IMPROVED SCREENING FOR BINGE EATING DISORDER IN PRIMARY CARE

by

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ABSTRACT

JOSETTE M. GIUFFRIDA. Improved screening for binge eating disorder in primary care. (Under the direction of DR. TERESA CATING)

Binge Eating Disorder (BED) has come into focus with its listing in Diagnostic and Statistical Manual, 5th edition (DSM-5). Primary care is an appropriate place to screen for BED. However, some primary care providers are not aware of the disorder or of the importance of screening for it. The purpose of this study was to develop an improved, evidence-based screening tool to effectively screen for BED in primary care. With early detection of the disorder, providers could proceed with further evaluation, referrals and treatment, as appropriate, improving health and financial outcomes. A sample of 100 patients answered the newly developed Eating Questions (EQ) and the Binge Eating Disorder Screener-7 (BEDS-7) screening tools. The relationship between the two questionnaires was examined using Cohen's Kappa (k). Agreement between BEDS-7 and EQ was statistically significant (k= .827, p= .000), signifying that EQ was answered the same as the BEDS-7. Additionally, McNemar's test showed that the proportions of negative and positive results were not statistically different between the two screening tools, with a p-value of 0.6547. Since the EQ answered the same as BEDS-7 for screening in a sample population, the BEDS-7 can be replaced with EQ in the project site. Sustainability of the EQ can be attributed to it being brief and easily applied to electronic medical records (EMR).

DEDICATION

To my loving and patient husband, who supports my pursuits to be the best I can be, and encourages me to go after my dreams, your kindness and understanding of how I use my time, helped me make it through. To my mother, you were at all of my graduation ceremonies, beaming with pride. I know that you have been watching over me during this journey, with that same beaming glow.

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I owe many thanks to my committee. Dr. Teresa Cating, committee chair, guided me through the process, sharing her wealth of knowledge and expertise. Her consistent encouragement is not quantifiable. Dr. Kathleen Jordan is an endless source of inspiration. She is truly remarkable at all that she sets out to do. Years of thanks and appreciation go to Dr. Thomas Lessaris. He has been my mentor in clinical practice since agreeing to precept me in clinical all those years ago. Your knowledge is immense and I am grateful to have collaborated with you for so many years. Special thanks go to Novant and UNCC for allowing me the opportunity to improve on current practice and contribute to primary care and those who provide it. Lastly, thank you to all the professionals from different disciplines who added to this project by providing contacts, insight, and encouragement along the way.

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LIST OF ABBREVIATIONS

AN Anorexia Nervosa

APA American Psychiatric Association

BED Binge Eating Disorder

BEDS-7 Seven Item Binge Eating Disorder Screener

BES Binge Eating Scale

BN Bulimia Nervosa

CITI Collaborative Institutional Training Initiative

DSM Diagnostic and Statistical Manual

EDS-PC The Eating Disorder Screen for Primary Care

EMR Electronic Medical Record

EQ Eating Questions

FA Food Addiction

GI Gastrointestinal

IRB Institutional Review Board

MD Doctor of Medicine

NP Nurse Practitioner

PCP Primary Care Provider

QEWP The Questionnaire on Eating and Weight Patterns

SCOFF Screening for Eating Disorders

SDE Screen for Disordered Eating

SWOT Strengths, Weaknesses, Opportunities, and Threats

UNCC University of North Carolina at Charlotte

US United States

YFAS Yale Food Addiction Scale

CHAPTER 1: INTRODUCTION

1.1 Background

Eating disorders are psychiatric disorders that present a major health burden in the United States (US), with Binge Eating Disorder (BED) being more prevalent than anorexia nervosa (AN) and bulimia nervosa (BN), combined (Maguen et al., 2018). In the US, 2.8 million adults are affected by BED (Forman, 2018). The lifetime prevalence rate of BED is 2.6%, and the 12-month prevalence rate is 1.2%, with a mean lifetime duration of 14 years (Forman, 2018). The average age of onset is later than other eating disorders, occurring at approximately 25.4 years old, with symptoms likely beginning in late childhood and adolescence (Tanofsk-Kraff et al., 2013). Although BED has gained recognition as a mental health condition since being listed in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5), recognition is limited in the medical community due to lack of awareness about the newly defined eating disorder (American Psychiatric Association, 2013; Herman et al., 2016). Screening questionnaires for BED have been in existence; however, the length of time to complete them, and the effectiveness of the questions included, caused difficulty with incorporating screening into a busy practice. A need exists for updated screening instruments in both clinical and research settings (Yanovski, Marcus, Wadden, & Walsh, 2015). The newly developed Eating Questions (EQ) is a brief, two question screening tool for BED designed to be utilized in a busy primary care office to effectively screen for the disorder.

The diagnosis of BED can be made with criteria listed in the DSM-5 (APA, 2013). The criteria include episodes of binge eating during which the amount of food consumed in a limited time period (e.g., two hours) is significantly larger than what most people would eat during the same amount of time, in similar circumstances. During the episodes, patients feel a loss of control over eating. Binge episodes must be associated with at least three of five characteristics: (a) eating more rapidly than normal, (b) eating until uncomfortably full, (c) eating large amounts of food when not physically hungry, (d) eating alone because of embarrassment by amount of food consumed, and (e) feeling disgusted with oneself, depressed, or guilty after overeating. Episodes occur at least once a week for three months. There should be no regular use of compensatory behaviors (e.g., purging, fasting or excessive exercise). Binge eating should not occur solely during the course of BN or AN. Severity is based on number of binges per week: mild (1 to 3), moderate (4 to 7), severe (8 to 13), extreme (14 or more).

