

**Introduction of Semaglutide as an Effective Option for Obese Patients Motivated to Lose
Weight**

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Abstract

Obesity has become a global crisis with a tremendous impact on patients and costs reaching billions of dollars each year. Prevention and treatment of this condition will be crucial to ongoing efforts to prevent its long-term complications. Health care providers may have the opportunity to educate patients and address weight management issues before serious complications develop. The United States Centers for Disease Control and Prevention, the American Heart Association, and many publications in the medical literature focus on methods that might be used to target weight loss with diet and exercise. Unfortunately, many patients have had little to no success with these methods and thus might benefit from pharmacological interventions. The purpose of this Quality Improvement (QI) project was to provide assistance to those patients seeking help with weight loss using a pharmaceutical tool that is supported by current research. I chose to treat obese male and female patients with BMIs >27 with semaglutide. Calorie intake, physical activity, and progress toward individual weight loss goals were monitored. The Kurt Lewin model and change theory was used to facilitate sharing of knowledge and to monitor progress through the stages of organizational change through implementation. Likewise, Plan-Do-Study-Act cycles were used as a pragmatic research tool to assist with the implementation of the planned intervention. 18 Patients enrolled in the QI study were provided with a prescription for semaglutide which was titrated to up to 2.4 mg per week. The patients were weighed initially and again at follow-up two to four weeks later, depending on the exact time that treatment was initiated. The findings revealed that administration of semaglutide resulted in a 16% loss of total body weight during this time interval, including weight losses of 3–11 pounds and reductions in BMIs ranging from 0.5–2.7 kg/m². Patients

reported improvements in sleep and overall quality of life, including better moods as well as improved health and appetite control.

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Obesity is characterized by abnormal or excess fat accumulation, calculated based on height and weight ratio and classified by the World Health Organization as overweight with a BMI greater than or equal to 25, and obesity greater than or equal to 30 (Obesity and weight, 2021) Obesity is a serious chronic disease with increasing prevalence throughout the United States. Obesity is also a growing global health crisis that has resulted in a substantial burden on health care systems worldwide (Friedrichsen, 2021). This condition not only has a significant effect on overall health and health care costs, but it also has a tremendous impact on individual productivity and military readiness (United States [U.S.] Centers for Disease Control and Prevention [CDC], 2021). Approximately one in five children and two in five adults in the U.S. currently struggle with obesity (U.S. Department of Health and Human Services, 2013); one in four adults are too heavy to serve in the military (U.S. Department of Health and Human Services, 2013). From 2017 to 2018, the prevalence of obesity in the U. S. had grown from 30.5% reported between 1999 and 2000 to its current level of 42.4% (CDC, 2021).

Health care costs associated with obesity are currently ~\$147 billion per year in the U. S. alone; this can be compared to healthcare costs of \$1,429 for each person that maintains a healthy weight (CDC, 2021). The 2013–2016 update from the Healthy People 2030 initiative reported that 38.6% of adults >20 years of age in the U.S. were obese (U.S. Department of Health and Human Services, 2013). Obesity rates will increase over the next decade; linear trends predict that 51% of the population will be obese by the year 2030 (Finkelstein et al., 2012).

Problem Description

As part of my clinical practice with Dr. Michael Annabi, El Paso, Texas, I frequently prescribed phentermine to assist patients with weight loss. However, phentermine is indicated for short-term use only, up to a maximum of 12 weeks. Although this drug is effective at stimulating the central nervous system and providing patients with a sense of satiation, it is an amphetamine-like stimulant that needs to be used with caution to avoid issues associated with addiction, dependence, and withdrawal. While phentermine use can result in a 5% weight loss, it should be prescribed with caution to patients diagnosed with hypertension or cardiovascular disorders (Yanovski & Yanovski, 2014). Because most of my patients have been diagnosed with hypertension, and I would rather avoid the risks of increasing complications, I was curious to identify an alternative treatment plan.

