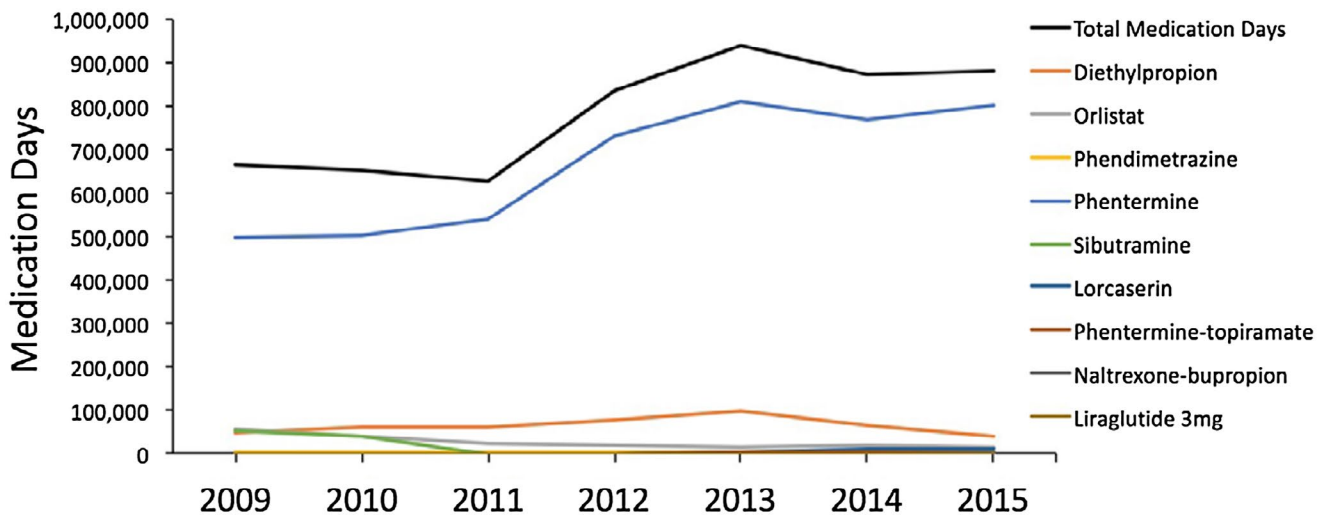


Figure 2 Temporal trends in medication days by medication type. During 2009 to 2015, the total number of weight-loss medication days increased because of an increase in the amount of phentermine prescribed.

TABLE 2 Regional variation in rates of prescribing weight-loss medications

	Overall	High region	Low region
Total medication days	6,475,480		
Phentermine	4,961,729 (76.6%)	96.3%	60.9%
Diethylpropion	788,359 (12.2%)	20.3%	0%
Orlistat	277,209 (4.3%)	7.4%	0.1%
Sibutramine	182,599 (2.8%)	17%	0.4%
Lorcaserin	132,136 (2.0%)	3.6%	0.1%
Phendimetrazine	83,250 (1.3%)	2%	0%
Phentermine/topiramate	25,930 (0.4%)	2.5%	0%
Naltrexone/bupropion	23,438 (0.3%)	0.6%	0%
Liraglutide 3 mg	830 (<0.1%)	<1%	0%

medications and adopting new classes of medications when the disease being treated is diabetes compared with obesity. Most patients receiving weight-loss medications were women (84% of all prescriptions), which is consistent with previous national trends from 1991 to 2011 (18). In this study, receipt of a weight-loss medication also varied by race and ethnicity. Such variation has not been comprehensively investigated in the literature.

Despite the low weight-loss medication utilization rates seen in the current study and others, an interesting finding within this PORTAL network cohort was the 32.9% increase in medication days in 2015 compared with 2009, led by the increase in phentermine prescriptions. Previous studies reporting on US national trends in weight-loss medications have shown higher rates in the early 2000s compared with the 1990s (but recognizing peak utilization of weight-loss medications in 1996, the year prior to the removal of fenfluramine and dexfenfluramine from the market); however, phentermine was still consistently the most commonly used weight-loss medication (18,19). From 2003 to 2011, US national trends also showed increasing use of phentermine, which remained the most prescribed weight-loss medication during that

period (18). While the earlier data showed a plateau in phentermine use between 2010 and 2011, our results shed new light on the increasing weight-loss medication days among the geographically dispersed PORTAL health networks through 2015, possibly associated with another finding from this study that phentermine was more commonly prescribed for more than 4 months.

There are several barriers to the prescribing of weight-loss medications. A lack of consistent, uniform, and complete insurance coverage for these medications may be a significant barrier to use for many patients. Furthermore, the uptake of insurance coverage for weight-loss medications tends to evolve over time and can be slow. In the case of liraglutide 3.0 mg, it is likely that insurance coverage was very low during the last year of the time period investigated in this study, as this medication was only FDA approved in December 2014. Current use of liraglutide 3.0 mg is likely to be higher now, as insurance coverage for it has improved nationally. A recent survey of 4,465 consumers about insurance coverage for weight-loss treatments found that only 21% of respondents reported that their insurance would cover weight-loss medications. This was a level of coverage that was less than that for weight-loss