BED has associations with hypothyroidism, nutritional issues, obesity, diabetes, polycystic ovarian syndrome, sleep apnea, and dieting with weight cycling (Oliver-Pyatt, 2017). Approximately 50% of individuals with BED are overweight or obese. The remaining individuals are normal weight and less likely to seek treatment (Forman, 2018). Possible comorbid psychiatric conditions associated with BED are major depressive disorder, bipolar disorder, borderline personality disorder, post-traumatic stress disorder, attention deficit hyperactivity disorder, substance use disorder, and anxiety disorders (Hudson, Huripi, Pope, & Kessler, 2007). BED affects mental, social, and physical aspects of health, which can lead to a large economic burden from healthcare costs and loss of productivity.

1.2 Problem Statement

The seven-item Binge-Eating Disorder Screener (BEDS-7) was in current use in the primary care office that was the setting for the scholarly project (Herman et al., 2016). The providers using the tool had concluded that it was not effective for screening due to lack of understanding and time. The first question was misunderstood without further explanation by a provider. Additional interviewing by providers found that patients may answer the question differently after explanation. Time is limited during office visits and the length of time to complete a seven-item screener was a concern. The development of a new, brief, easily understood screening questionnaire for the primary care setting was needed.

1.3 Purpose

Many Doctor of Nursing Practice (DNP) projects focus on improving processes and outcomes in practice. In 2011, the Health Resources and Services Administration defined quality improvement as a systematic and continuous process that leads to measurable improved health outcomes for targeted groups (as cited in Moran, Burson, & Conrad, 2017). Timely detection can prevent subsequent medical and mental health issues, and can assist with early intervention aimed at improving prognosis (Maguen et al., 2018). The purpose of this DNP scholarly project was to develop an improved, evidence-based screening tool to effectively screen for BED in primary care. With early detection of the disorder, providers could proceed with further evaluation, referrals and treatment, as appropriate, improving health and financial outcomes.

1.4 Clinical Significance

Prior to the development of the new screening tool, the primary care providers (PCPs) were given a survey to complete regarding awareness of BED, opinions regarding the need for screening, effectiveness of the current screening tool used, and what would improve screening. It was agreed that there was a lack of awareness, but that BED should be screened for in the primary care setting, and that the BEDS-7 screening tool was ineffective due to its length and possible lack of understanding of the first question. Many people are most likely to seek care from their PCPs, rather than specialty providers. Screening for BED in primary care allows for varying ethnicities, cultures, genders, socioeconomic statuses, and those with psychiatric and mental health conditions to be included in screening.

1.5 Clinical Question

The clinical question developed for the DNP scholarly project was: For adults in the primary care setting, how effective is a new Binge Eating Disorder questionnaire compared to the currently-used questionnaire at screening for Binge Eating Disorder?

1.6 Project Objectives

The objectives for this DNP scholarly project were to: (1) develop an evidence-based questionnaire that was brief and effective to screen for BED in primary care by utilizing PCPs input, (2) examine the new screening tool's effectiveness by comparing it with the BEDS-7 tool used as a standard of care in the office, and (3) enable future access on the electronic medical record (EMR) for use at a healthcare system-wide level for sustainability.

CHAPTER 2: LITERATURE REVIEW AND THEORETICAL FRAMEWORK

A review of the literature was performed using CINAHL, PubMed, and Cochrane Review. Key words entered included: "Binge Eating Disorder," "Binge Eating Disorder and Screening," "Binge Eating Disorder and Assessment or Diagnosis," "Binge Eating Disorder and Comorbidity," "Binge Eating Disorder and Cost," "Binge Eating Disorder and Prevalence or Incidence." Only peer-reviewed articles were selected.

2.1 Epidemiology and Gender

BED has been described since the 1950's but only recently brought into focus for study. Given that the inclusion of BED in psychiatric diagnostics is fairly recent, epidemiologic data is limited (Streigel-Moore & Franko, 2003). The literature examines gender and BED, with the emphasis on gender being a fixed marker to identification of BED (Streigel-Moore & Cachelin, 2001). Much of the literature focuses on women. BED is more common in women than men, with lifetime prevalence rates of 3.5 and 2.0, respectively, with a median age of onset at 23 years (Forman, 2018). Men do overeat, or binge, but do not have the amount of distress or loss of control associated with meeting full BED diagnostic criteria (Hudson et al., 2007).

Gender differences in BED have been demonstrated in two studies by the same group of researchers (Udo et al., 2013, 2014). In a primary care setting sample, men with BED were more likely than women with BED to meet diagnostic criteria for metabolic syndrome, at 57% vs 31%, respectively, controlling for race and BMI (Udo et al., 2013).

The second study showed that men with BED were more likely to show characteristics of metabolic syndrome, including elevated blood pressure and triglycerides, and women were more likely to have elevated total cholesterol (Udo et al., 2014).

