Identifying and Addressing Barriers and Facilitators to Bariatric Surgery within VA: Aim 2

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I. PROJECT SUMMARY

Obesity is the second leading cause of death in the U.S. The treatment of obesity and its related comorbidities, including cardiovascular disease and diabetes, exceeds $150 billion annually. “Morbidly” or “severely” obese patients – defined by a body mass index [BMI] of $\geq$ 35 kg/m^2 or greater - are especially high risk for serious complications due to the metabolic and physiologic derangements that occur with severe obesity. Within the Veterans Health Administration (VA) system, nearly 600,000 patients are severely obese. These Veterans exert significant costs on the VA system, experience poorer quality of life, and have shortened lifespans. Bariatric surgery is the most effective treatment for severe obesity for weight loss, comorbidity resolution, and quality of life. Bariatric surgery is supported as a treatment option by many national societies, including those representing primary care and endocrinology. However, less than 1% of Veterans who qualify for bariatric surgery undergo it. Reasons for low utilization are unclear, although our preliminary research suggests that there are various patient, provider and system level barriers to severe obesity care. This goal of this study is to identify patient, provider and work system elements that influence the treatment choices that severely obese patients make within VA.

I. BACKGROUND AND SIGNIFICANCE

Severe obesity is a major health threat for U.S. Veterans. Obesity has become a worldwide epidemic over the past 40 years as non-nutritious, inexpensive food has become widely available and a sedentary lifestyle has emerged for many people.[1] Obesity is now the second leading cause of death in the U.S. and is expected to overtake smoking as the leading cause of death in the near future.[2] More than one in three U.S. adults is obese and nearly 7% (18 million adults) are “morbidly” or severely obese, which is defined as having a body mass index > 40 kg/m^2 or $\geq$ 35 in addition to an obesity-related comorbidity such as coronary artery disease.[3] More than 300,000 U.S. Veterans are severely obese, which represents nearly 7% of U.S. Veterans.[4]

Currently, we have little understanding of how severely obese patients navigate treatment options. Since the implementation of MOVE! in 2006, primary care providers (PCPs) have been prompted by a clinical reminder in the Computerized Patient Record System (CPRS) to discuss weight management with all Veterans who have a BMI $\geq$25 kg/m^2. Interested patients can be referred to MOVE!, where they learn strategies for losing weight through dietary changes and exercise. Upon MOVE! completion, severely obese patients can be referred for bariatric surgery consultation if they are deemed to be acceptable surgical candidates. Compared to medical weight loss strategies, bariatric surgery provides superior weight loss and comorbidity resolution, decreases long-term mortality and improves quality of life. Even though bariatric surgery is included as a covered benefit for severely obese Veterans who meet BMI criteria established by the National Institutes of Health, our preliminary findings indicate that only 1/3 of the nearly 1,000 severely obese Veterans evaluated at the William S. Middleton VA in 2013 accepted a referral to MOVE!. Of those patients, 10% were referred for bariatric surgery consultation. Less than 0.5% of severely obese Veterans ultimately underwent bariatric surgery. This suggests that bariatric surgery is currently underutilized given its effectiveness and low complication rate.

In Aim 1, we interviewed severely obese Veterans and the providers that treat them to identify and understand the facilitators and barriers that affect treatment decisions. An analysis of the transcripts of these interviews led us to the conclusion that patient knowledge was a major barrier to treatment. Subsequently, our team worked to develop an educational video that could be used to teach Veterans what their treatment options were within the VA. This video was presented to four patient stakeholder panels and multiple providers for feedback. We updated the video iteratively according to the feedback we received. The result was an 18 minute educational video that will be presented to Veterans in this pilot study.

The VA is well positioned to lead national improvements in bariatric surgery care. With implementation of the “MOVE!” program in every VA medical center for more than five years, obesity screening has occurred for more than 95% of Veterans.[5,6] This high rate of obesity screening via a centralized program for weight management is unique and represents an opportunity for policy and practice refinements to have a large impact.

