MANAGEMENT OF OBESITY IN PRIMARY CARE: A CROSS-SECTIONAL NEEDS ASSESSMENT SURVEY OF BEHAVIORAL WEIGHT MANAGEMENT INTERVENTIONS FROM THE PATIENT PERSPECTIVE

by

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SIGNED: __Cassandra Jenks________________
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ABSTRACT

Over two thirds of adults in the United States are affected by overweight or obesity. Weight management, which requires multi-component, intensive interventions targeting dietary and physical activity behaviors, should be offered as part of routine primary care services. Unfortunately, there is a paucity of evidence to guide the implementation of feasible and effective strategies within primary care settings. This DNP Project utilized a cross-sectional descriptive needs-assessment to survey obese patients’ perceptions and preferences regarding weight and the primary care provider role in weight management. The findings from the needs assessment were used to inform the development of a feasible, patient-centered, weight management program.
INTRODUCTION

Two of every three adults in the United States (U.S.) are at risk for the negative physical, functional and psychosocial consequences of overweight and obesity (Ogden, Carroll, Kit, & Flegal, 2014). The current weight epidemic necessitates the development of comprehensive and creative strategies for weight management. Primary care providers should screen for obesity and offer weight management interventions, similar to the processes for diagnosis and management of hypertension or diabetes. The United States Preventive Services Task Force (USPSTF) recommends screening all adults age 18 and older for obesity, and offering intensive, multicomponent health-behavior interventions for those who screen positive (Moyer, 2012). Unfortunately, the majority of patients within the U.S. do not receive weight counseling from their primary care providers (Kraschnewski, et al., 2013; LeBlanc, O’Connor, Whitlock, Patnode, & Kapka, 2011b). Barriers to weight counseling in the primary care setting include limited time, inadequate compensation, and lack of knowledge and resources (Kolasa & Rickett, 2010).

Numerous studies have found that multi-component behavior-based weight loss interventions can produce clinically significant weight loss (LeBlanc et al., 2011b). However, due to the heterogeneity of weight-loss intervention studies, the efficacy and effectiveness of individual intervention components remains unclear. Meta-analysis conclusions cannot be derived for specific intervention elements, still the current literature does support intervention concepts including individualized goal setting, self-monitoring, and at least monthly counseling sessions (Appel et al., 2011; Bennett et al., 2010; Bennett et al., 2012; LeBlanc, O’Connor, Whitlock, Patnode, & Kapka, 2011a; Ma et al., 2013; Pellegrini et al., 2012). The role of the
primary care provider within weight management interventions remains yet unanswered by the current literature. Very few weight management studies have been conducted in the primary care setting utilizing staff and resources available to primary care providers (LeBlanc et al., 2011b). Interventions conducted within academic settings are not readily translated into the primary care setting, leaving a gap in the current literature regarding the translation of evidence to practice.

Given the scarce evidence available to examine interventions implemented in primary care, the question of what behavioral interventions are feasible and effective for the primary care setting remains unanswered. Behavioral weight management interventions intended for the primary care setting must be reasonably suited for the structure, workflow, personnel, and fiscal procedures of the office setting. Behavioral weight management interventions should also reflect the preferences and priorities of the population they are intended for. Before developing and implementing interventions targeting weight management, the population affected by this problem must first be assessed (Zaccagnini & White, 2014). A needs assessment of obese patients seeking primary care was designed and implemented to examine their wants, perceptions and preferences regarding weight management. The results from the needs assessment were used to guide the development of a weight management program. The overarching mission of the weight management program is to achieve sustainable weight-related behavior change and long-term healthy weight maintenance.

There are numerous ways to screen for unhealthy body size, including weight, body mass index, waist circumference, bio-impedance, skin-fold calipers and underwater weighing. Mechanisms such as bio-impedance and underwater weighing can provide a more comprehensive and accurate assessment of a person’s body composition, however they may be
unavailable or logistically unrealistic. Body mass index is an acceptable measure of body composition that is commonly used in evidence-based clinical recommendations and research (LeBlanc et al., 2011b). BMI is low-cost, reliable, quick, and convenient for both patient and provider. Evidence supports the use of BMI to identify adults with higher risk for future weight-related morbidity and mortality (LeBlanc et al., 2011b). Using BMI as a measure of health risk, overweight is defined by a BMI of 25 to 29.9 kg/m², and obesity is defined by a BMI of 30 kg/m² or greater (Moyer, 2012).

**Background Knowledge**

**Prevalence and Health Burden**

There are limited data available to evaluate U.S. weight trends prior to the mid-20th century, however historic reports from national surveys, military recruits and veterans suggest obesity trends began rising as early as the mid-19th century (Flegal, Carroll, Ogden, & Curtin, 2010). With the implementation of the National Health and Nutrition Examination Survey (NHANES) program in the 1960s, more robust data became available to evaluate the weight status of the U.S. population (CDC, 2014). According to NHANES data, the prevalence of obesity remained fairly stable from 1960 to 1980, and then began increasing in the 1980s at a rate of seven to eight percent (Flegal et al., 2010). That increasing trend continued for two decades in to the late 1990s and early 2000s (Flegal et al., 2010). Recent estimates suggest the obesity prevalence among U.S. adults has remained stable in women over the past 15 years and stable in men over the past 10 years (Flegal et al., 2010; LeBlanc et al., 2011b; Ogden et al., 2014). While obesity prevalence may no longer be on a steep rise, the number of U.S. adults affected by obesity and overweight remains dangerously high. According to recent NHANES
data (2011-2012) 68.5% of all adults over age 20 are overweight and 34.9% are obese (Ogden et al., 2014).

The negative physical, functional, and psychosocial consequences of excess body weight have been well documented. Overweight and obesity are associated with increased risk of cardiovascular disease, certain types of cancer, type two diabetes, respiratory diseases, osteoarthritis, gall bladder and liver disease, pregnancy complications, disability, shortened life expectancy and decreased health-related quality of life (Jia & Lubetkin, 2005; LeBlanc et al., 2011b; Moyer, 2012; WHO, 2014). The risk of coronary heart disease increases by 49% with obesity (LeBlanc et al., 2011b). Obese men are over six times more likely to develop type-two diabetes, and obese women are twelve times more likely (LeBlanc et al., 2011b). More than 80% of type-two diabetes can be attributed to obesity (Bray, 2014). Increasing BMI is associated with increased risk for endometrial, gall bladder, esophageal, thyroid, colon and renal cancer (Bray, 2014; LeBlanc et al., 2011b). Musculoskeletal complaints can be caused by or worsened from excess body weight, and over time can lead to painful joint degeneration and disability (WHO, 2014). The greatest risk factor for developing obstructive sleep apnea is obesity. With a 10% increase in body weight there is a six-fold risk increase for developing obstructive sleep apnea (Strohl, 2014). Obesity is also associated with depression and decreased health-related quality of life (LeBlanc et al., 2011b; Jia & Lubetkin, 2005).

Obesity is associated with increased risk of death, especially among those younger than age 65, making young to middle age adults of particular interest for weight-loss and weight-maintenance interventions (LeBlanc et al., 2011b). Depending on age and race, obesity reduces life expectancy by 6 to 29 years (LeBlanc et al., 2011b). The leading causes of death among the
obese are ischemic heart disease, diabetes, lung disease, and cancer (LeBlanc et al., 2011b). While the trend of obesity prevalence has reached a plateau over the past decade, the majority of U.S. adults continue to be at risk for major health concerns related to weight (Flegal, et al., 2010; Ogden et al., 2014). Second to smoking, obesity is the leading cause of early, preventable death in the U.S. (Daddario, 2007). Obesity is a detrimental and commonly occurring condition among U.S. adults that is both preventable and treatable.

**Determinants of Weight**

Weight is the balance of energy intake and energy expenditure. The following equation is a simplified framework for understanding weight regulation: \[\text{ENERGY IN} + \text{ENERGY OUT} = \text{CHANGE IN WEIGHT}\]. When energy intake is greater than energy expenditure, weight gain occurs. If there is an energy deficit, weight loss occurs. When energy intake and expenditure are equal, weight is maintained. Figure 1 represents this framework within the environmental context (Figure 1). This framework of energy balance is fairly simple; however, the complex physiologic mechanisms of energy regulation make it challenging to apply. There are protective regulatory processes that interact to safeguard the body from starvation, preserve adequate energy stores, and prevent large shifts in body mass (Hill, Wyatt, & Peters, 2012). Metabolic signaling mechanisms can influence both energy intake and expenditure by affecting appetite and regulating energy storage within the body. It is beyond the scope of this project to explore physiologic metabolic regulation in detail, but homeostatic and hedonic mechanisms will be briefly discussed as examples of the complexity of energy regulation.
FIGURE 1. Weight Determinant Model.
(Weight is the result of complex, interdependent and multifaceted interactions among people and their environments.)

