Retention and Attrition in Bariatric Surgery Research: A Qualitative Study

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RETENTION AND ATTRITION IN BARIATRIC SURGERY RESEARCH: A
QUALITATIVE STUDY

A Dissertation
Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for
the degree of Doctor of Philosophy

By
William F. Gourash

August 2017
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2017
RETENTION AND ATTRITION IN BARIATRIC SURGERY RESEARCH: A
QUALITATIVE STUDY

By

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Approved June 29, 2017

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ABSTRACT

RETENTION AND ATTRITION IN BARIATRIC SURGERY RESEARCH: A QUALITATIVE STUDY

By

William F. Gourash

August 2017

Dissertation supervised by Joan Such Lockhart, PhD, RN, ANEF, FAAN

Problem: Longitudinal bariatric surgical research studies often lack information on retention and attrition of study participants and the strategies utilized to optimize these. The potential for attrition bias with adverse effects on validity, reliability, and generalizability increases over time. The many factors potentially affecting retention and attrition in research, have been understudied.

Purpose: The purpose was to explore factors affecting research participation of bariatric surgical patients who are subjects in the Longitudinal Assessment of Bariatric Surgery (LABS) study. The research questions explored research participants’ perceptions, motivations, and attitudes concerning participation in the study, specifically participation in annual in-person visits as well as routine annual clinical follow-up, and factors that impeded or facilitated “complete” participation.
Design and Methods: A qualitative descriptive design with a non-probability, maximal variation sampling technique were utilized. Because the purpose was to explore factors related to research participation from the perspective of bariatric surgical research subjects, the statistically nonrepresentative stratified sampling approach was employed primarily according to levels of prior bariatric surgical research participation. Data collection consisted of one-time individual interviews. The Applied Thematic Analysis process guided the content analysis.

Results: Thirty-six interviews were completed and arrived at analytic saturation. Fifteen motivational themes were identified. The 3 most frequently cited were: Sharing one’s own experiences to help others, study participation was helpful to my own goals, and desire to support research. Motivation changed over time and did not appear related to prior participation. A small majority (22) responded that they would return to annual research visits with poor weight loss. Extensive questionnaire completion was perceived as a significant barrier. A sizable subgroup (15) of participants perceived distance to the center and travel time as a barrier. Study participants perceived strategies that better enabled them to manage their time and availability and provided them with a progress report of personal measurements as beneficial. A majority viewed a financial honorarium and travel reimbursement positively (31 of 33) and supportive to their participation (19 of 31).

Conclusion: The motivations, barriers, and facilitators to research retention identified in this study provides an evidence-base from which to further develop current and new retention strategies. Further research should focus on evaluating the effectiveness of retention strategies and developing an optimal selection process for retention strategies.
DEDICATION

This document is dedicated to my wife, Linda and my two daughters, Theresa (Wheesa) and Catherine (Cassie) who stood by me, supported me and encouraged me through the many years, the highs and especially the lows. It was your love that motivated me onward.

Additionally, I dedicate this document and am indebted to the Lord Jesus Christ, “for nothing is impossible to God” (Luke 1:37).
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Chapter 1

1 Introduction

1.1 Overview of the Topic

Research participant retention and attrition are relatively simple concepts but are complex phenomena. In research studies, the term retention is often used to refer to the process of keeping participants active in a research study (Gul & Ali, 2010), including the means and processes of maintaining relationships with participants to encourage them to continue full participation for the duration of the study (Patel, Doku, & Tennakoon, 2003). Retention may be depicted across a continuum of study participation. Conversely, attrition refers to the loss of active participation that occurs when research participants fail to complete the study or a portion of the study after enrollment (Patel et al., 2003). Excluding subjects who have died, attrition can be subdivided as follows: (1) subjects who refuse further participation (withdrawal); (2) subjects without viable contact information and; (3) subjects who fail to respond, either fully or partially (Bhamra, Tinker, Mein, & Ashcroft, 2008; Kesselring, 1985; Mein, Johal, et al., 2012; Ribisl et al., 1996; Young, Powers, & Bell, 2005). These subdivisions can be depicted statistically. Significant attrition may result in an attrition bias when the attributes of those who have dropped out or have failed to complete portions of the study differ in a non-random way from those who remain active. Attrition bias can degrade the internal and external validity of the research and possibly the power of the sample (Amico, Harman, & O'Grady, 2008; Friedman, Furbery, & DeMets, 2010; Szklo & Nieto, 2007). There are statistical techniques to determine if the initial sample differs significantly from the remaining sample on key characteristics (Abraham & Russell, 2004; Foster & Brickman, 1996; Mazumdar et al.,
However, prospective methodological approaches to prevent attrition are preferable (Given, Keilman, Collins, & Given, 1990; Harris, 1998; Mason, 1999). There is no absolute standard for acceptable rates of attrition, but bias is usually of concern if the rate exceeds 20% (Amico et al., 2008; Fewtrell et al., 2008; Kleschinsky, Bosworth, Nelson, Walsh, & Shaffer, 2009; Mason, 1999). The relationship between retention and attrition appears to be reciprocal—strategies that increase retention tend to reduce attrition, and strategies that prevent attrition generally maintain or increase retention (Given et al., 1990; Kleschinsky et al., 2009; Ribisl et al., 1996).

1.2 Background of the Study
1.2.1 Retention and Attrition in Longitudinal Research

A large portion of bariatric surgical research is longitudinal in nature. Longitudinal studies are appropriate for bariatric surgical research because they allow investigators to examine long-term outcomes and understand factors that predict or mediate outcomes (Belle et al., 2007; Menard, 2002). With these advantages come the significant logistical challenges of retaining and locating adequate numbers of participants at sequential follow up time points (Kleschinsky et al., 2009; Ribisl et al., 1996).

Documentation of retention and attrition has been poorly developed in many longitudinal studies (Amico et al., 2008; Bhamra et al., 2008; Ribisl et al., 1996). Thus, the potential for attrition bias in many longitudinal studies is largely unexplored. Some longitudinal studies have investigated reasons for participant attrition, including factors associated with or predictive of attrition (Bhamra et al., 2008; Mein, Johal, et al., 2012; Young et al., 2005). In a systematic literature review investigating attrition, multivariate analyses demonstrated two main independent factors were related to increased attrition: increasing age and cognitive impairment (Chatfield, Brayne, & Matthews, 2005). Other factors, which have been found to be associated
with attrition in some nonbariatric surgery longitudinal studies include: lower socio-economic status, lower level of education, having living children, retirement, social participation and obesity (Kesselring, 1985).

Reasons cited for participant attrition in longitudinal studies include: participation being perceived as too time consuming, a dislike for being repeatedly contacted, and a dislike for specific aspects of a study (e.g. sensitive interview topics, venipuncture, clinical measurements & examinations, cognitive testing) (Bhamra et al., 2008). However, “little is known about longitudinal research participants’ views on which research methods and measures are most acceptable and sensitive” to their needs (Shipman et al., 2008, p. 913). A greater understanding of participants’ perspectives is vital for successful retention (Shipman et al., 2008). Mein et al. (2012) recommend that “understanding the motivation behind “participation” or “drop out” may prevent further loss of valuable longitudinal information and assist the continuation of longitudinal studies”. Mein et al. investigated reasons for sustained participation in their Whitehall II Study, a longitudinal study of the elderly, which utilized a qualitative design involving interviews and focus groups. Findings from the Whitehall II Study indicated that “rather than being wholly motivated by altruism, as the research staff had assumed, participants were motivated by the benefits they perceived”, especially the information and clinical medical care received, and the perception of loyalty and membership associated with participation in the study. (Mein, Seale, et al., 2012, p. 2345). However, the degree to which Mein et al.’s findings apply to other specific populations (such as bariatric surgical research participants) has not been explored.

1.2.2. Attrition and Retention in Bariatric Surgical Research

As in the general longitudinal research literature, retention and attrition data have not been adequately reported in the bariatric surgical literature (Garb, Welch, Zagarins, Kuhn, &
Romanelli, 2009; Higa, Ho, Tercero, Yunus, & Boone, 2011; Moroshko, Brennan, & O'Brien, 2011a, 2012). Historically, some successful long-term studies of bariatric surgery have demonstrated high retention rates (MacDonald et al., 1997; Sjostrom et al., 2012), but generally retention in clinical bariatric surgical research and practice is challenging, especially beyond 12-months after surgery. A meta-analysis of outcomes for laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic adjustable gastric banding (LAGB) studies reported a high proportion of patients ‘lost to follow-up’ as early as one year post-surgery. At two years, attrition was 49.8% for LAGB and 75.2% for LRYGB and at greater than three years, attrition was 82.6% and 89% respectively (Garb et al., 2009). There is some data on the effect of follow-up on weight loss after bariatric surgery. Shen et al. (2004) demonstrated a statistically significantly greater early weight loss in patients followed regularly (more than six visits a year), and de Riele et al. (2010) found that patients ‘lost to follow-up’ were more likely to have poor weight loss. Despite minimal data, it is generally accepted among clinicians that patients who regularly return for clinical follow-up are more likely to attain and maintain weight loss, whereas those lost to follow-up are more likely to have poor weight loss or weight regain (Kim, Madan, & Fenton-Lee, 2014).

The literature identifies a number of patient demographic and behavioral characteristics that possibly affect bariatric surgical research and clinical retention, including: age, gender, race, marital status, socioeconomic status, preoperative BMI, travel distance, and psychological condition (DeNino, Osler, Evans, & Forgione, 2010; J.C. Gould, G. Beverstein, S. Reinhardt, & M.J. Garren, 2007; Harper, Madan, Ternovits, & Tichansky, 2007; Jenkins, Xanthakos, Zeller, Barnett, & Inge, 2011; Lara et al., 2005; Toussi, Fujioka, & Coleman, 2009; E. Wheeler, A. Prettyman, M.J. Lenhard, & K. Tran, 2008b). However, a systematic review of attrition in
bariatric aftercare reported that few consistent findings were evident. Although, greater pre-surgical weight and greater travel distance to follow-up clinic were more commonly associated with attrition, conclusions were limited due to the small number of studies and differences among studies with respect to methodology, types of bariatric surgery, and variables considered (Moroshko et al., 2012). Recently, M.A. McVay, K.E. Friedman, K.L. Applegate, and D.D. Portenier (2013) investigated demographic, psychosocial, and weight-related variables associated with medical and behavioral health appointment attendance in Roux-en-Y gastric bypass patients. In multivariate analysis, race/ethnicity and phobic anxiety remained significant predictors of medical attendance, while travel distance to the clinic predicted behavioral health attendance. The authors recommended that future studies focus on patients’ perceptions of the value of follow-up care among other variables.

Retention strategies have been minimally discussed in the bariatric surgery research literature. Two systematic reviews of research retention strategies yielded 21 and 28 articles that identified retention strategies and outcomes. There were no such articles in the bariatric surgery literature (Booker, Harding, & Benzeval, 2011; Robinson, Dennison, Wayman, Pronovost, & Needham, 2007). Subsequent to these reviews, LABS published its retention strategies and 24-month retention data (W.F. Gourash et al., 2013).

1.2.3 Attrition, Retention, and Retention Strategies in LABS-2

The LABS-2 study retention and attrition rates at two years were recently published (W.F. Gourash et al., 2013). Although the retention was higher and the attrition was lower than the vast majority of bariatric surgery research studies, there are still grounds for concern. LABS-2 is a multicenter, observational longitudinal study, in which a cohort of 2458 adults were prospectively enrolled before bariatric surgery and followed periodically after surgery (Belle et al., 2013). LABS attrition is best expressed using the following attrition subcategories:
death (0.7%); inactivation or “withdrawal” (1.5%); those “not able to be located” at the 24-month time point (3.9%); and those “fully not responsive” (2.3%). The additional attrition statistic, those who were “partially not responsive” which is reflected by the portion of data requested that is missing or unavailable was only partially presented in the LABS retention manuscript. At a high level, LABS-2 data collection contained two broad elements: (1) an “in-person visit,” consisting of physical measurements, clinical questionnaires, and blood and urine sampling; and (2) a battery of greater than 20 self-assessment forms, usually completed by the participant at home. At 24-months, 66.2% of those eligible (excluding deaths and those who had “withdrawn”) completed an “in-person visit” which yielded greater than 30% attrition of these data (including those who “missed visits” or were “fully unresponsive”). The self-assessment battery non-completion was not presented. However, it is likely that a less but significant data attrition exists with the self-assessment battery as with the “in-person visits”.

Retention, like attrition, is a complex phenomenon and is not captured by a single statistic (Kleschinsky et al., 2009; Ribisl et al., 1996). Retention in its broadest aspect measures the study subject participation compared with that requested by the investigators in the protocol. It is reflected in a continuum of statistics that define participation from minimal (e.g. vital status only) to completion of all the data requested. At 24 months, LABS recorded “vital status” of those eligible, for 97.3%, “data obtained” (any data form completion) of 93.8%, weight data on 92.2%, and “in-person visit” completion of 66.2%. LABS has done extremely well with the majority of attrition and retention parameters, but remaining areas of concern include completion of the “in-patient visit” and self-assessment questionnaire battery (with data attrition of approximately 30% or retention of 70%). There is reasonable concern as to how LABS-2 has progressed with regard to data attrition and retention at later time points, given that retention has
progressively decreased and attrition increased with post-operative time after 2 years (W.F. Gourash et al., 2013).

LABS-2 employed an array of strategies for improving retention. They included: honorarium, expense reimbursement, gifts with LABS logo, laboratory results, activity monitor results, visit-specific tracking, continual updating of contact information, standardized scheduling and contact protocols, comprehensive participant locating protocols, regular newsletter, website, birthday, holiday and surgery anniversary cards, home research visits, and regularly collected participant retention surveys (W.F. Gourash et al., 2013). The utilization of these strategies was successful as reflected in the overall retention and attrition data. However, the relative value and cost of each of these strategies as a means of increasing retention and avoiding attrition in any specific participant situation has not been systematically studied.

The LABS-2 study included three retention surveys: (1) the Retention Survey – Follow-up visits (RSF) administered at an “in-person” visit; (2) the No-in-person visit (NIV) administered to those who complete the self-assessment questionnaires without an “in-person visit;” and (3) the Inactivated participants survey administered to those who become inactivated. LABS clinicians, investigators, and analytical staff developed the surveys without systematic and direct participant involvement. Additionally, there was no psychometric development or evaluation performed on the questionnaires. The surveys capture information only from those who were still participating. The “inactivated “participants completed very few surveys, and those who did not complete the self-assessment battery or “missed” the complete visit were not represented. Despite these limitations, the retention surveys were useful in guiding the addition and modification of the retention strategies. However, the LABS-2 study
may yield incomplete or unclear information for subjects retained throughout the study and little to no information for “withdrawn” and “fully or partially not responding” subjects.

1.3 Statement of Problem

In summary, research participant retention and attrition are relatively simple concepts, but are also complex phenomena. In many longitudinal studies—and particularly in longitudinal bariatric surgical research—study retention and attrition, as well as the strategies utilized to maximize retention and decrease attrition, are often not reported. When participant retention and attrition are reported, there is often little detail about the various levels of participation or the proportion of the data set collected per participant. Additionally, the factors potentially affecting retention and attrition have not been adequately explored in the research. Attrition increases over time and may result in attrition bias, i.e., adverse effects on validity, reliability, and generalizability. In order to reduce attrition and the potential for attrition bias, researchers must understand the perceptions, motivations, and attitudes of bariatric surgical research participants about their research participation.

1.4 Purpose of the Study

The purpose of this qualitative descriptive study was to explore factors related to research participation from the perspective of bariatric surgical patients of various levels of research participation. Subjects were drawn from the population of participants of Longitudinal Assessment of Bariatric Surgery at the University of Pittsburgh. This study explored the following factors related to research participation:

- participants’ current and past perceptions, attitudes, and motivations regarding research study participation and annual research visits;
- the differences of perceptions, attitudes and motivation among research participants of differing prior study participation level;
- the relationship to research participation of the specific bariatric procedure, weight loss, and of complications requiring subsequent bariatric surgery;
• the relationship to research participation by preoperative demographic and psychosocial characteristics;
• perceived barriers to research participation;
• changes that would increase the likelihood of “complete” research participation;
• participants’ current and past perceptions, attitudes, and motivations regarding participation in routine clinical bariatric surgical follow-up evaluations; and
• the perceived relationship (if any) between participation in bariatric surgical research and attending regular clinical bariatric surgical follow-up evaluation.

The qualitative method was chosen to address the research questions because it provided the ability “to ask questions that are meaningful to participants and to likewise receive responses in participants’ own words and native cognitive constructs” (Guest, MacQueen, & Namey, 2012, p. 13). Qualitative methodologies can be used to address research questions from an exploratory (“content driven”) perspective or a confirmatory (“hypothesis driven”) perspective (Guest et al., 2012). Given the minimal direction from the literature regarding the perceptions, attitudes, and motivations regarding bariatric surgical research study participation, the exploratory approach was selected in the present study. Using this approach, specific codes/analytic categories were not predetermined but were to be derived from the data. The focus was placed on participants’ perceptions (the participant’s view) (Appiah-Poku, Newton, & Kass, 2011; Hudmon et al., 1996), attitudes (inclinations, feelings, and ideas) (Thurstone, 1928; Waltz, Strickland, & Lenz, 2005) and motivations (reasons for behavior) (Rollnick, Miller, & Butler, 2008). The qualitative exploratory method also allowed the use of appropriate inductive probing.

1.5 Research Questions

The following research questions provide clarity to the purpose of the study and specifically indicate the phenomena to be explored:

1. What are research participants’ perceptions, attitudes, and motivations regarding
participation in the research study and annual research visits?
2. Do the participants’ perceptions, attitudes, and motivations regarding participation in the research and annual research visits
   a. differ among participants of different levels of study participation?
   b. change over the time?
   c. have any relationship with preoperative demographic and psychosocial characteristics?
   d. show any relationship to bariatric procedure type, weight loss success or failure, or the presence of surgical complications?
3. What are perceived barriers to “complete” research study participation, especially the annual in-person research visits and how might these barriers be resolved?
4. What do participants think would help them to continue or increase the likelihood of “complete” participation in the research study, especially in-person research visits?
5. What are participants’ perceptions, attitudes, and motivations regarding participation in routine clinical bariatric surgical follow-up evaluations?
6. Do participants perceive any relationship between participation in bariatric surgical research and annual research visits and participation in routine clinical bariatric surgical follow-up evaluation?

1.6 Definition of Terms

Research Participants. For the purposes of this study, this will refer to subjects who participated in the Longitudinal Assessment of Bariatric Surgery (LABS-2) research study.

Participant Perceptions, Attitudes, and Motivations. Participants’ perceptions refers to the participant’s view (Appiah-Poku et al., 2011; Hudmon et al., 1996); participants’ attitudes refers to participants’ inclinations, feelings, and ideas (Thurstone, 1928; Waltz et al., 2005); and participants’ motivations refers to participants’ articulated reasons for their behavior (Rollnick et al., 2008). The qualitative exploratory method allows the use of appropriate inductive probing.

