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Longitudinal Assessment of Bariatric Surgery (LABS): Retention strategy and results at 24 months

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Abstract

Background—Retaining participants in observational longitudinal studies following bariatric surgery is difficult yet critical because the retention rate affects interpretation and generalizability of results. Strategies for keeping participants involved in such studies are not commonly published.

Objective—To review LABS retention strategies and present the 24-month retention data

Methods—The LABS Consortium monitors an observational cohort study of 2458 adults enrolled prior to bariatric surgery at 10 centers within the United States (LABS-2). To maximize data completeness, the investigators developed retention strategies including flexible scheduling, a call protocol, reminder letters, abbreviated visit options, honoraria, travel reimbursement, providing research progress reports, laboratory results, newsletters, study website, and retention surveys. Strategies for locating participants included frequent updates of contact information, sending registered letters, and searching medical and public records.

Results—At 12 and 24 months, 2426 and 2405 participants remained active, with vital status known for 98.7% and 97.3% and weight obtained for 95.2% and 92.2% respectively. There were 148 missed visits (6.2%) at 24 months primarily because of inability to contact the participant. Only 15 (0.6%) active participants at 24-months missed all follow-up visits. Though 42

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participants could not be located or contacted at 6 months, data were obtained for 23 (54.7%) of them at 12 months, and of the 52 participants who could not be located or contacted at 12 months; data were obtained for 18 (34.6%) at 24 months.

Conclusion—Longitudinal studies provide the ability to evaluate long-term effects of bariatric surgical procedures. The retention achieved in LABS is superior to many published reports but requires extensive effort and resources. This report identifies useful retention strategies. Further research is needed to identify the efficacy and cost effectiveness of specific retention strategies.

Keywords

retention; attrition; follow-up; bariatric surgery; longitudinal research

Introduction

Retention is the process of keeping participants in a research study or in active clinical follow-up⁽¹⁾. It includes developing and maintaining relationships with participants to encourage them to continue participation for the length of the study⁽²⁾. Attrition is the failure to complete participation after enrolling in a research study^(3,4). Retention and attrition data and retention strategies have not been adequately reported in the bariatric surgical literature^(5,6,7,8).

Historically, some successful long-term studies of bariatric surgery have been reported which demonstrated high retention rates^(9,10) but generally, retention in clinical bariatric surgical research and practice is challenging, especially beyond 12-months after surgery. A recent 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 ‘lost to follow-up’ as early as 1 year post-surgery with attrition at two years of 49.8% for LAGB and 75.2% for LRYGB⁽⁵⁾. Concerns about low retention and high attrition revolve around safety, quality, efficacy, and accuracy of reports. Additionally, an important concern is that patients lost to follow-up are more likely to have poor weight loss⁽¹¹⁾. Should low retention lead to bias, both internal and external validity of the study are degraded which limits the ability to draw inferences^(8,12-14).

The objective of this manuscript is to present the Longitudinal Assessment of Bariatric Surgery study (LABS) retention strategies, the 24-month participant retention data, an analysis of participants who “missed” research visits, and a subjective ranking of the efficacy of the retention strategies in use.

Method

LABS is a multi-center, observational, longitudinal study that includes cohorts of adults enrolled prior to bariatric surgery and followed periodically after surgery. The goals of LABS are to assess the risks and health benefits associated with bariatric surgery and to identify aspects of the procedures, as well as patient characteristics, associated with optimal outcomes⁽¹⁵⁾. LABS consists of LABS-1 which studied a large cohort of consecutive patients undergoing bariatric surgery to determine short-term safety⁽¹⁶⁾ and LABS-2 which includes a smaller cohort with more extensive data collection and longer follow-up to address questions of longer-term safety and efficacy. LABS-2 enrolled adults (at least 18 years old) who had not had previous bariatric surgery and who were seeking bariatric surgery provided by LABS-certified surgeons at 10 clinical centers, in 6 geographic areas of the United States. The participating clinical centers are the University of Pittsburgh Medical Center (Pennsylvania), Columbia University Medical Center, Weill-Cornell University Medical Center, and Valley Hospital (New York), University Health Systems of Eastern

North Carolina (now the Vidant Medical Center) and East Carolina University (North Carolina), Neuropsychiatric Research Institute (North Dakota), Oregon Health & Science University and Legacy Good Samaritan Hospital (Oregon), and Virginia Mason Hospital and the University of Washington (Washington). LABS has a Data Coordinating Center at the University of Pittsburgh Graduate School of Public Health. Of those who consented, 2458 participants proceeded to surgery between March 24, 2006 and April 24, 2009 and comprise the LABS-2 cohort. All centers had institutional review board approval. The study is registered at www.clinicaltrials.gov (NCT00465839).

LABS-2 required a baseline evaluation of 1½ -2 hours that included multiple self-assessment forms, multiple physical measures, blood and urine collections, physical activity monitoring and medical assessment, often by consultants in addition to the surgeon. Post-operative data collection time points following surgery were: 30-days, 6 months, 12 months and annually thereafter. The 30-day and 6-month visits were abbreviated and the 12-month and subsequent annual visits were similar to the baseline visit through the first five years of follow-up.