2.2 Race/Ethnicity

Epidemiologic studies have found comparable rates of BED among African American, Hispanic and Caucasian people. However African-American and Hispanic people are underrepresented in formal clinical studies (Grilo White, Barnes, & Masheeb, 2013). Among the reviewed literature, data is identified for the population, without focus on specific ethnic classification and some with under-representation. Grilo et al. (2013) identified 142 participants as responders for obese binge eaters in a primary care setting, of which 74% were female, and 26% male. Forty three percent were Caucasian, 37% African-American, 13% were Hispanic-American, and 7% were of other ethnic groups. It would seem that the majority of respondents in this study were white females. Caucasian individuals may be more likely to utilize mental health services for BED as compared to other ethnic groups (Marques et al., 2012). It is important to assess for BED across both genders and all ethnicities.

2.3 Comorbidity

Psychiatric and medical comorbidities associated with BED have been examined. Grilo et al. (2013) reported findings that 37% of those with a BED diagnosis had a current psychiatric disorder, and 67% had at least one lifetime psychiatric disorder. For lifetime diagnoses, the most prevalent were mood (49%), anxiety (41%), and substance use (22%). Additional findings from this study suggest that current psychiatric comorbidity, rather than lifetime or past diagnoses, is associated with more severe current

BED presentation. The authors recommended further study in primary care settings to examine implications of co-morbidity on providing treatment and outcomes.

Forman (2018) listed the associated psychiatric diagnoses and the percentage of BED patients that experience them. Prevalence was 37% for specific phobia, 32% for social anxiety disorder, 32% for unipolar major depression, 26% for posttraumatic stress disorder, 20% for attention deficit hyperactivity disorder, and 21% for alcohol use disorder. Comorbid personality disorders are also common, including prevalence for any personality disorder at 29%, avoidant personality disorder at 12%, borderline personality disorder at 10%, and obsessive-compulsive disorder at 10%.

Medical comorbidities associated with BED include obesity, diabetes, and metabolic syndrome. Other medical conditions can be linked as well, with many of them being related to obesity. J. Mitchell (2016) cited that the risk for BED among patients with type II diabetes varies from a high of 25% to a low of 1.4%, and that those with BED and diabetes had an earlier onset. J. Mitchell (2016) also found, in a sample of BED patients seeking treatment for obesity, 60% had components of metabolic syndrome, with other studies indicating 43% and 44% of BED patients had metabolic syndrome components. A substantially increased risk of type II diabetes was identified among those treated for BED and BN (Raevuori et al., 2014). The overall risk among the patients was higher in males. Recommendations include exploration of the relationship between BED and glucose metabolism, as well as further prospective studies for glucose dysregulation, matching for BMI (Raeuvuori et al., 2014; Mitchell, J., 2016).

2.4 Cost of BED

Despite BED's prevalence as an eating disorder, the data for cost and economic burden of BED in the US is limited. Agh et al. (2015) identified direct healthcare costs of BED to range between $2,372 and $3,731 per year. Indirect costs were more difficult to gather data for since patients may seek treatment for other related conditions, both medical and psychiatric. Contrasting those figures, Bellows et al. (2015) identified one-year total unadjusted healthcare costs for 2011 to be $33,716 USD.

Ling, Rascati, and Pawaskar (2015) were among the first to identify both direct and indirect costs of BED in the US. Annual adjusted average cost, based on work productivity loss (for N=845) was $19,327 for BED patients and $9,032 for non-BED patients. Total costs, including direct and indirect, showed an annual mean of $35,519 for BED respondents vs. $19,598 for non-BED. Limited cost data exists for BED; therefore, healthcare related costs and the overall economic burden of BED, need further study.

2.5 Current Screening Tools

Literature supports the need to accurately assess for BED. It is critical to detect eating disorders in a timely manner to improve outcomes. Several screening instruments are available to assess for eating disorders in different settings. The SCOFF questionnaire is a brief screening tool that can be used in primary care. The title is derived from one letter in each of the five questions that the survey uses (Hill, Reid, Morgan, & Lacey, 2010). The Eating Disorder Screen for Primary Care (EDS-PC) is another brief tool that can be used for screening (Cotton, Ball, & Robinson, 2003).

Screen for Disordered Eating (SDE) was developed by Maguen et al. (2018) and was compared with two other screening tools for eating disorders. The SDE

outperformed the Eating Disorder Screen for Primary Care (EDS-PC) and SCOFF in identification of cases or true non-cases. The study was limited by its sample population and difficulty with generalizability. These are appropriate for eating disorder screening, but not specific to BED. Other common tools were examined for overlap of BED and food addiction (FA). Burrows, Skinner, McKenna, and Rollo (2017) examined the relationship between the Binge Eating Scale (BES) and Yale Food Addiction Scale (YFAS). It was found that an overlapping relationship exists between BED and FA.

Questionnaires for BED have been evaluated in different settings. The Binge Eating Scale (BES) was studied in a bariatric surgery-seeking population and found to be a valid screener for BED in this setting, with expected false positives (Grupski, et al., 2013). This application is relevant to this study because in primary care, there is the ability to refer a patient for bariatric surgery. Prior to the referral, patients can be screened for BED, as they are considered weight-loss seeking patients.