Participation in Research. In broad terms, participation consisted of a research visit and completion of self-report questionnaires. This study focused on the specific requirements of participation in the LABS study. Subjects were required to attend an annual research visit, which included (1) physical measurements (weight, BMI, percent body fat, fitness, neck
circumference, waist and hip circumference, and physical activity/fitness); (2) completion of coordinator-administered surveys, which focused on subsequent hospitalization and medical procedures, physical activity, depression, suicidal ideation or actions, and medication usage; and (3) a blood draw of 8 collection tubes or about 50cc of blood. Additionally, participants completed a battery of between 16 to 19 questionnaires, which addressed a broad range of topics, including psychosocial, behavioral, medical and quality of life. These self-report surveys were often completed prior to or after the research visit at the subjects’ home, but were occasionally completed during the visit. The research visit usually lasted about one hour and completion of the questionnaire battery usually took about 1-1.5 hours.

Levels of Prior Study Participation. The levels of subject participation are based on the first 5 years of LABS-2 data and are as follows: (1) completion of all in-person annual research visits and the majority (14 or more) of the self-assessment questionnaires were submitted; (2) one or more missed in-person annual research visits, but the majority of self-assessment questionnaires (14 or more) or completed all in-person visits but did not complete the majority of self-assessment forms at one or more visits; (3) completion of one or more minimal data visits (missed annual visit and completion of fewer than 5 self-assessment forms); (4) one or more entirely missed visits (no data for the time point); and (5) Inactivated or Withdrawn from the LABS study. These participation levels were developed utilizing the LABS steering committee meeting data and participant retention reports in conjunction with discussion with the LABS Data Coordinating Center and the University of Pittsburgh site research coordinators.

Bariatric Procedure Type. In this study, the procedure will be either Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) or Laparoscopic Adjustable Gastric Band (LAGB).
**Weight Loss Success and Failure.** Weight loss success for the purposes of this study is defined as 25% of pre-surgical body weight or greater weight loss at 5 years postoperative for LRYGB and greater or equal to 15% pre-surgical body weight or greater weight loss at 5 years for LAGB (Coleman, Toussi, & Fujioka, 2010; Halverson & Koehler, 1981; Oria & Moorehead, 2009; Pories, Flickinger, Meelheim, Van Rij, & Thomas, 1982; Reinhold, 1982). Weight loss failure is 12.5% or less weight loss at 5 years postoperative for LRYGB and 10% or less weight loss at 5 years postoperative for LAGB (Coleman et al., 2010; Halverson et al., 1981; Oria & Moorehead, 2009; Pories et al., 1982; Reinhold, 1982).

**Bariatric Surgical Complications.** In the context of this study, “bariatric surgical complication” refers to a subsequent bariatric surgery as defined by LABS—“when a bariatric procedure is performed on a participant who already has had a previous bariatric surgery while enrolled in LABS” and a Subsequent Bariatric Procedure (SBP) Form has been completed. Additionally, “bariatric surgical complication” also includes participants who were found to have an “internal hernia” and underwent a surgical procedure reported by the participant on the Health Care Utilization (HCF) Form.

**Routine Clinical Bariatric Surgical Follow-up Evaluations.** In the context of this study, this term refers to an evaluation that was (1) conducted by any bariatric surgical team member, and (2) not intended for research purposes, but rather for evaluation and monitoring of the patient’s bariatric surgical progress. The subjects/patients did have the option of scheduling research visits in conjunction with their clinical evaluation; the visits were separate and the research visit was conducted by research personal for research purposes.
1.7 Significance to Nursing

The research questions investigated in this study explored bariatric surgical longitudinal research participant perceptions, motivations, and attitudes regarding research participation. These research questions were constructed to fill knowledge gaps observed in the literature. The data obtained will add to the scientific understanding of subject participation in longitudinal research, especially bariatric surgical research, with an emphasis on the factors that affect participant attrition and retention. The data will set the foundation for evidence-based retention strategies. Additionally, the data from this study may provide a foundation for further descriptive, hypothesis-based research and facilitate the development of practical strategies to increase retention and decrease attrition of research participants. Finally, this data may also contribute to the development of a conceptual model of retention and attrition in longitudinal research.

Participant motivation, values, beliefs, and personal meaning are all components of the Participant aspect in the Ecological Theory of Attrition (Marcellus, 2004). This model is participant-centered and demonstrates a transactional influence between the participant, researcher, study and environment.

Nurses have cared for bariatric surgical patients since the early 1960’s when the initial bariatric surgical procedures were developed (e.g. Jejunal Ileal Bypass) (Buchwald, 2002). However, the nursing specialty of care of the morbidly obese and bariatric surgical patient did not develop into a recognized nursing specialty until the late 1990’s and early 2000’s (Davis & Gourash, 2006) and culminated in the development of the Certified Bariatric Nurse Certification in 2007 (Berger et al., 2010). However, many areas of bariatric nursing practice remain understudied. For example, there has been little examination of the short and long-term outcomes.
of bariatric surgical nursing interventions and their effects on overall bariatric surgical outcomes (e.g. weight loss and weight maintenance, comorbidity improvement and remission, quality of life, health status, and complications). As described earlier in the introduction, the attrition for clinical and research bariatric surgical follow-up is high at one to two years postoperative, and increases with time. Clinically, bariatric surgical patients should be evaluated postoperatively by a bariatric surgical team (usually anchored by a nurse) at least once a year for life (Mechanick et al., 2013). Insight into the motivations, attitudes, and perceptions of bariatric surgical research participants will enable nurses participating in nursing research and nursing clinical practice to develop and test retention strategies to improve retention and decrease attrition. Longer-term research participation and more frequent clinical engagement will improve the validity and quality of nursing research with bariatric surgical patients. Such improvements may increase the overall quality and effectiveness of bariatric surgical nursing interventions and care, and thereby improve the health of bariatric surgical patients in the long term.

Finally, there is a practical significance to the research as well. Although the LABS-2 study did not receive extension after 6-31-2014, this data has practical application for the LABS-2 ancillary studies (especially LABS 3 Diabetes and Psychosocial) and potential for future follow-up of the LABS-2 site sub cohorts. Specifically, this study will provide data to compare and confirm the LABS-2 retention survey data when published and will foster further development of these surveys and encourage the use of retention surveys as an ongoing aspect of retention planning in other studies. Additionally, this study data will provide information with which LABS strategies aimed at increasing retention and minimizing attrition may be modified, new ones developed, and the strategic application further honed. Thus, the present
study may provide the basis to enhance LABS-2 ancillary and potential future LABS-2 cohort study retention activities.
Chapter 2

2 Review of the Literature

2.1 Introduction

The purpose of this qualitative descriptive study was to explore factors related to research participation from the perspective of bariatric surgical patients of various levels of research participation who are University of Pittsburgh participants of the Longitudinal Assessment of Bariatric Surgery. Chapter 1 established the study’s problem statement and identified the research questions. This chapter, the review of the literature located the problem and research questions in relation to prior knowledge.

2.2 Link to the Published Literature Review

An integrative review of the literature was performed to explore factors related to retention and attrition in the bariatric surgical literature. It was anticipated that there was little prior research. Thus, the integrative method was utilized to better understand retention and attrition in the bariatric surgery literature by enabling the use of experimental and nonexperimental research in the review. This review was published in Surgery for Obesity and Related Diseases and the journal provided the following link to access the article via ScienceDirect: http://www.sciencedirect.com/science/article/pii/S1550728915008473 (W. F. Gourash, Lockhart, Kalarchian, Courcoulas, & Nolfi, 2016). The initial version submitted to the journal, a “pre-print copy,” follows in 2.3.
2.3 Pre-Print Copy of Literature Review Manuscript

Retention and Attrition in Bariatric Surgery Research: An Integrative Review of the Literature

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Abstract

Background: Bariatric surgery research, often longitudinal, bears the challenge of maintaining retention and decreasing attrition of participants to avoid bias.

Objective: To explore factors influencing the retention and attrition for bariatric surgical research participants.

Methods: Databases searched included: PubMed, CINAHL, Scopus, and others. As a secondary aim, studies reporting on retention/attrition factors in clinical follow-up visits were included.

Results: Of the 1145 articles retrieved, 44 met inclusion criteria, and underwent qualitative analysis. Four descriptive articles focused on longitudinal research participation and 40 on clinical follow-up visits. Willingness to participate in research was high (92%) and decreased with more invasive procedures or extra visits. A large observational longitudinal-study presented
24-month retention/attrition data (92% for some data and 66% visit completion) and the retention strategies employed. One study indicated that research follow-up possibly increased clinical follow-up and another demonstrated a higher retention by increasing compensation. No consistent, modifiable demographic or psychosocial variables associated or predictive of retention or attrition in clinical follow-up were identified.

**Conclusion:** Research on factors related to participant retention and attrition is sparse. It is essential for studies to document retention/attrition data. Existing research has demonstrated a patient willingness to participate in research and that retention strategies have been successful in the short term. Further research should explore the motivations, perspectives and attitudes of bariatric surgical research participants regarding participation and explore predictors to develop evidence-based retention strategies. Research has yet to identify consistent and modifiable demographic or psychosocial variables predictive of clinical follow-up., possibly due to the heterogeneity of follow-up across studies. Further Investigation into follow-up definition, content, counseling approaches and new telemedicine technologies may prove helpful in developing predictors and evidence-based strategies. The relationship between research and clinical retention and attrition deserves further characterization.

**Keywords:** patient compliance, retention, attrition, follow-up, aftercare, bariatric surgery, retention strategies, and longitudinal research.
Introduction:

Obesity is a chronic disease (Allison et al., 2008). Therefore, a large portion of obesity and bariatric surgical research is longitudinal allowing investigators to document outcomes following surgery and to understand factors that predict or mediate outcomes (Belle et al., 2007; Menard, 2002). With these strengths come the significant logistical challenge of locating and retaining adequate numbers of participants at sequential follow-up time points (Kleschinsky et al., 2009; Ribisl et al., 1996). The challenges of long-term bariatric surgical research follow-up may be comparable to the challenges of longitudinal clinical follow-up, a core feature of bariatric surgical care. A 2009 meta-analysis of outcomes for laparoscopic adjustable gastric banding (LAGB) and laparoscopic Roux-en-Y gastric bypass (LRYGB) studies reported a high proportion of patients were lost to follow up as early as 1 year after surgery. Attrition at two years was 49.8% for LAGB and 75.2% for LRYGB (Garb et al., 2009).

Research participant retention and attrition are relatively simple concepts but are complex phenomena. In research studies, the term retention is used to refer to the process of keeping participants active in a research study (Gul & Ali, 2010), and includes the means and processes of maintaining relationships with participants to encourage them to continue full participation for the duration of the study (Patel et al., 2003). Conversely, attrition refers to the loss of active participation by research participants in the study or a portion of the study after enrollment (Patel et al., 2003). Retention and attrition are often expressed in statistics depicting full, partial, or complete loss of subject participation at follow-up. For example, the Longitudinal Assessment of Bariatric Surgery (LABS) study, a multi-centered, observational study of 2458 bariatric surgical participants (Belle et al., 2013) reported “some data” on 93%, in-person research visit follow up of 66%, and inactivation or death of 2.2% at 2 years (W.F. Gourash et al., 2013).
Significant attrition can result in an *attrition bias*, when the attributes of those who have dropped out or have failed to complete portions of the study differ in a non-random way from those who remain active. Attrition bias degrades internal and external validity and can possibly degrade the power and generalizability of the sample (Amico et al., 2008; Friedman et al., 2010; Szklo & Nieto, 2007). There is no absolute standard for acceptable rates of attrition, but bias is usually of concern if the rate exceeds 20% (Amico et al., 2008; Fewtrell et al., 2008; Kleschinsky et al., 2009; Mason, 1999). There are statistical techniques to determine if the initial sample differs significantly from the remaining sample on key characteristics (Abraham & Russell, 2004; Foster & Brickman, 1996; Mazumdar et al., 2007; Philipson et al., 2008; Ribisl et al., 1996). However, prospective methodological approaches to prevent attrition are preferable (Given et al., 1990; Harris, 1998; Mason, 1999). By definition, the relationship between retention and attrition would appear to be reciprocal. Strategies that increase retention should reduce attrition, and strategies that prevent attrition are expected to improve retention (Given et al., 1990; Kleschinsky et al., 2009; Ribisl et al., 1996).

The purpose of this literature review is to explore what is known concerning factors related to retention and attrition in bariatric surgical research. The primary aim is to identify psychosocial, demographic or other factors associated with participant retention and attrition in longitudinal research, and to explore strategies to increase retention and reduce attrition. The secondary aim is to identify factors, predictors and strategies associated with postoperative clinical follow-up care.
Method:

An integrated review method allowed for the simultaneous inclusion of experimental and non-experimental research in order to fully understand the phenomena of concern (Whittemore & Knafl, 2005). Such reviews are used to define concepts, review theories and analyze methodological issues of a particular topic (Whittemore & Knafl, 2005). Integrated reviews are especially useful where the literature is less developed (Broome, 2000). The guiding structure for the process of this research synthesis was that described by Harris Cooper (Cooper, 1998). Although not a systematic review, this review was conducted and reported using means consistent with the latest Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement whenever possible (Moher, Liberati, Telzlaff, Altman, & PRISMA, 2009).

Initially, PubMed was searched for the keywords “retention” and “attrition” and multiple synonyms or related words derived from the literature (e.g. compliance, adherence, follow-up, dropout). Additionally, multiple synonyms for types of bariatric surgery were identified from the literature. Test searches revealed few pertinent manuscripts. However, these manuscripts were analyzed with regard to the MEDLINE’s Medical Subject Headings (MeSH) in order to identify the terminology utilized to classify concepts of retention and attrition as well as bariatric surgical procedures. Records for all manuscripts thought to be pertinent to the topic were dissected and key MeSH terms were identified. This process led to the development of the final search strategy demonstrated in Figure 1. The same process was utilized to the degree applicable with following databases depending on their subject heading development: EBSCO PsycINFO, CINAHL, Scopus and ProQuest Dissertations & Theses. These search strategies are included online in Appendix A.
Databases were searched on September 1, 2014. Papers were included if they were written in the English language, published in peer-reviewed journals (primary research, case report, review and expert opinion articles), textbooks or dissertation services, and explored any aspect of research participant or clinical patient retention or attrition in bariatric surgical patients. This review incorporates articles that reported retention or attrition issues as primary outcomes as well as those with emphasis on alternative outcomes (e.g. weight loss, quality of life, comorbidity), but included retention or attrition factors. There was no restriction placed on the study design. However, a patient age restriction was used (18 years and older) because associated factors and predictors of retention and attrition for those under age of 18 are likely to be significantly different. No date limiters were utilized in the database searches.

Results:

The first author screened the search results by reviewing the titles and abstracts (and sometimes the full text) to assess whether the article met the inclusion criteria. Citations and abstracts of articles meeting the criteria were included into the qualitative analysis as described by Whittemore & Knafl (Whittemore & Knafl, 2005) utilizing the analysis process outlined by Miles and Huberman (Miles & Huberman, 1994). The complete articles were abstracted and entered into the NVivo qualitative analysis software using the categories identified in Appendix B. Additionally, the “ancestry” technique was utilized by reviewing the references of pertinent articles to find important articles that may not have appeared in the database search results (Garrard, 2013). See Figure 2 for the flow diagram for the article selection process.

The search produced 44 publications meeting the criteria. There were four primary research articles, reports of findings prepared by the investigator who conducted the studies,
focusing on the primary aim and 31 primary research articles on the secondary aim. Additionally, the search identified six review articles, 1 case study and 1 expert opinion article as well as 1 textbook chapter, all focusing on the second aim. All of the relevant studies identified in the six review articles (Ahmad, Esmadi, & Hammad, 2012; Karmali et al., 2013; Kim et al., 2014; Moroshko, Brennan, & O'Brien, 2011b; Moroshko et al., 2012) were captured in the database searches except those by Galioto and colleagues (Galioto, Gunstad, Heinberg, & Spitznagel, 2013) which presented new relevant information from articles that collectively but not individually meet the inclusion criteria and thus this review is described in detail.

**Bariatric surgical longitudinal research participant retention and attrition**

Table 1 presents the four study citations that focused on the primary aim including a brief summary. Tichansky et al. (Tichansky, Madan, Ternovits, Fain, & Kitabchi, 2007) surveyed a convenience sample of 97 bariatric surgical postoperative patients regarding their willingness to participate in bariatric surgical research. Ninety-two percent were willing to participate. Ninety-three percent would agree to additional blood tests at routine clinical follow-up visits dropping to 74% if subjects would be required to undergo additional blood draws. Ninety-seven percent would agree to donate fat samples during surgery and 76% would agree to a sample taken one month after surgery. Fifty-five percent would agree to have a “small catheter or tube” placed percutaneously for sample collection. When asked about compensation there was no consensus with regard to the amount of compensation but 80% wanted some compensation ranging from under $50 to greater than $150. The authors concluded that willingness to participate in research was high and decreased with increasing time commitment and the invasiveness of the research activities.
The LABS study published 24-month retention and attrition data, retention strategies and an analysis of “missed” research visits (W.F. Gourash et al., 2013). At 24 months, vital status was known for 97.3% of subjects; some additional data was known for 93%. Weight was recorded for 92.2%; in-person visits were recorded on 66.2%, missed visits on 6.2%, 1.5% of subjects had been “inactivated” and 0.7% had died. The most common reason for missed research visits was “could not be contacted or located” (62.8% of missed visits), and it was recognized that some participants who missed earlier visits would return and participate in data collection for a later visit. Finally, an array of retention strategies were described and six were ranked by the research coordinators as more effective: tangible strategies included honoraria and travel reimbursement and clinical data progress reports; intangible strategies included visit-specific tracking and continual updating of contact information, standardized scheduling, and contact protocols and comprehensive protocols for locating participants. Due to the limited amount of information retrieved from inactivated participants and the low total number, LABS focused on retention strategies to prevent attrition. Another tool was the use of annual “retention surveys” used to guide retention strategy development and modification. LABS implemented a wide range of overlapping retention strategies, presented comprehensive and reasonable retention statistical results. Conclusions were that retention is difficult; attrition is unavoidable but can be minimized; missing a visit does not mean “lost to follow-up” and retention requires considerable effort and resources that may not be available to clinical practice.

In the two remaining studies, retention and attrition were secondary topics. Creativity and persistence can improve recruitment or retention. In a longitudinal cohort of 100 bariatric surgical patients 13-15 years post-surgery, Mitchell and colleagues (Mitchell et al., 2001) undertook an interview study focused on updating weight loss and health status and exploring
binge eating and psychopathology. Initially, 70 participants of the cohort agreed to participate, 16 refused, 8 were deceased and 6 could not be located. Concerned that the 16 who refused would have a worse outcome and bias the results, the investigator requested and received permission from the Institutional Review Board (IRB) to increase the financial incentive from $15 to $100. This was successful in recruiting 8 of the 16 who refused, and there was a final sample of 84.7% of those thought to be alive.

Aarts et al. (Aarts et al., 2014) reported on the long-term outcomes of 201 LAGB patients. Patients were expected for routine postoperative follow-up of 6 visits in the first 2 years followed by annual visits. Follow-up was reported as 87% of visits completed in the first 5 years. However this number dropped to 59% for the second 5 years. At years ten and fourteen, they instituted a research visit that reported on 99% of the living participants. After the year 10 research visit, routine clinical follow-up visits increased to 74% through year 14. It seemed that the research visit at year 10 retrieved some participants who were “lost to follow-up” back into active clinical follow-up.

In summary, only four descriptive articles were identified with regard to retention and attrition of bariatric surgical patients participating in research. There were no studies that identified associations or predictors and only one study identified and evaluated retention strategies. However descriptive data demonstrates a high willingness of bariatric surgical patients to participate in research, which decreased with increasing time commitment and the invasiveness of the research activities and requires some monetary reimbursement/remuneration. Research retention is difficult as is clinical aftercare follow-up and attrition is unavoidable but can be minimized using a comprehensive implementation of retention strategies. Increased reimbursement and possibly other creative modalities may be helpful to recruit some patients.
into long-term research follow-up and thus minimize potential attrition bias. Finally, participating in a research study may have a positive effect on clinical aftercare retention.

