Baseline Characteristics of PATHWEIGH: A Stepped-Wedge Cluster Randomized Study for Weight Management in Primary Care

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ABSTRACT

PURPOSE To describe the characteristics of patients and practice of clinicians during standard-of-care for weight management in a large, multiclinic health system before the implementation of PATHWEIGH, a pragmatic weight management intervention.

METHODS We analyzed baseline characteristics of patients, clinicians, and clinics during standard-of-care for weight management before the implementation of PATHWEIGH, which will be evaluated for effectiveness and implementation in primary care using an effectiveness-implementation hybrid type-1 cluster randomized stepped-wedge clinical trial design. A total of 57 primary care clinics were enrolled and randomized to 3 sequences. Patients included in the analysis met the eligibility requirements of age \geq 18 years and body mass index (BMI) \geq 25 kg/m² and had a weight-prioritized visit (defined a priori) during the period March 17, 2020 to March 16, 2021.

RESULTS A total of 12% of patients aged \geq 18 years and with a BMI \geq 25 kg/m² seen in the 57 practices during the baseline period (n = 20,383) had a weight-prioritized visit. The 3 randomization sequences of 20, 18, and 19 sites were similar, with an overall mean patient age of 52 (SD 16) years, 58% women, 76% non-Hispanic White patients, 64% with commercial insurance, and with a mean BMI of 37 (SD 7) kg/m². Documented referral for anything weight related was low (<6%), and 334 prescriptions of an antiobesity drug were noted.

CONCLUSIONS Of patients aged ≥ 18 years and with a BMI ≥ 25 kg/m² in a large health system, 12% had a weight-prioritized visit during the baseline period. Despite most patients being commercially insured, referral to any weight-related service or prescription of antiobesity drug was uncommon. These results fortify the rationale for trying to improve weight management in primary care.

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INTRODUCTION

besity remains one of the greatest current public health challenges, contributing to 4,000,000 deaths and 120,000,000 disability-adjusted life-years globally in 2015.¹ Despite the human and economic costs of obesity, its treatment is rarely prioritized in the health care setting. Reasons for lack of weight management prioritization are extensive and complex. Lack of clinician education on effective weight management and processes that systematically address weight loss and weight-loss maintenance long-term are commonly cited.² The advent of better tools and access to them might be the key to reversing this trend. Intensive behavioral therapy for obesity is now a covered benefit under Medicare.³ Medications for weight loss are increasingly efficacious, and some have shown decreases in weightrelated complications.⁴⁻⁷ Bariatric surgery can lead to substantial weight loss and reverse potentially life-threatening conditions such as heart disease and diabetes in both adolescents and adults.⁸⁻¹¹ Integrating these new approaches into primary care practice represents both a substantial challenge and a significant opportunity.

To support primary care clinicians in using evidence-based treatments for obesity, our team, comprising physicians (primary care and endocrinology) and behavioral health professionals, developed a set of disease prioritization tools for weight management in primary care called PATHWEIGH. We built tools into Epic (the electronic medical record used by our institution) (Epic Systems Corp) that

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were designed to remove barriers for clinicians to provide, and patients to receive, care for weight. Specifically, placards are placed in the clinic alerting patients that they can request a weight-prioritized visit, the duration of which varies based on the clinician's schedule. Seventy-two hours before a weight-prioritized visit, a questionnaire is sent to patients via the patient portal, which captures key historical information (ie, history of weight gain, current behaviors, barriers, and goals) and imports the patient-recorded information into the clinician's note, which ultimately guides the conversation and treatment plan. Pilot work showed a 7.2% body weight decrease for patients with PATHWEIGH vs 2.1% with standard-of-care (SOC) over a period of 18 months.¹² Early success garnered the endorsement of our regional health system leadership to implement PATHWEIGH in all 57 of its primary care clinics, with funding from the National Institutes of Health. The objective of the present analysis was to describe baseline characteristics of qualifying patients at the beginning of the study, to provide insight into the state of weight-management efforts before intervention.