The Questionnaire on Eating and Weight Patterns (QEWP) was developed for use in field trials based on proposed criteria for BED outlined in the Diagnostic and Statistical Manual, 4th edition (DSM-IV), and in DSM-IV TR, as identified in the appendix as the need for further study (APA, 1994; Yanovski et al., 2014). The QEWP was then revised, based on DSM-5 criteria, which had changed slightly. The revisions included changing “binge days” to “binge episodes,” a reduction in the threshold of binge frequency from two episodes to one episode per week, and a reduction in symptom duration from six months to three months (Yanovski et al., 2014). A convenience sample was used to assess readability among scientific and nonscientific staff members at the authors’ sites. Comments from those completing the revised questionnaire, as well as

from investigators with expertise in BED and BN, provided feedback for the final version of the questionnaire. Yanovski et al. (2014) concluded that the QEWP-5 is a screening tool appropriate for use in research or clinical settings to identify patients who may have BED. The limitations of the questionnaire are that it is rather lengthy, with 26 questions, and that the decision rules for it are complex, requiring the examiner's judgement for some questions related to amount of food consumed.

The most recent screening tool is the seven-item Binge-Eating Disorder Screener (BEDS-7). Herman et al. (2016) developed a brief, patient-reported screening tool to identify patients with probable BED so further evaluation and treatment could be provided. It was developed in 3 phases which included the development of an initial item pool based on DSM-5 diagnostic criteria, existing tools, and input from clinical experts (January 2014); cognitive debriefing interviews to test and refine draft items (March 2014); and quantitative evaluation to finalize and develop a scoring algorithm for the screener (June 2014–July 2014). Ultimately, 7 items were retained in the algorithm that maximized sensitivity and obtained the highest possible specificity. The authors discussed the BEDS-7 maximizing sensitivity at 100%, while preserving the content of the DSM-5 criteria. A high rate of false positives was attributed to individuals who did not meet diagnostic criteria for BED during the clinic interview for BED, but reported they were regularly engaging in excessive overeating episodes, had lack of control over the behavior, and were distressed about the behavior. Limitations of the study were that only a small number of individuals were diagnosed with BED (n=16) from clinical interviews, and that the questionnaire yielded a specificity of 38.7% from the sample population of 97. The strength of the tool is that it is shorter than previous screeners,

based on DSM-5 criteria, and may have broader applicability beyond primary care and general psychiatry. The BEDS-7 was currently used in the primary care office that is the setting for the scholarly project. The belief of the providers using the tool is that there is a high rate of false-negatives due to the lack of understanding of the first question, which, when answered with a no, prevents the remainder of the questionnaire from being completed.

2.6 Theoretical Framework

The theoretical framework for this DNP scholarly project is Lewin's (1951) change model. Lewin's model includes three stages through which change agents proceed to make a change become part of a system (Mitchell, G., 2013). The three stages are unfreezing (the point when change is needed), moving (the point when change is initiated), and refreezing (the point when equilibrium is established). In the DNP scholarly project setting, the providers in the primary care office noted that the currently used screening tool is not adequate for assessment of BED. This unfreezing stage involves recognizing the need for change. In this case, it is the need for a new screening tool. The development of the screening tool is part of the movement stage, which includes taking action, making changes, and involving people. Providers have input on the new tool and will administer the tool to the appropriate patients. Once a new tool has been created and implemented, evaluation of the tool will be done. The use of an accurate tool will then be utilized in the office. The stage of refreezing occurs when providers confidently use the new, accurate screening tool.

CHAPTER 3: METHODOLOGY

3.1 Subjects

Primary care is an appropriate place to screen patients for BED since patients may only seek assistance from their primary care provider. For the purposes of this study, only adults were screened. All adults (18-64) were asked to complete the screening tool during their annual physical exams. Patients seeking assistance with weight loss or expressing distress in relation to food were screened with the tool, as deemed necessary by their provider. A provider could choose to exclude a patient, using clinical judgement. A patient with active BN would be excluded since the DSM-5 criteria explicitly states that with BED, there are no compensatory behaviors, like vomiting. Patients were provided with information stating that completing the questionnaire was voluntary and their choice would not affect the care they receive (see Appendix D).

3.2 Setting

The setting for the project was an internal medicine and pediatric primary care office. In addition to the project leader, two other providers in the practice participated in the implementation. They are both MDs, double boarded in pediatrics and internal medicine. On average, each provider sees four adult patients for annual physical exams per day, and five patients per week for weight loss or diet concerns. All providers have CITI training certificates, and the project proposal was submitted to the IRB at Novant Health. All providers met repeatedly regarding the tool development. A plan was created

for how the tool would be implemented. The input from providers contributed to face validity of the newly developed tool.