**Bariatric surgical clinical follow-up retention and attrition**

Table 2, located in the Appendix C online, presents a brief summary description of the individual studies on the topic of bariatric surgical patient retention and attrition in “clinical follow-up” that were identified. Forty articles will be discussed in the following categories. First, reasons why patients do not attend routine clinical follow-up from the patients’ and professionals’ perspectives are explored. Second, a number of cohort studies have focused on associations and predictors of routine clinical follow-up with weight loss and demographic and psychosocial variables related to attrition and retention. Third, strategies to increase retention and decrease attrition for clinical follow-up care have received some attention. Finally, the review article by Galioto et al. (Galioto et al.) will be presented exploring the association of cognitive function and clinical follow-up.

**Reasons for not attending clinical follow-up visits**

Only a few studies have explored patient reasons for not attending clinical follow-up visits. Gould et al. (J. C. Gould, G. Beverstein, S. Reinhardt, & M. J. Garren, 2007) divided their sample of RYGB patients into groups according to follow-up status. Group 1 (n=34) attended every follow-up visit requested for 3-4 years. Group 2 (n=41) attended every appointment for 1 year and then were lost to follow-up at or beyond 2 years. Group 3 (n=10) were those who had been lost to follow-up by 1-year postoperatively. The most common reason provided for those with poor visit attendance (21 participants) in Group 2 was lack of insurance coverage. Four subjects cited travel distance, 2 patients stated that they felt fine and saw no value, 2 patients took up care with another practice. However the majority (n=23) did not provide a reason for
stopping their visits. Most recently, Vidal et al. (Vidal et al., 2014) in Spain studied 263 RYGB and VSG patients for 8 years postoperative. Forty-six of these subjects (17.5%) were designated as non-adherent, defined as not attending any follow-up appointment beyond 6 months. On a self-report survey, the main reasons given for non-adherence were: work-related problems (12), family-related circumstances (mainly the care of close relatives) (6), having moved outside the city or to the country (5), weight regain (4), forgot their appointment (3), considered follow-up unnecessary (1), pregnancy (1) and death (1). Thirteen did not answer. There was no relationship demonstrated between reasons for non-adherence and poor weight loss (defined as < 50% EWL).

TeRiele et al. (te Riele et al., 2010) in the Netherlands studied 73 of 93 “lost to follow-up” LAGB patients and found that the reason given by patients for non-compliance with follow-up were generally non-specific with 84% citing an inability or unwillingness to make an appointment and “other health problems.” He did find that these patients were more likely to have poor weight loss. In a qualitative study in Australia of patients’ perspective on LAGB aftercare attendance, Moroshko et al. (Moroshko, Brennan, Warren, Brown, & O’Brien, 2014) using a qualitative design identified five themes in “non-regular attendees”: the aftercare content is more relevant early on after the surgery, non-sufficient follow-up from the center, failure and shame due to not being able to meet the providers’ weight loss expectations, not feeling comfortable with a provider that does not understand their struggle to lose weight. Despite these barriers, patients voiced an intention to reconnect. This was an Australian study where GPs functioned to adjust the gastric bands, which is not typical in the US.

Healthcare providers are perplexed by the disconnect that seems to exist between what patients are taught preoperatively and the poor attendance with postoperative follow-up care. Seidl hosted a expert panel discussion with bariatric nursing and dietitian personnel (Seidl,
Rochin, Wright, & Cowart, 2012). They identified several barriers to patient retention with regard to post-operative follow-up from their experience: distance to the office, finances (lower socioeconomic status), embarrassment that they have not been successful, privacy and not wanting to be seen in the office by others, the thought that they do not need to come because the surgery fixed the problem, they are doing so well that they do not need to follow-up, and no usable contact information for the office staff to contact them to remind them to follow-up. Harper et al. demonstrated in a LRYGB cohort of 105 that a significant number of patients (40%) would not comply with regular follow-up at one year unless they are prompted to do so by the bariatric clinic. They postulated that patients may feel that they are doing well from a surgical and lifestyle perspective and do not believe that continual follow-up is necessary. Alternatively, they thought patients may not be progressing as they expected and may be embarrassed to return for follow-up due to a perception of failure or they may be dissatisfied with the results of the surgery, the bariatric surgeon, and/or staff or some patients may simply forget their appointments and require reminding as indicated in his study.

Reasons for missed clinical visits or patients lost to follow up have not been adequately characterized with the current surveys. The qualitative study of Moroshko et al. (Moroshko et al., 2014) identified significant patient emotional difficulties related to the expectations of the care provider. These results show promise and may be useful in developing retention/attrition strategies. However, the findings in these LAGB patients will need to be replicated in the US and in RYGBP/VSG patients. Continued research in this direction might begin to ease the incongruence between the perceptions of healthcare providers and those of patients on the question of why patients stop attending clinical follow-up visits.
**Associations and predictors: Attendance at follow-up visits and weight loss**

One of the key aspects when discussing patient attendance with post-surgery clinical follow-up visits is the positive association and, in some cases, predictive value of postoperative clinical follow-up visits with weight loss. This has been documented in a number of studies as far as four years post-surgery (Compher, Hanlon, Kang, Elkin, & Williams, 2012; Dixon et al., 2009; J. C. Gould et al., 2007; Harper et al., 2007; Kim et al., 2014; Pontiroli et al., 2007; R. Shen et al., 2004; Sivagnanam & Rhodes, 2010). Initially and intuitively, due to required band adjustment, LAGB patients who were compliant with follow-up appointments were demonstrated to have greater weight loss than those who were not compliant (R. Shen et al., 2004). Subsequently, a meta-analysis of four studies and 365 patients documented that at one year post gastric bypass an increase in %EWL was associated with patients being compliant with follow-up visit attendance (mean difference 6.38% EWL, 95 % CI 1.68-11.15) (Kim et al., 2014). Compher et al. (Compher et al., 2012) were able to demonstrate with logistic regression that a greater number of clinical follow-up visits predict greater weight loss at 12 and 24 months. Others have demonstrated a positive relationship between clinical follow-up and weight loss (J. C. Gould et al., 2007; Harper et al., 2007; Pontiroli et al., 2007; Sivagnanam & Rhodes, 2010) or that missing visits (attrition) is related to less weight loss (Dixon et al., 2009; El Chaar et al., 2011; Magro et al., 2008; te Riele et al., 2010; Toussi et al., 2009). Additionally, there is some longer-term evidence that follow-up visit attendance attrition is associated with decreased maintenance of weight loss and more weight regain (Aarts et al., 2014; Freire, Borges, Alvarez-Leite, & Correia, 2012; Magro et al., 2008).

However, some investigators have found no association between weight loss and follow-up care attendance (Schrader et al., 1990; Vidal et al., 2014; Welch et al., 2011). Welsh et al.
(Welch et al., 2011) undertook a comprehensive exploration in 100 patients of clinical, behavioral and psychosocial factors thought to be associated with better weight loss in RYGB patients. Utilizing stepwise regression analysis on outcomes 2-3 years following surgery, attendance at clinic visits was not related to % EWL. Mathus-Vliegen (Mathus-Vliegen, 2007) on behalf of the Dutch Bariatric Surgery Group investigated the longer-term results of 313 (those with known contact information) of 451 bariatric surgical patients (VBG and RYGB) for whom there was no protocol for follow-up in place after the first 1-2 years after surgery. They utilized home visits and telephone interviews supplemented with medical records. The cohort who participated (76.4%) were a mean of 8.2 (SD 4.5) years after surgery and demonstrated weight loss of 45.2 (SD 29.3) % EWL which was thought to be satisfactory. Additionally, Kim et al. (Kim et al., 2014) stated in the discussion of their meta-analysis that the explanation for the positive relationship that they found between clinical follow-up attendance and weight loss continues to be unclear.

There is some consensus with regard to the positive relationship between attendance at follow-up care visits and weight loss. However, there are some studies with conflicting results. This may result from the variability from study to study regarding the definition of and content of “a clinical follow-up visit.” There is no doubt significant variation in the visit content, the provider’s discipline, philosophical approach and knowledge as well as the provider’s patient relationship/communication skills. Postoperative clinical visit attendance is probably not an adequate or reasonable indicator of a patient’s compliance to the behavioral and nutritional changes required of bariatric surgery. Additionally, evidence-based agreement with regard to the essentials of the content of a postoperative visit at the different postoperative time points (e.g. bariatric surgical patient anticipatory guidance), and the optimum follow-up schedule is lacking.
A number of investigators have recommended an increased number and better methodological quality of investigation into more specific indicators of compliance to required postoperative nutritional, physical activity and health behaviors (Ahmad et al., 2012; Lara et al., 2005; M. A. McVay, K. E. Friedman, K. L. Applegate, & D. D. Portenier, 2013). Further research directed at establishing the true value of post surgery follow-up with regard to safe and successful patient outcomes seems vital to enhance patient retention and minimize attrition. There is additional usefulness in establishing the value of follow-up visits in the perceptions of healthcare professionals and patients. Finally, it is reasonable to hypothesize a more dynamic relationship between visit content and counseling interactions which are regarded by patients as more supportive and useful would result in better visit attendance and enhance a broad range of bariatric surgical patient outcomes.

**Associations and predictors: Demographic, psychosocial and other factors related to clinical follow-up**

A number of demographic and psychosocial factors have been explored for a relationship with postoperative clinical follow-up care retention and attrition. The vast majority have been studies of two years or less post-surgery. With regard to demographic variables, current employment has been positively associated with retention (E. Wheeler, A. Prettyman, M. J. Lenhard, & K. Tran, 2008a) and the Caucasian race has been shown in one study to be predictive of retention (M. A. McVay et al., 2013). Age, preoperative BMI, marital status and payment status have been reported with conflicting evidence (Aarts et al., 2014; J. C. Gould et al., 2007; Lara et al., 2005; Rosik, 2005; Schrader et al., 1990; Sockalingam et al., 2013; Vidal et al., 2014; Wheeler et al., 2008a). Socioeconomic status and gender have variably been reported to be not
predictive or to be associated (J. C. Gould et al., 2007; M. A. McVay et al., 2013; Schrader et al., 1990; Sockalingam et al., 2013).

The most studied psychosocial variables are related to psychiatric disorders (depression diagnosis, positive depression screening, Axis I and II psychiatric disorders, and any psychological disorder). Results have been mixed with the majority of studies suggesting no association with the exception of bipolar disease, which has demonstrated only an increased association with attrition (Gill et al., 2012; M. A. McVay et al., 2013; Pontiroli et al., 2007; Sampang, 2010; Schrader et al., 1990; Sockalingam et al., 2013; Toussi et al., 2009; Wheeler et al., 2008a). McVay et al. (M. A. McVay et al., 2013) demonstrated low phobic anxiety was predictive of bariatric clinical follow-up attendance. With step-wise multiple regression analysis applied to compliance data from clinical follow-up visits and scores on the subscales and identified questions of the Millon Behavioral Health Inventory (1982) (Millon & Meagher, 1982), Vogel (Vogel, 1991) identified four significant predictors of compliance. They were: high score on the Respectful Style subscale, patients who indicated they were expecting improvement in their self-concept subsequent to the surgery and weight loss, patients who did not indicate boredom as a reason for overeating, and patients who did not indicate that they were having surgery to avoid future medical disability. Pontiroli et al. (Pontiroli et al., 2007) with 48 months of follow-up data on a cohort of 172 persons identified narcissistic personality disorder to be associated with poor attendance at scheduled follow-up visits. Sockalingam et al. (Sockalingam et al., 2013) reported that avoidant relationship style (a feature of social support) was predictive of clinical follow-up visit attrition. High emotional eating reported preoperatively was explored by Poole et al. (Poole et al., 2005) and found to be associated with clinical visit attrition. Finally, with regard to
psychosocial variables, Schrader, through logistic regression analysis, found no relationship with spousal support or a history of spousal violence (Schrader et al., 1990).

Other variables that have been explored with regard to the relationship of retention and attrition for postoperative follow-up visit attendance include the following: post-surgery time, travel distance, knowledge of the operation, fibromyalgia, the comorbidities of diabetes mellitus, hypertension and hyperlipidemia. Increasing time was found to be associated with attrition (DeNino et al., 2010; Freire et al., 2012). Fibromyalgia was associated with good clinical visit retention (Toussi et al., 2009), although the presence of diabetes mellitus, hypertension or hyperlipidemia were not associated (Pontiroli et al., 2007). Travel distance has been studied with conflicting results (DeNino et al., 2010; J. C. Gould et al., 2007; Lara et al., 2005; M. A. McVay et al., 2013; Sivagnanam & Rhodes, 2010; Sockalingam et al., 2013). Knowledge of the operation was explored by Schroder et al. (Schrader et al., 1990) and found to have no predictive value with regard to follow-up.

Establishing predictors of postoperative visit attendance and attrition with the goal of enabling the development of strategies to enhance retention and minimize attrition continues to be important. However, to date there has been little consistency in demographic and psychosocial factors uncovered. This may also be a reflection of the heterogeneity or variation in postoperative follow-up visits. Depression and the presence of psychiatric disorders do not seem to be independent predictors. Phobic anxiety, narcissistic personality disorder and avoidant relationship style appear to have support as negative predictors. Travel distance continues to be studied and its impact on clinical follow-up seems negative but is unclear and probably situational. Factors that surprisingly have received little investigation are the role of the patient’s
knowledge of the general mechanism of action of the surgery and the purposes of clinical follow-up (Ahmad et al., 2012; Schrader et al., 1990).

**Strategies to increase clinical follow-up visit attendance**

Strategies intended to increase patient retention and decrease attrition have been minimally discussed in the bariatric surgical literature. The only tested strategy is that of Harper et al. (Harper et al., 2007), already mentioned, where prompting follow-up adherence was demonstrated to be needed at 12 months and effective in that patients were responsive. “Shared medical appointments” (SMAs) were not developed primarily as a retention strategy although this was thought to possibly have that effect. They were designed to improve patients’ access to their physicians and improve physician productivity. They have been demonstrated in 3 studies to have high patient satisfaction (91% of those who participated scheduled a subsequent SMA, rated 4.13 +/- 0.163 on a scale of 1 to 5 with 5 being excellent, and 96% stated they would recommend SMAs to others (Kaidar-Person et al., 2006; Lorentz, Swain, Gall, & Collazo-Clavell, 2012; Seager et al., 2012). Additionally, preliminary cost and time effectiveness were demonstrated. The use of teleconferencing and tele-video/telemedicine approaches were suggested in the review by Ahmad and have had some initial development and investigation.

Teufel et al. (Teufel et al., 2012) developed the BaSe Program to increase compliance especially in rural areas. They describe the program as a videoconferencing-based aftercare intervention that targets the promotion of and compliance with required lifestyle changes, using a mixture of 14 in-person and video-conferenced group sessions over the first postoperative year. No post implementation studies have been published. However, Vilallonga et al. (Vilallonga et al., 2013) have completed preliminary investigation on utilizing the “Internet of Things” (IoT) technology to monitor medical parameters remotely and collect data and communicate with patients. They
studied an IoT group of 10 LRYGB and LVSG patients (and a 23-patient control group) incorporating a WIFI scale, email (surveys and free text communication) and telephone communication with professional care staff. Greater than 90% in both groups were satisfied with the type of follow-up they received, 60% of the IoT group did not find it necessary to meet the doctor in the outpatient clinic for the duration of the study length of postoperative months 1 through 9. Ninety percent reported they were satisfied with this new approach.

Seidl (Seidl et al., 2012) reported on an expert panel discussion focused on “engaging patients throughout their journey”. A number of retention strategies that these experts had utilized were discussed: support groups with stimulating speakers, establishing a preferred method of communication with each patient, newsletters, a frequently updated website, and the use of social media offering activities at off-site locations. Finally, Moroshkoto et al. (Moroshko et al., 2014) in her qualitative study of 24 Australian LAGB participants where adjustments of the band were often completed by the general practitioners (GPs), reported that the patients perceived that GPs did not understand their perspective and provided advice that was not relevant to their bariatric surgical situation. To encourage attendance and other care aspects, she concluded that post LAGB patients may require strategies that encourage patients’ active participation such as motivational interviewing and empowered patient education.

Reminders prompting patients prior to upcoming visits is now a well-established retention strategy by most bariatric surgical practices. SMA’s have potential and have been shown to be logistically possible and acceptable to patients. More investigation is needed into the efficacy, essential content, cost and time effectiveness and patients’ experience and value. Still in beginning stages is the use of videoconferencing, telemedicine and digital remote clinical data monitoring. This area seems to have significant potential to redefine clinical follow-up after
bariatric surgery and significantly affect patient and provider access and communication. Telemedicine in all of its forms will undoubtedly redefine and broaden concepts of retention and attrition beyond clinical visits to aspects more directly related to outcomes.

**Cognitive function and association with clinical follow-up visit attendance**

Galioto et al. (Galioto et al., 2013) demonstrated that preoperative executive function and memory performance predicted 12 and 24-month post-operative BMI and memory performance predicted weight loss (Spitznagel et al., 2013; Spitznagel et al., 2011). In another study, cognitive functioning was able to account for 15% of the variance in percent total weight loss at 24 months and 46% of the variance in BMI. They argue that it is reasonable to consider that cognitive functioning could moderate adherence including follow-up visit attendance in bariatric surgical patients. The connection between abnormalities in cognitive function now associated with obesity and investigation into how these abnormalities may be moderating adherence to clinical and research visits and behavioral and nutritional change is a promising and important area of investigation.

**Discussion:**

The literature review of participant retention and attrition in bariatric surgical research identified four descriptive articles. These suggest that bariatric surgical patients have a general willingness to participate in research studies especially if research visits can coincide with routine clinical follow-up care. There was less willingness to participate in procedures that are more invasive or visits scheduled outside the routine clinical follow-up. The LABS study comprehensively presented the continuum of retention and attrition statistical data ranging from complete inactivation through partial to full completion of questionnaires and scheduled in-
person visits, but these details are not provided for most bariatric surgical longitudinal studies (W.F. Gourash et al., 2013). LABS purposefully developed a focus on retention strategies in an effort to collect data unbiased by attrition. They presented acceptable levels of retention/attrition and an array of retention strategies. However individual strategies were not separately evaluated for efficacy or cost effectiveness. The Mitchell et al. (Mitchell et al., 2001) study emphasized how potential bias in attrition (in this case non-recruitment of cohort members) can be minimized with an increased monetary remuneration strategy. Aarts et al. (Aarts et al., 2014) reported the possibility that participation in bariatric research may potentiate compliance with clinical follow-up visits.

Tichansky et al. (Tichansky et al., 2007) in their survey found that research subjects appreciate having the research data collected at the same time as their clinic visit. However, to date there is no prospective study to verify this. The LABS study, which collected research data totally separate from clinical care observed that some participants attended research visits regularly and did not attend follow-up clinical visits and vice versa. Additionally, some participants came to both follow-ups on the same day. In the first post-surgery year, they did not collect quantifiable data on this but subsequently added these questions to the data set and are expected to report on this. The relationship between participation in bariatric surgical research studies and the participation in routine clinical follow-up will require further comprehensive exploration to better understand the impact on retention and attrition of each.