Homeostatic regulation of eating behavior occurs when hormone-signaling processes produce hunger and satiety cues in response to energy supply and demand. The two primary
signaling mechanisms of hemostatic regulation are leptin and ghrelin (Lutter & Nestler, 2009). Leptin, secreted by adipose tissue, decreases food intake and stimulates the use of energy stores; ghrelin, secreted by the gastrointestinal tract, increases food intake and stimulates energy storage (Lutter & Nestler, 2009; Seagle, Strain, Makris, & Reeves, 2009). These hormones create feedback mechanisms in response to energy supply that regulate hunger and satiety cues. The homeostatic regulation works to maintain a stable energy supply. Eating behavior is also regulated through a hedonic pleasure-reward response, which is mitigated by the release of neurochemicals, primarily dopamine (Seagle et al., 2009). Laboratory studies suggest that homeostatic and hedonic processes interact when leptin and ghrelin levels alter the hedonic dopamine signaling (Lutter & Nestler, 2009). Chronic stress can also play a role by affecting leptin and ghrelin levels (Lutter & Nestler, 2009). Eating behaviors are driven by interconnected processes of hormonal signaling, neurochemical release and psychosocial experiences. These homeostatic and hedonic examples of eating behavior regulation demonstrate the complex physiologic and contextual interactions that influence eating patterns.

In addition to these physiologic mechanisms, there are numerous cultural, social, economic and community aspects that influence energy intake and output behaviors. For example, the presence of parks and walking paths is a community aspect, access to stores with healthy food options is an economic aspect, and the expectation of consuming meals at social gatherings is a cultural aspect. Environmental aspects that promote energy-positive behaviors contribute to what is called the obesity-promoting or “obesogenic” environment (Elinder & Jansson, 2009; Kirk et al., 2010). Any environmental characteristic that hinders healthy weight maintenance is generally considered part of the obesogenic environment (Kirk et al., 2010).
Obesogenic Environment

There has been a tremendous growth of literature over the past 15 years exploring the relationship between the environment and body weight (Elinder & Jansson, 2009; Hill et al., 2012; Kirk et al., 2010; Poston & Foreyt, 1999; Swinburn, Egger & Raza, 1999). The modern U.S. obesogenic environment has since been recognized as a potential driving force of obesity (Elinder & Jansson, 2009; Hill et al., 2012; Kirk et al., 2010; Poston & Foreyt, 1999; Swinburn et al., 1999). Over time, there have been agricultural and technology advances, changes in economy, and social impacts on beliefs and value systems that have influenced the daily eating and physical activity patterns among U.S. adults (Seagle et al., 2009). The modern environment offers many energy-sparing conveniences while increasing the availability of large-portioned, calorie-dense foods. This has led to an imbalance of food supply and energy expenditure, with the available supply of energy intake often exceeding the opportunities for physical activity (Seagle et al., 2009).

The modern environment influences dietary patterns through the availability and quality of foods. Calorie-dense foods are widely accessible and often at an affordable price. Fast-food “value menus” offer a wide array of options, ranging from 20-calorie side salads, to hamburgers and chicken sandwiches with over 400 calories and 20 grams of fat (Burger King, n.d.; McDonald’s, n.d.; Wendy’s, n.d.). With such low-cost, calorie-dense food options, over half the daily energy needs can be purchased with just a few dollars. Retail stores, whose primary product is not food-related, often offer candy, salted snacks and sugary drinks within reach of the cash register (Farley, Baker, Futrell, & Rice, 2010). This frequent access to snacks and drinks found while shopping for clothing, filing the car with gas or picking up prescriptions forces
consumers to say no to treats they would not otherwise have considered eating. National survey trends suggest that increased frequency of eating occasions has significantly contributed to the increase in total energy consumption by U.S. adults over the past few decades (Duffey & Popkin, 2011; Palmer, Capra & Baines 2009). Living in a food-rich environment with convenient access to frequent, often unhealthy, eating opportunities encourages overconsumption and greater energy intake.

Total energy intake is also impacted by portion sizes and food marketing. Marketed meal, drink and snack portions have more than doubled or tripled over the past several decades, and are on average at least twice the standard serving size (Seagle et al., 2009; We Can!, 2013). Offering these larger portion sizes leads to greater energy intake (Steenhuis & Vermeer, 2009). Even though a smaller portion may be the standard serving size and provide adequate satiety, larger portions sizes are often more appealing due to their perceived greater value (Steenhuis & Vermeer, 2009). Larger portion sizes also contribute to portion distortion, which is the misperception of larger portions as being appropriate serving sizes (Seagle et al., 2009; Smith & Ditschun, 2009; Steenhuis & Vermeer, 2009). Portion distortion is reinforced by the use of larger plates, bowls, silverware, and packaging containers. The larger-sized structures contribute to increased consumption by creating the illusion of a smaller portion regardless of the actual serving size (Smith & Ditschun, 2009). This is easily illustrated by taking two servings of the same amount of food, and placing one on a small plate and one on a large plate. The smaller plate will give the appearance of holding more food, even though both servings are equal. Increased market portion sizes, large portion preference due to value perception, and portion distortion all lead to unintentional overeating.
The modern, obesogenic environment allows people to fulfill their daily needs without requiring as much routine physical activity. Drive through services allow meal ordering, prescription refills, dry cleaning and banking to all be addressed from the driver’s seat of a car. Washing machines, self-propelled vacuums and dishwashers reduce the activity burden of cleaning a home. Escalators and moving walkways allow greater distances to be covered for far less energy expenditure. Opportunities to engage in physical activity are influenced by various features of the built environment, including transportation systems, access to parks and recreation areas, perception of neighborhood safety and walkability, and workplace activity (Kirk, Penney, & McHugh, 2010; Swinburn et al., 2011). Industry changes have significantly decreased the energy demands of the U.S. workplace. Today, only 20% of private industry jobs require moderate-intensity physical activity, whereas nearly half of such jobs in the 1960s required moderate-intensity physical activity (Church et al., 2011). Estimates from the U.S. Bureau of Labor Statistics suggest that occupation-related energy expenditure has decreased over the past 50 years by over 100 calories per day (Church et al., 2011).

One method to demonstrate the impact of modern technology on daily physical activity is to study the physical activity trends among a community void of modern technology. The Old Order Amish Community abstains from using modern advances such as electrical appliances, gasoline-powered transportation, and other contemporary conveniences (Bassett, Schneider, & Huntington, 2004). Their preferred livelihood of labor-intensive farming reflects the U.S. labor milieu of a century ago, making this an ideal community for such an inquiry (Basset et al., 2004; Bassett, Wyatt, Thompson, Peters, & Hill, 2010). On average, adults among the Old Order Amish Community walked about three times as many steps per day as adults living in the
modern U.S. (Basset et al., 2004; Bassett et al., 2010). Obesity is very rare among this population, affecting only 9% of adult women and no adult men. About one quarter of adult men and women were found to be overweight. Compared to modern U.S. adults, the Old Order Amish were found to have significantly higher levels of activity and lower rates of obesity. This comparison does not prove direct causation, yet it does demonstrate the possible impact of modern amenities on the activity level of U.S. adults today.

Over the past four decades, there has been a trend of positive energy balance that is reflected in the rates of overweight and obesity. This shift in energy balance suggests the body’s regulatory mechanisms are unable to maintain an equal balance of energy intake and expenditure in the modern environment (Hill et al., 2012). There is only weak evidence to confirm the link between the obesogenic environment and obesity, however the lack of convincing evidence is more likely due to research limitations and challenges of measuring poorly defined environmental factors rather than a lack of correlation (Elinder & Jansson, 2009; Kirk et al., 2010). Environmental influences that encourage high caloric intake, discourage physical activity, and provide energy-sparing amenities likely contribute to the current obesity epidemic.

**Weight Management in Primary Care**

The United States Preventive Services Task Force (USPSTF) recommends screening all adults age 18 and older for obesity, and for all patients with a BMI of 30 kg/m² or greater to be offered or referred for intensive, multicomponent behavioral interventions (Moyer, 2012). Behavioral weight loss interventions should focus on lifestyle changes that increase physical activity and promote healthy eating, with an emphasis on calorie restriction (LeBlanc et al., 2011b). Behavioral interventions should preferably include cognitive and behavior management
techniques to both achieve and maintain healthy lifestyles (LeBlanc et al., 2011b). Unfortunately, the majority of patients within the U.S. do not receive weight counseling from their primary care providers (Kraschnewski, et al., 2013; LeBlanc et al., 2011b). In fact, the rate of weight loss counseling for obese patients has declined from 40% in 1995-1996 to 30% in 2007-2008 (Kraschnewski, et al., 2013). Primary care providers have reported several barriers to weight counseling including limited time, inadequate compensation, and lack of knowledge and resources (Kolasa & Rickett, 2010). There are an increasing number of clinical items being addressed during primary care visits, without a proportional increase in the length of visits, leaving primary care providers with less time to spend on each item (Abbo, Zhang, Zelder, & Huang, 2008). Considering the limited time and resources primary care providers have for each patient and the absence of specific weight management recommendations, primary care providers are in need of setting-specific best practices to guide the implementation of feasible and effective weight management interventions.

USPSTF recommendations for weight loss interventions include high intensity group and/or individual counseling during the first year, support for healthy eating, increased physical activity, methods for overcoming barriers to change, self-monitoring, and strategies for long-term maintenance of healthy behaviors (USPSTF, 2012). The USPSTF recommendations provide a framework for weight loss programs, but they do not include guidance on how to deliver each element. Most weight-loss intervention studies include multiple intervention elements with varying degrees of intensity, methods of delivery, and sparse reporting of intermediate and distal outcome measures (LeBlanc et al., 2011a; LeBlanc et al., 2011b). Due to these evidence limitations, statistical conclusions cannot be made about the individual effects of
each intervention element (LeBlanc et al., 2011b). However, there are intervention elements that are common among effective weight loss programs studied in the primary care setting, and these will be further discussed here.