METHODS

Design

The full protocol for this study has been published.¹³ In brief, we are using an effectiveness-implementation hybrid type-1 design with a stepped-wedge cluster randomized sequence to assess the effectiveness of PATHWEIGH on patient weight loss and weight-loss maintenance, as well as to determine patient, clinician, and clinic-level factors associated with its effectiveness and implementation.^{14,15} This article describes 12 months of data collection during the baseline period (ie, the year before intervention). Hence, these data are considered the initial control condition for weight management (ie, SOC). Clinics were subsequently randomized to 3 sequences using covariate constrained randomization to balance potential confounders in the stepped-wedge design. The intervention will be implemented sequentially in the *57* participating clinics in 3 steps over a 4-year period.

Outcomes

After collection of the baseline preintervention data (presented herein), the intervention was deployed and is currently ongoing. The eventual aims of this study are to (1) compare the effectiveness of PATHWEIGH vs SOC on patient weight loss and weight-loss maintenance, (2) identify patient, clinician, and clinic-level factors that are associated with weight loss and weight-loss maintenance, and (3) describe factors associated with practice adoption, implementation, and maintenance of PATHWEIGH. To achieve aims 1 and 2, prespecified data from eligible patients are extracted from the electronic medical record and deidentified with the support of the joint Health Data Compass Warehouse project (healthdatacompass.org) using a proprietary process. Raw data are delivered to research statisticians for cleaning, preparation, and data analysis. Here, we present data for patients' first eligible weight-prioritized visit (defined below) during the 1-year baseline, control, preintervention SOC period.

Participants

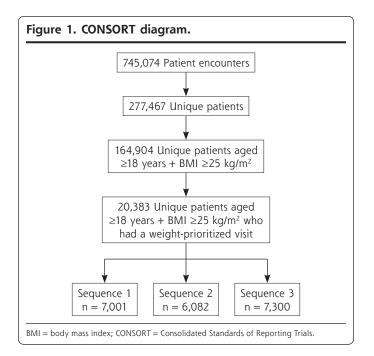
Overall data handling during the baseline period (March 17, 2020 to March 16, 2021) is presented in the Consolidated Standards of Reporting Trials diagram (Figure 1), which shows how many patient visits occurred at the clinics, how many discrete patients were seen, how many patients were age ≥ 18 years with a body mass index (BMI) ≥ 25 kg/m², and how many patients who were age ≥ 18 years with a BMI ≥ 25 kg/m² had a weight-prioritized visit (either in person or via telehealth). The latter group are the target group of interest and are described herein. A weight-prioritized visit was defined by the research team for the purpose of establishing a control condition preintervention to which the intervention will eventually be compared. The patient may or may not have requested a specific visit to discuss their weight. Focusing on weight would have been at the discretion of the patient or clinician. Weight-prioritized visits are defined as a visit with a clinician with a National Provider Identifier and ≥ 1 of the following: (1) the chief complaint or reason for the visit being "overweight," "obesity," or "weight" (excluding "weight loss" that appeared unintentional), (2) weight-related International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes for billing E66-E.66.9, Z68.25-45, or (3) use of a brief standardized obesity-focused history of present illness questionnaire administered during the rooming process (also known as the Obesity Brief History of Present Illness [HPI]). There were no systematic weight-management interventions occurring in any of the clinics for the data collection period. Information is also collected on the clinicians and clinics and will be examined as possible predictors of patient weight loss.

Measures

Patient-level data included demographic information, health metrics, diagnoses, procedures, and treatments. Patient age was censored at 90 years to protect patient privacy (given the few and therefore potentially identifiable patients of this age).