Context

After reviewing my 10-day Reflective Practice Log that documented a clinical needs assessment of patients in my practice, I documented, reviewed, and reflected at length on my findings. Among my findings, I discovered that some of my phentermine treatment interventions did not result in effective weight loss. I identified three opportunities based on population/patient, intervention/indicator, comparison/control, outcome, and time (PICOT) questions that might be addressed to improve the care I currently provide to my patients. I met with my Doctor of Nursing Practice (DNP) chairperson and together we selected one QI project. Once the chairperson approved the project, I initiated a literature review and collected several sources. The 5 sources discussed in the paragraph to follow were those with the highest level of evidence that validated the goals of my QI project.

A study by Wadden et al. (2021) included 611 adults who were overweight or obese who underwent 68 weeks of treatment with once-weekly treatments of subcutaneous semaglutide or placebo. These interventions were combined with intensive behavioral therapy and a low-calorie diet to be followed for the first eight weeks. The results of this study revealed significantly greater overall reductions in body weight among those treated with semaglutide compared to placebo (16.0% *versus* 5.7%, respectively; $P < .001$).

Rubino et al. (2021) reported the results of a study that enrolled 803 participants who were overweight or obese and then completed a 20-week course of treatment with subcutaneous semaglutide at 2.4 mg per week. The mean weight loss in this patient cohort was 10.6%. A randomized trial that featured semaglutide *versus* placebo for an additional 48 weeks revealed continued weight loss.

Similarly, Wilding et al. (2021) reported the results of a double-blind trial that included 1,961 non-diabetic adults with BMIs ≥ 30 in a 68-week trial with once-weekly semaglutide (2.4 mg/week) plus lifestyle intervention. Patients treated with semaglutide exhibited weight reductions of at least 5% as well as improved cardiometabolic risk factors and increases in participant-reported physical functioning compared to those treated with the placebo. Overall, administration of semaglutide resulted in sustained reductions in body weight that increased throughout the 68-week treatment trial.

Friedrichsen et al. (2021) conducted a double-blind, parallel-group trial that included 72 obese adults who were randomized to once-weekly semaglutide (2.4 mg/week) or placebo for 20 weeks. A full evaluation of appetite, gastric emptying, and energy intake revealed that patients treated with semaglutide exhibited reduced hunger and food consumption and experienced

increased fullness and satiety compared to those treated with placebo. The results of the study revealed that patients treated with semaglutide responded with an average 9.9% reduction in body weight compared to only 0.4% among patients treated with a placebo.

Rubino et al. (2022) also reported the results of a randomized, open-label, 68-week, phase 3b trial that included 338 participants presenting with BMIs ≥ 30 or BMIs >27 with one or more weight-related comorbidities other than diabetes. Patients were treated with semaglutide (titrated up to 2.4 mg per week) or once daily liraglutide (3.0 mg), both with adjustments to diet and physical activity. Among the findings, the authors reported a mean weight loss of 15.8% from baseline to 68 weeks in patients treated with semaglutide compared to a mean weight loss of 6.4% among patients treated with liraglutide.

The results from the literature review provide a clear understanding of how semaglutide might be used to treat obese patients with a BMI >27 kg/m². The knowledge gained from these clinical trials will provide insight into new ways to treat obesity and reduce its associated complications, including type 2 diabetes (T2DM), heart disease, hypercholesterolemia, asthma, anxiety, depression, and some cancers. It may also reduce health care costs and promote an overall healthier lifestyle.

Upon completion of my literature review, I gained approval to proceed from my worksite supervisor. I sent all the necessary information to the Institutional Review Board at the University of Texas at El Paso for their consideration and approval. Once I received my letter of approval FWA No: 00001224, I initiated the QI project.

Available Knowledge

The prevalence of adult obesity and BMIs ≥ 30 kg/m² has increased since the 1970s (CDC, 2021). Obesity can lead to many other diseases, including T2DM, heart disease, hypercholesterolemia, asthma, anxiety, depression, and some cancers (U.S. Department of Health and Human Services, 2013). A healthier lifestyle that includes regular physical activity and an appropriate diet will help individuals to achieve and maintain a healthy weight.

