# Baseline characteristics of PATHWEIGH: a stepped-wedge cluster randomized study for weight management in primary care



E. Seth Kramer, DO, MPH<sup>1</sup>, Leigh Perreault, MD<sup>2,3</sup>, Krithika Suresh, PhD<sup>1, 6</sup>, Carlos Rodriguez, PhD<sup>1</sup>, L. Miriam Dickinson, PhD<sup>1</sup>, Emileigh Willems, PhD<sup>4</sup>,

Peter C. Smith, MD<sup>1</sup>, Johnny Williams II, MPH<sup>1</sup>, R. Mark Gritz, PhD<sup>5, 6</sup>, Jodi Summers Holtrop, PhD, MCHES<sup>1, 6</sup>

<sup>1</sup>Department of Family Medicine; University of Colorado Anschutz Medical Campus, Aurora, CO; USA <sup>2</sup>Department of Medicine; Division of Endocrinology, Metabolism and Diabetes; University of Colorado Anschutz Medical Campus, Aurora, CO; USA <sup>3</sup>Department of Epidemiology; Colorado School of Public Health, Aurora, CO; USA <sup>4</sup>Department of Biostatistics and Informatics; Colorado School of Public Health, Aurora, CO; USA <sup>5</sup>Department of Medicine; Division of Health Care Policy and Research; University of Colorado Anschutz Medical Campus, Aurora, CO; USA <sup>6</sup>Adult and Child Center for Outcomes Research and Delivery Science; University of Colorado Anschutz Medical Campus, Aurora, CO; USA



# Background

PATHWEIGH is a set of disease prioritization tools for weight management built into EPIC (the electronic medical record) and deployed in primary care. It is being studied with supportive implementation strategies in an effectiveness-implementation hybrid type 1 cluster randomized stepped wedge design. The goal of the study is to examine the effectiveness of PATHWEIGH on patient weight loss and weight loss maintenance, as well as patient, provider and clinic level factors associated with its effectiveness and implementation. The objective of the current analysis describe baseline characteristics of eligible patients at the beginning of the study to provide insight into the current state of weight management efforts pre-intervention.

# Methods

Fifty-seven primary care clinics in Colorado were enrolled and randomized to three constrained using covariate sequences randomization. The current analysis describes the baseline characteristics of the patients and clinics while conducting standard-of-care (SOC) for weight management. Eligibility requirements for patients were age >18 years and body mass index (BMI) ≥25 kg/m<sup>2</sup> who had a weightprioritized visit in the prior year. A weightprioritized visit was defined as a chief complaint or reason for visit that included "weight", "overweight", and/or "obesity", ICD-10 codes for weight or use of an intake questionnaire for weight.

# Results

20,383 patients met these eligibility requirements between March 17, 2020 and March 16, 2021, the vast majority of whom were identified by weight-related ICD-10 codes. This cohort represents 12% of patients ≥18 years and body mass index (BMI) ≥25 kg/m² seen at the clinic during this baseline period. The three randomization sequences of 20, 18, and 19 sites were similar with an overall median age of 53 years (IQR: 39-65), 58% women, 76% non-Hispanic whites, 64% commercial insurance, and median BMI of 36 kg/m² (IQR: 32-41). No sequence differences were seen for vital signs, relevant laboratory values, or numbers of comorbidities or medications that cause weight loss or weight gain. Referral for anything weight-related was low (<6%) and only 334 prescriptions of an anti-obesity medication were noted.

<sup>1</sup>n (%)