3.3 Measurement Tools

The newly developed tool, entitled Eating Questions (EQ), is a two-question screening tool that was used in the project (see Appendix A). It originally was drafted as five questions with measurement focused on days per week of binge episodes, which identifies severity of BED, while including DSM-5 diagnostic criteria (APA, 2013). After discussions and input from the other providers, it was revised to include two questions that focused more on the DSM-5 criteria of loss of control and emotions related to overeating, and less on the severity or number of episodes (APA, 2013). The plan is to add a "drop down" box on the EMR, containing the severity questions, at a later time. On the bottom of the questionnaire, the provider noted age, gender, and whether or not the other questionnaire was positive or negative. The new questionnaire was appropriate for primary care since it was brief, and screened for the feelings associated with binge eating per the DSM-5 criteria (APA, 2013).

A second tool was administered at the same time as the EQ (see appendix B). It is the BEDS-7, used in the project site's office to screen for BED (Herman et al., 2016). Permission to use the BEDS-7 was obtained from the pharmaceutical company who owns the rights (see Appendix C). The new tool and the BEDS-7 were provided to the appropriate patients. Since the BEDS-7 was a current standard in the practice, it was scanned into the patient's chart, and providers used it according to their current practice. Age, gender, and whether the BEDS-7 was positive or negative, was noted on the new tool. The completed new tool was not a part of the patient's chart and was stored safely,

without any identifying data, per IRB guidelines. The number of patients testing positive for BED using the BEDS-7 was compared to the number of patients testing positive for BED with the new screening questionnaire, the EQ.

3.4 Intervention and Data Collection

After discussion with the Institutional Review Board at Novant, it was determined that gender, age, and a positive or negative result of screening does not qualify as identifiable health information. Therefore, a signed consent form was not needed. Data was collected over a four-month period by the CITI-trained providers in the primary care office that was the setting for the project. Four months allowed for an adequate sample size, given that providers may have had time off during implementation, during which they would not obtain results. A modest sample size number goal was N of 100. The appropriately selected patients were given the new questionnaire, with the statement of voluntary completion, and the BEDS-7 questionnaire. Once completed, the providers noted the information on the EQ tool regarding gender, age, and positive or negative BEDS-7. The provider also noted positive or negative for the EQ, with a plus or minus sign at the top of the tool. If either or both questions were answered yes, the EQ tool was considered positive. After completion, the BEDS-7 was scanned into the patient's chart. The EQ tool was separated, without any patient identifiers, and stored appropriately.

After the four-month timeframe, the collected EQ tools were evaluated. Data was compiled, which included positive or negative on EQ and BEDS-7, gender, and age. The appropriate SPSS test was used to compare data, with a significance level of $p<0.05$. Comparisons were made between both questionnaires.

3.5 SWOT Analysis

The four components of a SWOT analysis include strengths, weaknesses, opportunities and threats. They provide a map for issues encountered during project planning (Bonnel & Smith, 2018). Further defined, the SWOT analysis examines internal strengths and weakness, along with external opportunities and threats (Moran, Burson, & Conrad, 2017). The analysis lays the groundwork for how to proceed with project planning.

For this study, strengths included provider and staff participation (internal stakeholders) for development of the new tool, as well as implementation. Face validity was provided by providers with a combined forty years of experience in primary health care. Having the knowledge and experience to determine patient needs and assess for health concerns are key in primary care. A brief questionnaire that can be incorporated into a wellness exam, or with those seeking assistance with weight, was another strength of the project. It entailed streamlining assessment while meeting the needs of patients. Having quick access to relevant resources was another strength. There was access to a nutritionist with knowledge of BED and the ability to assist the patients. The ability for providers to make a formal diagnosis, prescribe medication, and make referrals are beneficial for assessing for BED.

Lack of time may be considered a weakness. Providers often feel rushed and overwhelmed with the cumbersome amount of documentation that must be done on a daily basis. The tool may have added another element. However, the plan was to incorporate a new, more streamlined and focused questionnaire to replace the old one. Patient participation may be another weakness. Asking patients to complete yet another

form may appear tedious, or possibly invasive. Concerns about the purpose of completing the questionnaire were addressed as they arose. Prior to the study, completing the BEDS-7 had not caused concern for most patients who were asked to complete it.

Opportunities for implementation included increased identification of BED for other primary care offices. The tool may become system wide, with inclusion on the electronic medical record (EMR). Utilization of available support groups for BED and/or any of the comorbid mental health or medical conditions associated with BED are positive aspects of identifying BED. BED may cause or be caused by comorbid conditions that need specialized treatment. Within the organization are the specialists that may receive referrals and requests for their input in treating patients. They include nutritionists, psychologists/psychiatrists, GI specialists, cardiologists, sleep specialists, endocrinologists, and orthopedists. Collaboration across many specialties provides another example of an opportunity. If detected early and treated effectively, health care dollars can be saved by improving prognosis and decreasing downstream complications associated with BED.

Threats included lack of stakeholder participation or buy-in, and lack of utilization by other providers within the system. Patients may not have wished to participate in screening or have been willing to proceed with further evaluation or treatment. Providers may not have prioritized BED as an important condition to screen for. The importance of practicing evidence-based medicine came into focus for limiting threats to the project.

CHAPTER 4: RESULTS AND DISCUSSION

4.1 Project Findings/Results

A sample of 100 patients answered the EQ and BEDS-7 screening tools. Of those answering both questionnaires, 67% were female, 33% were male. Most patients answering the questionnaires were 46-55 years old (n=28, 28%), followed by those who were 36-45 years old (n=23, 23%). See Figure 1 for age distribution.