The intervention delivery method does not seem to influence the effectiveness of the intervention. Group and individual sessions, face-to-face visits, remote communication, and self-directed, coach-led, and technology-based interventions have all demonstrated significant weight loss outcomes when incorporated in a multicomponent weight loss program (Anton et al., 2012; Bennett et al., 2010; Bennett et al., 2012; Greaney et al., 2009; Ma et al., 2013; Moyer, 2012; Pellegrini et al., 2012; USPSTF, 2012). In a two-year randomized controlled trial Appel and colleagues (2011) found both face-to-face and remote (via phone, website, and email) weight-loss interventions resulted in clinically and statistically significant weight loss. The interventions were delivered by weight-loss coaches, and the role of the primary care provider was to review the progress during routinely scheduled visits (Appel et al., 2011). A six-month comparative effectiveness trial found the combination of a standard weight loss intervention and a technology-based intervention produced greater weight loss and had higher retention rates than either intervention alone (Pellegrini et al., 2012). The individual components of the technology-based intervention (monitoring armband, website, and monthly phone calls) were not individually analyzed, therefore the impact of each component is unknown (Pellegrini et al., 2012). Self-monitoring of weight, dietary habits and physical activity can be achieved through various formats including diet and activity journals, computerized tracking systems, voice response systems and pedometer step counts (Anton et al., 2012; Appel et al., 2011; Bennett et al., 2012; Greaney et al., 2009; NHLBI, 2012; ter Bogt et al., 2009; USPSTF, 2012). A
comparison of coach-led in-person classes vs. self-directed video-based classes found both methods demonstrated feasibility and effectiveness in the primary care setting (Ma et al., 2013). There is not one clearly superior method of intervention delivery. Further research is needed on intervention delivery utilizing the staff and resources available in the primary care setting.

The intervention intensity does play a significant role in weight loss outcomes. In general, interventions with more sessions in the first year resulted in greater weight loss, even after controlling for other intervention elements and study differences (LeBlanc et al., 2012b). Trials with 12 to 16 sessions produced an average loss of 5.3 kg (LeBlanc et al., 2012b). Systematic review of the literature found low to moderate intensity counseling by primary care providers, without other intervention elements, did not result in clinically significant weight loss (Tsai & Wadden, 2009). High intensity intervention is defined as having at least two visits per month for the first three months with 12 to 26 visits in a year, moderate intensity is at least monthly contact, and low intensity is less than monthly contact (Moyer, 2012; Tsai & Wadden, 2009). Intensive programs that incorporate a variety of weight loss components are effective for weight management (USPSTF, 2012).

Calorie restriction and regular physical activity are the mainstays of weight management. Calorie-restricted diets produce clinically significant weight loss regardless of the macronutrient content (Fernandez, Casariego, Rodriguez & Pomar, 2012; Sacks et al., 2009). Diet and exercise combined is more effective than either alone for weight loss maintenance (Dick, 2004). A literature review and systematic analysis of weight loss interventions found 77% of initial weight loss was maintained with combined diet and exercise, whereas 56% was maintained with diet only and 53% with exercise only (Dick, 2004). In addition to aiding weight loss maintenance,
aerobic, resistance, and strength training exercise are associated with increased mood, improved lipid profile, increased fitness level, increased lean tissue mass, and a decreased risk of type-two diabetes, heart disease and hypertension (Dick, 2004). According to the National Heart, Lung, and Blood Institute the activity goal for overall health and reduction of disease risk is 30 minutes of moderate activity per day, for prevention of weight gain is 60 minutes of moderate to vigorous activity per day, and for maintenance of weight loss is 60 to 90 minutes of moderate physical activity per day (NHLBI, 2012). This activity does not have to be done all at once to observe the positive health effects. Increments of at least 10 minutes of physical activity will still be effective (NHLBI, 2012).

In summary, interventions including calorie restriction, regular physical activity, individualized goal setting, self-monitoring, and at least monthly counseling sessions have demonstrated clinically significant weight loss (Appel et al., 2011; Bennett et al., 2010; Bennett et al., 2012; LeBlanc et al., 2011a; Ma et al., 2013; Pellegrini et al., 2012). The role of the primary care provider in implementing these interventions for weight management remains unclear.

**Intended Improvement**

Primary care providers are faced with the challenge of providing comprehensive, high quality care addressing prevention, wellness, chronic disease management and treatment of acute concerns, all within brief office visits. Primary care providers are in need of best practice recommendations and resources to guide the implementation of weight management interventions. To develop realistic and sustainable interventions, the needs of obese patients seeking primary must be considered an essential part of the intervention development process. A
needs assessment of obese patients seeking primary care was conducted to help inform the development of a weight management program. The weight management program is intended to serve as both a resource and tool for primary care providers to offer comprehensive weight management counseling to patients with obesity.

**Study Questions**

The primary questions included: (1) Do obese patients in the primary care setting want their primary care provider to offer weight management counseling and interventions? (2) What behavior-based weight management interventions are preferred by obese patients in the primary care setting?

Secondary questions that addressed patient perceptions included: (1) Do patients perceive themselves as overweight? (2) Do patients perceive negative emotional and/or physical consequences of their weight? (3) Is weight-management important to patients?

**FRAMEWORK**

Weight management is primarily achieved through behavioral interventions. Weight management research should therefore be structured within behavioral frameworks, and obesity treatment and prevention strategies should be informed by models of behavior change. The Transtheoretical Model and Health Belief Model were used within a social ecology framework to inform the development of this study.

**Social Ecology Framework**

Ecology is defined as a division of science that studies the interrelationship between living things and their environments (Ecology, n.d.). Social ecology focuses on the cultural, structural, institutional, and social contexts of the human-environment interaction (Stokols,
Within a social ecology framework, human behavior results from complex interdependent exchanges between an individual and their surroundings. Behavior determinants arise from both internal and external mechanisms. Examples of internal behavior mechanisms include genetics, neurochemical patterns and psychological dispositions (Sallis, Owen, & Fisher, 2008). External factors arise from social and cultural interactions, public policies, community structure, and the physical environment (Sallis et al., 2008). Using a social ecology model, health behavior can be studied within the context in which it occurs, emphasizing the role of environment (Sallis et al., 2008).

According to Stokols’s Social Ecology Model for Health Promotion (1992), there are four core assumptions regarding the dynamics of health. First, personal wellbeing is influenced by individual qualities, by the physical and social environment, and by the dynamic interactions that take place between them (Stokols, 1992). According to the first assumption, interventions designed to target health behavior change should be sensitive to the interactions of behavior, biology, and environment. Second, human environments are a complex collection of geography, architecture, technology, culture, economy, politics, and both objective and perceived qualities (Stokols, 1992). This means environment is both socially and individually constructed. Each person will have a unique experience as they interact with their environment. Those experiences will shape their perceptions, thereby creating an environment that is unique to them. The third assumption is that people interact with their environment on varying levels, including individual, small group, organizational, and population based (Stokols, 1992). Experiences and perceptions can be influenced by interactions occurring on any of these levels. The second and third assumptions tell us that behavioral interventions must be flexible to fit unique and individually
constructed environments. Lastly, the environment both influences and is influenced by the people interacting with it (Stokols, 1992). We shape our environment, and our environment in turn shapes us. The fourth assumption presumes that interventions can be designed to target environmental changes that will promote healthy behaviors. These four core assumptions speak to the significance of environmental context for behavioral-based weight management.

**Transtheoretical Model of Change**

The Transtheoretical Model (TTM) was first developed in the early 1980s (Prochaska, Reddings, & Everys, 2008). At that time over 300 theories of psychotherapy and behavior change existed and the TTM emerged from a study aimed at integrating the most prominent of those 300 theories (Prochaska et al., 2008). Early observations revealed that behavior change occurs through several stages rather than one distinct event, and from this realization, the Stages of Change was developed (Prochaska et al., 2008). The TTM Stages of Change was initially applied to smoking cessation. It has since been expanded to include many physical and mental health behaviors, including obesity and sedentary lifestyles (Prochaska et al., 2008). The Stages of Change can be applied to weight-related behavior change as a tool for assessing readiness for change and to help individualize the intervention approach.

The Stages of Change has six stages – precontemplation, contemplation, preparation, action, maintenance, and termination (Prochaska et al., 2008). With precontemplation, there is no intention to initiate a behavior change. This stage is often related to a knowledge deficit regarding the impact of a certain behavior, or prior failure at behavior change (Prochaska et al., 2008). Contemplation occurs when there is recognition of the need for behavior change, but there is hesitation to take action due to the possible negative effects of that change (Prochaska et al.,
Those in the stages of precontemplation and contemplation are not usually receptive of action-oriented interventions (Prochaska et al., 2008). Preparation precedes the stage of action, usually taking place the month before action and often including initial steps to change, such as joining a gym. Preparation is the ideal time for action-oriented interventions (Prochaska et al., 2008). The action stage occurs once the specific, risk-reducing health behavior change has occurred (Prochaska et al., 2008). The maintenance phase begins after the behavior change has been maintained for six months, and is characterized by prevention of relapse (Prochaska et al., 2008). Termination occurs when there is an absence of temptation to relapse and 100% confidence that the healthy behavior can be continued in challenging situations (Prochaska et al., 2008). Understanding that change is a process that occurs over time should help guide the approach to behavioral interventions. Each patient may be at a different stage of change, and interventions should be selected to best fit their stage. Weight management requires a lifelong commitment to a healthy lifestyle, and it should be considered a chronic condition that requires ongoing support throughout the entire process of behavior change.