Patient BMI was extracted from the electronic medical record or when unavailable was computed using height and weight; BMI values were excluded if they were identified to be likely erroneous (height <54 in, >90 in, weight >600 lbs). Vital signs were identified as those that occurred at the weight-prioritized visit. Restrictions were imposed to censor values suggesting entry error (diastolic blood pressure <40 or >140 mm Hg, heart rate <30 or >200 beats per minute, respiratory rate <6 or >50 breaths per minute). Laboratory tests, procedures, and screening tools (2-, 8-, and 9-item Patient Health Questionnaire [PHQ-2, -8, -9] and 7-item Generalized Anxiety Disorder scale [GAD-7])^{16,17} were restricted to

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the most recent measures that occurred within 2 weeks before or 6 months after the weight-prioritized visit. Medications were only selected if the patient acknowledged them as active during the baseline period and may have been prescribed by any health care clinician in the system (eg, beyond primary care). Medications associated with weight gain and weight loss are described in <u>Supplemental Table 1</u>. Referrals and receipt of bariatric surgery were selected if they occurred during the baseline period but after the weight-prioritized visit. Comorbidities were identified based on *ICD-1()-CM* codes for billing and were captured if they occurred in the patient's health record during the baseline period. Clinician-level data included sex and number of weight-prioritized visits conducted. Clinic-level data included type (academic, nonac-ademic, affiliate), location (urban, rural), and specialty (family medicine, general internal medicine, both).

Statistical Analysis

We used descriptive statistics (mean, median, frequency, proportion) to summarize the patient, clinician, and clinic characteristics overall and by randomization sequence. Given the large sample size, we report on clinical rather than statistical differences.

RESULTS

Patients

During the period March 17, 2020 to March 16, 2021, a total of 164,904 patients aged \geq 18 years with a BMI \geq 25 kg/m² had a visit at 1 of 57 primary care clinics. Of these, 20,383 (12%) had a weight-prioritized visit. The average number of weight-prioritized visits per patient during the 12-month data collection period was 1.39 (range, 1-20) with a mean time of 94.2 days between visits among patients with >1 visit. There were a total of 32,306 weight-prioritized visits during the baseline period, for which approximately 98% were identified by *ICD-1*()-*CM* codes used for billing, 4.4% were identified by a chief complaint or reason for visit as "weight," "overweight," or "obesity" (identification schemes were not mutually exclusive), and none were identified by

Characteristic	Missing n (%)	Overall N = 20,383	Sequence 1 n = 7,001	Sequence 2 n = 6,082	Sequence 3 n = 7,300
Age, mean (SD), y	NA	52 (16)	53 (16)	52 (16)	52 (16)
Sex, No. (%)	1 (<0.1)				
Female		11,844 (58)	3,903 (56)	3,790 (62)	4,151 (57)
Male		8,538 (42)	3,098 (44)	2,291 (38)	3,149 (43)
Race/ethnicity, No. (%)	NA				
Hispanic or Latine		2,673 (13)	859 (12)	872 (14)	942 (13)
Non-Hispanic Asian		281 (1.4)	111 (1.6)	76 (1.2)	94 (1.3)
Non-Hispanic Black or African American		1,091 (5.4)	312 (4.5)	368 (6.1)	411 (5.6)
Non-Hispanic White		15,520 (76)	5,440 (78)	4,529 (74)	5,551 (76)
Non-Hispanic other		680 (3.3)	235 (3.4)	191 (3.1)	254 (3.5)
Unknown		138 (0.7)	44 (0.6)	46 (0.8)	48 (0.7)
Insurance, No. (%)	NA				
Commercial		13,015 (64)	4,535 (65)	3,915 (64)	4,565 (63)
Medicaid		1,729 (8.5)	467 (6.7)	465 (7.6)	797 (11)
Medicare		5,388 (26)	1,910 (27)	1,634 (27)	1,844 (25)
Self-pay		251 (1.2)	89 (1.3)	68 (1.1)	94 (1.3)

use of the "obesity brief HPI" intake questionnaire, despite the latter being encouraged as SOC. Baseline patient demographic characteristics are presented in Table 1 and were similar between the 3 sequences. Patients were mostly commercially insured (64%), Non-Hispanic White (76%), women (58%), with an average age of 52 years. The number of patients insured by Medicaid was low overall (8.5%).