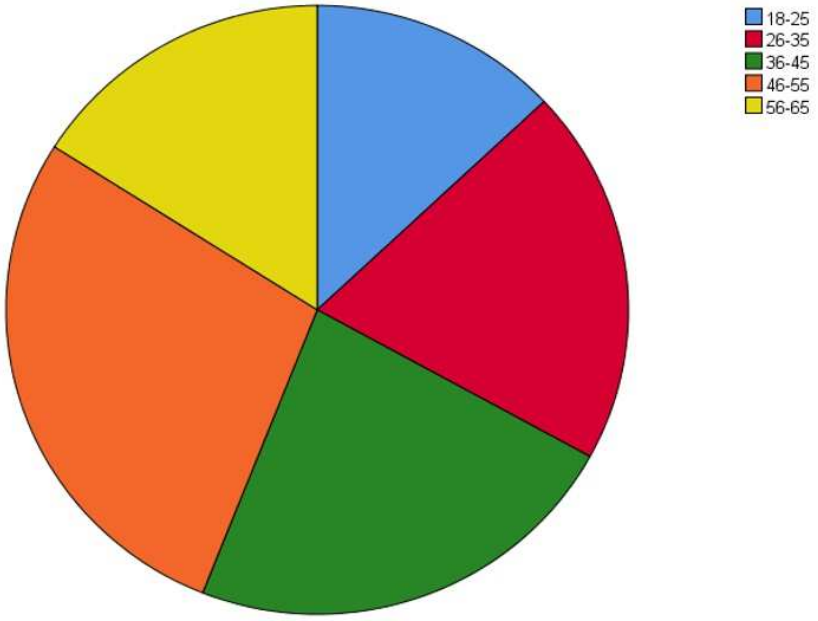

Figure 1. Age distribution of 100 respondents

Table 1 shows the age range of those who answered negative or positive on the EQ. Based on age ranges, the highest percentage of those answering positive was in the 36-45-year age group (n=23) at 21.7 % (n=5), followed by the 26-35 age group (n=20) at 20% (n=4).

Table 1. Crosstabulation Negative/Positive EQ by Age Range

		Age Range					
		18-25	26-35	36-45	46-55	56-65	Total
Negative	Count	12	16	18	23	13	82
	% within neg/pos eq	14.6%	19.5%	22.0%	28.0%	15.9%	100.0%
	% within age range	85.7%	80.0%	78.3%	85.2%	81.3%	82.0%
Positive	Count	2	4	5	4	3	18
	% within neg/pos eq	11.1%	22.2%	27.8%	22.2%	16.7%	100.0%
	% within age range	14.3%	20.0%	21.7%	14.8%	18.8%	18.0%
Total	Count	14	20	23	27	16	100
	% within neg/pos eq	14.0%	20.0%	23.0%	27.0%	16.0%	100.0%
	% within age range	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Table 2 shows the age range of those who answered negative or positive on the BEDS-7. Similarly, based on age range, the highest percentage of positive answers came from the 36-45-year age group, with five out of the 23 in the group answering positive for 21.7%. However, the next highest percentage came from the 18-25-year group, comprised of 14, with three answering positive, or 21.4%.

Table 2. Crosstabulation Negative/Positive BEDS by Age Range

		Age Range					Total
		18-25	26-35	36-45	46-55	56-65	
Negative	Count	11	17	18	23	14	83
	% within neg/pos beds	13.3%	20.5%	21.7%	27.7%	16.9%	100.0%
	% within age range	78.6%	85.0%	78.3%	85.2%	87.5%	83.0%
Positive	Count	3	3	5	4	2	17
	% within neg/pos beds	17.6%	17.6%	29.4%	23.5%	11.8%	100.0%
	% within age range	21.4%	15.0%	21.7%	14.8%	12.5%	17.0%
Total	Count	14	20	23	27	16	100
	% within neg/pos beds	14.0%	20.0%	23.0%	27.0%	16.0%	100.0%
	% within age range	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Table 3 identifies the percentage of those answering negative or positive on the EQ between genders. Among those answering the EQ, 90.9 % of males tested negative, and 9.1% males were positive, while 77.6% of females answered negative and 22.4% of females were positive. Additionally, for the EQ, 36.6% testing negative were male, 63.4% were female, 16.7% of positives were male and 83.3% were female.

Table 3. Crosstabulation of Negative/Positive EQ by Male/Female

			Male/Female		
			Male	Female	Total
Neg/Pos EQ	Negative	Count	30	52	82
		% within neg/pos eq	36.6%	63.4%	100.0%
		% within male/female	90.9%	77.6%	82.0%
		% of Total	30.0%	52.0%	82.0%
	Positive	Count	3	15	18
		% within neg/pos eq	16.7%	83.3%	100.0%
		% within male/female	9.1%	22.4%	18.0%
		% of Total	3.0%	15.0%	18.0%
Total		Count	33	67	100

Table 4 similarly identifies those with negative or positive answers on the BEDS-7 by male or female. Among the same 100 patients answering the BEDS-7 tool, 87.9 % of males tested negative, 12.1% of males tested positive, 80.6% of females tested negative and 19.4% were positive. Additionally, 34.9% testing negative were male, 65.1% were female and, of those testing positive, 23.5% were male and 76.5% female.