Semaglutide is a synthetic agent with a spectrum of activity that mimics that of glucagon-like peptide-1 (GLP-1). GLP-1 is a peptide hormone that is expressed in the gut, brainstem, and the endocrine pancreas that circulates systemically and controls energy balance via interactions with its receptor (Drucker, 2022). The actions of GLP-1 help to control the food intake and contribute to weight loss without changes in energy expenditure or promoting delayed gastric emptying (Friedrichsen, 2021). O' Neil (2018) reported the results of a randomized, double-blind, placebo, and active-controlled multicenter dose-ranging phase 2 trial featuring semaglutide to promote weight loss. The project was conducted at 71 clinical sites in eight countries and enrolled 957 patients with BMI ≥ 30 kg/m² who were treated with semaglutide doses that were titrated upward every 4 weeks for 52 weeks. All semaglutide doses were well-tolerated and presented no new safety concerns. The most common adverse events were dose-related gastrointestinal symptoms, primarily nausea, like those reported previously in response to GLP-1 receptor agonists.

GLP-1 neurons in the hindbrain and hypothalamus are important for transducing signals transmitted in response to GLP-1-mediated receptor activation that ultimately led to reduced food intake and weight loss (Drucker, 2022). Semaglutide-receptor interactions were detected in the hypothalamus, brainstem, and septal nucleus and led to a reduction in food intake (Drucker, 2022). According to Drucker (2022, p. 3):

“Transcriptional responses to semaglutide detected in neurons, glial cells, astrocytes, tanycytes, vascular and leptomeningeal cells and ependymal cells. The AP exhibited the greatest number of differentially expressed mRNA transcripts, including Bdnf, Ghrh, Pam, Ptpn, Vgf, Cartpt, and Pdyn. Notably, the majority of Glp1r+ and glucose-dependent insulinotropic polypeptide receptor (Gipr)+ cells within the AP did not co-express both receptor mRNAs.”

Rationale

I used the Lewin translational framework model to translate and implement effective interventions that influence both individual and collective determinants of health by addressing policy, practice, and future research (Lewin, 1958). Evidence incorporated into common practice to generate new guidelines for “preventing, diagnosing, and treating exposure, illness, and disease; formalizing new public health interventions; institutionalizing local, regional, state, national, or international policy practices; informing standard risk management protocol; or motivating behavior change at individual, family, group, or population levels” (National Institute of Environmental Health Sciences, 2019).

Lewin’s model can be used by leaders to share knowledge and identify the stages that are needed to process and implement organizational change. The model includes three specific stages: unfreezing, changing, and refreezing. The process of unfreezing begins with a successful evaluation of the internal and external factors and identification of the strategy that will be most effective for promoting change within an organization. This stage includes assessments of task assignments, customer service, and performance outcomes. In this case, the unfreezing step focused on our decision to make attempts to reduce the prevalence of obesity and its

complications in our patient cohort. In the refreezing stage this is what helps provide the support and training needed to sustain the change. It assists to anchor the changes into culture for future success. The refreezing stage, change is implemented via active planning within the current state of the organization. Stakeholders committed to planning and the development of change management structures will be needed to achieve successful change (Hussain, 2018).

Specific Aims

Strategies to address weight loss management and behavior are integral to patient-centered care; these are among the six aims of healthcare defined by the Institute of Medicine (Agency for Healthcare Research and Quality [AHRQ], 2018). Health care professionals should address obesity as a chronic disease during its earliest stages and should not wait until other complications develop. The impact of obesity might be minimized by incorporating efforts to provide patient-centered care via an evaluation of an individual's weight and BMI and early discussions of various treatment options. Thus, this QI project aimed to offer a treatment option in which semaglutide was provided as an option for obese individuals who were not losing weight in response to short-term treatment with phentermine and were able to continue long-term treatment to sustain weight loss.

Methods

Interventions

The Plan-Do-Study-Act (PDSA) cycle method was used to direct this project. The Institute for Healthcare Improvement (2022) promotes the use of PDSA cycles as a valuable tool for promoting change and accelerating improvement. This model also provides insight into

quality improvement modifications that may offer better results when implemented on a larger scale.

Plan: The Plan phase of this project consisted of a meeting with the primary care practice manager to determine the overall interest in provider participation. A brief overview of the project was provided together with opportunities for follow-up after each physician was informed of the specific request. I also participated in a follow-up call meeting with the primary care office staff during which I explained the project proposal to the providers in greater detail.