Baseline health metrics were also not materially different between the 3 sequences (Table 2). Baseline means for BMI (~37 kg/m²), anthropometric data, vital signs, and laboratory values of interest (liver, kidney, and thyroid function tests, as well as lipids and hemoglobin A_{tc}) were similar between sequences. Similar percentages of patients were using medications associated with weight gain (12%) as with weight loss

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Characteristic	Missing No. (%)	Overall n = 20,383	Sequence 1 n = 7,001	Sequence 2 n = 6,082	Sequence 3 n = 7,300
Height, mean (SD), cm	2 (<0.1)	170 (10)	170 (10)	169 (10)	170 (10)
Weight, mean (SD), kg	NA	107 (23)	107 (23)	107 (23)	107 (23)
BMI, mean (SD), kg/m²	NA	37 (7)	37 (7)	38 (7)	37 (7)
Heart rate, mean (SD), beats/min	1,411 (6.9)	79 (13)	79 (13)	79 (13)	80 (13)
Respiratory rate, mean (SD), breaths/min	4,686 (23)	16 (2)	17 (2)	16 (2)	16 (2)
Systolic BP, mean (SD), mm Hg	1,218 (6.0)	126 (15)	128 (15)	126 (14)	126 (15)
Diastolic BP, mean (SD), mm Hg	1,221 (6.0)	79 (10)	80 (10)	79 (10)	79 (10)
Body temperature, mean (SD), °F Laboratory values of interest	2,304 (11)	97.78 (0.72)	97.80 (0.71)	97.67 (0.74)	97.84 (0.70
TSH, mean (SD), mIU/L	5,487 (27)	2.48 (4.79)	2.60 (4.85)	2.46 (5.50)	2.39 (4.01)
Triglycerides, mean (SD), mg/dL	3,600 (18)	168 (117)	170 (111)	165 (98)	168 (135)
HDL cholesterol, mean (SD), mg/dL	3,634 (18)	45 (14)	45 (14)	45 (15)	45 (14)
ALT, mean (SD), U/L	2,780 (14)	33 (41)	32 (24)	33 (63)	33 (26)
AST, mean (SD), U/L	2,780 (14)	30 (32)	30 (26)	31 (47)	30 (21)
HbA ₁ , mean (SD), %	5,420 (27)	6.06 (1.26)	6.13 (1.32)	6.02 (1.20)	6.04 (1.26
eGFR, mean (SD), mL/min/1.73m ²	8,568 (42)	77 (19)	80 (20)	77 (18)	75 (18)
Drug regimen that causes weight gain, No. (%)	NA	2,427 (12)	829 (12)	724 (12)	874 (12)
Drug regimen that causes weight loss, No. (%)	NA	2,212 (11)	709 (10)	640 (11)	863 (12)
Using O ₂ /CPAP/BPAP, No. (%)	NA	3,550 (17)	1,108 (16)	1,143 (19)	1,299 (18)
PHQ-2 completed, No. (%)	NA	17,133 (84)	6,002 (86)	5,041 (83)	6,090 (83)
Score on screen for depression/anxiety, mean (SD)			. ,	. ,	. ,
PHQ-8	1,520 (7.5)	1 (4)	1 (4)	2 (4)	1 (4)
PHQ-9	15,939 (78)	9 (7)	9 (7)	8 (7)	9 (7)
GAD-7	16,955 (83)	8 (6)	8 (6)	7 (6)	9 (6)
Smoking status, No. (%)	868 (4.3)				
Never	NA	12,211 (63)	4,117 (63)	3,759 (63)	4,335 (62)
Former	NA	5,823 (30)	1,972 (30)	1,754 (30)	2,097 (30)
Current	NA	1,481 (7.6)	449 (6.9)	421 (7.1)	611 (8.7)

ALT = alanine aminotransferase; AST = aspartate aminotransferase; BMI = body mass index; BP = blood pressure; BPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; eGFR = estimated glomerular filtration rate; GAD-7 = 7-item Generalized Anxiety Disorder scale; HbA_{1c} = glycated hemoglobin; HDL = high-density lipoprotein; NA = not applicable; PHQ-2 = 2-item Patient Health Questionnaire; PHQ-8 = 8-item patient health questionnaire; PHQ-9 = 9-item patient health questionnaire; TSH = thyroid-stimulating hormone.