Table 4. Crosstabulation Negative/Positive BEDS-7 by Male/Female

			Male/Female		
			Male	Female	Total
Neg/Pos BEDS	Negative	Count	29	54	83
		% within neg/pos beds	34.9%	65.1%	100.0%
		% within male/female	87.9%	80.6%	83.0%
		% of Total	29.0%	54.0%	83.0%
	Positive	Count	4	13	17
		% within neg/pos beds	23.5%	76.5%	100.0%
		% within male/female	12.1%	19.4%	17.0%
		% of Total	4.0%	13.0%	17.0%
Total		Count	33	67	100

The relationship between the two questionnaires was examined using Cohen's Kappa (k). Agreement between BEDS-7 and EQ was statistically significant (k= .827, p= .000), signifying that EQ was answered the same as the BEDS-7. Additionally, McNemar's test showed that the proportions of negative and positive results were not statistically different between the two screening tools, with a p-value of 0.6547.

4.2 Discussion of Results

Similar to the literature, among the 100 participants screened for BED, more women tested positive than men. However, more women answered the questionnaires than men, signifying that more women presented for their annual exams, or signaled a need to be screened. Additionally, in the study setting, the highest number of people

completing the questionnaires were 46-55 years old, at 28%, which was 5% more than the 36-45-year-old age group. Therefore, this age group most often presented for their physical exams or signaled a need to be screened.

The EQ had the highest number of positive screenings in the 36-45-year-old age group. The literature identifies the average age of onset at 25.4 years old, with a mean lifetime duration of 14 years (Forman, 2018; Tanofsk-Kraff et al., 2013). The results of this study suggest that those being screened were not at the onset, but rather further into having BED criteria. The BEDS-7 did identify more with positive screening in the 18-25-year-old group than the EQ, when based on age group. However, there were too few participants to draw any conclusions about effectiveness of the screening tools among age groups.

The objective was to improve upon the current binge eating screening tool in a primary care office. Discussion among providers identified the importance of awareness and efficiency. In addition, creating the EQ with primary care input was key to planning and implementation, as well as identifying the usefulness of such a screening tool. Since the EQ answered the same as BEDS-7 for screening in a sample population, the BEDS-7 can be replaced with EQ in the office that was setting for the scholarly project. The new EQ screening tool was an improvement over the current BEDS-7 screening tool due to brevity and the ease of incorporation in the EMR for PCP use for ongoing screening.

CHAPTER 5: SUMMARY AND RECOMMENDATIONS

5.1 Project Strengths and Limitations

There were several strengths of the study. All patients who received questionnaires answered both, there was no attrition, providers expressed increased knowledge of BED, data was collected quickly, and the screening tools showed a strong Cohen's Kappa. Limitations included the possibility of human error when providers selected positive/negative when documenting on EQ, four questionnaires were discarded due to missing information. In addition, the small sample size of 100, and the simultaneous administration of both screening tools, were potential limitations.

5.2 Summary

Binge Eating Disorder is now listed in DSM-5 and literature supports the need for further evaluation and development of screening tools. BED is a costly disease with multiple comorbidities; effective screening can improve outcomes by preventing or improving the downstream issues. This project demonstrated that EQ is a solution to improve the efficiency of screening for BED in primary care, which is the ideal place to utilize referral resources and treatment modalities. Downstream problems and costs related to BED can be decreased with early detection provided by an efficient and effective screening tool such as the EQ. EQ demonstrated similar screening capability as the BEDS-7, which is based on the DSM-5 criteria.

5.3 Recommendations

Future study recommendations include methods to increase awareness and knowledge of BED and its comorbidities, and to identify the most efficient and effective ways to screen for BED in the appropriate clinical settings. Additionally, identifying age appropriate screening methods across age groups, and including younger groups in screening, would improve outcomes, since symptoms may likely begin in late childhood and adolescence (Tanofsk-Kraff et al., 2013). Successful interventions for treatment hinge on early detection. Primary care is a critical starting point for screening, further evaluation, referral for treatment and further diagnostic evaluation, as warranted.

Sustainability includes inclusion on the EMR, and a future drop-down menu with additional questions for use in primary care. Collaboration among other primary care providers would improve awareness of BED and the availability of an effective screening tool on the EMR. The EQ can be shared to all providers in the system, allowing for use of the EQ among a large network of health care providers.

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APPENDIX A: EATING QUESTIONS SCREENING TOOL

Eating Questions +/-

In the last 3 months, one or more times a week, have you:

Felt out of control while eating? (Yes/No) _____

Felt guilty, disgusted, or depressed after an overeating episode? (Yes/No) _____

Please do not write below this line

Age_____

Gender_____

BEDS-7 (+/-)_____

APPENDIX B: BEDS-7 SCREENING TOOL

A guide to using the Binge Eating Disorder Screener-7 (BEDS-7)

This patient-reported screener is designed to help you quickly and simply screen adults whom you suspect may have binge eating disorder (B.E.D.).

This tool was developed by Shire US Inc and is intended *for screening use only.* It should not be used as a diagnostic tool.