Some, but not all, clinical follow-up research findings and recommendations for further research are applicable with regard to bariatric surgical research participation. Research visits differ from clinical follow-up visits in that they are relatively homogeneous for a given study. The participant has been given instruction on the content (clearer visit expectations), and has
consented to participate. These differences may enhance the investigation of reliable predictors and the development of retention/attrition strategies applicable in similar study protocols.

The clinical strategy of prompting for return visits was incorporated into the LABS retention strategies and appears to validate the practical usefulness for research visit retention. The significant bariatric surgical patient acceptance of SMAs would encourage the development of a research visit modality that will allow for individual and group data collection. A shared visit might enhance the collaborative study participant experience and may enhance data and visit retention. Clinical experience would suggest that patients take an interest and can become invested in one another’s success.

Another clinical strategy that seems to have significant potential with regard to research participant retention/attrition is remote communication and data collection utilizing the digital communication (email, videophone, videoconferencing) and IoT technologies. Digital communications offer potentially less tedious methods for scheduling, interviewing and transmitting study information. The technology is already in use to allow weight, vital signs, and anthropometric measures to be obtained digitally from the patient while at home. Defining the reliability and validity of these measures and communications and implementing them into research protocols as appropriate may help to decrease the burden for the participant and hopefully positively impact retention.

In their recommendations for further research, Compher et al. stated “interviews or focus groups might help to identify the motivators and barriers experienced by patients regarding attendance at post-gastric bypass clinical visits as a first step towards development of strategies that can be tested” (Compher et al., 2012, p. 933). McVay et al. (M. A. McVay et al., 2013) and Moroshkoto et al. (Moroshko et al., 2012) suggest further study of patients’ perceptions of the
value of follow-up care as well as patients’ experiences of guilt or shame related to their weight loss at various time points. These suggestions with regard to clinical follow-up visits are most applicable to bariatric surgical research participation. From the longitudinal research perspective, Shipman et al. state that “little is known about longitudinal research participants’ views on which research methods and measures are most acceptable and sensitive” to their needs (Shipman et al., 2008, p. 913). Mein et al. (2012) also recommend understanding the motivation behind “participation” or “drop out” in a longitudinal study. To date there have been no studies other than the limited cross-sectional survey study by Tichansky et al. (Tichansky et al., 2007) that have systematically addressed the participants’ motivations, perceptions, and attitudes with regard to research participation in bariatric surgical research participation.

A recent development in bariatric surgical research stimulated by the NIH is the exploration of ‘big data’ with emphasis on Electronic Medical Record (EMR) sources and less emphasis on prospective longitudinal observational studies. There is consensus that longitudinal clinical outcomes of bariatric surgery (weight change, comorbidity remission, complications and their trajectories) are important to investigate. However, advantages to ‘big data’, large sample size, real world data and significantly less cost must be balanced against inevitable missing and poorly defined data and poor patient retention and high attrition. No matter which approach is utilized, high patient/participant retention and low attrition are crucial elements to maintaining the integrity of the approach.

Big data research approaches using EMRs, may be in part a response to the disparity in “data and patient retention” between free market and “government” health care systems. Clinical outcome data is much easier to obtain in countries that have centralized government healthcare insurance/medical record systems. However, research utilizing high-grade data collection
utilizing strict protocols and certified data collectors will have similar challenges in government and non-government healthcare systems.

**Strengths and Limitations**

The use of an integrated review method allowed for the simultaneous inclusion of experimental and non-experimental research in order to capture the most publications with any potential of broadening the understanding of the phenomena of retention and attrition in bariatric surgical research and clinical follow-up. Prior reviews have included a much narrower selection of literature. A limitation of this review was a focus on prospective, longitudinal research follow-up and it did not include randomized controlled trials or experimental designs with interventions. Additionally, it excluded longitudinal research that did not include in-person follow-up visits (e.g., survey or phone interview research). Lastly, it did not include the retention aspects of cohort studies; large or small that did not have aims (primary or secondary) related to participant retention or attrition.

**Conclusions:**

Research on factors related to participant retention and attrition in bariatric surgical research is sparse. It is essential for longitudinal research to document retention/attrition data and evaluate for potential bias. Existing research has demonstrated a patient willingness to participate in research and that retention strategies have been successful in the short term at attaining reasonable retention and attrition. Further research should explore the motivations, perspectives and attitudes of bariatric surgical research participants regarding research participation as well as predictors in order to develop evidence-based strategies to increase retention and minimize attrition.
Research has yet to identify consistent and modifiable demographic or psychosocial variables associated with or predictive of clinical follow-up, which may be due to the heterogeneity of content, frequency, counseling approach and practitioners across studies. Further Investigation into patient perspectives, the clinical follow-up definition, content and counseling approaches, in addition to new telemedicine technologies may prove helpful in developing evidence-based strategies. The relationship between research and clinical retention and attrition is not well characterized and deserves further characterization and study to delineate applicability of research strategies to clinical care and vice versa.

References:


doi:10.1016/j.soard.2010.10.019


doi:10.1381/0960892053268499


Trier-Bieniek, A. (2012). Framing the telephone interview as a participant-centered tool for qualitative research: a methodological discussion. *Qualitative Research, 12*(6), 630-644.


### Table 1. Selected manuscripts with focus on Bariatric Surgical Research Retention and Attrition

<table>
<thead>
<tr>
<th>Author (yr)</th>
<th>Finding</th>
<th>Aim *</th>
<th>Intervention</th>
<th>Study Time points</th>
<th>n (a) initial n (b) follow-up (%)</th>
<th>Design</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aarts et al. (2014) (Aarts et al., 2014)</td>
<td>Clinical follow-up of 87% in the first 5 yrs. and dropped to 59% in the second 5 yrs.; There was a research visit at year 10 &amp; 14. Clinical follow-up for the 10 - 14 yr. interval was 74%. Almost 1/2 of the patients were lost to follow-up for &gt; 2 yrs. at some point.</td>
<td>2</td>
<td>LAGB</td>
<td>0 - 13.6 mean yrs.</td>
<td>(a) 201 (b) 191 (plus 8 dead)</td>
<td>Retrospective consecutive case cohort</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Gourash et al. (2013) (W.F. Gourash et al., 2013)</td>
<td>Retention/attrition data presented as a continuum (Inactivated 1.5%, Deaths 0.7%, Missed visit 6.2%, Vital status 97.3%, Some data obtained 93.8%, Weight 92.2%, In-person visit 66.2%). Retention strategies described.</td>
<td>1</td>
<td>RYGP, LRYGB LAGB, LVSG, LBPD/DS</td>
<td>24 mo.</td>
<td>(a) 2458 (b) 2391 (97.3%)</td>
<td>Prospective case cohort</td>
<td>OR, WA, ND, PA, NC, NY USA</td>
</tr>
<tr>
<td>Mitchell et al. (2001) (Mitchell et al., 2001)</td>
<td>Due to fear of recruitment &quot;bias“ in the sample, the investigators acquired permission from IRB to increase incentive to participate (15$ to 100$) to recruit those who had initially refused. Successful in recruiting 8 of 16.</td>
<td>2</td>
<td>RYGB</td>
<td>13-15 yr.</td>
<td>(a) 100 (92 alive) (b) 78 (78%)</td>
<td>Retrospective consecutive case cohort</td>
<td>ND USA</td>
</tr>
<tr>
<td>Tichansky et al. (2007) (Tichansky et al., 2007)</td>
<td>92% willingness to participate in research, 93% of these would agree to have additional blood samples drawn, 74% if required and additional draw, 98% agreed to donate fat sample at surgery and 76% would donate 1 month postop.</td>
<td>1</td>
<td>Laparoscopic Bariatric Surgery</td>
<td>Postoperative</td>
<td>(a) 97</td>
<td>Cross-section Survey</td>
<td>TN USA</td>
</tr>
</tbody>
</table>

* 1 = Retention/attrition primary aim of study being evaluated; 2 = Retention/attrition a secondary aim of study being evaluated
Figure 1. Bariatric Surgery Research Retention and Attrition PubMed Search Strategy

Figure 2. Flow diagram for the article selection process for the review.

Articles identified through database searching
n = 1183

Additional articles identified through other sources (e.g. “ancestry” technique)
n = 15

Articles after duplicates removed
n = 1145

Articles abstracts screened
n = 1145

Articles excluded
n = 1013

Full text articles evaluated
n = 132

Full text articles excluded
N = 88

Articles included in qualitative synthesis
n = 44
Appendix A.

Additional Bariatric Surgery Research Retention and Attrition Database Search Strategies:

CINAHL

(( (Retention OR Patient Participation OR Dropout* OR Follow-Up OR Attrition OR Treatment Completer* OR Adherence OR Nonadherence OR Compliance OR Noncompliance) OR (Retention OR Patient Participation OR Patient Dropouts OR Follow-Up Studies OR Lost To Follow-Up OR Patient Compliance) ) And ( (Bariatric Surgery OR Gastroplasty OR Obesity/Surgery OR Bariatric Surgery OR Bariatric Surgical OR Gastric Bypass OR Gastric Banding) )))

PsycINFO

(Retention OR Patient Participation OR Dropout* OR Follow-Up OR Attrition OR Treatment Completer* OR Adherence OR Nonadherence OR Compliance OR Noncompliance OR Retention OR Patient Participation OR Patient Dropouts OR Follow-Up Studies OR Lost to Follow-Up OR Patient Compliance) AND ((DE "Treatment Dropouts") OR (DE "Experimental Attrition") OR (DE "Posttreatment Followup")) AND (Bariatric Surgery OR Weight Loss Surgery OR Obesity Surgery OR Gastric Bypass OR Gastric Band* OR Sleeve Gastrectomy OR Bilopancreatic Duodentectomy)

ProQuest Dissertations

(all("bariatric surgery") OR all("weight loss surgery") OR all("obesity surgery") OR all("gastric bypass") OR all(gastric band*) OR all("sleeve gastrectomy") OR all("bilopancreatic duodentectomy")) AND (all(RETENTION) OR all("PATIENT PARTICIPATION") OR all(DROPOUT*) OR all(FOLLOW-UP) OR all(ATTRITION) OR all(TREATMENT Completer*) OR all(ADHERENCE) OR all(NONADHERENCE) OR
all(COMPLIANCE) OR all(NONCOMPLIANCE) OR all(“Follow-up Studies”) OR all(“Lost to Follow-Up”) OR all(“Patient Compliance”)

**SCOPUS**

((TITLE-ABS-KEY(bariatric surgery) OR TITLE-ABS-KEY(weight loss surgery) OR TITLE-ABS-KEY(obesity surgery) OR TITLE-ABS-KEY(gastric bypass) OR TITLE-ABS-KEY(gastric band*) OR TITLE-ABS-KEY(sleeve gastrectomy) OR TITLE-ABS-KEY(bilopancreatic duodentectomy)) AND (TITLE(retention) OR TITLE(patient participation) OR TITLE(dropout*) OR TITLE(follow-up) OR TITLE(attrition) OR TITLE(adherence) OR TITLE(compliance))) AND NOT INDEX(Medline)
Appendix B.

Categories utilized for Manuscript Abstraction:

0. Author, Year of publication
1. Focus: Research or Clinical Follow-up Attendance
2. Purpose
3. Aims
4. Design
5. Method
6. Sample (#, gender, age, BMI, selection process)
7. Setting
8. Follow-up time points
9. Intervention (Bariatric Procedure(s))
10. Dependent Variables
11. Independent Variables
12. Data Source or instrument
13. Definition of Attrition and/or Retention
14. Results: Attrition and/or Retention rates
15. Predictors or positive associations
16. Non-predictors or negative associations
17. Retention and/or attrition strategies
18. Conclusions
19. Comments
# Appendix C.

## Table 2. Selected manuscripts with focus on Clinical Bariatric Surgical Follow-up Retention and Attrition

<table>
<thead>
<tr>
<th>Author (yr.)</th>
<th>Finding</th>
<th>Aim</th>
<th>Surgery</th>
<th>Study Time Points</th>
<th>n (a) initial n (b) follow-up (%)</th>
<th>Design</th>
<th>Setting</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmad et al. (2012) (Ahmad et al., 2012)</td>
<td>38 y/o who was not compliant with long-term follow-up visits presented with severe anemia and iron and vitamin B12 deficiency due to non-compliance with vitamin supplements.</td>
<td>1</td>
<td>RYGBP</td>
<td>5 y</td>
<td>(a,b) 1</td>
<td>Case Report &amp; Review</td>
<td>MO USA</td>
<td>(a) Attendance at postoperative follow-up visits</td>
</tr>
<tr>
<td>Compheer et al. (2012) (Compheer et al., 2012)</td>
<td>Percent of weight lost over time was greater for attenders than non-attenders (B=1.47, 95% CI 0.47 to 2.48, p=0.0044); Percent weight loss over time was significantly greater for those with more visits (p = 0.0001); With successful weight loss defined as &gt;=50% EWL, attender subjects had a greater frequency of successful weight loss at 12 months (NA=50% vs. A = 81.3%, p=0.01) and 24 months (NA= 57.1% vs. A=84.4%, p = 0.02); The odds of &gt;= 50% EWL at 12 months increased 3.3-fold with each unit increase in the # of visits (p=0.002). At 24 months, the odds of &gt;=50% EWL increased 2.8-fold with each unit increase in the number of visits (p=0.003)</td>
<td>2</td>
<td>RYGB</td>
<td>12 &amp; 24 m</td>
<td>(a) 60</td>
<td>Retrospective case cohort study</td>
<td>PA USA</td>
<td>(a) Attender - Returned for a clinic visit at 12 months (b) Non-attender - did not return to clinic for 12 month visit</td>
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<tr>
<td>DeNino et al. (2010) (DeNino)</td>
<td>A linear trend for a decreasing likelihood of follow-up with the passage of time (P = 0.005); The effect of the travel distance to the</td>
<td>1</td>
<td>LAGB</td>
<td>.5, 3, 6, 9, 12 m</td>
<td>(a) 116 (b) .5 = 72% 3 = 80% 6 = 64%</td>
<td>Retrospective consecutive case cohort</td>
<td>VT USA</td>
<td>(a) # of follow-up visits</td>
</tr>
<tr>
<td>Study Ref</td>
<td>Study Design</td>
<td>Location</td>
<td>Clinic Type</td>
<td>Visit Duration</td>
<td>Variables</td>
<td>Results</td>
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<td>et al., 2010</td>
<td>Clinic on the percentage of follow-up visits postoperatively was not significant (p=0.4);</td>
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<td>Dixon et al. (2009)</td>
<td>The mean # of follow-up visits in the 2 years postoperative was 19.6 +/-8.8; Readiness to change (RTC) not associated with clinic follow-up for 2 years (p=0.14); Postoperative clinic follow-up visits and weight loss demonstrated a positive correlation (r=+0.16, P=0.02, but not linear; Strong relationship between poor weight loss and poor follow-up attendance (P&lt;0.001; The effect of poor attendance was most noticeable in men.</td>
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<td>El Chaar et al. (2011)</td>
<td>Postoperative compliance demonstrated a weak correlation with %EWL at 12 months after LAGB (r=-.23, p&lt;0.05) but not after LRYGB (r=-.09, p=0.2); Patients compliant with their preoperative appointments were less compliant with their postoperative appointments after either procedure (p&lt;0.01).</td>
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<td>Freire et al. (2012)</td>
<td>Nutritional follow-up attendance decreased dramatically as time passed (p=0.01) (0-2 yr: 85.3% attendance; 2-5 yr: 69.7% and 5 yr: only 3% engaged in nutritional follow-up visits); Lack of post operative nutritional counseling visits was associated with weight regain (p&lt;0.01)</td>
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<td>Gill et al. (2012)</td>
<td>Multivariate analysis identified attrition rate was 53.9% in the medical clinic and 11.9% in the surgical clinic; Multivariate analysis identified</td>
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<td>Reference</td>
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<td>al., 2012</td>
<td>younger patient age (mean age 36.9 yr. vs. 42.6 yr., p=0.02), and lower BMI (Odds ratio 0.96, p&lt;0.001) were predictors for attrition.</td>
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<td>Gould et al. (2007) (J. C. Gould et al., 2007)</td>
<td>A difference was identified in Group 1 and Groups 2 &amp; 3 (74% vs. 60% EWL, p&lt; 0.05 at 3 yr.; Distance traveled to the clinic was similar for each group (35-40 miles for group 1 vs. 3) (p&gt; 0.5 for all comparisons); Age, gender, or initial body mass index not associated with EWL (p &gt; 0.05); Groups 2 &amp; 3 provided reasons why they did not continue follow-up.</td>
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<td>Harper et al. (2007) (Harper et al., 2007)</td>
<td>Group A was prompted to return for 1 year visit after they did not return by 14 months: % EWL was greater in Group B (76 vs. 65%, p &lt;0.003); More patients had successful weight loss (defined by 50% IBW) in Group B versus Group A (P &lt; 0.02).</td>
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<td>Kaidar-Person et al. (2006) (Kaidar-Person et al., 2006)</td>
<td>SMAs offers the patient prompt access to medical care (less waiting time for an appointment p = 0.0046 for new patients and p= 0.06 for return patients); High satisfaction (mean 4.5 of 5 point rating scale); 91% scheduled a subsequent SMA and 96% indicated they would recommend SMAs to others.</td>
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<table>
<thead>
<tr>
<th>Study</th>
<th>Patient Visit Details</th>
<th>Follow-Up Details</th>
<th>Study Design</th>
<th>Location</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LRYGB</td>
<td>3 - 4 y</td>
<td>(b) 681 (57%)</td>
<td>Retrospective case cohort</td>
<td>WI USA</td>
</tr>
<tr>
<td>1</td>
<td>LRYGB</td>
<td>12-14 m</td>
<td>(a) 130 (Group 1= 34, Group 2= 41, &amp; Group 3= 10 (45 excluded due to lost to follow-up or not qualify)</td>
<td>Retrospective consecutive cohort</td>
<td>TN USA</td>
</tr>
<tr>
<td>2</td>
<td>LAGB &amp; LRYGB</td>
<td>Postop</td>
<td>(a) 242 patient visits in 33 groups (28 LRYGB &amp; 5 LAGB)</td>
<td>Cross-sectional survey</td>
<td>FL USA</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Distance Compliance</td>
<td>Method</td>
<td>Patients</td>
<td>Follow-up</td>
<td>Location</td>
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<tr>
<td>Lara et al. (2005) (Lara et al., 2005)</td>
<td>Travel distance was a negative prediction of compliance for the 9 mo. Visit only ((p=0.035); 6-month visit (p = 0.088); Males were more likely compliant with 12-month visit (p=0.04); Age not predictive of compliance (p=0.827)</td>
<td>Retrospective consecutive case cohort</td>
<td>WI, MN &amp; IA USA</td>
<td>(a) 150 (&lt; 50 miles = 115, 50 - 100 miles 21, &gt; 100 miles = 14)</td>
<td></td>
</tr>
<tr>
<td>Lorenz et al. (2012) (Lorentz et al., 2012)</td>
<td>92.5%, 93% &amp; 88.6% at 3, 6, &amp; 12 mo. content with group format; 83%, 85.2%, &amp; 75.7% at 3, 6 &amp; 12-mo responded that they would not prefer to have only individual visits in the future; On average, 5 patients were seen within 4.9 provider hours compared with 10.4 hours with individual model.</td>
<td>Cross-sectional survey</td>
<td>MN USA</td>
<td>(a) 199 (b) missed visits &lt; 10% 3% LAGB</td>
<td></td>
</tr>
<tr>
<td>Margo et al. (2008) (Magro et al., 2008)</td>
<td>Among patients in whom surgery failed (&lt; 50% EWL), 60% never underwent nutritional follow-up and 80% never underwent psychological follow-up.</td>
<td>Prospective consecutive case cohort</td>
<td>Sao Paulo Brazil</td>
<td>(a) 782 (b) 363 (46.5%)</td>
<td></td>
</tr>
<tr>
<td>Mathus-Vliegen E.M.H. (2007) (Mathus-Vliegen, 2007)</td>
<td>No protocol-wise follow-up after 2 yr.; Cohort maintained a mean (s.d.) loss of 32.1 (22.6) kg and 45.2(29.3) %EWL 8.2 (4.5) years after the operation, about 2/3 of the largest weight loss they achieved after 17 month postoperatively; Weight losses obtained in the first 17 months after the operation eroded somewhat with time but notwithstanding this, ensued in satisfying outcomes.</td>
<td>Retrospective consecutive case cohort</td>
<td>Netherlands</td>
<td>(a) 451 (313 with known contact information) (b) 239 (76.4%) VBG (201) RYGB (35)</td>
<td></td>
</tr>
<tr>
<td>McVay et al. (2013) (M. A. McVay et al., 2013)</td>
<td>Medical appointments: 75.3% high &amp; 24.7% low appointment attendees; Behavioral health appointments: 59.9% high &amp; 40.1% low attenders; 6-month %EWL contributed significantly to attendance at 12-month medical follow-up appointments (OR = 1.074;</td>
<td>Retrospective consecutive case cohort</td>
<td>NC USA</td>
<td>(a) 538 (b) Medical: 3 m 85.9% 6 m 68.2% 12 m 69.1% Behavioral Health:</td>
<td></td>
</tr>
</tbody>
</table>
95% CI = 1.028-1.123; P<.01; Medical appointments: Univariate analysis: >age (p=0.04), Caucasian (p=0.003), & phobic anxiety (p=0.03), Multivariate analysis: phobic anxiety [OR] = .9744; 95% CI = 0.952-0.997; [<0.05] and Caucasians [OR] = .288; 95% CI = 0.107-0.777; [<0.05]; Behavioral Health appointments Multivariate analysis: travel distance [OR] = .995; 95% CI = 0.990-0.999; [<0.05].