(11%). Weight-related comorbidities were also not different between sequences (Table 3).

Across the sequences, the prevalence of patients currently using oxygen, continuous positive airway pressure, or bilevel positive airway pressure was 16% to 19% (Table 2). Most patients (84%) were screened for anxiety and depression using the PHQ-2 at the time of their visit in primary care. Of those who received additional screening (92.5% had a PHQ-8, 22% had a PHQ-9, and 17% had a GAD-7 performed; these were not mutually exclusive), the mean values for PHQ-8, PHQ-9 and GAD-7 were 1, 9, and 8, respectively, where cut points of 5 and 10 represent mild and moderate depression/anxiety for all 3 scales. The proportion of patients reporting as current smokers (8%) was less than the national average¹⁸ and similar across sequences. Documented referral for anything weight related (ie, to a dietician, endocrinology, bariatrics) was low (<6%), and only 334 unique prescriptions of an antiobesity drug were noted across all sequences (Table 4).

Clinicians

At the time of this analysis, a total of 514 primary care clinicians (physician, physician assistant, or nurse practitioner) saw a patient aged \geq 18 years with a BMI \geq 25 kg/m² and conducted an initial weight-prioritized visit during the baseline period (March 17, 2020 to March 16, 2021). These clinicians were mostly female (60%) with an average of 62 (SD 92) weight-prioritized visits during the baseline period (Table 5).

Clinics

Descriptive statistics for the 57 clinics participating in the study have been described elsewhere.¹³ Most of the clinics were nonacademic, family medicine practices and were located in urban or suburban settings. Characteristics, including type of practice, specialty, location, average numbers of patients seen, and percent of patients insured by Medicaid, were balanced across the sequences during the covariate constrained randomization.¹³

DISCUSSION

During the past decade, numerous strategies have been proposed to curtail the global epidemic of obesity.¹⁹ To date, no program has been able to show widespread reach, effectiveness, adoption, implementation, and maintenance. PATH-WEIGH aims to be the first pragmatic, scalable, and sustainable approach to weight management, with aspirations to disseminate nationally and internationally. We strive to shift the prevailing paradigm from treating weight-related complications to treating weight in primary care. However, it is well known that implementing sustainable change in primary care is notoriously difficult.^{20,21} To address our ultimate aim, it was essential to first capture information about the state of usual care, to which the intervention will eventually be compared.

Table 3. Weight-Related Comorbidities Present in \ge 3% of Patients					
Comorbidity, No. (%)	ICD-10- CM Code	Overall N = 20,383	Sequence 1 n = 7,001	Sequence 2 n = 6,082	Sequence 3 n = 7,300
Hypertension	110	8,790 (43)	3,130 (45)	2,607 (43)	3,053 (42)
Dyslipidemia	E78.x	7,942 (39)	2,984 (43)	2,297 (38)	2,661 (36)
Type 2 diabetes	E11.x	4,095 (20)	1,428 (20)	1,224 (20)	1,443 (20)
Anxiety	F41.x	3,901 (19)	1,392 (20)	1,201 (20)	1,308 (18)
Obstructive sleep apnea	G47.3x	3,873 (19)	1,334 (19)	1,033 (17)	1,506 (21)
Low back pain	M54.x	3,000 (15)	1,023 (15)	892 (15)	1,085 (15)
GERD	K21.x	2,829 (14)	1,007 (14)	876 (14)	946 (13)
Depression	F32.x	2,333 (11)	902 (13)	631 (10)	800 (11)
Osteoarthritis	M15.x-M19.x	1,295 (6.4)	501 (7.2)	374 (6.1)	420 (5.8)
CAD	l25.x	835 (4.1)	321 (4.6)	228 (3.7)	286 (3.9)
CKD	N18.x	810 (4.0)	296 (4.2)	205 (3.4)	309 (4.2)
NAFLD	K76.0	676 (3.3)	256 (3.7)	187 (3.1)	233 (3.2)

CAD = coronary artery disease; CKD = chronic kidney disease; GERD = gastroesophageal reflux disease; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modifications; NAFLD = nonalcoholic fatty liver disease.