A meeting was then held with the front office staff, medical assistants, the office manager, and the providers. The purpose of this meeting was to ensure that everyone understood the plan and focus of the project. The protocol was explained clearly at this meeting and preliminary plan for project implementation were established. The process involved the identification of patients with BMIs ≥ 27 kg/m² and at least one weight-related comorbidity who were seeking to lose weight. Patients were excluded if they presented with a thyroid nodule or a history of pancreatitis or neoplastic disease. The entire team understood the plan.

A review was requested from both Institutional Review Board (IRB) and the facility site. The IRB found this project to be exempt from further review. Approval was obtained from the project site, the Michael Annabi Outpatient Clinic. Preliminary dates were established to facilitate pre-implementation discussions, implementation, and post-intervention discussions.

Do: The “Do” phase of this project included a pre-implementation discussion with the provider, office staff, and office manager. This was followed by the implementation phase. The front office scheduled appointments for patients who were specifically seeking assistance with weight loss management. The medical assistants identified potentially eligible patients based on

their vital signs, BMI ≥ 27 kg/m², initial weight, and/or specific interest in weight loss management. Patients were also screened for diagnoses that included non-alcoholic fatty liver disease, cardiovascular disease, and chronic kidney disease. All participants were provided with a printed packet that described the various treatment options available from the provider. Information in this packet included the patient's current BMI, strategies to manage weight without feeling hungry, instructions on adjusting recipes to reduce calories, foods that might lead to more rapid satiation, education on healthy eating plans, the importance of physical activity and amounts recommended per week by the CDC, calories burned based on activity level, applications to assist with calorie counting, and the serious nature of the complications that can develop in patients with chronic obesity. The information provided was consistent with CDC guidelines and recommendations for activity, calorie counting, lifestyle modifications, and the importance of complications that can occur with long-term obesity.

Patients that met the aforementioned criteria and agreed to start medication were provided with the first dose of semaglutide while at the clinic. The goal was to titrate the drug dose from 0.25 mg to 2.4 mg per week during the first month of treatment. Each patient was also provided with a questionnaire focused on present weight, BMI, target weight loss goal, problems faced when attempting weight loss, and previously pharmacological interventions. Patients were asked to document (1) their daily physical activity and caloric intake for four weeks, (2) participation in counseling sessions with a dietician, and (3) any side effects experienced while on semaglutide. They were also asked to provide follow-up information on any improvements in sleep, quality of life, mood, and general feelings of health and well-being, including appetite and energy levels. Improvements in blood pressure, liver enzymes, and renal function were also noted. Patients were educated on administration and the ongoing treatment plan and were

followed up in two to four weeks. The program also included a post-intervention discussion focused on implementation and suggestions for future use.

Study and Act: Findings from all participants were gathered on a tracking sheet. Analysis of these findings was performed, and information was provided to the health care staff at the post-intervention meeting. Feedback from the office staff was discussed and used to modify our ongoing management of these patients. Among the changes, we learned that the educational aspects of this program took considerable time and thus we avoided scheduling patients on days when this could not be easily accommodated. Results were analyzed and recommendations for future use were developed. The data obtained from the tracking sheets provided us with specific data as well as an overall impression of the success of this intervention. We found that the PDSA process was effective when applied to pragmatic trials. The reactions of clinic staff to this process may facilitate the integration of evidence-based interventions into routine care processes.

Study of Interventions

Using Lewin's theory framework model of change, patients were educated on evaluating their personal preparedness for change. Patients were asked to consider their current comfort zone with respect to dietary intake and exercise. During the two to four weeks of this study, we had the opportunity to evaluate and motivate the patients to monitor their own intake and activity levels. As part of the unfreezing stage, patients become motivated for change as they consider the pros and cons of the treatment strategies. Providers assisted patients with calorie counting and exercise helped them evaluate their starting points and final weight goals. During this transition stage, "unfrozen" patients were introduced to a new way of losing weight and monitoring their progress toward their personal weight loss goals. During the refreezing stage,

patients report that they have accepted the change and choose to continue treatment because they experienced remarkable results. The patients report that they were excited with these results and encouraged to continue ongoing weight management.