Moroshko et al. (2014) (Moroshko et al., 2014)
Four common processes developed from all patient descriptions: barriers to attendance, purely medical service, non-patient centered approach and behavioral & psychological aspects of behavioral changes; Regular attended reported: commitment to aftercare, a need to make the band work, regular monitoring motivated attendance and happiness with the improved health; Non-regular attendees perceived: that after care is more relevant early on, insufficient follow-up offered from the center, failure and shame, not comfortable to be vulnerable and an intention to reconnect.

Pontirolli et al. (2007) (Pontirolli et al., 2007)
% of attendance at scheduled visits was predictive of weight loss at 12, 24, 36 & 48 months in the 3 models tested (F = 5663); Narcissistic personality was associated with weight loss at 12 mo. (P=0.0114) and 24 mo. (P=0.0251) but not at 36 and 48 mos.; Narcissistic personality was associated negatively with % of attendance at scheduled visits; Other Axis I & axis II diagnoses were not
associated with attendance at scheduled visits or weight loss; Presence of HTN, DM, & hyperlipidemia were not associated with attendance at scheduled visits or weight loss.

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Summary</th>
<th>Follow-up Duration</th>
<th>Follow-up Type</th>
<th>Cohort Details</th>
<th>Country/Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poole et al. (2005) (Poole et al., 2005)</td>
<td>Emotional eating was associated with poor compliance that included visit non-attendance ($p = 0.015$)</td>
<td>2</td>
<td>LAGB</td>
<td>12 m</td>
<td>(a) 9 Controls &amp; 9 Poor compliance Retrospective case matched cohort</td>
</tr>
<tr>
<td>Rosik et al. (2005) (Rosik, 2005)</td>
<td>Patients who attended all of their follow-up appointments tended to be older ($n = 34$, $M = 43.18$, $SD = 11.38$) than patients who did not ($n = 15$, $M = 34.33$, $SD = 7.34$; $t (47) = 2.76$, $p &lt;.008$).</td>
<td>1</td>
<td>LRYGBP</td>
<td>1 w &amp; 1, 3 &amp; 6 m</td>
<td>(a) 54 Retrospective consecutive case cohort</td>
</tr>
<tr>
<td>Sampan J.A. (2010) (Sampa ng, 2010)</td>
<td>Adherence to the 6-month ($p = 0.574$) and 12-month ($p=0.526$) post-operative visits were not associated with depression. Further analysis with multiple regression to account for cofactors demonstrated follow-up visit attendance and %EWL independent of depression.</td>
<td>1</td>
<td>LAGB</td>
<td>6 &amp; 12 m</td>
<td>(a) 246 (b) 6-mo = 195 (79.3%) 12-mo = 146 (66.7%) Retrospective case cohort</td>
</tr>
<tr>
<td>Schrade et al. (1990) (Schrad er et al., 1990)</td>
<td>The following pre-operative psychosocial factors by step-wise multiple regression analyses were not predictive of dropping out from follow-up: gender, marital status, socioeconomic status, payment</td>
<td>1</td>
<td>RYGB, Gastroplasty, Gastrogastronomy</td>
<td>6, 12, 24, &amp; 36 m.</td>
<td>(a) 72 (b) 75% 6 mo., 80.1% 12 mo., 70.1% 24 mo., &amp; Retrospective cohort</td>
</tr>
</tbody>
</table>
status, past psych history, knowledge of the operation, postop expectations, parental support for surgery, parental obesity, violent parents, spouse support for surgery, spouse alcoholism, and violent spouse.

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention/Outcome</th>
<th>Follow-Up</th>
<th>N</th>
<th>Location</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seager et al. (2012) (Seager et al., 2012)</td>
<td>SMA mean satisfaction rating of 4.13±0.163 (on a scale of 1 to 5, 1 very poor and 5 excellent) which represented an increase (p&lt;0.01) compared to preconceptions before the clinic (3.59±0.175). A cost analysis estimated a yearly saving of £4,617 or 65.1% compared to 1:1 appointments.</td>
<td>2</td>
<td>LAGB</td>
<td>5-28 wks.</td>
<td>(a) 47</td>
</tr>
<tr>
<td>Shen et al. (2004) (R. Shen et al., 2004)</td>
<td>Group A = 70% LAGB, Group B: 30% LAGB, Group C = 46% LRYGB &amp; Group D = 66% LRYGB; Saline volume was relatively = in both LAGB Groups; Group A %EWL = 42% and Group B %EWL = 50% (p=0.005); Group C %EWL = 66.1% and Group D %EWL = 67.6% (p = NS); Visit attendance correlated with %EWL in LAGB &amp; not LRYGB.</td>
<td>1</td>
<td>LAGB</td>
<td>1 y (a)</td>
<td>(a) 355 (b) 301</td>
</tr>
<tr>
<td>Sivagnanam et al. (2010) (Sivagnanam &amp; Rhodes, 2010)</td>
<td>Relationship between # visits and weight loss at 12 months - Median %EWL at 12 months after LABG grouped by 1-3, 4-6, 7-9, and more than 10 follow-up attendances was 41, 48, 54, and 69%, respectively; Median %EWL of 1-3 FUs compared with %EWL of 10 or &gt; FUs (P &lt; .05); Only trend of fewer follow-up visits as the distance from the center of follow-up increased (p=0.05, Pearson's correlation)</td>
<td>1</td>
<td>LAGB</td>
<td>1, 2, &amp; 3 y (a)</td>
<td>(a) 150 (b) 1 y 59% 2 y 65% 3 y 47%</td>
</tr>
<tr>
<td>Study</td>
<td>Methodology</td>
<td>Results</td>
<td>Country</td>
<td>Notes</td>
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<tr>
<td>Sockalin gam et al. (2013) (Sockalingam et al., 2013)</td>
<td>Multivariate logistic regression: avoidant relationship style was only predictor of non-adherence (odds ratio (OR) = 0.961, (CI) 0.923 - 0.998), P &lt; 0.05 and a 5 point change in ECR-16 avoid scores would yield a 19.5% (OR = 0.0805) decrease in the likelihood of attending bariatric aftercare appointments; Gender, positive depression screen, age, travel distance to the bariatric surgery center, pre-surgery and BMI were not predictor of non-attendance</td>
<td>Retrospective consecutive case cohort</td>
<td>CA USA</td>
<td>(a) Attender group = attended at least 1 postoperative appointment after 6 mo. (b) Non-attendance group = did not attend 1 appointment after mo. 6.</td>
<td></td>
</tr>
<tr>
<td>teRiele et al. (2010) (te Riele et al., 2010)</td>
<td>44 of those who returned to follow-up (60%) had failed therapy (&lt; 25%EWL) versus 16.3% (59 of 362, p &lt; 0.001), 27% (66 of 244, p &lt; 0.001) &amp; 42% (31 of 74, p = 0.026) after 2, 4 and 8 years respectively in the regular group. Reasons for non-compliance were generally non-specific.</td>
<td>Retrospective consecutive case subcohort</td>
<td>Nieuwein Netherlands</td>
<td>(b) Failure to attend follow-up for 18 months</td>
<td></td>
</tr>
<tr>
<td>Toussi et al. (2009) (Toussi et al., 2009)</td>
<td>Most frequent compliance issue was missed appointments. 65% of patients missed their designated appointments before surgery and 72% after surgery; Patients who missed appointments after surgery were more likely to have high BDI-II scores (r = 0.43, P = 0.005), have a diagnosis of depression (r = 0.39, P = 0.003), and have a psychological disorder of any kind (r = 0.34, P = 0.01). Patients with fibromyalgia were less likely to miss appointments with the physician (r = −0.29, P = 0.03).</td>
<td>Retrospective cohort chart review study</td>
<td>CA USA</td>
<td>(a) Attendance at follow-up visits</td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>Methodology</td>
<td>Follow-up Duration</td>
<td>Data</td>
<td>Study Type</td>
<td>Country</td>
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<tr>
<td>Vidal et al. (2014) (Vidal et al., 2014)</td>
<td>Completion of survey by patient or relative; 46 (17.5%) Non-adherent with visits; The mean (SD) age was significantly different between the nonadherent patients and those who completed the follow-up [41.7 (8.6) vs. 45.4 (9.0), p=0.01]. No relationship was found between reasons for non-adherence and poor weight loss (&lt; 50% EWL); 30 reported with unsuccessful weight loss (&lt;50%EWL), seven (30.4%) were in the non-adherent group and the remaining 23 (10.6 %) in the adherent group (P=0.046).</td>
<td>0 - 8 years</td>
<td>(a) 263 (b) 250 (95%)</td>
<td>Retrospective consecutive case subcohort</td>
<td>Spain</td>
</tr>
<tr>
<td>Vilallonga et al. (2013) (Vilallonga et al., 2013)</td>
<td>90% of patients in Internet of Things (IoT) group were satisfied with intervention; 60% did not find it necessary to meet the doctor in the outpatient clinic; IoT group patients considered it valuable in saving time, and considered seeing their weight progress continually graphed extremely motivating. IoT technology can monitor medical parameters remotely and collect data (e.g. Wi-Fi scale).</td>
<td>1 - 9 m</td>
<td>(a) 33 (10 IoT group, 20 Standard Care group)</td>
<td>Prospective cohort</td>
<td>Barcelona Spain</td>
</tr>
<tr>
<td>Vogel D.S. (1991) (Vogel, 1991)</td>
<td>Step-wise multiple regression of the participants scores of Millon Behavioral health Inventory (1982). Greater compliance with follow-up appointments (CFA) with those that scored high/low on the following scales or choose a specific response was found: 1. Respectful scale (r=.47, p&lt;.005). 2. those who did not indicate they were having surgery to avoid future medical disability (r=-.36, p&lt;.02). 3. who expected changes/improvement in their self-</td>
<td>2 y</td>
<td>(a) 39 (b) 27 (69%)</td>
<td>Retrospective consecutive case cohort</td>
<td>New England USA</td>
</tr>
</tbody>
</table>
concept or general mood ($r = -0.36$, $p < 0.02$), 4. those that did not indicate boredom was a reason for their overeating and overweight ($r = 0.41$, $p < 0.01$).

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Follow-up Details</th>
<th>Predictors of Adherence</th>
<th>Retrospective Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welch et al. (2011) (Welch et al., 2011)</td>
<td>Mean frequency of clinic follow-up was five visits over 2 years (out of a total of eight scheduled clinic visits): Using multiple regression analysis follow-up visit attendance was not significantly related to weight loss outcome.</td>
<td>1</td>
<td>RYGB primary and revision, 0.5, 1.5, 3, 6, 9, 12, 18, 24 &amp; 36 m</td>
<td>(a) 100 (75%) (b) - 75 (75%) 2-3 yr. Retrospective consecutive cohort MA USA</td>
</tr>
<tr>
<td>Wheeler et al. (2008) (Wheeler et al., 2008a)</td>
<td>Block entry logistic regression statistical analysis. The predictors that indicated more likely adherence were: increasing patient age ($p = 0.031$), being single ($p = 0.001$), and being employed ($p = 0.014$). The predictors that indicated less likely adherence were: self-payment for appointments ($p = 0.023$) and a greater BMI ($p = 0.000$). Not predictive were psychological variables (BDI &amp; eating habits (EAT)).</td>
<td>1</td>
<td>LRYGB (84.3%) &amp; LAGB (15.7%) 1, 2, 3, &amp; 6 months</td>
<td>375 (316 84.3% LRYGB, 59 15.7% LAGB) (188A &amp; 187NA)</td>
</tr>
</tbody>
</table>

* 1 = Retention/attrition primary aim of study being evaluated; 2 = Retention/attrition a secondary aim of study being evaluated.
Chapter 3

3 Methods

3.1 Introduction

The purpose of this qualitative descriptive study was to explore factors related to research participation from the perspective of bariatric surgical patients of various levels of research participation. The above mentioned integrative review of the literature concluded that research on factors related to participant retention and attrition in the bariatric surgery literature is sparse. Additionally, further research should explore the motivations, perspectives and attitudes of bariatric surgical research participants regarding participation to develop evidence-based retention strategies. This chapter describes the methodology that was used for this study including a discussion of the research design, the sample and participant selection, inclusion criteria, procedures for protection of human subjects, interview instrument review, process for data collection, analysis of the data and methodological rigor.

3.2 Research Design

The method chosen for this inquiry was “qualitative description” as described by Margarete Sandelowski (Sandelowski, 2000, p. 334; 2010). Qualitative research can be defined as “any research that uses data that does not indicate ordinal values” (Nkwi, Nyamongo, & Ryan, 2001). Sandelowski suggests that the qualitative description method is reasonable for studies that have as their goal “a comprehensive summary of events in the everyday terms of those events” (Sandelowski, 2000, p. 334) . It is the method of choice “when straight description of phenomena are desired” and to obtain straight-forward answers to questions to that are of special importance to practitioners and researchers (Sandelowski, 2000, pp. p-334).
Studies that utilize this method stay relatively close to their data and the surface meaning of words and events. This is not meant to suggest that they are void of analysis (Sandelowski, 2000). Qualitative research designs may be placed on a continuum moving from those staying closest to the data to those moving farthest from the data. Findings from closest to the data to farthest would be include thematic survey (exploratory description) to conceptual thematic description (descriptive analysis) to Interpretive Explanation (explanatory) (Sandelowski, 2010).

The research questions that compose this study do not require interpretive, conceptual or otherwise highly abstract rendering of the data but are best answered with a descriptive content/thematic analysis. The analysis needed is not highly interpretive and does not need to be viewed in terms of a conceptual, philosophical or highly abstract framework. The desired interpretation of the data would yield that of “low-inference” or likely to result in easier consensus among researchers (Sandelowski & Barroso, 2007; Wolcott, 1994). Of the available qualitative methods, qualitative description offers the unique ability to utilize many design techniques to conform fully to the purpose of the inquiry. It is typically characterized by “an eclectic but reasonable combination of sampling and data collection, analysis and re-presentation techniques” (Sandelowski, 2000, p. 334).

3.3 Setting

The setting for this study was the Pittsburgh Tristate area that includes western Pennsylvania, northern West Virginia and eastern Ohio. The study participants were recruited from subjects of the University of Pittsburgh site of the Longitudinal Assessment of Bariatric Surgery (LABS-2) study. Interviews took place in-person in the office or clinic of the Minimally Invasive Bariatric and General Surgery Division, the participant’s home or other
appropriate private location that was agreeable between the investigator and the participant. Additionally, interviews took place by telephone at the request of the participant.

3.4 Sample

3.4.1 Participant Sampling Approach.

The population selected for this study was bariatric surgical patients who are participating in longitudinal research. Congruent with the exploratory research purpose and design, this study utilized a non-probability, maximal variation sample, which, by definition, does not involve random selection (Bernard & Ryan, 2010; Guest, Namey, & Mitchell, 2013). Consistent with the qualitative method, ‘purposeful sampling’, a specific type of non-probability sampling, was the guiding principle for the sampling strategy (Green & Thorogood, 2009; Miles & Huberman, 1994; Morse & Richards, 2002). In purposeful sampling, logic and power “lie in selecting information-rich cases for study in depth … those [cases] from which one can learn a great deal about issues of central importance to the purpose of the inquiry” (Patton, 2002, p. 230). The goal of purposeful sampling is to choose optimal examples of the phenomenon—participants who reflect the spectrum of attitudes, perceptions and motivations regarding retention and attrition in bariatric surgical research subjects.

This study recruited from the participants of the University of Pittsburgh Medical Center (UPMC) LABS-2 cohort of 545 baseline participants, the largest of the LABS-2 clinical sites (approximately 20% of the entire LABS-2 cohort) (Belle et al., 2013), where currently there are 8 inactivated participants excluding deaths. As mentioned above, participants had four characteristics, attributes or independent variables that were considered to be factors that could significantly affect their perceptions, attitudes and motivations regarding research follow-up participation after bariatric surgery. The primary variable was the subject’s prior LABS-2 research participation history. The other variables were as follows: weight loss success or
failure, the specific bariatric procedure type, and complications requiring additional bariatric surgery. Operational definitions of each of the variables were provided earlier (Chapter 1.6 Definition of Terms). Given this situation, where key characteristics that may influence how the phenomenon manifests, have been identified, a stratified sampling for the individual interviews is very reasonable (Crabtree & Miller, 1999; Marshall & Rossman, 2011; Patton, 1990). The statistically non-representative stratified sampling technique of Trost (1986) where a sample can be developed on variations of the independent variables seems to be an especially good fit. He suggests seven steps: first, list a number of relevant “independent” variables, second, eliminate those variables from the list which are less visible or discernible, third, decide if the format of the variables should be dichotomized or trichotomized and where the cut should be, fourth, combine the selected variables into a property space; fifth, recognize that some cells can be logically empty; sixth, recognize that some cells might be empirically empty, and seventh, fill the cells with participants in order to construct a sample (See Appendix 1, the Statistically Non-representative Stratified Sampling Strategy). Each subject represented a combination of characteristics. A cell could contain more than one participant. The sample was not meant to be statistically representative. The stratification purpose was to insure variation along the independent variables and promote the heterogeneity of the sample (Trost, 1986).