# Baseline Period Characteristics of Eligible Patients with a Weight Prioritized Visit

Characteristic <sup>1,2</sup>	Missing (%)	Overall N = 20,383
Height (cm)	2 (<0.1%)	170 (10)
Weight (kg)	-	107 (23)
BMI (kg/m²)	-	37 (7)
Heart Rate (bpm)	1,411 (6.9%)	79 (13)
Respiratory Rate (rpm)	4,686 (23%)	16 (2)
Systolic BP (mmHg)	1,218 (6.0%)	126 (15)
Diastolic BP (mmHg)	1,221 (6.0%)	79 (10)
Temperature (°F)	2,304 (11%)	97.78 (0.72)
Lab values of interest		
TSH (mIU/I)	5,487 (27%)	2.48 (4.79)
Triglycerides (mg/dl)	3,600 (18%)	168 (117)
HDL (mg/dl)	3,634 (18%)	45 (14)
ALT (U/L)	2,780 (14%)	33 (41)
AST (U/L)	2,780 (14%)	30 (32)
A1c (%)	5,420 (27%)	6.06 (1.26)
eGFR (ml/min/1.73m <sup>2</sup> )	8,568 (42%)	77 (19)
Using medications that cause weight gain	-	2,427 (12%)
Using medications that cause weight loss	-	2,212 (11%)
Using O2/CPAP/BIPAP	-	3,550 (17%)
PHQ2 Completed	-	17,133 (84%)
Score on screener for depression/anxiety		
PHQ8	1,520 (7.5%)	1 (4)
PHQ9	15,939 (78%)	9 (7)
GAD7	16,955 (83%)	8 (6)
Smoking Status	868 (4.3%)	
Never	, ,	12,211 (63%)
Former		5,823 (30%)
Current		1,481 (7.6%)

<sup>&</sup>lt;sup>1</sup>Continuous variables are reported as Mean (SD); Categorical variables are reported as n (%)

<sup>2</sup>A1c, hemoglobin A1c; ALT, alanine Aminotransferase; AST, aspartate aminotransferase; eGFR, estimated glomerular filtration rate; HDL, high density lipoprotein; TSH, thyroid stimulating hormone; CPAP, continuous positive airway pressure; BPAP, bilevel positive airway pressure; PHQ, personal health questionnaire; GAD, generalized anxiety disorder.

# Total number of patient encounters n = 745,074Total number of unique patients n = 277,467Total number of unique patients $\geq 18$ years + BMI $\geq 25$ kg/m² n = 164,904Total number of unique patients $\geq 18$ years + BMI $\geq 25$ kg/m² who had a weight-prioritized visit n = 20,383Sequence 1 Sequence 2 Sequence 3 n = 7,001Patient referrals and treatment

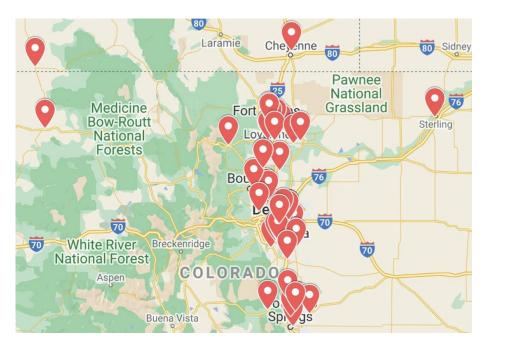
Weight-related treatments <sup>1</sup>	Overall	
Referrals	N = 20,383	
Bariatrics	366 (1.8%)	
Behavioral Health	448 (2.2%)	
Dietician	1,144 (5.6%)	
Endocrinology	1,070 (5.2%)	
Health and Wellness	832 (4.1%)	
Bariatric procedure performed	68 (0.3%)	
Prescriptions		
Buproprion-naltrexone/Contrave	44 (0.2%)	
Phentermine/Pondin/Fastin	258 (1.3%)	
Liraglutide/Saxenda	5 (<0.1%)	
Lisdexamfetamine/Vyvanse	14 (<0.1%)	
Orlistat/Xenical/Alli	1 (<0.1%)	
Phentermine-topiramate/Qsymia	12 (<0.1%)	

## **Conclusions**

Of patients ≥18 years and body mass index (BMI) ≥25 kg/m² seen in the 57 primary care clinics, only 12% had a weight-prioritized visit during the baseline period. Despite most being commercially insured, referral to any weight-related service or prescription of anti-obesity medication was uncommon. These results underscore the need for the work that will follow. There is a clear and critical need for pragmatic approaches to weight management in primary care.

## Limitations

First, because of the lack of a standard, PATHWEIGH will be compared to usual care, rather than SOC, in practice. Second, our definitions of a weight-prioritized visit may also be imprecise. Third, this analysis is limited to patients ≥18 years old with a BMI ≥25 kg/m² which may not be a fully representative sample. Finally, the baseline data collection occurred during the COVID-19 pandemic, including the initial lockdown period, which limited access to in person medical care and led to weight gain in many patients.



Location of primary care clinics in CO & WY included in this analysis

Competing interests: Leigh Perreault has received personal fees for consulting and/or speaking from Novo Nordisk, Sanofi, Elli Lilly, Boehringer Ingelheim, Astra Zeneca, Medscape, WebMD and UpToDate. All other authors have no conflicts to disclose.