The approach to assessing the impact of semaglutide on patient health and well-being was based on the results of the randomized control trials evaluated as part of the literature review. These studies revealed that administration of semaglutide resulted in improvements in cholesterol levels, fatty liver, BMI, mood, appetite, and overall health. Patients were followed-up with post-treatment weight and BMI measurements. The approach chosen focused on long-term improvements not only with respect to weight loss but also overall health status. Previous weight loss strategies that included phentermine were limited to 90 days and thus focused primarily on lifestyle interventions and calorie counting. By contrast, treatment with semaglutide resulted in long-term effects with no evidence of rebound weight gain after discontinuation of the medication.

Initially, the evaluation phase involved scheduled four-week follow-ups; however, this proved to be inconvenient because it did not correspond with other deadlines. Instead, the patients were asked to complete the audit form at home and to bring it to each follow-up appointment. Qualitative data were collected with open-ended questions, evaluation, and feedback regarding medication, activity, and treatment outcomes. The data collected from the patients were analyzed to generate conclusions regarding this intervention.

Measures

The process used shaped the steps taken to achieve the desired degree of progress and patient outcomes. Information from the survey helped us to assess current patient status and to

identify factors affecting their results and interventions that might be used to promote ongoing weight loss. The health care team followed up with each patient to determine both weight and BMI measurements before and after the intervention.

Ethical Considerations

The project was fundamentally designed and conducted according to ethical principles to ensure the quality, safety, and value of health care services provided as well as opportunity costs, privacy, and accommodations required by the clinic staff. Ethical considerations were used to guide this project and to adhere to a code of conduct that ensured that the data were collected and utilized following patient privacy laws.

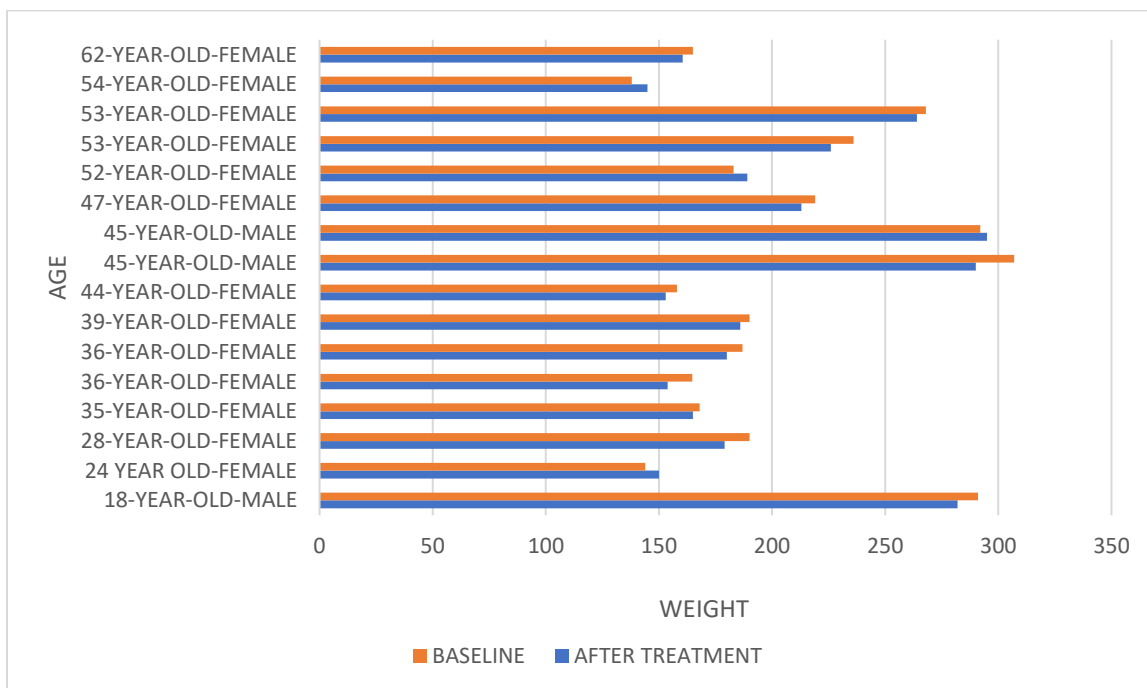
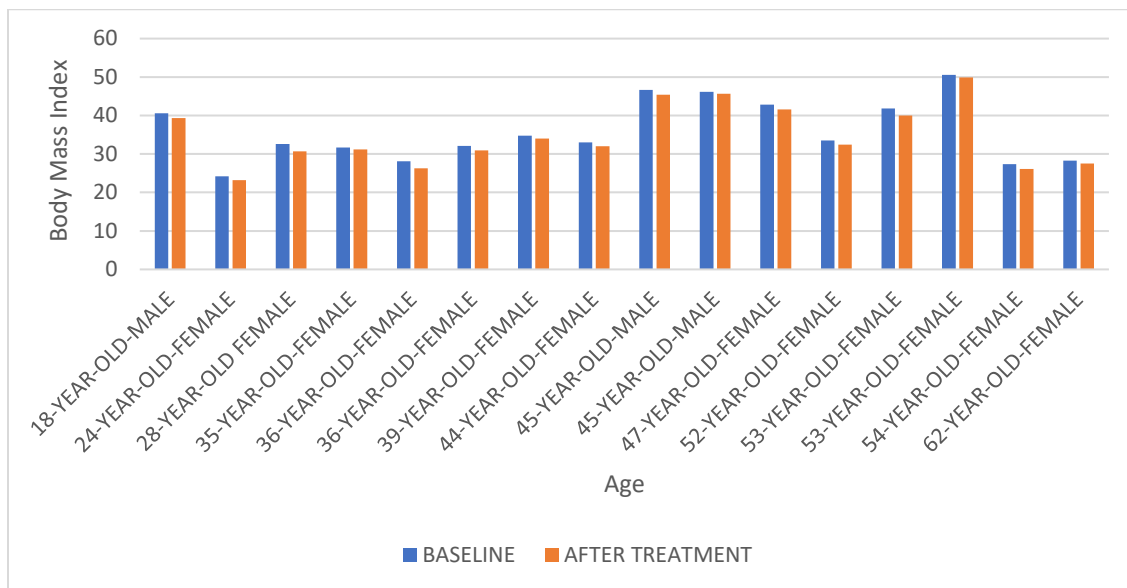
Analysis