Table 4. Patient Referrals and Treatment					
Characteristic	Overall N = 20,383	Sequence 1 n = 7,001	Sequence 2 n = 6,082	Sequence 3 n = 7,300	
Referrals, No. (%)					
Bariatrics	366 (1.8)	122 (1.7)	94 (1.5)	150 (2.1)	
Behavioral health	448 (2.2)	133 (1.9)	248 (4.1)	67 (0.9)	
Dietician	1,144 (5.6)	407 (5.8)	396 (6.5)	341 (4.7)	
Endocrinology	1,070 (5.2)	321 (4.6)	356 (5.9)	393 (5.4)	
Health and wellness	832 (4.1)	239 (3.4)	325 (5.3)	268 (3.7)	
Bariatric procedure performed, No. (%)	68 (0.3)	23 (0.3)	23 (0.4)	22 (0.3)	
Prescriptions, No. (%)					
Bupropion-naltrexone (Contrave)	44 (0.2)	15 (0.2)	16 (0.3)	13 (0.2)	
Phentermine (Pondin/Fastin)	258 (1.3)	94 (1.3)	68 (1.1)	96 (1.3)	
Liraglutide (Saxenda)	5 (<0.1)	1 (<0.1)	1 (<0.1)	3 (<0.1)	
Lisdexamfetamine (Vyvanse)	14 (<0.1)	6 (<0.1)	3 (<0.1)	5 (<0.1)	
Orlistat (Xenical/alli)	1 (<0.1)	1 (<0.1)	0 (0)	0 (0)	
Phentermine-topiramate (Qsymia)	12 (<0.1)	5 (<0.1)	4 (<0.1)	3 (<0.1)	

The present analysis describes the baseline (preintervention) characteristics of patients, clinicians, and clinics for 57 primary care sites in which PATHWEIGH will be deployed. Of patients aged \geq 18 years with a BMI \geq 25 kg/m² seen in the 57 primary care clinics, 12% had a weight-prioritized visit during the baseline period. Despite most patients being commercially insured, documented referral to any weight-related service or prescription of antiobesity drug (in primary care or elsewhere) was uncommon. These results underscore the need for the work that will follow.

Obesity is increasingly recognized not only as a risk factor for disease, but a disease unto itself.²² Despite this fact, <1% of people with any degree of overweight or obesity are offered anything other than lifestyle advice,²³ suggesting

> that the medical community at large has yet to embrace its designation as a disease state. The Centers for Medicare and Medicaid Services Healthcare Effectiveness Data and Information Setmandated measurement of BMI might be the tipping point to turn this tide. Body mass index is currently measured for only 30% to 60% of patients.²³⁻²⁵ Measurement of BMI has been linked to increased diagnosis and treatment of obesity.²⁶⁻²⁸ Data collected during the baseline/control period for the present trial show 90% capture of BMI for patients seen during this time in primary care. Of these patients, 20,383 aged ≥ 18 years with a BMI ≥ 25 kg/m² received enough care for their weight that the clinician used a weight-related *ICD-10-CM* code for billing. These

results are encouraging and imply fertile ground for the introduction of a novel approach to weight management in primary care.