3.4.2 Sample Size Justification

In qualitative research, where most often nonprobability sampling is utilized, there is a consensus in the literature that there are no accepted computations of power analyses to determine a priori the minimum number of participants needed (Guest et al., 2013; Kerr, Nixon, & Wild, 2010; Morse, 2000; Onwuegbuzie & Leech, 2007; Sandelowski, 1995b). Determination of adequate sample size historically has rested on the concept of ‘data or theoretical saturation’; “the point at which no new information or themes are being observed in the data” (Glaser & Strauss,
Thus, adequate and final sample size is determined during the data analysis after data collection has started and usually near the end of data analysis.

Many factors have been cited as having influence on the number of participants needed for an interview study in order to reach saturation: the nature and complexity of the study topic, the purpose and scope of the study, the quality of data collected, study design and specific qualitative method, the aim and type of purposeful sampling, the sample homogeneity, the degree of instrument structure, and the analyst’s categorization style (Guest et al., 2013; Morse, 2000; Sandelowski, 1995b). Reviews of the literature concerning qualitative interview studies for estimates of the sample size required to achieve adequate data saturation yielded a range of 1 to 200 participants depending on the specific qualitative method (Guest, Bunce, & Johnson, 2006; Kerr et al., 2010). There were none that focused on the qualitative descriptive method. The vast majority of the recommendations were not evidence based.

Guest et al. (2006) implemented a study to provide an evidence-based recommendation for the sample size required to attain saturation in an interview study. The authors operationalized saturation (analyzing code development, code definition changes and thematic prevalence) and systematically documented the degree of data saturation and variability over the course of thematic analysis. They concluded that saturation for the most part occurred by the 12th interview although basic elements for metathemes were present as early as six interviews and recommended that 12 interviews would be adequate for most qualitative research which aimed to understand common perceptions and experiences among a group of relatively homogeneous individuals. This estimate is congruent with many of the estimates in the literature (Bernard & Ryan, 2010).

Guest’s recommendation was not fully applicable for this study because we utilized a heterogeneous stratified sample so as to take into consideration the span of prior research subject
participation and factors that could significantly affect participation. It would be expected with a heterogeneous sample that a larger number of interviews would be required (Guest et al., 2013; Sandelowski, 1995b). Patient-reported Outcome (PRO) qualitative interview research, which contributes to labeling claims for medicinal products, is strictly regulated by the Food and Drug Administration (FDA) and requires the use of heterogeneous interview samples (Kerr et al., 2010). The FDA guidance for PRO research places value on the diversity of the included sample (U.S. Department of Health and Human Services Food and Drug Administration (FDA), 2009). The FDA guidance does not make any specific sample size recommendation guidelines except that the study analyses reach saturation. However, subsequently the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) convened a task force to focus on best practice guidance regarding content validity in PRO research and to address the topic estimating sample size for PRO qualitative research. They recommended for interview research to project “a sample size of 20-30, even though saturation may be reached earlier in the interview process” (Rothman et al., 2009, p. 1081).

In summary, the nonrepresentative stratification sampling approach for this study established a framework of 32 interviews to ensure variation along subject’s prior research participation and the 3 other independent variables. Additionally, there were 8 participants who withdrew who were approached. After a review of the literature and specifically taking into account the work of Guest et al. (2006) and the ISPOR Task Force sample projection recommendation (Rothman et al., 2009), we concluded that a sample size of 30-40 interviews would be adequate to reach saturation, which is the determinate of sample size in qualitative research. Additionally, we utilized the Applied Thematic Analysis approach of Guest to guide the data analysis (Guest et al., 2012).
3.5 Inclusion Criteria

In review, because the study purpose was to explore factors related to research participation from the perspective of bariatric surgical research subjects, stratified sampling was employed primarily according to four levels of prior bariatric surgical research participation in the LABS study as well as those who have withdrawn. The “statistically nonrepresentative stratified sampling” approach described by Trost (1986) was selected to guide the stratification to ensure variation along the independent variables and support heterogeneity of the sample. Three other non-primary independent variables, which have been identified in the literature (J.C. Gould et al., 2007; M.A. McVay et al., 2013; Moroshko et al., 2011a, 2012; Pontiroli et al., 2007; R Shen et al., 2005; Stein, Wing, Lewis, & Raghunathan, 2011; te Riele et al., 2010) as potentially affecting bariatric surgical patients’ participation in longitudinal research were incorporated in the stratification: weight loss success, bariatric procedure type and complications requiring additional bariatric surgery (revision, reversal or internal hernia repair).

Additionally, all of the inactivated or withdrawn participants (a total of 8 participants) were approached due to the lower probability of their full participation in this ancillary study. If they choose not to participate, the investigator asked them if they would provide in a few sentences to summarize their experience participating in the study, why they withdrew and if anything could have been done to prevent their withdrawal. This process was discussed with the Institutional Review Board (IRB) and in the IRB submission. There were no specific exclusion criteria except those who were unavailable or unable to participate in an interview.

The projected total sample included approximately 30-40 interviews. However, consistent with the qualitative method with concurrent data collection and analysis (iterative approach), ‘saturation’ was the guiding principle for the final sample number which is established when the
data in each category demonstrates replication (Green & Thorogood, 2009; Guest et al., 2013; Miles & Huberman, 1994; Morse & Richards, 2002; Sandelowski, 1995a) and is simply defined as data adequacy— the point when no new information is obtained from additional qualitative data (Morse, 1995).

3.5.1 Operationalization of the Stratification Process.

The LABS Data Coordinating Center (DCC) performed the stratification as described above and depicted in Appendix 1 Statistically Non-representative Stratification Sampling Strategy. The primary stratifying variable was the level of study participation, followed by weight loss success and failure, bariatric procedure type, and surgical complication. The information to perform the stratification was available in data previously collected from participants by the LABS study. The specific LABS data collection form information is listed in Appendix 2 Stratification Variables: Specific LABS Form Locations. When the stratification of the sample was completed and a listing of LABS participants who were potential retention study subjects, their associated stratification categories and LABS ID numbers and stratification grid were sent to the University of Pittsburgh LABS site research coordinators. The research coordinators added the LABS participants’ preferred contact information and provided this spreadsheet listing to the retention study PI.

3.5.2 Recruitment and Enrollment.

The PI carried out recruitment. After IRB approval, the PI sent an “Invitation to Participate in the Study Letter” (Appendix 3) to the potential participants identified in the stratification process. This letter described the study, contained all of the informational elements required by the IRB for the consenting process, invited them to participate in the study and informed them that the PI would be calling them by phone. Then, the PI made contact with
LABS participants by phone to discuss the study and verbally invite their participation. On the phone, the PI briefly described the study and what participation would include utilizing the information from the above-mentioned letter and the “Recruitment Script and Verbal Consent Documentation Form” (Appendix 4) as a guide. For those not interested in participation, they were thanked for taking the time out to discuss participating in this study. For those interested in participating in the study, options for the date, time and location were discussed. Options for the preferred “in-person” interview included any convenient and mutually acceptable private location (e.g. participant’s home, a conference room at Magee Women’s hospital the location of the Minimally Invasive Bariatric and General Surgery (MIBGS) clinic, the MIBGS administrative office conference room or a Duquesne University School of Nursing conference room). The PI documented their verbal consent or non-consent on the “Recruitment Script and Verbal Documentation Form”.

Additionally, if an in-person interview was not convenient for the participant, they took place by telephone. Given that this study incorporates a stratification of the sample by level of past participation in the LABS-2 study, it was expected that participants with a low level of past participation would be difficult and reluctant to participate and recruit. This group may feel threatened discussing their past participation face-to-face. Traditionally in qualitative research, there has been an assumption that face-to-face interviews are superior to telephone interviews due to the concern for the lack of visual cues (Novick, 2008). A review by Novick (2008, p. 397) concludes, “there is little evidence that data loss or distortion occurs or that interpretation or quality of findings is compromised when interview data are collected by telephone.” Sturges compared telephone and face-to-face qualitative interviewing in a study of perceptions of jail inmate visitors and corrections officers. Analysis of the transcripts indicated no significant
differences in the interviews. Holt (2010) investigated the participants’ experiences with narrative interviewing by telephone and concluded, “there is no need to consider the use of telephones for narrative interviewing as a “second-best” option” (Holt, 2010, p. 120). Trier-Bieniek (2012) defined qualitative telephone interviews as participant-centered and noted that they produce more honest data due to participants’ being increasingly accustomed to virtual communications in recent years and especially when exploring sensitive topics. Thus, within this study, it was reasonable to offer the telephone interview approach with participants who wanted to participate but were not able to participate in a face-to-face interview.

For participating in the study (one 60 – 90-minute interview) participants received a remuneration of $50 and up to $25 of reimbursement for parking and transportation. After a scheduling decision was reached, a consent form was sent to them for review. The participant was called the day prior to the scheduled interview as a reminder. The PI reviewed the consent form with each participant at the start of each interview and addressed any questions or concerns raised by the participant at that time.

3.6 Procedures for the Protection of Human Subjects

The potential risk to the participants in this study was characterized as “minimal risk” as defined by Duquesne University’s and the University of Pittsburgh’s Institutional Review Boards. Minimal risk is defined as follows: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (i.e., of the general population) or during the performance of routine physical or psychological examinations or tests” (Institutional Review Board of the University of Pittsburgh, 2009, p. 30). This study was approved by the Duquesne University and the University of Pittsburgh Institutional Review Boards. Approval Letters are in Appendix 5.
The potential risks to participants in this study included the risk of breach of confidentiality and risks associated with the inconvenience in reporting about medical follow-up. First, the risk of a breach of confidentiality was low, and was discussed with the patient in the consent, where it was noted that this would most likely have a minimal effect or impact on future insurability, employability, or have a negative impact on family relationships, and/or result in stigmatization. Steps were taken to minimize such an occurrence. All information collected for this research study was kept confidential. Participants’ names were used only for the informed consent form and Excel spreadsheet of contact information. Participants were given unique study identifiers, which were written on all data collected. In addition, data collection documents were kept in a locked file cabinet or locked room and a secure database that was only accessible to the investigators (and appropriate and IRB credentialed research staff). There was close communication between the PI, the interview transcription, data entry personnel and the research staff to ensure the quality and accuracy of the data collected. Each member of the study team met with the PI and reviewed confidentiality issues, prior to having contact with research subjects.

A second risk to patients was the possible inconvenience of participating in an aural interview recounting their study participation experience and where some of the questions may be upsetting in that they may cause reflection on their lack of success (i.e. weight loss) or on a complication with their bariatric surgery. Participants were informed that they could decline to answer any questions they did not wish not to answer. In addition, the PI interviewer was a seasoned clinical nurse of 30 years’ experience. A plan was developed with the PI of the LABS UPMC site to provide additional intervention if required. The minimal risks associated with participation in this study were reasonably outweighed by the study’s potential benefit.
With regard to the LABS-2 inactivated or withdrawn participants (a total of 8 participants), a waiver for written consent was requested from the IRB (as per the IRB staff recommendation) to obtain limited information from them if they choose not to participate in the entire study. Because information with regard to their experience with participation in bariatric surgical research if not obtained would have significantly biased the results of the study and compromised the study purpose, it would have been impractical to obtain this information through any other modality. The information was of minimal risk to the participant, and therefore it was reasonable to request a waiver for written consent to obtain limited information. The investigator asked them if they would provide, in a few sentences, a summary of their experience participating in the study, why they withdrew, and if anything could have been done to prevent their withdrawal.

There were no direct benefits to patients who participated in this LABS ancillary study. Their participation may benefit other patients who undergo metabolic weight control surgery. With the knowledge derived from this study, clinicians and researchers may be able to develop more effective follow-up retention strategies so as to increase the safety, positively affect surgical outcomes, and improve the validity, reliability and generalizability of the LABS-2 study and other bariatric surgical research. The results of the LABS retention surveys demonstrated that the vast majority of LABS-2 participants (> 90%) have indicated that “helping others” motivates their return for study visits.

3.7 Research Questions

1. What were participants’ perceptions, attitudes and motivations regarding participation in the research study and annual research visits?
2. Did the participants’ perceptions, attitudes and motivations regarding participation in the research and annual research visits
   a. differ among participants of different levels of study participation?
   b. change over the time?
c. have any relationship with preoperative demographic and psychosocial characteristics?
d. show any relationship to bariatric procedure type, weight loss success or failure, or the presence of surgical complications?

3. What were perceived barriers to “complete” research study participation, especially the annual in-person research visits and how might these barriers be resolved?
4. What did participants think would help them to continue or increase the likelihood of “complete” participation in the research study, especially in-person research visits?
5. What were participants’ perceptions, attitudes and motivations regarding participation in routine clinical bariatric surgical follow-up evaluations?
6. Did participants perceive any relationship between participation in bariatric surgical research and annual research visits and participation in routine clinical bariatric surgical follow-up evaluation?

3.8 Measures

The interviews were operationalized utilizing a combination of a standardized open-ended question approach and an interview guide approach as described by Patton (1990). In the standardized open-ended question approach, the interviewer utilized a list of basic questions worded precisely in a predetermined fashion, which ensured that the interviews covered the same basic material with each participant. As part of the interview guide approach, the interviewer also drew from a list of broad questions and issues which allowed the interviewer “more flexibility in probing and more decision-making flexibility in determining when it is appropriate to explore certain subject’s responses in greater depth or even to undertake whole new areas of inquiry that were not originally included in the interview instrument” (Patton, 1990, p. 287). The combination of these approaches ensured that the interviewer covered the same basic topics with each participant in a similar fashion and additionally, and allowed the interviewer to seek further clarification and follow the interviewee’s lead to potentially important additional information.

Kvale and Brinkman (2009) suggest that interviewers construct an interview agenda by presenting the research questions with interview questions together in a format that allows the
interviewer to see how the interview questions relate dynamically to the research questions. The preliminary “interview agenda” was developed by the investigator from review of the study purpose, the research questions, information from the LABS-2 quantitative retention surveys, and a pilot study (See Appendix 6, the Initial Interview Agenda). The PI implemented an IRB approved “pilot” study titled “A descriptive qualitative pilot study of bariatric surgical patient perceptions, attitudes, and motivations regarding annual clinical follow-up”. This study was constructed to work out the method logistics in preparation for this study. The focus was restricted to clinical bariatric surgical follow-up retention so as to quickly recruit participants. Specifically, the goals of the study were to: test out and practice the combined standardized open-ended question and interview guide approach, increase the patient understanding of the interview questions by continually refining the question terminology, practice the logistics of audiotaping and interview transcription, become increasing familiar with the analysis software and content/thematic analysis analytic approach. This pilot study reached its recruitment goal of 8 subjects and the interviews were completed and underwent preliminary analysis. Face validity of the interview questions was established. The interview question list was reviewed by a panel of research coordinators from the University of Pittsburgh Medical Center LABS study site and a mixed professional panel of research and healthcare practitioners (research coordinators, investigators, nurses, midlevel practitioners, surgeons and dieticians) from the Division of Minimally Invasive Bariatric and General Surgery. Specifying, probing and follow-up questions were further developed and added in an iterative fashion from the participant response as the interviews proceeded. (Kvale & Brinkmann, 2009).
Additional descriptive, psychosocial, and outcome data that had already been collected by the LABS-2 study was used to further characterize the participants and the interview data collected. See Appendix 7 Demographic and Psychosocial Characterization Variables.

3.9 Procedures for Data Collection

Data collection was in the form of one-time individual interviews with a descriptive emphasis, lasting about 60 to 90 minutes, using a combination of the interview guide approach and a standardized open-ended question approach (Kvale & Brinkmann, 2009; Patton, 1990). The interview recordings were subsequently transcribed verbatim into electronic textual documents and the transcription were verified by the PI as accurate.

3.9.1 Data Collection

Sandelowski (2000, p. 337) states that data collection in qualitative descriptive studies usually focuses on the “who, what and where of events or experiences, or their basic nature and shape”. She recommends that data collection include minimally to moderately structured open-ended individual and/or focus group interviews. Knowledge produced through interview research is an active process between the interviewer and interviewee in a conversational relationship (Kvale & Brinkmann, 2009). It is “contextual, linguistic, narrative and pragmatic” (Kvale & Brinkmann, 2009, p. 17 & 18). The research questions elaborated above are directed toward exploring research retention and attrition issues from the perspective of patients and research study participants. The questions seek to reveal attitudes, perceptions and motivations. These research questions are congruent with Sandelowski’s observations as well as the knowledge produced by interview research.

After each participant was enrolled, an appointment was arranged to undertake the interview. The interview lasted about 30-90 minutes. The interviews progressed according to the interview agenda. They were recorded with two Sony Linear PCM-M-10 digital recorders as
per recommendations of the UPMC Audio-Visual Department. The digital record was professionally transcribed to a digital source with the expertise from Verbalink, a professional translating and transcribing service.

Interview quality in interview research is associated with mastery of questioning techniques, knowledge of the research topic, sensitivity to the social relation of the interviewer and interviewee and awareness of the epistemological and ethical interview aspects. The interviews were carried out by a PI with more than 30 years of clinical interviewing experience as a nurse and nurse practitioner. The PI has carried out an individual and focus group interview for his Master’s thesis (W.F. Gourash, 1985). The PI had 20-years of clinical work experience in the specialty of bariatric surgery and functioned as research coordinator for the LABS study for eight years. In addition, the PI received support from the co-investigators who had extensive expertise in qualitative research and interviewing technique.

The additional descriptive, psychosocial, retention and outcome data collected by the LABS study to be utilized to further characterize the participants and the interview data collected (Appendix 7) was requested from the LABS DCC periodically as the sample was recruited.

3.10 Procedures for Data Analysis

Data analysis consisted of a content analysis of the textual verbatim transcription of the interview recording utilizing an exploratory “conventional content analysis” approach (Hsieh & Shannon, 2005) consisting of classifying different relationships of coded data into topics, categories, and eventually themes that were recurrent in the data and supporting these themes with participant quotes in the result presentation (Green & Thorogood, 2009; Guest et al., 2012; Morse & Field, 1995, 1998). Data analysis was guided by the Applied Thematic Analysis
process—a rigorous, yet inductive, set of procedures designed to identify and examine themes from textual data in a way that is transparent, credible and iterative (Guest et al., 2012).

Content analysis is a flexible research method for analyzing text data and has come into wide use in the healthcare literature in the last 20 years (Hsieh & Shannon, 2005). It can be defined as “a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns” (Hsieh & Shannon, 2005, p. 1278). It is well-suited for the analysis of verbal or textual data obtained from a qualitative descriptive study (Sandelowski, 2000).

Analysis for this study utilized an exploratory “conventional” content analysis of the interview data as described by Hsieh and Shannon (2005). It is generally used when the study aim is to “describe” a phenomenon and the text will be analyzed as a proxy for experience (Bernard & Ryan, 1998) which allows access to the individuals’ perceptions, attitudes, feelings, knowledge, and behaviors (Guest et al., 2012). Researchers avoid using preconceived categories or themes and allow “the categories and names of categories to flow from the data” (Hsieh & Shannon, 2005, p. 1279). The researcher reviewed the transcriptions of the individual interviews and categorized the participant responses using a coding system. The Applied Thematic Analysis process, a rigorous, yet inductive, set of procedures designed to identify and examine themes from textual data in a way that is transparent, credible and iterative will be utilized to guide the analysis (Guest et al., 2012). This was a comparative process, comparing the accounts with one another and classifying different relationships of codes into categories, topics and eventually themes that were recurrent in the data set (Green & Thorogood, 2009; Guest et al., 2012; Morse & Field, 1998).
The investigator utilized NVivo 11 Plus Qualitative Data Analysis Software (QRS International Pty Ltd, Version 11.4.1, 2017) for digital planning and management of the data. The software allowed for data project management from its initial inception of the planning document, through data gathering, coding, categorizing, and reporting. This allowed the investigator to begin the data analysis process with the inception of data collection, the hallmark of qualitative analysis. In addition, the range of operations within the capacity of the software (analysis of attributes, coding, to “memoing”, searching, and querying) allowed for continuity of data analysis and potential re-analysis.