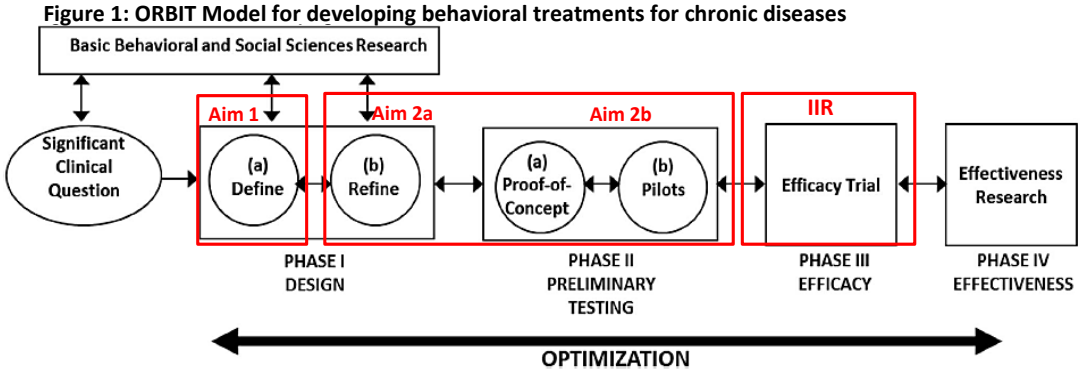
Summary of Significance: This study addresses an important public health issue: pursuing effective treatment options for more than 600,000 severely obese Veterans. Currently, less than 1% of severely obese patients pursue bariatric surgery, despite its known effectiveness in comorbidity resolution and improved quality of life. Very little published data exists to explain why so few Veterans pursue this treatment option. The knowledge generated in this study will provide information on whether an educational video designed to enhance shared decision-making is feasible and acceptable to Veterans

II. RESEARCH DESIGN, METHODS, and DATA ANALYSIS

Study Aim: Pilot-test an educational video that aligns patient preferences with treatment options to optimize the care that severely obese Veterans receive.

Purpose and goals: We will assess acceptability and feasibility of implementing the educational video and seek evidence of a signal as to whether patient knowledge and decision-making are improved with use of an educational video. Using ORBIT[7] as our framework (Figure 1), this is considered phase IIb preliminary testing of our intervention.

Figure 1: ORBIT Model for developing behavioral treatments for chronic diseases



The goal of phase IIb interventions are to "determine whether a clinically significant benefit on the behavioral risk factor can be achieved in a larger, more representative sample and whether this benefit is above and beyond the passage of time, nonspecific attention, or other treatment options."[7] Successful execution of this component of the study will provide the results needed for phase III behavioral intervention testing in a subsequent, adequately powered, efficacy trial (for which an IIR will be submitted).

Creating an educational video for severe obesity care: The research team has reviewed the qualitative findings from Aim 1, identified the relevant codes and themes, and generated an 18 minute video regarding severe obesity treatment options within the VA. The video contains information about diet, exercise, and healthy behaviors, weight management medications, and bariatric surgery.

Study design: This is a randomized controlled trial comprising an intervention arm and a usual care arm. Patient outcomes will be assessed before and after Veterans observe the video according to the plan outlined in **Table 1.**

Study setting: The trial will occur at the Madison VA. The Madison West VA Clinic will be used as a recruitment site if recruitment at Madison VA is low.

Study population and recruitment: Veterans with severe obesity between the ages of 18 and 75 who are scheduled to attend an in-person MOVE! visit at the Madison VA will be identified via chart review (all upcoming MOVE! visits beginning in May 2019 within the Madison VA system). Recruitment will be extended to Madison-West clinic if recruitment at Madison VA is not sufficient. Patients who have had bariatric surgery, had a bariatric information session, or been referred for bariatric surgery within the last year will be excluded as well as patients with a positive pregnancy status/intention, illicit drug use, or who have a psychological or medical condition preventing them from meaningfully participating in our intervention. Patients who have participated in piloting the intervention will also be excluded. Those patients who do not speak English or do not have regular access to a telephone will also be excluded. Severe obesity will be defined as a body mass index $\geq$ 35 in

CPRS. Veterans will qualify as severely obese if their BMI is ≥ 35 within the last six months of being referred to MOVE!. Given that more than 300 severely obese patients were referred to the Madison VA MOVE! program annually, meeting our recruitment goal (up to 40) will require participation of 20% of severely obese patients over the course of a year.

Research staff will use CPRS, outpatient MOVE! appointment requests from CDW, and/or automated reports to identify Veterans with severe obesity between the ages of 18 and 75 who are scheduled to attend an in-person MOVE! visit at the Madison VA. Research staff will review upcoming MOVE! clinic appointments for eligible patients. Subsequent visits and subject eligibility will be assessed weekly. Eligible patients who have a MOVE! visit following 7 or more days of newly reviewed upcoming clinic visits will be sent a recruitment letter and/or email ahead of their visit with a brief explanation of the study inviting them to participate. The letter and/or email will state that the research team may call and/or email them up to 3 times over the next 3 months. Patients who agree to participate in the study over the phone, and who qualify for the study will be asked to arrive at their MOVE! visit 50 minutes early to go over the consent process and be placed into intervention/usual care arms.