**Health Belief Model**

The Health Belief Model (HBM) addresses the multifaceted determinants of health-related behavior, including psychosocial and contextual factors, making this a useful framework for developing weight management interventions. The major concepts of the Health Belief Model explore a person’s likelihood of making a behavior change, given their individual perceptions and contextual influences. Individual perceptions include the perceived susceptibility to and severity of a given health threat, and the perceived benefits and barriers to making behavior change to address that health threat (Daddario, 2007; Rosenstock, 1974). Contextual
influences include any cues that prompt behavior change, as well as demographic, social and structural variables (Daddario, 2007; Rosenstock, 1974). A representation of the HBM (Figure 2) designed after Rosenstock (1974), has been modified with the addition of self-efficacy and expanded connections between concepts.
FIGURE 2. Health Belief Model.
(Modified after: Rosenstock, I. M. (1974). Historical origins of the Health Belief Model. Health Education Monographs, 2(4). The Health Belief Model can be used as a framework to understand and develop interventions for weight-related health behaviors.)
Perceived susceptibility is the degree of vulnerability a person feels regarding a particular illness (Janz & Becker, 1984). A person may believe they have a high or low likelihood of facing an illness or disease based on their knowledge, their personal experience with the disease, or experience with others who have been affected by this disease. Perceived severity is the estimation of the personal impact an illness or disease may cause (Daddario, 2007). This includes physical and social consequences of pain, disability, death, effects on family life, work performance and social relations (Janz & Becker, 1984). Perceived benefits are the anticipated positive effects than can result from performing a certain action or behavior (Daddario, 2007). Perceived barriers include any potentially negative effects of an action, such as cost, inconvenience, discomfort, or use of time (Janz & Becker, 1984). These four beliefs are subjective interpretations, founded in experience and perception, not necessarily fact. Cues to action are internal and external events that trigger a behavior response (Rosenstock, 1974). Cues to action can be something formal such as a reminder notice from the dentist, a quick subconscious glance at an informational poster, or something as fleeting as a sneeze (Rosenstock 1974). Self-efficacy refers to the confidence a person has in their ability to perform a particular action or behavior (Daddario, 2007).

In applying the HBM to weight management, perceived susceptibility refers to the vulnerability a person feels regarding the negative impact of being obese. A person may be aware they are obese, but not feel vulnerable to, or at risk for developing hypertension, cardiovascular disease or diabetes because of their weight. Perceived obesity severity refers to the estimated impact weight-related disease may cause. A person who is obese may be aware of their risk of diabetes, but not be concerned with the potential burden and complications that may
arise because of diabetes. Examples of perceived barriers to weight loss include poor exercise
tolerance, pain associated with physical activity, dislike or expense of foods deemed healthy and
difficulty moderating intake of unhealthy, highly palatable food items. Perceived benefits of
weight loss may include increased energy, improved mobility, better sleep and improved self-
image. Weight management cues to action may appear in many different forms. A message from
a health care provider, feelings of fatigue while playing with one’s children, difficulty buttoning
up a pair of pants, and a high blood pressure reading can all serve as triggers for behavior
change. Weight-management self-efficacy is often hindered by unsuccessful attempts at weight
loss and challenges of the obesogenic environment. To motivate weight related behavior change,
counseling should focus on the risks and consequences associated with obesity, on the benefits of
weight loss, ideas for overcoming barriers to behavior change, and encouragement that weight
loss can be achieved.

The HBM can be used as a framework for developing weight management interventions
aimed at the specific components that drive health behavior change. Framing interventions
within the context of the model allows providers to select interventions based on individual
perceptions and needs. For example, a person who is not interested in addressing their weight
may benefit from interventions targeting perceived susceptibility and severity of obesity or
benefits of weight loss. Someone who is interested in weight loss but has poor self-efficacy may
benefit from action-oriented interventions that support their confidence in their ability to achieve
weight loss.
METHODS

A needs assessment was conducted at Green Valley Family Practice to evaluate the priorities and preferences regarding weight management from the patient perspective. Prior to developing and implementing interventions targeting weight management, the population affected by this problem must first be assessed (Zaccagnini & White, 2014). The needs assessment asked the group of interest about their weight management needs and perceptions (Berkowitz & Nagy, 2014). The findings from the needs assessment were then used to develop interventions for clinical practice. The group of interest for the needs assessment included obese adults, age 18 to 65 who were being seen at Green Valley Family Practice.

Ethical Issues

The questionnaire collection method, administered during patient waiting time, was designed to minimize any disruption in the flow of patient care. The design of the needs assessment accounted for patient privacy and confidentiality concerns. Patient privacy was respected by distributing the questionnaire to patients within the exam room. Patients were not publicly asked to participate in the study, and their decision was not reflected in their health care record. Survey participation or non-participation did not impact the scheduled patient-provider visit. The provider was not informed of the patient participation status, unless the patients choose themselves to notify their provider. Demographic data, height, weight and questionnaire responses were collected. No personally identifiable data was collected. The principal investigator was not directly involved with patient care at the site. There were no reasonably foreseeable principal investigator conflicts of interest. The study did not involve interventions or procedures and posed minimal to no risk to the participants. Obtaining a signed informed consent
from participants would have generated the only document linking the participant to the study, creating a risk for breach of confidentiality. Therefore, written informed consent was not obtained. Informed consent to participate was implicit upon completion of the questionnaire. The study proposal was reviewed by the Institutional Review Board (IRB) of the University of Arizona and was approved prior to any participant contact or data collection (Appendix C).

**Setting**

Green Valley Family Practice is located in Green Valley, Arizona. Green Valley Family Practice is one of four family practice locations belonging to Arizona Medical Services. The practice is open Monday through Friday, from 7:30 am to 5:00 pm. The practice has one full time family nurse practitioner and one part time family physician. Within the same office building, there are also part time gastroenterology, urology and cardiology services who share the building. The family practice side has one to two medical assistants, usually one per provider. There are also reception staff who handle patient check-in, check-out and scheduling for all of the specialties.

**Planning the Needs Assessment**

A survey questionnaire was chosen as the measurement instrument because of its direct method of obtaining information, ease of administration, and ability to maintain anonymity (Waltz, Strickland, & Lenz, 2010). A questionnaire allows respondents to disclose their attitudes, beliefs and opinions without the influence of personal interaction. Some of the challenges of questionnaires are the inability to clarify item meanings, motivate and encourage responses, or clarify respondent answers (Waltz et al., 2010). Therefore, it was important to ensure instruction and item clarity, and appropriate comprehension level.
The questionnaire was developed by the principal investigator, with review from the DNP Project Committee, to meet the following two primary objectives: 1) assess the attitudes, beliefs and preferences of patients regarding behavior-based weight management interventions in the primary care setting, and 2) assess the patient perception of weight and weight management. The primary-care based intervention items discussed on the survey are founded in the USPSTF recommendations and a review of the current literature. The respondents indicated their agreement, neutrality, or disagreement with each item on a 3-point Likert scale. The questionnaire was pretested for readability by a small convenience sample. The convenience sample included five adults, age range 24 to 55, 60% female, and education range from high school to college degree. The pretest convenience sample was administered the questionnaire, and then interviewed regarding clarity, reactions to items, and any suggestions for improvement. The questionnaire was reviewed by three independent weight management specialists for content validity. According to the Flesch-Kincaid test, the questionnaire is at a reading grade level of 6.2, reading ease score of 67. The reading ease score is based on a scale from 0 to 100, with a goal usually set between 60 and 70 (Office Online, 2014). The cover letter has a 12th grade reading level with a reading ease score of 40. The three-page packet including the cover letter and questionnaire is at a reading grade level of 9.3 with a reading ease score of 51.

**Methods of Evaluation**

In this descriptive, cross-sectional survey a convenience sample of patients were asked to participate in the study. Inclusion criteria were age 18 to 65, BMI of 30 kg/m² or greater, English speaking, and the ability to read the survey and provide written answers to the questions. On the day of their scheduled visit, after the patient was brought to the visit room, the medical assistant
introduced the research project and asked permission for the principal investigator to speak with them about the project. With permission, the principal investigator entered the room, provided a brief introduction and explanation of the research survey, gave the patient a survey packet and requested their participation. The principal investigator then exited the patient room. The patient was given the opportunity to decide their participation status in the privacy of the visit room. Patients were asked to return the questionnaire, completed or not, to a sealed box with an opening to drop in the survey. The box was located at the checkout desk. The cover letter of the questionnaire included a statement of the request for research participation, an explanation of the research purpose, statement of any risks or benefits of participation, description of how confidentiality will be maintained, contact information for the principal investigator should the patient have any questions, and a statement that completing the questionnaire implies consent to participate in the research study. The patients were informed they may keep the cover letter for their records. The minimum number of responses needed was twenty, based on time and resource constraints. Height and weight were self-reported by the participants, which was then used to calculate BMI.