Baseline demographic data for the patients receiving a weightprioritized visit in our health care system's primary care clinics reflect that patients are mostly commercially insured, White women, aged in the mid-50s, which is highly consistent with other reports.^{24,25,29} Despite this demographic, early signs of weightrelated complications were recognized. For example, the mean BMI of 37 kg/m², together with the high plasma triglyceride and hemoglobin A_{1c} levels observed, is consistent with high rates of metabolic syndrome in this group.³⁰ In addition, the mean estimated glomerular filtration

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Characteristic	Overall N = 514	Sequence 1 n = 172	Sequence 2 n = 152	Sequence 3 n = 190
Clinician sex, n (%)				
Female	308 (60)	95 (55)	96 (63)	117 (62)
Male	203 (39)	77 (45)	55 (36)	71 (37)
Unknown	3 (0.6)	0 (0)	1 (0.7)	2 (1.1)
Weight-prioritized visits, mean (SD)	62 (92)	63 (113)	64 (80)	58 (81)
Total visits (including WPV), mean (SD)	1,229 (955)	1,300 (999)	1,319 (936)	1,094 (917)

code or misclassification based on chief complaint or reason for visit. Third, the analysis is limited to patients aged ≥ 18 years with a BMI ≥ 25 kg/m² who had a weight-prioritized visit in the 57 primary care clinics during the period March 17, 2020 to March 16, 2021. This population might not be representative of areas with greater racial and ethnic diversity, different socioeconomic conditions, or in underserved or unin-

rate was in the range for stage 2 chronic kidney disease.³¹ Although these diagnoses might not be commonly managed in primary care, our findings should prompt health care clinicians to consider prioritizing weight management as a way to harmonize therapy.

Most of the primary care clinics in the present study are nonacademic, community-based clinics located in urban or suburban areas. The baseline characteristics of the clinics and clinicians might or might not resemble those domestically as well as abroad. Nevertheless, practice patterns for weight management adopted by the clinicians are highly consistent across primary care regardless of setting.³²⁻³⁵ In general, the literature reports that clinicians are reluctant to treat obesity as a chronic, progressive medical disease.² Our data reveal that referral for anything weight related was low (<6%), and only 334 prescriptions of an antiobesity drug were noted for 20,383 patients. To address the low rate of treating obesity, our health system designed an intake questionnaire to facilitate weight management (ie, the Obesity brief HPI). During the time of this data collection, no clinician used that intake questionnaire, which raises the question of whether any SOC actually exists for weight management, and if so, how it might be captured in the electronic medical record. Clinical trials are required to offer SOC to their placebo-treated participants. Arguably, the 500-kcal per day caloric restriction and 150-minutes/week of moderate aerobic activity recommended in clinical trials testing antiobesity drugs^{36,37} might be more rigorous than what patients receive in a medical setting despite knowing that the former renders nominal weight loss. These observations were made in primary care but most certainly extend throughout all health care contexts and speak to the need for collaborative, long-term approaches to weight management.

There are several limitations to the present analysis. First, we aimed to establish baseline SOC; however, it does not appear that SOC for weight management truly exists. Therefore, PATHWEIGH will ultimately be compared with usual care, rather than SOC, in practice. Our findings are consistent with other reports that comprehensive weight management is uncommon in primary care. Second, our definitions of a weight-prioritized visit might be imprecise, whether by differing rigor of care resulting in a weight-related *ICD-1*0-*CM*

sured populations or do not choose to have care at a large health system practice. Patients meeting the age and BMI criteria who did not have a weight-prioritized visit were excluded from this analysis, which might create selection bias in the data. Lastly, the baseline data collection occurred during the coronavirus disease 2019 pandemic, including the initial lockdown period, at which time in-person access to medical care was limited, and many people might have experienced weight gain.

In conclusion, >160,000 patients aged \geq 18 years with a BMI \geq 25 kg/m² were seen (mostly in person) in 1 of the 57 health system primary care clinics during the period March 17, 2020 to March 16, 2021, approximately 12% of whom had a weight-prioritized visit. Thus, 88% of patients who were eligible for a weight-prioritized visit did not have one. Even for those patients who were seen for their weight, very little was done in terms of medical treatment or referral to someone specializing in weight management. These results unmask an enormous unmet need to develop pragmatic approaches to implementing weight management in primary care.

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Key words: body mass index; primary care; weight management

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Supplemental materials

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