Reductions in BMI and weight loss in response to our intervention are shown in Figure 1. We found that three of the patients enrolled in our study lost three pounds, three patients lost four pounds, two patients lost five pounds, two patients lost six pounds, two patients lost seven pounds, one patient lost nine pounds, one patient lost 10 pounds, and two patients lost 11 pounds. Body mass indices (BMIs) also improved post-treatment showed for all patients that continued with the study. Among these improvements, five patients responded with reductions in BMI of 0.5–0.8 kg/m² while another seven and four patients exhibited reductions of 0.9–1.5 and 1.6–2.7 kg/m², respectively. Patients enrolled in our study reported improvements in sleep, quality of life, and overall mood. They reported that they felt healthier with improved appetite control. Overall, all patients experienced some weight within 2 to 4 weeks of initiating therapy with semaglutide.

Results

Figure 1

Body Mass Indices (BMIs) and body weights before and two to four weeks after initiation of semaglutide treatment



Discussion

Summary

This project aimed to identify a longer-term treatment option that can be used to promote weight loss, most notably in patients already diagnosed with hypertension. While phentermine has been used to promote weight loss, it must be discontinued after 12 weeks of use. The findings from our study revealed that administration of semaglutide results in long-term efficacy and promoted an average weight loss of 16% compared to results typically obtained in response to phentermine or other GLP-1 agonists. The project not only provided much-needed assistance to patients motivated to lose weight, but it also led to improvements in overall health and lifestyle. The survey was an important aspect of this study, as it provided us with patient feedback that was used to assist them in formulating an evaluation of their overall progress and management of ongoing weight loss progress. The project also helped patients to determine key factors that might be affecting their weight. Completion of the feedback form was among the most challenging aspects for patients enrolled in our study. Over the course of the QI project, team participation increased to ~90% and correlated with changes in the long-term treatment plan.