The internal validity of the study design was strengthened by the standardized and impersonal nature of the questionnaire format, minimizing the risk for interviewer bias (Waltz et al., 2010). Respondent anonymity also contributed to internal validity by reducing bias created when sharing personal information. The questionnaire study design introduced risk to internal validity by limiting participation to respondents who are English speaking and literate. Close-ended questions limit the depth and complexity of responses. The external validity of the study design was limited by the small sample size, convenience sampling, and single site of data
collection. Including a description of the setting and participant characteristics allows readers to determine the applicability of the findings to their own settings (Ogrinc et al., 2008).

RESULTS

Survey Administration

The survey administration took place over the course of four days. On day one and day four there was a nurse practitioner present for the full day, a physician present for a half day, and two medical assistants. On day two and three, there was one nurse practitioner and one medical assistant present for the full day. The patients, providers, medical assistants, and office staff were receptive to the survey process. Nearly all patients agreed to speak with the principal investigator when asked by the medical assistant. After the survey data collection, informal interviews with the nurse practitioner and medical assistants revealed the survey process did not interfere with routine clinic operations nor did it delay patient care. All participants were able to complete the survey during waiting times before and during their visit. Several patients expressed gratitude for the survey purpose, informing the principal investigator of their personal struggle with weight management and interest in interventions for weight loss. Some patients had visible reactions when the principal investigator stated “weight management” or “healthy body weight,” demonstrating a quick change in their affect once the study purpose was introduced. Weight-related topics can be difficult for some patients to discuss. Therefore, the patient response was carefully observed and therapeutic listening was provided when appropriate.

Minor adjustments were made to the survey process to minimize interference with the clinic workflow. The medical assistants did not review the schedule for full inclusion criteria due to the time burden of calculating the BMI immediately after rooming the patient. They used
inclusion criteria of age 18 and older and ability to read, write and speak English to identify possible study participants. All consenting patients identified as possible study participants were administered the survey. After survey administration, the completed surveys were reviewed to determine further inclusion criteria of BMI equal to or greater than 30 kg/m\(^2\) and age 65 or less.

**Findings**

**Respondents**

A total of 79 surveys were distributed over four days. Of the total number distributed, 74 surveys were returned producing a response rate of 94%. Of the 74 returned surveys, four were incomplete and 42 did not meet the age and BMI inclusion criteria, leaving 28 total surveys for analysis. The majority of the respondents (54%) were between the ages of 26 to 45 and over one-third (36%) were between the ages of 46 to 65 (Figure 3). As illustrated (Figure 4), 7% of the respondents did not include education level, 14% have college degrees, 39% have completed some college, 14% have completed high school or equivalent, and 25% have completed less than high school education. The majority (64%) of the respondents were female. Sixty-one percent of the respondents reported white race, 4% reported black, 21% reported other, and 14% did not provide a response. Forty-six percent identified as Hispanic ethnicity, 39% as non-Hispanic, and 14% did not provide an ethnicity response. The survey respondents’ BMI ranged from 30.4 to 52.2, with a mean of 36.4 (Figure 5).
FIGURE 3. Respondent Age Distribution.
FIGURE 4. Respondent Education Distribution.
Survey Questions

The majority of respondents agreed they are overweight, their weight is bad for their health, and that maintaining a healthy body weight is important to them. The majority of respondents agreed they do want help from their health care provider with weight loss. The majority agreed they want to verbally discuss weight management with their provider, they want help developing healthy weight loss goals and they want help improving their exercise habits. Half of respondents agreed with wanting help to develop healthier eating habits, and half were neutral. Less than one-third agreed with wanting to see their provider twice monthly to address
weight management, and one-quarter disagreed. One-fifth of respondents disagreed with wanting written diet and exercise guidelines. There was greater agreement response for written exercise guidelines (46%) compared to written diet guidelines (39%). A complete list of the survey questions and response data is shown below (Table 1).

**TABLE 1. Survey Questions and Responses.**

<table>
<thead>
<tr>
<th>Survey Questions</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel that I am overweight.</td>
<td>93</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>I want my health care provider to help me lose weight.</td>
<td>68</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td>I want help developing healthier eating habits.</td>
<td>50</td>
<td>50</td>
<td>0</td>
</tr>
<tr>
<td>I want help with improving my exercise habits.</td>
<td>57</td>
<td>36</td>
<td>7</td>
</tr>
<tr>
<td>My current weight is bad for my physical health.</td>
<td>79</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>I want to see my provider twice a month to address my weight.</td>
<td>29</td>
<td>46</td>
<td>25</td>
</tr>
<tr>
<td>I want written diet guidelines from my provider.</td>
<td>39</td>
<td>39</td>
<td>21</td>
</tr>
<tr>
<td>I want my provider to help me develop healthy weight loss goals.</td>
<td>54</td>
<td>36</td>
<td>11</td>
</tr>
<tr>
<td>Maintaining a healthy body weight is important to me.</td>
<td>89</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>I want to verbally discuss weight management with my provider.</td>
<td>57</td>
<td>36</td>
<td>7</td>
</tr>
<tr>
<td>I want written exercise guidelines from my provider.</td>
<td>46</td>
<td>32</td>
<td>21</td>
</tr>
<tr>
<td>My current weight is bad for my emotional well-being.</td>
<td>57</td>
<td>29</td>
<td>14</td>
</tr>
</tbody>
</table>

*Note: Answers are reported in percentages.*

**DISCUSSION**

Findings from the needs assessment were evaluated to answer the primary and secondary study questions. Regarding the primary study questions, survey participants indicated they do want their PCP to offer weight management counseling and interventions. The needs assessment found that patients do want help identifying healthy weight loss goals and they want to verbally discuss weight management with their provider. Of those surveyed, only the minority reported interest in written guidelines and twice monthly visits. Categories with the greatest disagreement were written diet guidelines, written exercise guidelines and twice monthly visits. These findings suggest that participants prefer verbal counseling to written guidelines. Participants would like to
see their provider for weight management, however there is not a majority preference for intensive twice monthly visits. Participants also indicated a greater interest in interventions for improved exercise habits compared to eating habits.

Regarding the secondary study questions, the needs assessment suggested that participants do perceive themselves as overweight. The majority of participants perceive negative physical and emotional health consequences of their weight. Participants agree that maintaining a healthy body weight is important to them.

The survey administration had a response rate of 94%. This high response rate was likely influenced by the recruitment format and the minimal time burden of completing the survey. The face-to-face request for participation created a personal, friendly request that helped highlight the importance of each individual’s opinion. Also, the survey was completed during visit down time, creating very little time burden on the participants. They were already in an office waiting to see their provider, therefore unlikely to have many other tasks or activities demanding their attention.

Limitations of the study included the small sample size, the convenience sampling method, and the limitation of the survey to only English speaking, literate patients. A large-scale survey at multiple primary care sites would allow for more aggregate data and the development of a program tailored to a broader population. Randomized sampling would decrease bias introduced by the day of the week and seasonal changes in the population demographic. Many of the patients at Green Valley Family Practice are Spanish speaking; therefore, a significant percentage of that primary care population was not included in the study.
There were several lessons learned throughout the survey administration process. When administering a pen and paper survey, it is important to have the tools available for the participants to complete the survey. The office staff offered the use of clipboards and pens to distribute with the surveys, however it would be wise to include these items in the planning process. While waiting to be seen by their provider, many patients exited the visit room asking where to place the completed survey. The consent script included instructions to place the completed surveys in a box at checkout, but these instructions were not effectively communicated to every patient. Many patients had strong reactions once the topic of weight management was brought up, therefore they may have stopped listening to the rest of the instructions. Stating the survey instructions prior to stating the survey purpose may help improve the clarity of instructions. In addition, many patients interrupted the consent script with questions about the survey or its purpose, therefore providing a very brief, concise consent script may also help improve communication effectiveness.

**WEIGHT MANAGEMENT PROGRAM**

The multi-component weight management program incorporates findings from the needs assessment and recommendations from the current literature, within the theoretical framework that guided this project. The weight management program is structured into a three-month intensive phase, followed by an ongoing maintenance phase. The three-month intensive phase includes six structured patient visits. The visits are intended to be fifteen-minute weight management (WM) visits, allowing the provider and patient to focus entirely on weight management. Dedicating entire visits to weight management emphasizes the importance of achieving a healthy body weight. The visits will be numbered one through six when they are
scheduled, to inform the provider which step of the program the patient is on. Each visit has a corresponding education packet for the provider to use during the visit. For example, if a patient is scheduled for their third weight management visit, their schedule would read WM 3, and the provider would use the packet labeled as visit three. This ensures the patient receives comprehensive weight-behavior education without the burden of tracking or reviewing previously covered topics, or trying to fit a plethora of topics into one visit. The ongoing maintenance phase includes once monthly fifteen-minute weight management visits for weight monitoring and continued counseling.

The six structured visits are intended to be scheduled twice monthly for the first three months, with once monthly visits thereafter. Interventions with more counseling sessions in the first year have demonstrated greater weight loss results, whereas low to moderate intensity counseling have not demonstrated clinically significant results. However, given that less than one-third of survey participants wanted to see their provider twice monthly to address weight management, and one-quarter do not want twice monthly visits, the program can be offered with less intensive scheduling to meet the preferences and needs of the patient. After the three-month intensive phase, patients will be encouraged to continue scheduling once monthly weight management visits.