Study Procedures:

Our researcher will meet each patient who has been recruited in a private room to go over the consent process. If patients are interested in participating in the study, they will be asked to sign a written informed consent to participate in the study as well as a HIPAA form to collect process measures. They will also complete a demographic survey.

1. Participants will then be randomized to the intervention or usual care arm with probability equal to 1/2 (i.e., 1:1 randomization) using a computerized random number generator in blocks (size < 10; all study personnel except the statisticians are blinded to block size).The randomization assignment will be revealed to the patient by the un-blinded researcher. If the patient is randomized to the intervention, he/she will be shown the educational video the same day. The educational video is an 18 minute video that describes the risks of obesity and explores the three weight management options available to patients with severe obesity (BMI ≥ 35) in the VA. The video explains the weight loss treatments the VA offers, how to access them, what eligibility criteria patients might have to meet to obtain them, and describes the typical health outcomes for each treatment. Patients will also hear stories from Veterans who went through one particular treatment option. Patients randomized to usual care will not be shown the educational video.

2. Patients will be asked to complete a post-assessment within 7-14 days of their MOVE! visit. Patients randomized to the intervention arm will also be asked to participate in a 10-minute interview in addition to the post-intervention assessment. The post-intervention assessment and interview (intervention arm only) will be scheduled prior the patient's MOVE! visit. This post-assessment will be completed over the phone approximately 7-14 days after their MOVE! visit. Veterans may be reminded of this call via text message, phone call, or email prior to their appointment. They may also opt out of receiving a reminder. All email communications will come from a researcher's VA email account. Following their post-assessment call (and regardless of whether they complete their post-assessment call), a monetary incentive will be provided to participants for their time ($50).

Measures: Demographic data will be collected at baseline, prior to learning of randomization assignment. Signal of effect (patient outcomes), intervention fidelity, acceptability of the intervention, and feasibility measure will be collected during the pre- and/or post-intervention period as outlined in **Table 1**.

Table 1: Measures for Pilot Testing (Pre and Post-Intervention)					
Measure	**Pre**	**Post**	**Reliability**	**Validity**	**Group**
Patient Demographics	X		N/A	N/A	Both
Patient Outcomes					
Primary patient outcome: Behavioral intentions in pursuing any of the 3 treatment options in the VA		X			Both
Secondary patient outcome #1: Preparation for Decision-making Scale (10 Qs)[3]		X	α=0.92-0.96[3]	Scores correlated with the informed (r=0.21;p<.01) and support (r=-0.13,p=.01) DCS subscales[3]	Both
Secondary patient outcome #2: Patient knowledge and attitudes (Informed Choice; 12 Qs)[4]		X	α=.82[4]	Mean knowledge score correlated with responses to open-ended questions designed to elicit their understanding of the test[4]	Both
Secondary patient outcome #3: Self-efficacy measure		X	N/A	N/A	Both
Secondary patient outcomes #4: Process and outcome measures, including patient checked the box for bariatric surgery or requested to go down the bariatric pathway or patient checked the box for MOVE! visits or requested to go down the MOVE! pathway; attending MOVE! bariatric visit, info session, bariatric referral, bariatric visit, bariatric surgery, bariatric outcomes		X	N/A	N/A	Both
Acceptability					
Acceptability to patients: Qualitative interview		X	N/A	N/A	Intervention only
Feasibility					
Recruitment and Attendance Rates	X	X	N/A	N/A	Both
ICC=Intra-class correlation coefficient; IRA=inter-rater agreement					

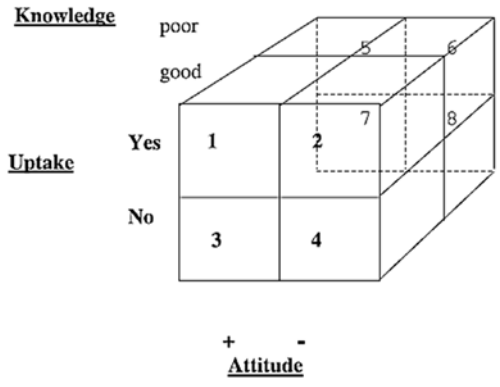
1. Patient demographics: Baseline patient demographics including age, gender, sex, race, BMI, comorbidities, pregnancy status (if female), and contact information will be obtained from the electronic health record.