Patients were evaluated two to four weeks after the clinic visit depending on the exact time that the medication trial was initiated. Several patients averaged their caloric intake, while others kept more accurate track of their intake. Likewise, some patients participated in physical exercise, while others did not engage in any significant activity. Side effects reported included headache, nausea, constipation, dizziness, and continuous hunger and typically persisted from one day to a full week, albeit with continuous improvement. Overall, patients reported

improvements in mood and that they felt healthier. They also reported improved appetite control, sleep, and blood pressure. Of the 18 patients evaluated, all lost weight except for one patient who needed to withdraw from the study because of an urgent surgical procedure that unfortunately led to further complications. Two patients failed to return for follow-up because of relocation out of the area.

Interpretation

Both the team and patients influenced the results of this study. As per suggestions from the team, office scheduling was adjusted, and designated days (Wednesdays and Thursdays) were identified to accommodate the time required for follow-up weight loss visits. For patients that could not be accommodated on those days, the health care team adjusted the schedule so that these patients could be provided with 30-minute appointments rather than the standard 15 minutes. Overall, patients enrolled in this study lost weight and reported improvements in overall health. The costs involved in the ongoing management of these patients were among the more challenging aspects of this study. While patients responded positively to the overall program, many could not afford the ongoing associated costs. While some patients had medical insurance that covered the costs of the weight loss program, many who did not qualify were unable to pay the \$800 to \$1,500 monthly cost for the medication. Several patients reported that they were able to purchase the same medication in Mexico at significantly lower cost (i.e., \$180 to \$261) and thus were able to continue.

Limitations

One limitation of this project was the lack of staff. Unfortunately, many members of the clinic staff left the practice after many years for personal reasons. As we were short-staffed at the

beginning of this project, patient follow-up remained a challenge. Perhaps if the staff members were not required to rotate through different tasks, the patient follow-up would have been more consistent throughout.

A second limitation was the amount of time set aside to carry out this project. While the initial follow-up was straightforward, follow-up during the final two weeks after drug implementation was more of a challenge. However, despite the limited time, patients continued with their ongoing care programs, and all showed progress with respect to weight loss.

Another important limitation was the cost of medication. While it was easy to initiate treatment, the costs associated with this medication regimen presented a significant barrier for most of the patients enrolled in our study. Similarly, this medication was not always available at their local pharmacies or complex prior authorization was needed.

The final limitation was the lack of follow-up. Many patients did not complete the follow-up forms which would have permitted us to track their activity and caloric intake. Likewise, some patients reported that they tracked their progress at home but failed to bring in the forms during their follow-up visit.

Conclusions

Several recommendations can be made to support further use in implementing the lessons learned from this QI project. They include but are not limited to evaluating a larger patient sample and identifying efforts to engage health care providers and staff in the office practice or clinic. These recommendations will provide us with an understanding of this intervention on a larger scale. Future studies might also include patients diagnosed with steatosis of the liver, kidney changes, and cardiovascular disease. Likewise, imaging and laboratory studies might be

included to support improvements in general health and reductions in the likelihood of developing serious comorbidities. Larger sample sizes will provide insight into the demographics associated with this type of intervention that will be needed to execute an effective randomized control trial. In this study, the patients were referred to one clinic and one provider; this can be expanded by providing education to other providers. These efforts will lead to greater generalizability as well as inclusiveness.

I also recommend changes to the educational materials to provide a focus on the pediatric population. This will provide parents who are attempting to address their own weight issues with an effective method to prevent obesity in their children who are at risk. The guidelines utilized for this project are for adults; however, the education can be expanded to the pediatric population.

Further exploration of the practice of documenting BMI as a part of weight management will also help by improving the frequency of provider-initiated conversations. While some of the obese patients in my practice did not meet the criteria for treatment with semaglutide, all patients benefit from the education that we provided. Some patients were unable to undergo treatment but understood the complications associated with obesity. The use of semaglutide to assist with weight loss to prevent the development of comorbidities suggests that it may become a critical medication that can effectively address this critical problem within a reasonable timeframe.

Unfortunately, the cost of ongoing treatment with semaglutide does have an impact on the outcomes. The current cost of this drug places it beyond the reach of many patients. Some patients reported that they were willing to pay for this medication because they felt that it facilitated weight loss and results in an overall improvement in their health and well-being.

Funding

No funding was provided for this project. If drug samples were available, treatment was initiated at the clinic visit. Some patients were unable to continue treatment due to the cost of this drug.

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