USING THE BEDS-7 IS SIMPLE:

STEP 1: QUESTION 1

If the patient answers "YES" to question 1, continue on to questions 2 through 7.

If the patient answers "NO" to question 1, there is no reason to proceed with the remainder of the screener.

STEP 2: QUESTIONS 2-7

If the patient answers "YES" to question 2 **AND** checks one of the shaded boxes for all questions 3 through 7, follow-up discussion of the patient's eating behaviors and his or her feelings about those behaviors should be considered.

STEP 3

Evaluate the patient based upon the complete *DSM-5®* diagnostic criteria for B.E.D.

The following questions ask about your eating patterns and behaviors within the last 3 months. For each question, choose the answer that best applies to you.

1. During the last 3 months, did you have any episodes of excessive overeating (i.e., eating significantly more than what most people would eat in a similar period of time)?	Yes	No

NOTE: IF YOU ANSWERED "NO" TO QUESTION 1, YOU MAY STOP. THE REMAINING QUESTIONS DO NOT APPLY TO YOU.

2. Do you feel distressed about your episodes of excessive overeating?	Yes	No

Within the past 3 months...	Never or Rarely	Sometimes	Often	Always
3. During your episodes of excessive overeating, how often did you feel like you had no control over your eating (e.g., not being able to stop eating, feel compelled to eat, or going back and forth for more food)?				
4. During your episodes of excessive overeating, how often did you continue eating even though you were not hungry?				
5. During your episodes of excessive overeating, how often were you embarrassed by how much you ate?				
6. During your episodes of excessive overeating, how often did you feel disgusted with yourself or guilty afterward?				
7. During the last 3 months, how often did you make yourself vomit as a means to control your weight or shape?				

APPENDIX C: APPROVAL LETTER TO USE BEDS-7 IN PROJECT

Josette Giuffrida <jskakey@uncc.edu>

BEDS-7

Smith, Seth <seth.smith@takeda.com> Wed, Feb 27, 2019 at 12:31 PM
To: Josette Giuffrida <jskakey@uncc.edu>
Cc: "Fantone, Danielle" <danielle.fantone@takeda.com>

Josette,

It was nice speaking with you today about screening for Binge Eating Disorder (BED) in your appropriate patient population. Your practice of using the BEDS-7 to screen for these patients and to further educate primary care practitioners on this disorder is appreciated. With this email, as we discussed, I am approving the use of the BEDS-7 for your scholarly activities.

Thank you,

Seth

Seth C. Smith, Jr., Pharm.D., MBA

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seth.smith@takeda.com

APPENDIX D: PATIENT INFORMATION LETTER

Patient Information

Your participation in this questionnaire is voluntary. You may choose not to participate. If you do decide to participate in this questionnaire, you may withdraw at any time. You may also decline to answer any question/s that you choose.

Your participation will involve completing a survey that should take less than 10 minutes.

Your responses will be confidential, and we will not collect any identifying information, such as your name, email address, date of birth, date of visit, or address.

If you have any questions about the survey, please contact Novant Health's human research oversight board at 336-718-9670 (the Institutional Review Board or IRB) or Josette Giuffrida at 704-316-5635.

By completing this questionnaire, you are consenting for your responses to be used in data analysis for the purposes of screening for binge eating disorder in primary care

Thank you for your time.

NH: Gilead Road Pediatrics and Internal Medicine

9615 Kincey Ave, Suite 100

Huntersville, NC 28078

704-316-5635

APPENDIX E: NOVANT IRB APROVAL

NOVANT HEALTH
Presbyterian Medical Center
200 Hawthorne Lane
Charlotte, NC 28204

DATE:	May 13, 2019
TO:	Josette Giuffrida, FNP, Medical Staff Services
	Thomas Lessaris, MD
FROM:	Vickie Zimmer, Director, Presbyterian Healthcare IRB
PROTOCOL TITLE:	Assessment of Binge Eating Disorder in Primary Care
PROTOCOL NUMBER:	19-1268
	Approval Date: May 13, 2019

The Presbyterian Healthcare IRB, operated by Novant Health, has reviewed the protocol entitled: Assessment of Binge Eating Disorder in Primary Care. The IRB has determined that this project meets one or more criteria contained within 45 CFR 46.101(b) exempting the project from the requirements of continued review. You are free to conduct your study without further reporting to the IRB. In the event that you revise your study significantly, this revision must be submitted for review to ensure that the study continues to meet the federal guidelines for exemption from review.

Attachments

Data Collection and Confidentiality for Binge Eating Disorder Screening in Primary Care

Patient Information Sheet

This exempt determination will be documented in the minutes of the June 20, 2019 IRB meeting. A copy of the protocol is maintained by the IRB office. All minutes and proceedings pertinent to this protocol are maintained by the IRB office. The Novant Health IRBs are registered with the Office of Human Research Protections (OHRP) and in compliance with the requirements of federal regulations 45 CFR 46, 21 CFR 50, 21 CFR 56 and internal policies as revised to date. If you have any questions or need additional information, please contact the IRB office at (336)718-9670 or irb@novanthealth.org.

Sincerely,

Mark Clemens, PhD
Presbyterian Healthcare IRB Chair