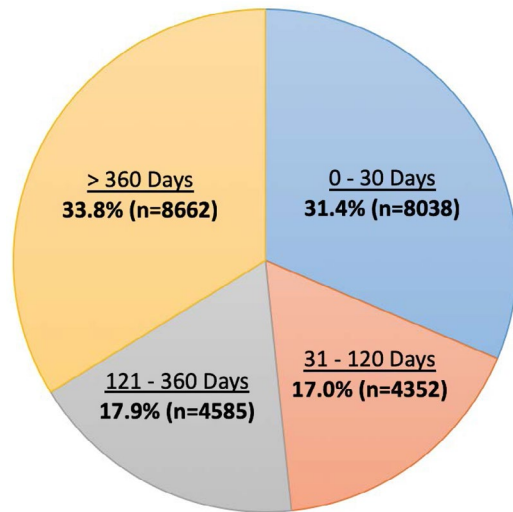


Figure 3 Phentermine treatment duration ($n=25,637$ patients).

surgery (23%) (20). Safety of these agents is also a concern for many patients and providers following the highly publicized problems seen with fenfluramine, dexfenfluramine, sibutramine, rimonabant, and herbal preparations containing ephedra alkaloids (21). This history of adverse events associated with this class of medications has made many patients and prescribers cautious. Patients and physicians may feel that these medications provide insufficient weight loss to justify their use. Although there is a growing body of evidence that a 5% weight loss provides health benefits, a survey of patients seeking behavioral weight-loss treatment reported hoping to achieve a 32% weight loss and that they would be disappointed if they lost only 17 kg (22). Finally, it may be that many care providers think that obesity is a behavioral problem and that the use of weight-loss medications is an inappropriate form of treatment (11,23). Many of these barriers are unique to the treatment of obesity and are not seen with the pharmacotherapy of other conditions.

One effect of these barriers to prescribing is that it appears a small number of prescribers are responsible for the majority of prescriptions written for weight-loss medications. We found that the providers who most frequently prescribed weight-loss medications were primary care physicians (PCPs) and not specialists. This was also the finding of previous studies (17). However, we cannot determine from the available data whether these individuals were practicing in primary care clinics or were prescribing weight-loss medications in clinics devoted to the treatment of patients with obesity. In addition, we are not able to determine how many providers at these care sites saw patients with obesity but never prescribed weight-loss medications. Recent data from a provider survey found that 76% of PCPs did not prescribe weight-loss medications long term and 58% had negative views of weight-loss medications, although rates of prescribing may be increasing (24,25). In a previous study, we surveyed PCPs in an integrated health care system serving a medically underserved population about obesity treatment. PCPs were less comfortable discussing weight-loss medications than other obesity treatments and thought that weight-loss medications were less effective than lifestyle change (12).

A second effect of the barriers to prescribing weight-loss medications is that there appears to be wide practice variation between clinical sites both in the rates of prescribing and the agents prescribed. This may be due to geographic differences in the insurance coverage for these medications or differences in the preferred medications prescribed by “frequently prescribing” providers. This marked degree of practice variation was seen in a previous study of VHA facilities (9).

As has been seen in previous studies, phentermine was found to be the most commonly prescribed weight-loss medication (18,19). Phentermine is only FDA approved for short-term use. However, current understanding of the role of weight-loss medications in obesity management is that long-term use is required for sustained benefits. In the earlier period examined by Hampp (18) (1991-2011), <5% of patients used phentermine for >1 year, but in this study, almost one-third did so and more than half used this medication for more than 3 months. Despite the availability of several new weight-loss medications since 2012, the number of unique patients receiving these medications did not change much during the time period examined. A recent study found that in low-risk individuals, a longer duration of phentermine use was associated with clinically significant greater weight loss up to 2 years after initiating the medication, with no observed increase in risk for incident cardiovascular events or death over 3 years of follow-up (26). Despite this promising observational evidence, there remains concern among clinicians about the long-term safety and efficacy of this agent. There is a need for a long-term randomized controlled trial to definitively establish the safety and effectiveness of protracted phentermine monotherapy.

Our study has several important limitations. First, it is possible that some patients were misclassified if weight-loss medication prescriptions occurred outside of our health systems. Second, we do not know the details on the insurance coverage for these medications in each region during the period of study and, as a result, cannot determine to what extent this drove low rates of prescribing or practice variation. Third, we do not know the total number of health care providers who saw these patients and so cannot determine the number of providers who did not prescribe any weight-loss medications. It should be noted that since 2015, more than 2,000 additional clinicians have received American Board of Obesity Medicine certification, and this number is increasing each year; therefore, the time period covered in this study may not be representative of modern day weight-loss medication prescribing practices, as there may be a greater number of “high prescribers” today. Fourth, we may have underestimated the overall rate of weight-loss medication prescribing, as the study was not designed to capture data on medications commonly prescribed off-label for weight loss when insurance coverage is low, such as metformin, bupropion, and topiramate. However, the strength of the study is the use of EMRs to collect data on both the types of patients receiving these medications and the providers prescribing them.

Future studies could use qualitative methods to understand the patient, provider, and care environment factors that may be responsible for the low rates of prescribing observed. In particular, factors that might explain the wide practice variations in prescribing rates and specific medications used between sites could be examined, as well as why women were much more likely to use one of these agents. Important questions also remain about the effectiveness and safety of weight-loss medications as they are used in clinical practice. The use of data from EMRs could help answer these important questions as well. **O**

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