3.11 Methodological Rigor

3.11.1 Validity and Reliability in Qualitative Research

Two concepts that are associated with ‘rigor’ in research inquiry are validity and reliability. There have been many definitions of both of these concepts offered in the literature with no single definition universally accepted as capturing the full meaning of each term (Winter, 2000). Validity is most commonly understood to mean that “one is assessing what one is intending to assess” (Guest et al., 2012, p. 80). Similarly, at the core of the many definitions of reliability (Winter, 2000) is the idea of “consistency when repeating or comparing assessments within a study” (Guest et al., 2012, p. 81). With regard to the relationship between validity and reliability, there seems to be a consensus that validity is of greater importance than reliability (Bernard & Ryan, 2010). There can be no validity without reliability and if validity is demonstrated, reliability can be established (Lincoln & Guba, 1985).

Some qualitative researchers have concluded that the concepts of validity and reliability are manifestations of the positivist tradition—which emphasizes empirical data, measurement and, scientific methods (Polit & Beck, 2008)—and are incompatible with qualitative research (Guest et al., 2012; Lincoln & Guba, 1985; Winter, 2000). Qualitative inquiry, which is
associated with the naturalist tradition, “is subjective, interpretive, and time and context bound.” “Truth” is relative and “facts” depend upon individual perceptions” (Morse & Richards, 2002, p. 167). Replicating a qualitative study may be next to impossible or at the least extremely tedious given the highly descriptive data set in a unique context (Sandelowski, 1993). It has been argued that from the qualitative viewpoint, criteria for validity and reliability must be different than in quantitative research (Lincoln & Guba, 1985). Suggested substitutions for the concept of validity include: trustworthiness, worthy, relevant, plausible, confirmable, credible, and representative (Morse & Richards, 2002; Winter, 2000). Suggested substitutions for the concept of reliability include: stability, consistency, predictability, accuracy and dependability (Morse & Richards, 2002; Winter, 2000). Although it may be true that validity and reliability will need to be determined differently in qualitative research, it is of paramount importance that ‘validity’ continues to be the qualitative researcher’s focus so as to attain the goal of accurate, useful, credible and legitimate inquiry (Maxwell, 1992). Additionally, Morse and colleagues (2002) have argued that validity and reliability should remain a vital force in qualitative inquiry for fear that creating alternative words may marginalize qualitative research from mainstream science and legitimacy.

Guest et al. (2012) define validity in qualitative research as “the credibility and accuracy of processes and outcomes associated with a research study” (p. 84). The core question with regard to validity within a research study is “how do we know if our data, and summaries and interpretation of them are valid?” (Guest et al., 2012, p. 85) Transparency and comprehensive documentation of the research process has been put forward as the critical evidence in arguing for the validity of findings, interpretations and conclusions in qualitative research (Miles & Huberman, 1994). There are no standardized tests or rules to ascertain the validity of a study, and
meticulously adhering to design paradigms and carefully documenting the data collection, analysis and interpretation processes is the best safeguard for validity in a given study (Miles & Huberman, 1994; Sandelowski, 1993). However, this does not absolutely guarantee validity but it does provide information for others to make informed assessment regarding the credibility of the research.

3.11.2 Enhancing Validity and Reliability

Guest et al. (2012) have suggested a number of techniques to enhance validity and reliability in qualitative research within the context of the Applied Thematic Analysis (AMA) process, which are similar to those of Morse & Richards (2002), Miles & Huberman (1994), and Creswell (2003). Strategies and techniques are discussed in the framework of the three stages of the research project: design, data collection, and data analysis. Those that are pertinent to this study are described.

In the design stage, the interview agenda was vetted by health care professionals and utilized with eight subjects in a pilot study developed to enhance the methodological aspects as previously discussed. A semi-structured interview agenda was selected to establish an interview flow as well as to enable possible topic comparisons to be made within the stratified groupings. Data collection and interview processes indicated on the interview agenda were structured to be consistent among participants while maintaining flexibility and the inductive nature of qualitative investigation.

All interviews were recorded in their entirety and transcribed by one service provider with a transcription protocol in place to promote consistency. NVivo qualitative analysis software system was utilized to maintain the documentation, memos and tracking for all aspects of the study providing an audit trail for all study activities especially the data analysis.
Finally, triangulation of data sources and methods offered other points of reference within the study to minimize intrinsic bias. The LABS study had been collecting annual retention surveys (Appendix 8) on participants who attended in-person visits or sent in a self-assessment packet or, if inactivated, returned a packet prior to the time of inactivation. The retention survey data were used preliminarily in the analysis to compare with the interview data. The main limitations of the survey data will be that by definition, they were likely not completed especially by those who were poor participators (e.g. missed visits) and there may be missing time points which will depend on the specific LABS participants recruited into this study. However, these data were considered reasonable to grossly evaluate as a potential indication of internal bias.

In the data collection phase, techniques to increase the study validity and reliability included ‘interviewer debriefing’ with regard to moderator bias and immediate monitoring of the data as it is generated. Preferably, immediately following the interview (or within 24 hours), the interviewers took time out to debrief, which involved reflecting on the interview interpersonal dynamic and aspects where any of the investigator’s potential bias (e.g. LABS study coordinator, bariatric surgical nurse) could have affected the interview. Additionally, the investigator monitored the data as it was generated to ensure consistent application of the data collection protocol. Consistent monitoring of the data also allowed for immediate feedback to improve the data collection process and the data quality and consistency. The investigator reviewed each interview from this perspective, documenting notes within 24 hours of the interview. Scheduling, the setting/location, the recording process, and other interview logistics were documented. Additionally, questions without response or inadvertently not asked, the use of inductive probes, and information on any especially novel features of the interview were examined and documented. Action items for potential changes in the process were generated and implemented.
for the subsequent interviews as appropriate. The debriefing and the monitoring process was documented as a portion of the overall project tracking an available for audit.

‘Member checking’ or eliciting feedback from participants with regard to the accuracy of the interview would potentially be difficult in the traditional approach of giving the participant a transcribed interview and requesting response. Potentially, half of the participants had a track record of being a poor research participant in the LABS study and may not be available for subsequent to the interview member checking. A variant that was implemented at the end of the interview just prior to participant debriefing, the investigator offered 2 or 3 keys points made by the participant to verify that the investigator understood them correctly. The participant was asked to comment on them and add other remarks, if desired.

The data analysis stage, where coding and themes are generated, is especially vulnerable for threats to validity and reliability. First, a “code book” was developed and meticulously maintained. This is the foundation of the AMA approach. This codebook cataloged the different code meanings and was updated throughout the study with an audit trail. Second, outlier or deviant case and negative or discrepant data were actively pursued for additional evaluation and analysis. These are data that generally run counter to the themes that seem logically and commonly developing. Third, themes generated from the data were supported with verbatim quotes in the presentation of the findings. This was a pivotal portion of the presentation of the data analysis in narrative. They demonstrate the connection of the “phenomenological world of the participant to the data summary and interpretation generated by the researcher” (Guest et al., 2012, p. 95). Finally, there are advantages of consistency with regard to utilizing a solo analyst and in this case particularly with regard to the application of reliable coding (internal reliability). However, in cases of a solo analyst, the use an auditor to demonstrate external reliability with an
outside review of the data and interpretations derived from the data was reasonable. The dissertation chair completed audits of data collection, code development and analysis.

In summary, a focus on validity (the credibility and accuracy of processes and outcomes associated with a research study) is essential for quality qualitative research. There are no standardized tests or rules to ascertain the validity of a study; meticulously adhering to design paradigms and carefully documenting the data collection, analysis and interpretation processes is the best-known approach. However, adhering to design paradigms and processes does not ensure validity in any particular research inquiry and the specific strategies and techniques chosen and their implementation should be critically examined. The words of Margarete Sandelowski offer a thoughtful coda to the above discussion: “Research is both a creative and destructive process; we make things up and out of our data, but we often inadvertently kill the thing we want to understand in the process. Similarly, we can preserve or kill the spirit of qualitative work; we can soften our notion of rigor to include the playfulness, soulfulness, imagination and technique we associate with more artistic endeavors, or we can further harden it by the uncritical application of rules. The choice is ours: rigor or rigor mortis” (Sandelowski, 1993, p. 8).

3.12 Summary

The purpose of this qualitative descriptive study was to explore factors related to research participation from the perspective of bariatric surgical patients of various levels of research participation who were subjects in the Longitudinal Assessment of Bariatric Surgery study. The research questions explored participants’ perceptions, motivations, and attitudes concerning participation in the study and specifically participation in annual in-person visits, barriers to “complete” participation, what might help them to continue or increase the likelihood of full participation as well as routine annual clinical follow-up, and any relationship between
participation in research and clinical follow-up. The qualitative descriptive research design described by Sandelowski (2000, 2010) was employed with a purposeful stratified sampling primarily according to levels of prior bariatric surgical research participation in the LABS study as well as those who have withdrawn utilizing the statistically nonrepresentative stratified sampling approach. Data collection consisted of audio-recorded one-time individual interviews using a combination of the “interview guide approach” and a standardized “open-ended question approach”. Data analysis consisted of a content analysis of the textual verbatim transcription of the interview recording guided by the Applied Thematic Analysis process, consisting of classifying different relationships of coded data into topics, categories, and eventually themes that were recurrent in the data.
Chapter 4 and Chapter 5

4 Results and 5 Discussion of the Results, Conclusions and Implications

4.1 Introduction

Chapters 4 and 5 describe the results of data analysis, the discussion of results, the conclusions and a dialogue regarding the implications especially for nursing research practice, limitations of the study, and recommendations for further research. This information will be presented in the form of published manuscript. At this time, the manuscript is in the journal submission and review process.

4.2 Exclusion of the Fifth Research Question

The following are the research questions that were crafted at the initiation of this study:

1. What are research participants’ perceptions, attitudes, and motivations regarding participation in the research study and annual research visits?
2. Do the participants’ perceptions, attitudes, and motivations regarding participation in the research and annual research visits differ among participants of different levels of study participation?
   a. change over the time?
   b. have any relationship with preoperative demographic and psychosocial characteristics?
   c. show any relationship to bariatric procedure type, weight loss success or failure, or the presence of surgical complications?
3. What are perceived barriers to “complete” research study participation, especially the annual in-person research visits and how might these barriers be resolved?
4. What do participants think would help them to continue or increase the likelihood of “complete” participation in the research study, especially in-person research visits?
5. What are participants’ perceptions, attitudes, and motivations regarding participation in routine clinical bariatric surgical follow-up evaluations?
6. Do participants perceive any relationship between participation in bariatric surgical research and annual research visits and participation in routine clinical bariatric surgical follow-up evaluation?
Of note, as the data analysis progressed it was apparent that the fifth research question was not the major focus or especially congruent with the majority of the research questions. Additionally, logistically the volume of data collected for analysis exceeded initial expectations and required consideration for limitation. Research Question #5, was thought to thematically detract from the central focus and purpose, exploring bariatric surgical research retention and attrition with research participants stratified by their prior participation. The dissertation committee was in agreement. The analysis and presentation of the results and conclusions regarding Research Questions #5 will be outside of this dissertation.
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APPENDIX 1

Statistically Nonrepresentative Stratified Sampling Strategy
Nonrepresentative Stratified Sampling Strategy

<table>
<thead>
<tr>
<th>Stratification Variables</th>
<th>Variable Category</th>
<th>Variable Category</th>
<th>Variable Category</th>
<th>Variable Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prior LABS-2 Research Participation History Category</td>
<td>LEVEL1</td>
<td>Completed all in-person annual research visits and the majority (&gt; or = 14) of the self-assessment forms</td>
<td>LEVEL2</td>
<td>Missed 1 or more in-person annual research visits but submitted majority of self-assessment questionnaires or completed all in-person visits but did not complete the majority of self-assessment forms at one or more visits.</td>
</tr>
<tr>
<td>2. Weight Loss Success</td>
<td>≤12.5%</td>
<td>≤10%</td>
<td>≥25%</td>
<td>≥15%</td>
</tr>
<tr>
<td>3. Bariatric Procedure Type</td>
<td>RYGB</td>
<td>LAGB</td>
<td>RYGB</td>
<td>LAGB</td>
</tr>
<tr>
<td>4. Complication Requiring Additional Bariatric Surgery</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Count of the Participants Needed to Complete the Stratification</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Category Definitions and Abbreviations:

1. **Prior LABS-2 Research Participation History Categories** = Completed all in-person annual research visits, Missed 1 or > in-person annual research visits but submitted majority of self-assessment questionnaires (14 or >) or completed all in-person visits but did not complete the majority of self-assessment forms at one or more visits, Completed 1 or > minimal data visits (no annual research visit & <5 self-assessment forms completed), Missed 1 or > entire visits (no data) (Categories are based on first 5 years of participation).

2. **Weight Loss Categories** = ≤10% percent of weight loss (%WL) for LAGB & ≤12.5% for RYGB & ≥15% (%WL) for LAGB & ≥25% (%WL) for RYGB (S. H. Belle et al., 2013) (Based on LABS-2 5 year data.)

3. **Bariatric Procedure Type** = Roux-en-Y Gastric Bypass (RYGB) or Laparoscopic Adjustable Gastric Band (LAGB).

4. **Complication Requiring Additional Bariatric Surgery** = Yes (Y) or No (N) to Subsequent Bariatric Surgery Form(s) or Healthcare Utilization form where internal hernia was reported.
APPENDIX 2

Stratification Variables: Specific LABS Form Locations
Stratification Variables: Specific LABS Form Locations

Preoperative Weight (Preoperative Form 4.0)

Most recent weight (Short Form SF 1.0 & 1.1; WGT .10, 1.1, 1.2, 2.0, 2.1 & 2.2; & Research Coordinator Assessment Follow-up RCAF 1.1 & 1.2)

Weight loss % WL

Subsequent Bariatric Surgery Form (SBP) (1, 2, 4.1 & 4.2)

Healthcare Utilization HCU Form with internal hernia repair indicated

Bariatric Procedure (Roux-en-Y Gastric Bypass RYB & Adjustable Gastric Band AGB)

Annual research visits completed and time point

EMSI visit(s) completed and time point

Annual research visit(s) missed (1 or more)

Self-assessment form completion (> 14 plus)

Self-assessment form minimal completion (< 5)

Minimal Data Set (no Annual Research Visit & < 5 self-assessment forms completed) 1 or >

Missed visits (no data) 1 or

Inactivated participants (Inactivation Form - IN2 1, 2, 3 & 4 and Retention Inactivated participants 1, 2, & 3)
APPENDIX 3

Invitation to Participate in the Study Letter
A Qualitative Study of Retention and Attrition in Bariatric Surgery Research Participants

Dear “Name”

I am contacting you because you have participated in the Longitudinal Assessment of Bariatric Surgery (LABS-2) Study. My name is William Gourash, CRNP, MSN. I have been a research coordinator with the LABS-2 study and the LABS study has given me your contact information to approach you and discuss participation in a research study. I am the Principal Investigator of a research study that is interested in learning about LABS participants’ experience, thoughts and attitudes with regard to their participation in bariatric surgical research. I will be undertaking this research as a portion of my requirements for doctoral degree in Nursing at Duquesne University and this research is supported in part by funds from the Division of Minimally Invasive Bariatric and General Surgery at the University of Pittsburgh Medical Center. The purpose of this study is to develop a better understanding of why it is that some people continue to participate in a research study and clinical follow-up over time while others drop out.

We are asking individuals who are participating, or previously participated, in the ‘Longitudinal Assessment of Bariatric Surgery (LABS-2) Study’ to spend 60 to 90 minutes with us “in-person” or by telephone and complete an interview. During this interview, we will ask ‘open-ended’ questions about your experience, thoughts, motivations and any barriers with regard to participating in bariatric surgical research and bariatric surgical clinical follow-up care. As part of this study, we will also review and update some basic information about you that was obtained during LABS-2, including information about your surgery, weight loss, and other basic information about your health and background.

Our goal is to explore the thoughts, attitudes and motivation of current and past research participants to develop a better understanding of the benefits of research, and the barriers to participating. Our hope is that this information will help us, and other researchers, develop better programs to improve participation in future bariatric surgery studies. To help us analyze the interview results, we will audiotape them, and then transcribe the tapes.

There is little risk involved in this study. No invasive procedures or medications are included. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. Another potential risk associated with your participation is the frustration or discomfort some people experience when they are asked questions that may be seem personal or sensitive. This is not unusual, and if you like, we will discuss your feelings and concerns when you have completed the interview. Of course, you don’t have to answer any questions that are particularly distressing to you.
There are no costs to you for participating in this study, and you will receive no direct benefit from participating in this study. We will provide a small token of our appreciation ($50) for taking time to complete this interview and reimbursement for your parking if applicable.

To protect your privacy and maintain the confidentiality of information we obtain from you, we will keep all information about you in a secure location. Paper records that could identify you will be stored in locked file cabinets, and electronic records will be stored in password-protected files. Access to this information will be limited to research team members.

We will do everything we can to protect your privacy and the confidentiality of your records, but just as with the use of your medical information for health care purposes, we cannot guarantee the confidentiality of your research records. However, no third party, including relatives, personal physicians or insurance companies, or other researchers will have access to your identifiable information, with two exceptions. First, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office, and authorized representatives of the Duquesne University Institutional Review Board may review your identifiable information for monitoring the appropriate conduct of this research study. Second, in very unusual cases, your personal information could be released if required by law.

Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after consenting to participate. Your decision will not affect your relationship with the University of Pittsburgh, Duquesne University, or UPMC.

I will be calling you by phone over the next few weeks to discuss your interest in participating in this study and answer any questions that you may have. If you have any questions or concerns, or if you do not wish to be contacted, please contact me at the number below.

Thank you,

PRINCIPAL INVESTIGATOR: William Gourash CRNP, MSN
Duquesne University, School of Nursing
University of Pittsburgh, Department of Surgery
3380 Boulevard of the Allies, Suite 390,
Pittsburgh, PA 15213

ADVISOR-CO-INVESTIGATORS: Joan Such Lockhart, PhD, RN, ANEF, FAAN
Anita P. Courcoulas, MD, MPH, FAC
APPENDIX 4

Recruitment Script and Verbal Consent Documentation Form
Recruitment Script and Verbal Consent Documentation

Investigator: This script will be used as a guide when contacting LABS-2 participants to assess their interest and in some cases document verbal consent to participate in the study: A Qualitative Investigation of Retention and Attrition in Bariatric Surgical Research.

Subject name: ____________________________  Call Date: __________

A. Introduction: Thank you for taking my call.
I am contacting you because you have participated in the Longitudinal Assessment of Bariatric Surgery (LABS-2) Study. My name is William Gourash, CRNP, MSN. I have been a research coordinator with the LABS-2 study and the LABS study has given me your contact information to approach you and discuss participation in a research study. I am the Principal Investigator of the study designed to learn about LABS participants’ experience, thoughts and attitudes with regard to their participation in bariatric surgical research. I will be undertaking this research as a portion of my requirements for doctoral degree in nursing at Duquesne University and this research is supported in part by funds from the Division of Minimally Invasive Bariatric and General Surgery at the University of Pittsburgh Medical Center.