Each structured visit focuses on a different aspect of weight management, and allows time to review what was previously discussed. The first four structured visits include written patient education handouts. Findings from the survey suggest that participants prefer verbal counseling to written guidelines, therefore written patient handouts are not included in every visit, and kept brief at a length of one-page. The patient handouts outline the topics for verbal
discussion, provide some brief information, and function as a guide for the counseling session. Survey findings also indicated a greater preference for interventions that focus on improving exercise habits as compared to eating habits. Visit five and visit six address barriers to healthy habits and strategies for ongoing weight management. These two visits were intentionally designed with vague counseling topics to allow the patient’s specific concerns to be addressed. During these visits, the patient can decide if they are more interested in discussing physical activity, eating habits, or both.

The majority of participants identified as being overweight and in need of weight management. This suggests the majority of patients surveyed are in the TTM stages of contemplation and preparation regarding behavior change for weight management. Survey participants indicated they do want their PCP to offer weight management counseling and interventions. The program emphasis was therefore placed on action-oriented interventions for weight management. Patients who are obese, but are not interested in weight management may be in the precontemplation stage of change. Precontemplative patients may benefit more from interventions focused on recognizing the problem of obesity, the importance of intervening, and the availability of weight management support.

Looking at the overlap between the weight management program and the HBM, one can see that individual perceptions can greatly influence health behavior actions. The survey findings suggest the majority of surveyed patients do perceive themselves as susceptible to the problem of obesity. The majority of participants do perceive themselves as overweight and they do perceive negative physical and emotional health consequences of their weight. Participants do perceive their weight as a threat to their health, and agree that maintaining a healthy body weight is
important to them. Interpretation of the survey results within the context of the HBM supports the development of interventions that target perceived barriers, perceived benefits, and action cues for weight management.
APPENDIX A:

SURVEY PACKET
CONSENT TO PARTICIPATE IN SURVEY RESEARCH

My name is Cassandra Jenks. I am a Family Nurse Practitioner student with the University of Arizona. I am asking for your participation in a quick survey.

The purpose of this survey is to help us better understand how your primary care provider can help patients reach and maintain a healthy body weight.

This survey will include a brief questionnaire of your social history and weight-loss opinions. The questionnaire will take about 10 minutes. It will be collected at the end of your visit today during check out.

Participating in this survey has no expected risks or harms. Participating in this survey may help us provide better weight-management care.

Your participation will remain confidential. We will not ask for your name or any information that could identify you personally. Your participation in this survey is voluntary and will not impact your care in any way.

Please keep this page and place the following two pages (completed or not) in the box at check out.

An Institutional Review Board responsible for human subjects' research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research. For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://ocr.arizona.edu/hssp.

For questions, concerns, or complaints about the study, you may contact the Principal Investigator Cassandra Jenks, MSN, NP-C, at huffmanc@email.arizona.edu

By taking this survey you agree to have your responses used for research purposes.

Version 2015/03/26
Instructions: The following information is being asked to better understand the needs of patients. Please circle your answers and record your most recent height and weight. Your answers will remain anonymous.

AGE:
- 18-25
- 26-35
- 36-45
- 46-55
- 56-65

EDUCATION:
- < High School
- High School/GED
- Some College
- College Degree

GENDER:
- Male
- Female

RACE:
- White
- Black
- Native Hawaiian
- American Indian
- Asian
- Other

ETNICITY:
- Hispanic
- Non-Hispanic

WEIGHT:

HEIGHT:
**Instructions:** Please answer whether you agree, feel neutral, or disagree with the following statements about weight loss and your health care provider. Answer by circling the numbers to the right of each statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel that I am overweight.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want my health care provider to help me lose weight.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want help developing healthier eating habits.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want help with improving my exercise habits.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>My current weight is bad for my physical health.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want to see my provider twice a month to address my weight.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want written diet guidelines from my provider.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want my provider to help me develop healthy weight loss goals.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Maintaining a healthy body weight is important to me.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want to verbally discuss weight management with my provider.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>I want written exercise guidelines from my provider.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>My current weight is bad for my emotional wellbeing.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
APPENDIX B:

WEIGHT MANAGEMENT PROGRAM
WEIGHT MANAGEMENT

PROGRAM

A Guide for Intensive Weight Management Counseling

Cassandra Jenks, MSN, NP-C

2015
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Instructions

This program is designed for primary care providers to use in collaboration with their clients to address weight management. This program serves as a resource for providers and a tool for implementing high-intensity weight management counseling. There are six structured sessions, each focusing on a specific aspect of weight management. This structured approach allows for comprehensive counseling to take place over the course of several visits. Each session includes provider notes, and there is a client handout for visits one through four.

It is recommended the client be scheduled for six weight management visits, with each visit numbered accordingly. For example, the third visit would be “weight management #3” and this would correspond with the packet section titled Weight Management Visit Three. High intensity counseling has demonstrated better weight loss outcomes as compared to moderate or low intensity, therefore it is recommended that the client be scheduled for twice monthly visits for the first three months, and monthly visits thereafter. High intensity counseling may not be feasible for all clients. Encourage high-intensity scheduling, but consider offering once monthly visits for the first six visits as an alternative option.

There is also a health log for client goal setting and self-monitoring. To create the health log, print pages six through nine double sided, fold in half and staple the two pages together along the fold. Ask the client to bring their health log along to every weight management visit.
Weight Management

Visit One
Energy In + Energy Out = Weight

Weight is a balance of energy.

Energy In = what we eat & drink. Energy Out = the activity we do.

When energy IN is greater, weight gain occurs.

When energy OUT is greater, weight loss occurs.

When energy IN = energy OUT, weight is stable.

**KEY TO WEIGHT LOSS:** Decrease energy input and increase energy output to create a negative energy balance.

**WHAT IS WEIGHT MANAGEMENT?**

- Intense exercise program (X)
- Sustainable
- Crash diet (X)
- Life-long
- Realistic
- Quick fix (X)

In your health log, record your current weight. Next, determine a 6 month weight loss goal. Your weight loss goal should be about 5% to 10% of your current body weight. Calculate and record your goal weight.

Weight can fluctuate from day to day, so weighing yourself everyday may seem frustrating as you see your weight go up and down. Weigh yourself ONCE A WEEK, in the morning, after you have used the restroom, but before eating or drinking anything. This helps minimize some of the fluctuation. Weigh yourself once a week and record it in your health log on the “TRACKER” calendar.
VISIT NUMBER & DATE
Weight Management Visit 1:
Weight Management Visit 2:
Weight Management Visit 3:
Weight Management Visit 4:
Weight Management Visit 5:
Weight Management Visit 6:

NOTES
### MY GOALS

#### WEIGHT

Starting weight: 
Goal weight @ 6 months: 

#### ACTIVITY

What?  How much?  How often?

#### NUTRITION

What?  How much?  How often?
<table>
<thead>
<tr>
<th>SUN</th>
<th>MON</th>
<th>TUES</th>
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</table>
1. Energy Balance

\[
\text{ENERGY IN} \quad + \quad \text{ENERGY OUT} \quad = \quad \text{WEIGHT}
\]

(Calories) \quad (Activity & Body Composition)

Weight is the product of energy balance. To achieve a change in weight, we must affect this equation and generate a negative energy balance. This can be achieved through decreasing energy input and/or increasing energy output.

Energy input is determined by caloric intake, regardless of which foods/macronutrients those calories come from. The foods we eat affect overall health and healthy eating should be encouraged, but overall weight is driven by calories.

Energy output is determined by exercise, daily activity, and body composition. Exercise includes any cardio, strengthening and stretching activities. Some people have a negative association with the word exercise, therefore using the word ACTIVITY may yield a more positive response. Daily activity is affected by a person’s occupation and daily routine, and can include habits such as taking the stairs and walking to places when possible. It takes more energy to maintain muscle than it does adipose tissue, therefore a person’s body composition will affect how much energy their body is consuming while at rest.

There are complex physiologic mechanisms that regulate the energy balance within our bodies. It is important to remember that each person’s energy balance is unique to them, and each person may have different energy requirements, dietary needs and activity tolerance.

However the important, broad concept is that weight change will occur by creating a negative energy balance, and weight maintenance is achieved when the energy intake matches the energy output.

2. Big Picture: A healthy and sustainable approach to weight management.

The goal of weight management is **NOT** to go on a diet, start a crazy unrealistic exercise program, do a dramatic cleanse, or lose weight very quickly.

The goal is to make life-long, realistic and sustainable lifestyle changes. Long-term healthy habits will help people lose weight and keep it off. Weight management is an on-going, life-long process that is never “done” or “fixed.” Focusing on just a number on a scale is too short sided to achieve long-term weight management. The **BIG PICTURE GOAL** of weight
management is to develop the knowledge and skills necessary to achieve a healthy lifestyle, and measurable outcome of that goal will be maintaining a healthy weight.