2. Primary patient outcome - Behavioral intentions: Behavioral intentions to pursue bariatric surgery or treatment in the MOVE! program will be assessed separately with five semantic differential items ranging from 1 to 7 (unlikely to likely; not possible to certain) following the methods of Azjen.[8]

3. Secondary patient outcome - Preparation for decision-making: Patients will complete the Preparation for Decision-making questionnaire which consists of 10-items that assesses the patient's opinion about the effect of the educational video had on his/her decision (e.g. "Did this educational material help you think about which pros and cons are most important").[9]

4. Secondary patient outcome - Informed choice: Patients who are knowledgeable about a treatment, have a favorable attitude toward it, and choose it are considered to have made an informed choice.[10] Similarly, patients who are knowledgeable but have an unfavorable attitude and do not pursue the treatment are also considered to have made an informed choice. Any other combination of knowledge, attitudes, and treatment choice is categorized as an uninformed choice (i.e. poor knowledge, positive attitude, pursues a treatment) (**Figure 2**). These knowledge and attitude domains will be assessed following the

Figure 2: Informed Choice Rubric



approach recommended by Marteau.[10] For the knowledge domain, we will adapt questions from a 10 question bariatric surgery questionnaire.[11] The attitude domain will be assessed using a 4-item semantic differential scale with 7-point rating scales (e.g. "I consider behavioral weight management or bariatric surgery to be: beneficial/harmful, important/unimportant). Due to the short duration of the study, we will not be able to measure actual treatment uptake (behavioral weight management or bariatric surgery). Rather, we will measure behavioral intentions, again using 7-point semantic differentials, as recommended by Azjen (e.g., unlikely/likely, definitely will not/definitely will pursue medical weight management or bariatric surgery).[8]

5. Secondary patient outcome – Self-efficacy: Self-efficacy to initiate bariatric surgery or MOVE! treatment (action self-efficacy) will be assessed with items developed for this study following the methods of Schwarzer.[12] The 11 bariatric surgery self-efficacy items began with the stem, "I am sure I can pursue bariatric surgery even if…" and included endings such as "I need to attend multiple visits with the dietician." The nine MOVE! self-efficacy items began with the stem, "I am sure I can lose weight in the MOVE! program even if" and included endings such as "my weight loss is slower than I would like it to be."

6. Process measures: We will record whether patients "checked" the bariatric surgery MOVE! visit box in their MOVE! intake form. We will record whether patients attended a MOVE! bariatric visit, attended a bariatric surgery info session, received a bariatric referral, attended a bariatric surgery visit, underwent bariatric surgery, and lost weight after bariatric surgery. We will also track the number of MOVE! visits the patient has as well as any change in weight. These variables will be obtained from a data pull from the Corporate Data Warehouse (VA Database) at the end of the study.

7. Acceptability to patients (patient interviews): Acceptability of the educational video to patients will be assessed during a 10 minute semi-structured interview that will be conducted during the post-intervention assessment phone call for patients in the intervention arm. The patient will be asked several questions about use of the educational video, including the extent to which the amount of information presented was appropriate, clear, and in hindsight, the ideal timing of administration of the educational video. Patients who complete the intervention via VVC will be asked questions about their experience using the VVC system.

8. Feasibility of recruitment: Feasibility will be assessed by measuring recruitment and retention rates. The recruitment rate is defined by the number of Veterans who indicate, during a recruitment phone call, that they will participate divided by the number reached. Reasons for declining will be captured and analyzed for future study design optimization. The retention rate is defined as the number who watch the video and complete all assessments, divided by the number scheduled. A priori feasibility targets are ≥ 60% recruitment and ≥ 80% retention.

Data analysis and sample size: Descriptive statistics will be used to characterize patient demographics, secondary patient outcomes, and acceptability by group. Analysis of the primary outcome will treat pre- and post-intervention outcomes as two repeated measures on each subject. The regression model will include a post-visit indicator, an intervention group indicator, and an interaction between the two, the coefficient of which will be the parameter of interest capturing the intervention effect. To account for the repeated measures within patient, the model will include a random patient effect.