B. Study Description:
The purpose of this study is to develop a better understanding of why it is that some people continue to participate in a research study over time while others drop out of the study.
The study consists of 60-90-minute interview, in-person or by phone, that consists of open-ended questions. During this interview, we will ask ‘open-ended’ questions about your experience, thoughts, motivations and any barriers with regard to participating in bariatric surgical research and bariatric surgical clinical follow-up care. As part of this study, we will also review and update some basic information about you that was obtained during LABS-2.
There is little risk involved in this study. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. Another potential risk associated with your participation is the frustration or discomfort some people experience when they are asked questions that may be seem personal or sensitive. Of course, you don’t have to answer any questions that are particularly distressing to you.
There are no costs to you for participating in this study, and you will receive no direct benefit from participating in this study. We will provide a small token of our appreciation ($50) for taking time to complete this interview and reimbursement for your parking or other expenses up to $25 if applicable.
To protect your privacy and maintain the confidentiality of information we obtain from you, we will keep all information about you in a secure location under lock and key and electronic records will be stored in password-protected files. Access to this information will be limited to research team members.
Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after consenting to participate. Your
decision will not affect your relationship with the University of Pittsburgh, Duquesne University, or UPMC.

C. Do you have any questions with regard to the study?

_____ YES

_____ Answered all questions.

_____ NO

D. Would you be interested in participating in the study?

_____ YES

Would you like to participate in an “in-person or telephone interview”?

_____ In-person – Schedule a time and place agreeable to the participant and Investigator

_____ Telephone – Schedule a time agreeable to the participant and Investigator

_____ Telephone – Participant would like to complete the interview on this call and will proceed to the Interview Guide ….

Did you receive the study introduction letter that was sent out to you?

_____ YES

_____ NO (send out another copy of the letter) Completed _____ Date: _______

_____ NO

Those who were Inactivated from the LABS-2 study: Would you be willing to provide in a few sentences a summary of your experience participating in the LABS study, why you withdrew and if anything could have been done to prevent your withdrawal. (Responses will be written down on the bottom of this sheet in a memo form).

All others: Thank you for taking the time out today to talk with me.

_____ NOT SURE OR NOT READY TO DISCUSS OR DECIDE

Would it be agreeable to you that I call back at a later time?

_____ YES (Another call time/day will be set up)

_____ NO
E. Thank you for taking the time out today to talk with me. My phone number is XXX-XXX-XXXX, should you have any other questions or want to discuss this study more.

Researcher Signature: ________________________  Date: ________________

Research Memo: _____ Yes  _____No

_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

Other Comments:

_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

Wfg 9-14-2015rev
APPENDIX 5

Institutional Review Board Approval Letters
Duquesne University Institutional Review Board (IRB)

Gourash, William
To: Joan Lockhart; Gourash, William
Subject: RE: Expedited Review Approved by Chair - IRB ID: 2015/11/12
To: William Gourash
From: Linda Goodfellow, IRB Chair
Subject: Protocol #2015/11/12 - Approval Notification
Date: 12/28/2015

The protocol A QUALITATIVE INVESTIGATION OF RETENTION AND ATTRITION IN BARIATRIC SURGERY RESEARCH has been approved by the IRB Chair under the rules for expedited review on 12/28/2015. The consent form, recruitment script, and other pertinent documents are stamped with IRB approval and one year expiration date. You should use the stamped forms as originals for copies that you distribute or display.

The approval of your study is valid through 12/27/2016, by which time you must submit an annual report either closing the protocol or requesting permission to continue the protocol for another year. Please submit your report by 11/29/2016 so that the IRB has time to review and approve your report if you wish to continue it for another year.

If, prior to the annual review, you propose any changes in your procedure or consent process, you must complete an amendment form of those changes and submit it to the IRB Chair for approval. Please wait for the approval before implementing any changes to the original protocol. In addition, if any unanticipated problems or adverse effects on subjects are discovered before the annual review, you must immediately report them to the IRB Chair before proceeding with the study.

When the study is complete, please terminate the study via Mentor by completing the form under the Continual Renewal tab at the bottom of your protocol page and clicking on terminate. Please keep a copy of your research records, other than those you have agreed to destroy for confidentiality, over a period of five years after the study’s completion.

If you have any questions, feel free to contact me.
Linda Goodfellow, PhD, RN, FAAN
Chair, Duquesne University IRB
goodfellow@duq.edu
Memorandum
To: William Gourash
From: IRB Office
Date: 9/21/2015
IRB#: PRO15070541
Subject: A QUALITATIVE INVESTIGATION OF RETENTION AND ATTRITION IN BARIATRIC SURGERY RESEARCH

The University of Pittsburgh Institutional Review Board reviewed and approved the above referenced study by the expedited review procedure authorized under 45 CFR 46.110 and 21 CFR 56.110. Your research study was approved under: 45 CFR 46.110.(6) 45 CFR 46.110.(7)

The IRB has approved the waiver for the requirement to obtain a written informed consent. The risk level designation is Minimal Risk.

Approval Date: 9/21/2015
Expiration Date: 9/20/2016

For studies being conducted in UPMC facilities, no clinical activities can be undertaken by investigators until they have received approval from the UPMC Fiscal Review Office. Please note that it is the investigator’s responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. Refer to the IRB Policy and Procedure Manual regarding the reporting requirements for unanticipated problems which include, but are not limited to, adverse events.

If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1480.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA0000600 (Children’s Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.
APPENDIX 6

Initial Interview Agenda
Interview Agenda

Briefing
As you know the LABS study is a longitudinal study or one that follows participants over time and in this case years. It is important for these types of studies to have as many participants as possible involved with attending the annual research visits and completing the survey questionnaires so that the results will adequately describe the participants bariatric surgical journey and have information on the majority of participants at all the time points.

Today, I would like to discuss your thoughts and feelings about the LABS study as well as participation in the annual research visits and completion of all study materials. Additionally, I like to discuss your thoughts and feelings with regard to routine bariatric surgical clinical follow-up.

An audio-recorder will be used to record the interview. The information discussed within this interview will remain confidential as stated in the study consent.

Do you have any questions before starting the interview?

Research Questions

1. What are participants’ perceptions, attitudes and motivations regarding participation in the LABS study, and the annual research visits?

Interview Questions

What was your perception of the LABS study when you initially agreed to participate?
What did you anticipated your participation to be?
What has your experience been in participating in the study?
Have you found any aspect of participation, especially with the in-person visit interesting, enjoyable, rewarding or worthwhile?
Have you found any aspect of participation, especially with the in-person visit, uninteresting, uncomfortable, tedious or not worthwhile?
What motivated you to initially participate in the study?

What is your current perception of the LABS study?
Has it changed over time?
If you were going to explain the LABS study to a friend, how would you describe it?
How would you describe your current participation in the study?
Are there aspects that you especially like?
Have you found any of the current aspects of participation, especially with the in-person visit, interesting, enjoyable, rewarding or worthwhile?
Have you found any of the current aspects of participation, especially with the in-person visit, uninteresting, uncomfortable, tedious or not worthwhile?
Has your motivation to for participation in the LABS study changed over time? If so, How?

Do you think your level of past participation in the study affected your current participation?
Do you think your current level of participation will affect your future participation?
What do you think has had the most effect on the level of your past participation in the study?

2. Do participants’ perceptions, attitudes and motivations regarding participation in the research and annual research visits change over time?

3. Do participants’ perceptions, attitudes and motivations regarding participation in the research study and annual research visits differ among research participants with regard to their prior study participation?
4. Are participants’ perceptions, attitudes and motivations regarding participation in the research study and annual research visits influenced by postoperative outcomes (e.g. type of bariatric procedure, weight loss success or failure, or the presence of a surgical complication)?

What do you think will have the most effect on the level of your future participation in the study?

Do you think the specific bariatric procedure you have undergone has affected your participation in the study? If yes, could you further explain?

Has your weight loss progress affected your participation in the study? If yes, could you further explain?

If you had a complication and had to have another surgical procedure, would this affect your participation? If yes, could you further explain?

5. What are perceived barriers to “full” research study participation, especially the annual in-person research visits and how might these be resolved?

What barriers to participating in LABS study, especially the in-person research visits have you experienced?

How did you resolve these barriers?

Are there any barriers to participating in LABS study, especially the in-person research visits, that you are currently experiencing? How are you resolving these barriers?

Do you see any barriers to participating in the LABS study, especially the in-person research visits, in the future?

How do you think these would best be resolved?

6. Is there anything that would increase the likelihood of “complete” participation in the research study especially the annual in-person research visit?

If we divide up participation into attending the annual research visit and completion of the questionnaires, what are your thoughts and feelings about each of these?

Are there any factors that would make it easier for you to participate in the annual research visit?

If no, rephrase. If yes, please explain.
Is there anything that the research staff might do to make it more likely that you would be able to attend the annual research visits?
If no, rephrase. If yes, please explain.
Are there any factors that make it difficult for you to complete the questionnaire packet?
If no, rephrase. If yes, please explain.
Are there any factors that make it easier for you to participate in completing the questionnaire packet?
If no, rephrase. If yes, please explain.
Is there anything that the research staff might do to make it more likely that you would be able to complete the questionnaire packet?
If no, rephrase. If yes, please explain.

Who do you follow-up clinically with regard to your bariatric surgery?
What has your experience been?
What are most important aspects for you?
What are the least important aspects for you?
Are there any aspects of bariatric surgical follow-up care that you have lacked in your experience?

For you, is there any relationship between your participation in the research study especially the annual in-person research visit and your clinical follow-up visits with the bariatric surgical team?
If yes, please explain.
If No, was there ever? If so, please explain.

Final thoughts
Do you have any final thoughts or feelings about the LABS study or participation in the study especially the in-person annual research visits that you would like to express?
Do you have any final thoughts or feelings about the relationships of annual research visits and follow-up with the bariatric surgical team that you would like to express? (Member Checking questions added here)

Debriefing
Thank you for your participation in this interview study. You have been most helpful. Your participation in these interviews is providing information that will help researchers to better understand bariatric surgical patients’ participation in research activities particularly the LABS study as well as participation in routine bariatric surgical clinical follow-up. This study will help researchers design and modify studies to make it easier and more convenient and more likely for participants to participate fully in longitudinal studies. In addition, it will provide information for a better understanding of bariatric surgical patients’ participation in clinical bariatric surgical follow-up. This will help bariatric surgical clinicians develop better strategies for long-term bariatric surgical follow-up.
APPENDIX 7

Demographic and Psychosocial Sample Characterization Variables from LABS Study and LABS Form Locations
Demographic and Psychosocial Sample Characterization Variables from LABS Study and LABS Form Locations

Demographic Information Baseline (DIB) Form and most recent Demographic Information Follow-up (DIF) Form

1. Marital Status
2. Educational Level
3. Student
4. Employed
4.1 Job Title
5. Employment Status
6. Income (Household)
7. Income (Personal)
8. Medical Insurance
8.1. Type of Medical Insurance

Pre-operative Form

2. Gender
3. Height (baseline)
4. Weight (baseline)
5. Ethnicity
6. Race
10.e. Functional Status (baseline)


The Short Form (36) Health Survey (SF36®) (total score) (baseline and latest available)
EQ-5D™ ‘Your health state today’ score (baseline and latest available)

Impact of Weight on Quality of Life-Lite (IWQOL lite©) – total score (baseline and latest available)

Interpersonal Support Evaluation List (ISEL) (total score) (latest available)

Work Productivity and Activity Impairment Questionnaire (WPAI Q) Question #5 (Health problems affected productivity) (latest available)

Impact of Weight Questionnaire (IW) (total score) (baseline and latest available)

Retention Survey Follow-up – In-person (RSF) (1, 2, 3, 3.1, 3.2, 3.3, 4)

No In-person Visit Retention Survey (NIV) (1, 2, 3.1, 3.2, 3.3)

Retention Survey Inactivated Participants (1, 2, & 3)
APPENDIX 8

Longitudinal Assessment of Bariatric (LABS) Retention Surveys
Retention Survey Follow-up – In-person (RSF)

<table>
<thead>
<tr>
<th>Entered: <em><strong>/</strong></em>/20___</th>
<th>Initials: _______</th>
<th>Verified: <em><strong>/</strong></em>/20___</th>
<th>Initials: _______</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID <em><strong>-</strong></em>-<em><strong>-</strong></em>-<em><strong>-</strong></em></td>
<td>For office use only.</td>
<td></td>
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</tbody>
</table>

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Retention Survey Follow-up, In-person (RSF): 01/01/2010
Form Completion Date ___/___/20___ Study Visit: ______

1. What encourages you to return for your study visits? (Please check no or yes to each)

   - [ ] No  [ ] Yes
   - a. Relationship with research staff
   - b. Already in the office for clinical follow-up
   - c. Ability to help others in the future
   - d. Compensation/reimbursement
   - e. Personalized feedback of study results
   - f. Live or work close by
   - g. Made a commitment/agreed to participate
   - h. Research is interesting to me.
   - i. Other, Specify: ____________________________

2. Do you think that the study visits can be improved?  [ ] No  [ ] Yes

   If yes, specify:

   - [ ] No  [ ] Yes
   - a. Shorter visits and/or less questionnaires
   - b. Schedule research visits the same time as clinic visits
   - c. Provide more personal or study related feedback
   - d. Provide more flexibility in scheduling of visits
   - e. Provide study visits in location closer to my home
   - f. Provide better details on how to prepare for the visit
   - g. More monetary compensation
   - h. Always room for improvement but no specific suggestions in mind
   - i. Other, Specify: ____________________________

3. Have you accessed the LABS participant web site?  [ ] No  [ ] Yes

   If No →
   3.1 Why not? (Please select ONLY one best answer)

   - [ ] 1. No computer/internet access
   - [ ] 2. Don’t know how to access the site
   - [ ] 3. Unaware of web site
   - [ ] 4. Not interested
   - [ ] 5. Too busy
   - [ ] 6. Other, Specify: ____________________________
   - [ ] 7. Forgot about it
   - [ ] 8. Not computer savvy

   If Yes →
   3.2. How many times have you visited the LABS participant web site?

   - [ ] 1-2 times
   - [ ] 3-4 times
   - [ ] 5-6 times
   - [ ] More than 6 times

   3.3. What is your favorite feature of the web site? (Please select ONLY one best answer)

   - [ ] 1. Study visit descriptions
   - [ ] 2. Recipes
   - [ ] 3. Health & Wellness Tips
   - [ ] 4. LABS data
   - [ ] 5. Clinical Site Map
   - [ ] 6. Other, Specify: ____________________________
Retention Survey Follow-up – In-person (RSF) (Continued)

Patient ID __ __ __ " __ __ __ __ __ 

4. Would you like to receive information regarding this study? ☐ 0. No ☐ 1. Yes

If yes,

4.1 How would you like study information communicated to you (please check no or yes for each)?

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ a. Mail</td>
</tr>
<tr>
<td>☑</td>
<td>☐ b. Website</td>
</tr>
<tr>
<td>☐</td>
<td>☐ c. E-mail</td>
</tr>
<tr>
<td>☐</td>
<td>☐ d. Written material given at your visit</td>
</tr>
<tr>
<td>☐</td>
<td>☐ f. Other, (please specify: ____________________)</td>
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</tbody>
</table>
No In-person Visit Retention Survey (NIV)

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<tr>
<th>Entered:  _ / _ / 20_</th>
<th>Initials: __________</th>
<th>Verified: _ / _ / 20_</th>
<th>Initials: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID __________*</td>
<td></td>
<td>Visit: ______________</td>
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</tbody>
</table>

For office use only.

Retention Survey (NIV) - Version 1: 02/28/2009

Form Completion Date  _ / _ / 20_

1. What are the reasons you are not returning for an in-person visit? (Please check no or yes to each)

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Relationship with research staff</td>
</tr>
<tr>
<td>b.</td>
<td>It wasn’t coordinated with my clinical follow-up</td>
</tr>
<tr>
<td>c.</td>
<td>Family responsibilities</td>
</tr>
<tr>
<td>d.</td>
<td>Not enough compensation/reimbursement</td>
</tr>
<tr>
<td>e.</td>
<td>No or not enough feedback of study results</td>
</tr>
<tr>
<td>f.</td>
<td>Travel time to medical facility</td>
</tr>
<tr>
<td>g.</td>
<td>Work responsibilities</td>
</tr>
<tr>
<td>h.</td>
<td>Previous visit was too long</td>
</tr>
<tr>
<td>i.</td>
<td>Can’t fit available visit times in my schedule</td>
</tr>
<tr>
<td>j.</td>
<td>I’m too ill or I’ve been hospitalized</td>
</tr>
<tr>
<td>k.</td>
<td>Other, Specify: ____________________________</td>
</tr>
</tbody>
</table>

2. What can we do to make it easier for you to return for an in-person visit? (Please check no or yes to each)

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Shorter visits and/or less questionnaires</td>
</tr>
<tr>
<td>b.</td>
<td>Schedule research visits the same time as clinic visits</td>
</tr>
<tr>
<td>c.</td>
<td>Provide more personal or study related feedback</td>
</tr>
<tr>
<td>d.</td>
<td>Provide more flexibility in scheduling of visits</td>
</tr>
<tr>
<td>e.</td>
<td>Provide study visits in location closer to my home</td>
</tr>
<tr>
<td>f.</td>
<td>Provide better details on how to prepare for the visit</td>
</tr>
<tr>
<td>g.</td>
<td>More monetary compensation</td>
</tr>
<tr>
<td>h.</td>
<td>Increase transportation reimbursement</td>
</tr>
<tr>
<td>i.</td>
<td>Always room for improvement but no specific suggestions in mind</td>
</tr>
<tr>
<td>j.</td>
<td>Other, Specify: ____________________________</td>
</tr>
</tbody>
</table>

3. Have you accessed the LABS participant web site?  □ 0. No □ 1. Yes

If No ⇒

3.1 Why not? (Please select ONLY one best answer)

- 1. No computer/internet access
- 2. Don’t know how to access the site
- 3. Unaware of web site
- 4. Not interested
- 5. Too busy
- 6. Other, Specify: ____________________________
- 7. Forgot about it
- 8. Not computer savvy

If Yes ⇒

3.2. How many times have you visited the LABS participant web site?

- 1-2 times
- 3-4 times
- 5-6 times
- More than 6 times

3.3. What is your favorite feature of the web site? (Please select ONLY one best answer)

- 1. Study visit descriptions
- 2. Recipes
- 3. Health & Wellness Tips
- 4. LABS data
- 5. Clinical Site Map
- 6. Other, Specify: ____________________________
Retention Survey Inactivated Participants

Enter: __/__/20__ Initials: _______ Verified: __/__/20__ Initials: _______  
Patient ID __-__-__-__-__-__-__  For office use only.

Retention Survey (Inactivated Participants) Version 1.0: 07/31/2007

Form Completion Date ___/___/20___ Inactivation date: ___/___/20___

1. What is the main reason you are not returning for your LABS follow-up appointments?
   - 1. Family responsibilities
   - 2. Travel time to medical facility
   - 3. Work responsibilities
   - 4. No longer interested in participating in a research project
   - 5. Did not like the research visit
   - 6. It’s not part of my clinic visit (inconvenient to schedule)

2. Are there any other reasons why you are unable to return to your LABS follow-up appointments?
   - 0. No
   - 1. Yes
   
   If yes, specify:

   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________

3. What could we have done to keep you in the study?

   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________

LABS  Version 1.0 07/31/2007
Page 1 of 1