3. Weight Loss Goal: 5% to 10% of body weight, over 6 months

<table>
<thead>
<tr>
<th>Example:</th>
<th>Starting weight: 240 lb</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Goal weight loss: 12-24lb / 6 months = 2 to 4 pounds per month</td>
</tr>
<tr>
<td></td>
<td>Goal weight: 216 – 228 lb</td>
</tr>
</tbody>
</table>

This is a realistic goal to start with. If someone is still overweight after losing 5% to 10% of their body weight, a new goal for the next six months can be established. A 10% weight loss can produce clinically significant effects and reduce some health risks associated with obesity. A 10% weight loss is a great accomplishment and should be applauded and celebrated! Goal setting is unique to each individual. Some may prefer to set a new weight loss goal once their current one is achieved. Others may prefer to maintain their new weight for a few months before setting a new goal. When setting weight loss goals, the importance of maintaining weight loss for sustained health benefits should be emphasized! We want to avoid dramatic weight fluctuations by focusing on healthy and realistic behavior changes that can be maintained long term. Help your client establish a reasonable weight loss goal and record this on their health log.
Weight Management

Visit Two
## SMART Goals

<table>
<thead>
<tr>
<th></th>
<th>Bad Example</th>
<th>Better Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specific</strong></td>
<td>You should be able to outline EXACTLY what the goal is.</td>
<td>“eat less at dinner”</td>
</tr>
<tr>
<td><strong>Measurable</strong></td>
<td>Defining goals in measurable terms allows you to be able to define when the goal is met.</td>
<td>“lose weight”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“eat healthier”</td>
</tr>
<tr>
<td><strong>Attainable</strong></td>
<td>Your goals should challenge you in a reasonable manner.</td>
<td>“run 10 miles every day”</td>
</tr>
<tr>
<td><strong>Relevant</strong></td>
<td>YOUR goals must be relevant to YOUR passions and priorities.</td>
<td>“develop healthier habits because my doctor says I have to”</td>
</tr>
<tr>
<td><strong>Time-Framed</strong></td>
<td>Setting a time frame can make goals more specific and promote accountability.</td>
<td>“walk more often”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“be able to do 20 pushups”</td>
</tr>
</tbody>
</table>

Try applying the concepts of SMART goals and come up with a few exercise goals to add to your health log.
VISIT TWO: PROVIDER NOTES

Recap from Visit One: To lose weight we need to create a negative energy balance. This should be done by developing realistic and sustainable healthy eating and activity habits. A weight loss goal was established. Next we will discuss how to develop SMART goals and establish some goals for exercise.

I. Setting SMART Goals

Specific: Identify a particular goal that can be tangibly defined. A non-specific goal such as “lose weight” could mean five pounds, fifty pounds or fitting into a pair of jeans that no longer fit. Vague goal: exercise more. Specific goal: Walk three days a week.

Measureable: Goals need to be expressed in measureable terms, or you will never know when you have achieved them. With the example of “lose weight,” when has the goal been achieved? After 10 pounds? After 1 pound? Measurable goals also help us track progress and gain a sense of accomplishment as we progress toward the final goal.

Attainable: Setting unrealistic goals will only reinforce that weight loss and healthy behavior change is too difficult to achieve. Goals should reasonably fit a person’s lifestyle and abilities. If walking a mile is not within a person’s current abilities, setting a goal to run a marathon will seem impossible. However, if you set a goal to walk 3 miles, then to run 3 miles, and to continue moving forward with realistic goals, perhaps a marathon can be achieved.

Relevant: Goals need to be important to the person who is trying to achieve them. If fitting into a pair of jeans means nothing to you, but you would feel great knowing that you can do 100 pushups, then your goal should focus on physical fitness rather than fitting into a pair of jeans. Goals must be relevant to a person’s values, priorities and passions.

Time-framed: Goals should include a time frame. This helps promote accountability and make goals measureable. If I keep telling myself, “I am going to start eating healthier eventually” that leaves a lot of room to make excuses. But if I decide that starting next week I will only eat what I pack for lunch while I am at work, that gives me a specific, measureable, and time-framed goal. Time frames are also used to improve the measurability of a goal. A goal to walk more often is too vague and difficult to measure. Setting a goal to walk three times a week provides much more clarity and structure.
2. Exercise Goals

Start by evaluating your client’s current exercise habits. Each person will have different exercise goals because their physical abilities will differ. A reasonable goal to work toward is 30 minutes of physical activity 5 times per week. This physical activity does not need to be done all at once. It can be broken into several 10-minute increments. For example, it can include a 10-minute walk before work, a 10-minute walk at lunch, and 10 minutes of strengthening exercises at home after work. For those capable of and interested in a more intense exercise regimen, 60 minutes of moderate to vigorous physical activity every day can help achieve and maintain sustained weight loss. Encourage clients to find exercise goals that fit their lifestyle and are interesting to them. Perhaps they want to start playing basketball again or have always wanted to try tennis – encourage these activities. Also encourage goals that are built into their daily routine to make them easier to accomplish. If a client’s normal routine is to watch the news every evening, their goals might include doing jumping jacks and sit ups during every commercial break.

IDEAS FOR PHYSICAL ACTIVITY:

- Walk on your lunch break.
- Go for a walk or a hike with friends instead of happy hour.
- Hula-hoop/jump rope/crunches/arm curls while watching TV.
- Every hour get up from your desk and do 10 squats and 10 pushups.
- When driving places, park toward the back of the parking lot.
- Take the stairs.
- When watching TV, lunge up and down the hallway every commercial break (instead of skipping them with DVR).
- Make plans with others for activity dates to help keep you accountable.

Work with your client to determine exercise goals. Encourage them to determine their own goals, with your input, and write them in their health-tracker. Remember these goals should be SMART – specific, measurable, achievable, relevant, and time-framed.
Weight Management

Visit Three
Healthy Eating Concepts

A healthy diet should include:

**LOTS** of vegetables and fruits

**SOME** lean protein

**SOME** complex carbohydrates

**A LITTLE** healthy fat

**TINY AMOUNT** of refined simple carbohydrates and sugary treats

- Weight is determined by **energy balance**.
- To lose weight we must consume less energy (calories) than we expend.
- The dietary key to weight loss is **limiting the amount of energy we eat**.
- Types of **food** and **portion sizes** affect the amount of energy we consume.
- To make sure we receive enough **NUTRITION** for the amount of energy we eat, it is important to eat foods that are high in nutrition.
- Healthy eating **goals** should focus on following the concepts above and eating reasonable portion sizes.
- The goal is **NOT** to go on a temporary **diet**.
- The **BIG PICTURE GOAL** is to develop healthy, realistic habits that you can continue long-term for **life-long health**.

Think about your usual eating habits during a typical week. Think about the concepts for healthy eating listed above. Try to find one or two eating habits you have that do not fit with these healthy eating concepts. With your provider develop a couple SMART goals to help improve these habits.

Next think about the amount of energy (calories) you typically eat. Find at least one habit that leads to eating low-nutrition, high-calorie-dense foods and develop a couple SMART goals to address this habit.
VISIT THREE: PROVIDER NOTES

Recap from Visit Two: We discussed how to set SMART goals and established some exercise goals. Review the exercise goals and how the client is doing with them. It has been at least a month since visit one, review the client’s initial weight and current weight. Celebrate and applaud any weight loss!!! Provide encouragement for efforts toward meeting exercise goals.

1. Healthy Eating Concepts

Healthy eating can be a controversial and complex topic. There are so many diets and health trends that arise and circulate. Some are supported by evidence, and some are the product of effective marketing. It is difficult to make very specific dietary recommendations that are safe and appropriate for each individual. This program will not promote nor discourage any specific dietary choices (i.e. organic, non-GMO, low-carb, glycemic-index based, paleo, etc.). This program will explore broad concepts of healthy eating that can be applied to most eating patterns and dietary needs.

A healthy diet should include variety, lots of vegetables and fruits, some lean healthy proteins, some complex carbohydrates, some healthy fats and very little sugary treats. Ideally fruits and vegetables should be fresh or frozen. Frozen produce is a great option when there is concern over frequent shopping trips and waste due to spoiling. Canned fruits and vegetables are less than ideal given the high sodium content. However canned are better than none, and some of the sodium can be rinsed off. Lean healthy protein sources include chicken, turkey, beans, legumes, fish and low-fat dairy products such as cottage cheese. Simple carbohydrates - such as white bread, pastas, bagels and pastries - turn into sugar very quickly once they are eaten; therefore these foods should be thought of more as sugary treats. Complex carbohydrates, such as whole grain bread, oatmeal, quinoa and brown rice, contain more nutrients and are broken down slower. They do not cause as much of a sudden blood glucose spike and insulin surge and simple carbohydrates, making them much healthier and more filling. Fat has gotten a bad name over the years. Fat in our diets does not make us gain weight. Excess ENERGY (i.e. too many calories) in our diets DOES make us gain weight. Fats are calorie dense, and therefore should be consumed in moderation. But a healthy diet does need to include healthy mono- and poly- unsaturated fats and omega fatty acids. Sources of healthy fats include nuts, fish, olive oil, and seeds such as flaxseed and sunflower seeds. Sugary treats, such as cookies, ice cream and pastries, should be consumed as TREATS, in small portions and on occasion.
Encourage clients to make it EASIER to make healthy choices. Make sure healthy food options are available in their homes, and avoid purchasing unhealthy foods, especially when moderation is a challenge. Pack a healthy lunch so the lunchtime meal is already decided. This avoids the challenge of making a healthy choice while ordering lunch, possibly with a hungry and stressed state of mind. Encourage your clients to let their family and friends know they are making changes to live a healthy lifestyle, and ask for support by respecting their healthy choices and not encouraging indulgences.