We aim to sequentially recruit up to 40 severely obese Veterans. Patients will be randomized to one of the two groups. Based on prior experiences from our co-investigator team and the literature on usability testing[17] this sample size will be sufficient to assess feasibility and acceptability and seek evidence of signal regarding intervention effects. A power calculation will not be performed given that we are not evaluating statistical significance of the intervention at this point; rather, we are seeking an indication of clinically significant change, preliminary data on within- and between-subject variability in these measures, and evaluation of the feasibility of the study (cite A). Quantitative data will be analyzed using SAS version 9.3 (or higher) (SAS Institute, Cary, NC).

Data analysis approach: The digital audio recordings from all patient interviews will be transcribed by a transcriptionist who will be supported with CDA research funds. We will use a directed approach to content analysis,[18] developing codes (descriptive labels) based on predetermined categories, such as those derived from interview questions. Any text that cannot be categorized with the pre-determined scheme will also be identified and categorized. Drs. Funk and Voils and our Researcher will analyze the first five patient transcripts. After analysis of the first patient transcripts, they will convene to adjudicate each coded phrase or idea. This procedure will be repeated for each subsequent transcript using the technique of constant comparison, ultimately developing a taxonomy of consensus codes.[19] Each transcript will then be re-coded according to this coding scheme. Then higher-level coding will be conducted to identify themes and trends in the data to consolidate feedback for refinement of the analysis. The theme matrix technique[20] will be used to identify patterns in the data based on patient characteristics. Data will be managed and categorized using NVivo.

III. Data and Safety Monitoring Plan

Dr. Funk will be alert for any potential problems related to this study, particularly the loss of confidentiality. Loss of confidentiality will be minimized and privacy of data will be maintained by conducting informed consent assessments, and audio recordings in private rooms. Before the start of interviews, we will ask that study participants do not use any names during the interviews. There is potential for psychological stress from the presence of an audio recorder and/or study staff at the interviews. Participants also face the risk of anxiety from talking about personal experiences. The interviewer is trained to be alert for any potential concerns related to subject sensitivity to audiotaping. Participants will be told that prior to the audio recording that if they feel uncomfortable being audiotaped after the recording has begun, they can withdraw from the study at any time. Any unanticipated problems or complications will be reported per the IRB's reporting guidance and the Information Security Officer (ISO), Privacy Officer (PO), and the Associate Chief of Staff (ACOS) for research will be notified according to VA protocol.

IV. Data and Record Keeping

Data collected on subjects from data pulls (CDW) and audit of health records (CPRS) will be entered into a secure excel spreadsheet within the PI's secure project folder housed on the VA server at the William. S. Middleton VA Medical Center that is only accessible by members of the research team. This list will also contain unique identifiers that will be linked to patient data. This linkage will allow research staff to track the enrollment process as well as link subject data. Any additional identifiable information will be coded prior to entry into the final dataset. Consequently, the final dataset that will be retained will not include any subject identifiers.

All interviews with subjects will be audio recorded. All audio will be recorded with an already-existing waivered DVR for interviewing. Prior to initiating recording, interview participants will be informed not to divulge their name or other identifiable information during the interview. All telephone interviews will be recorded via speakerphone and the audio will be uploaded to the PI's secure project folder on his VA computer. All assessment data will be entered into VA REDCap, an approved electronic database on the VA server at the William. S. Middleton VA Medical Center that is only accessible by members of the research team. Subjects will be assigned a unique identifier number in this database. This unique identifier will be linked to a separately maintained master list that contains subject identifiers located in a separate folder within Dr. Funk's project folder. This linkage will allow research staff to track the enrollment process. Any additional identifiable information will be coded prior to entry into the final dataset. Consequently, the final dataset that will be retained will not include any subject identifiers. All electronic data extracted from patient health records (CPRS) will be stored on the PI's project folder. Audio recordings, any notes taken during each interview, transcripts of audio recordings, assessment scores, signed paper consent forms, and signed HIPAA forms will be kept in a locked cabinet in the PI's research staff office at the William S. Middleton VA Medical Center. Data acquired from the Corporate Data Warehouse (VA Database) will be stored on the PI's secure project folder.

All data will be retained according to local VA requirements before it is destroyed. Should any incidents occur, the Information Security Officer (ISO), Privacy Officer (PO), and the Associate Chief of Staff (ACOS) for research will be notified according to VA policy. Furthermore, should any study personnel be removed from the research team, their access to research study data will immediately be terminated.

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