2. Setting Goals for Health Eating

Again it is important to emphasize SMART goals. Try to emphasize specific goals that align with your client’s personal lifestyle and preferences. For example, if someone cannot stand eating salads, then a goal of eating salad every day for lunch would not be very realistic or relevant. Healthy eating goals should be simple, specific and easily measured. The first set of goal setting is intended to focus on improving the health QUALITY of foods consumed. The second set of goal setting is intended to focus on decreasing the overall amount of CALORIES consumed.

IDEAS TO IMPROVE HEALTHY EATING:

- Limit intake of bread/pasta/grain products to one meal per day
- Eat 2 servings of fruit every day
- Eat 3 servings of vegetables every day
- Cook with low-fat meats (93% lean)
- Fill half your plate with veggies, one-quarter with lean protein & one-quarter with starch/grain.

IDEAS TO DECREASE CALORIE INTAKE:

- Do not drink soda or sugary beverages
- Substitute baked vegetables for chips
- Pre-measure appropriate portion sizes of snack and place into baggies
- When dinner out, ask the pre-dinner bread/chips/etc to be removed before you can eat them
- When dinner out, ask for a to go box at the start of your meal and pack away half of the meal before you begin eating
- Moderate alcohol intake – alcohol is high calorie and low nutrition
- Substitute whole fruits for dried fruits
Weight Management

Visit Four
ENVIRONMENT & WEIGHT

What does “Obesogenic Environment” mean?
We live in an environment that promotes obesity by encouraging weight gain. This may be due to greater energy intake: larger portion sizes, calorie-dense fast food. This may be due to decreased physical activity: lack of nearby parks or walking paths, jobs that involve sitting most of the day, use of escalators and elevators.

Ways to help make your environment “health promoting”:

Use smaller plates/bowls/silverware
- Smaller dishes make portions appear larger

Build activity opportunities into your daily routine
- Have weights sitting by your desk so you can do a few arm exercises every hour.
- Keep running shoes/gym clothes/yoga mat in the car so you have one less thing to remember.
- Make a decision to ALWAYS take the stairs, and stick to it.
- Keep a jump rope by the TV remote to remind you to jump rope during commercials.
- Avoid escalators, elevators and moving walkways whenever possible.
- Sit on a balance ball instead of a chair.

Make healthy food choices MORE convenient
- Have healthy snack options readily available so they quick and easy to choose
- Have veggies washed, chopped, and ready to eat in the fridge.
- Have low-sugar yogurt and fruit available for when that sweet tooth hits.

Make unhealthy food choices LESS convenient
- Keep sugary/unhealthy snacks and treats OUT of plain site.
- Get rid of the candy jar that sits on the counter.
- Put unhealthy foods on higher shelves, toward the back.

With your provider think of a few ways you can change your environment to help you achieve your activity and healthy eating goals.
VISIT FOUR: PROVIDER NOTES

Recap from Visit Three: We discussed healthy eating concepts and set goals for healthy eating. This week we will discuss the role environment plays in weight management.

1. Obesogenic Environment
   There is compelling evidence that environment has played a significant role in our current obesity epidemic. We live in a food-rich environment that promotes increased energy consumption, with modern conveniences that decrease our physical activity demands. This leads to a positive energy balance and encourages weight gain. Our modern environment has been labeled “obesogenic” which means obesity promoting. Some aspects of the obesogenic environment, such as societal influences, transportation systems and access to parks are beyond our control to change. There are some modern energy sparing conveniences that we may not want to change, such as the use of washing machines, powered lawn mowers and remote television controllers. There are however some small changes we can make to our environment and how we interact with it that may encourage healthier habits.

2. Changing Your Environment to Support Healthier Habits
   Use smaller plates/bowls/silverware
   - Larger food containers contribute to something called portion distortion, which is the misperception that larger portions are appropriate servings to be consumed at one time.
   - Using larger dishes makes any portion appear smaller. This can be illustrated by taking two equal-sized servings of food and placing one on a smaller plate and the other on a larger plate. You know that these two servings are equal size; however the serving on the larger plate will appear much smaller. Using smaller dishes will make a smaller serving size appear to be larger. By using smaller dishes, you will encourage the habit of taking smaller servings and reinforce appropriate portion size perception.

   Build activity opportunities into your daily routine
   - This can mean many different things depending on your current lifestyle/routine. The overall goal is to MAKE IT EASIER TO MAKE A HEALTHY CHOICE.

   Make healthy food choices MORE convenient & unhealthy food choices LESS convenient
   - Have healthy snack options readily available so they are equally quick and easy to choose as less healthy options.
   - Hide the unhealthy choices out of site. Do not purchase items that are difficult to moderate.
Weight Management

Visit Five
VISIT FIVE: PROVIDER NOTES

Recap from Visit Four: We discussed the interaction between environment and healthy eating behaviors, and came up with some ideas to change the environment to help meet the healthy eating activity goals.

1. Health Log Review

This visit we will review the HEALTH LOG. Ask your client about any benefits or changes he or she has noticed since starting the weight management program. Highlight the possibility of various types of benefits, including physical, emotional, social etc.

Evaluate your client’s weight loss progress. Weight loss can be a lengthy, challenging and overwhelming process. Avoid criticizing your client if their weight has remained stable or increased. Focus on the benefits of weight loss. Reassure your client that WEIGHT LOSS CAN BE ACHIEVED, and that it is worth the continued effort. Remind your client that you both have formed a collaborative team that will work together toward their goal of achieving and maintaining a healthy weight.

If your client has achieved weight loss, CELEBRATE THIS ACHIEVEMENT! Congratulate your client on their hard work.

2. Barriers to Healthy Habits

Next, ask your client about any barriers they have experienced with implementing their activity and healthy eating goals. Explore possible ways to address these barriers. When barriers to weight loss appear too daunting and impossible to overcome, behavior change becomes very difficult. Encourage your client to express their concerns regarding weight loss. Validate their concerns and explore creative solutions to overcome them.
Weight Management

Visit Six
VISIT SIX: PROVIDER NOTES

Recap from Visit Five: Last visit the health log was reviewed, and healthy habit barriers were discussed and addressed.

1. Health Log/Goal Review

Review the health log again this visit looking and the client’s weight trend and healthy habit goals. Review the barrier discussed last visit. Consider ADDING new goals to the health log if there are achieving their current goals and are ready for a new challenge. Consider MODIFYING their current goals if they no longer meet the SMART goal criteria. Try not to give up on appropriate goals that are well designed, but sometimes an initial goal simply does not align with a client’s priorities and abilities and therefore it is ok to change it.

2. Ongoing Weight Management

This visit concludes the six-visit intensive portion of the weight management program. The program recommendation is to continue with once monthly weight management visits to monitor progress and encourage ongoing development of healthy habits. Maintaining weight loss once it has been achieved requires a sustained commitment to healthy eating and activity habits. Strongly encourage clients to continue regular physical activity. Activity + dietary interventions are more effective together than either is alone for long-term weight loss maintenance.
APPENDIX C:

IRB EXPEDITED APPROVAL LETTER
Date: April 01, 2015  
Principal Investigator: Cassandra Aeclipse Jenkins  
Protocol Number: 1503763633  
Protocol Title: Management of Obesity in Primary Care: A Cross-Sectional Needs Assessment Survey of Behavioral Weight Management Interventions from the Patient Perspective  
Level of Review: Expedited  
Determination: Approved  
Expiration Date: March 30, 2018  

Documents Reviewed Concurrently:  
- Data Collection Tools: DNP PROJECT IRB Medical Assistant Introduction Script v3.2015.docx  
- HSPP Forms Correspondence: F107 v1.2014.doc  
- HSPP Forms Correspondence: F200 v2.2014 v3.28.2015.doc  
- HSPP Forms Correspondence: Signature page.pdf  
- Other: DNP PROJECT IRB References v2.2015-1.docx  
- Participant Material: DNP PROJECT IRB Survey v3.28.2015.docx  
- Recruitment Material: DNP PROJECT IRB Recruitment Consent Script 3.28.2015.docx  

This submission meets the criteria for approval under 45 CFR 46.110, 45 CFR 46.111 and/or 21 CFR 50 and 21 CFR 56:

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).  
- All research procedures should be conducted in full accordance with all applicable sections of the Investigator Manual.  
- The current consent with the IRB approval stamp must be used to consent subjects.  
- The Principal Investigator should notify the IRB immediately of any proposed changes that affect the protocol and report any unanticipated problems involving risks to participants or others.
• For projects that wish to continue after the expiration date listed above please submit an F212, Continuing Review Progress Report, forty-five (45) days before the expiration date to ensure timely review of the project.
• All documents referenced in this submission have been reviewed and approved. Documents are filed with the HSPP Office. If subjects will be consented the approved consent(s) are attached to the approval notification from the HSPP Office.

This project has been reviewed and approved by an IRB Chair or designee.
No changes to a project may be made prior to IRB approval except to eliminate apparent immediate hazard to subjects.
REFERENCES

Abbo, E. D., Zhang, Q., Zelder, M., & Huang, E. S. (2008). The increasing number of clinical items addressed during the time of adult primary care visits. *Journal of General Internal Medicine, 12*(12), 2058-2065. doi: 10.1007/s11606-008-0805-8