A Retention and Recruitment Subcommittee was formed before recruitment began. It included researchers, coordinators, and bariatric clinicians experienced in longitudinal and other research designs. The subcommittee developed a number of retention strategies, many of which were created following review of the retention literature and contact with personnel from other longitudinal studies, including Look AHEAD.

To standardize some procedures across clinical centers, the committee prepared a recruitment and retention chapter for the LABS Manual of Operations and Procedures (MOP). The guide delineated standard recruitment and retention strategies including a detailed call protocol for contact of participants, and suggestions for identifying and resolving retention problems, such as protocol non-adherence and behavioral issues indicating dissatisfaction or discouragement with aspects of their LABS experience. In addition to standardizing procedures, LABS' site geographical distribution, differing cultural values and IRB regulations required flexibility and customization by site. There are major differences between the high minority population of eastern North Carolina and the Anglo-Saxon, Native-American mix of Oregon and Washington. Retention strategies were implemented and retention was monitored so strategies could be revised to meet changing needs of study participants to remain engaged.

Retention strategies were in place for the 24-month visit. These strategies were implemented by all of the sites, except when not permitted by the local IRB (e.g. distributing laboratory results) or not standardized across sites due to demographic or geographical differences (e.g. variations in transportation modes used and miles travelled to determine travel reimbursement).

The retention strategies were designed to enhance voluntary participation in LABS and minimize potential barriers to retention, fulfilling endpoint goals. Tangible strategies include: an honorarium, travel reimbursement, a progress report that included cumulative physical measures over the course of the study (weight, BMI, % body fat, neck and waist girth, pulse and blood pressure), results from the physical activity monitor, select laboratory test results (e.g. lipids, Hemoglobin A1C), birthday, holiday or surgery anniversary cards and various gifts with the LABS logo (e.g. pens, water bottles). Intangible strategies are generally focused on interaction and communication. They are: a participant website (www.niddklabs.org), quarterly newsletters, and quarterly coordinator contact. Additionally, participant, family, emergency, and primary care physician (PCP) contact information are updated at each contact. Standard scheduling and contact protocols are utilized for the

preferred visit window, 2 months before and after the surgery anniversary date. The extended annual visit window is 6 months before and after the surgery anniversary date. Telephone calls per a standard call protocol, written communication and flexible scheduling options were designed for the convenience of the participants, including research visits conjoined with clinical visits. If a participant could not be scheduled and the visit window was closing, an “options” letter was utilized outlining reduced burden alternatives for participation (e.g. completing the self-report questionnaires by mail or a portion of them over the phone).

When participants could not be reached, a comprehensive protocol was initiated. Clinic or hospital scheduling databases, emergency contacts, certified registered letters, public-record and Internet people-search databases, including social media, were used to establish vital status and validate the participant’s address. If all attempts at locating a participant failed, medical records were reviewed and PCP follow-up information was requested, if permitted by the local IRB. Participants were purposefully not inactivated for missing even multiple visits due to the hope for re-engagement at a later time point.

A retention survey was developed and completed by participants at every study visit. This survey assessed participant attitudes, motivations, needs and barriers and results were used to make modifications to the retention strategies on an ongoing basis.

As a subjective measure of the effectiveness of the retention strategies at the 24-month time point, the research coordinators at each site were sent a list of the retention strategies. The research coordinators were asked to present a site consensus ranking the strategies according to their apparent efficacy.

Results

Select baseline characteristics of the LABS-2 cohort are presented in Table 1. The cohort (n=2458) reflects similar demographic characteristics to other large bariatric surgical cohorts except for a higher percentage of white participants (86.5 %) and a lower percentage of Hispanic participants (4.9%), perhaps reflecting the patient base in the sites participating in LABS^(17, 18).

Within 12 months of surgery, 10 participants (0.4%) in LABS-2 died and another 22 (0.9%) participants were inactivated, primarily due to participant choice. Between 12 and 24 months after surgery, another 7 (0.3%) died and 14 (0.6%) were inactivated (See Table 2). Eighteen (50.0%) of the 36 who were inactivated did not communicate any specific reason, either verbally or in survey response. Specific reasons for discontinuing participation included: no longer interested (n=5), too busy (n=4), work responsibilities (n=2), too burdensome (n=2), distance (n=2), poor surgical outcome (n=1), and unable due to health (n=1). One participant was discontinued due to noncompliance with the LABS-2 protocol.

Vital status was known for 98.7% and 97.3% at 12 and 24 months, respectively (Table 2). In Table 2, “Data Obtained” is defined as any data element from a self- or clinician assessment questionnaire, physical measurement or biospecimen. At least one data element was obtained for 96.5% and 93.8% participants at 12 and 24 months, respectively. Weights were available for 95.2% and 92.2% at 12 and 24 months, respectively. An in-person visit is defined as a face-to face evaluation of the participant by a LABS certified coordinator and 79.0% and 66.2% of participants had such a visit at 12 and 24 months, respectively.

“Missed” visits are defined as no data collected or only vital status known. Missed visits at 12 and 24 months occurred for 3.5% and 6.2%, respectively, of those still alive and participating in the study. The most common reason for a missed 24-month visit was “could

not be contacted or located” (93 of 148 missed visits, 62.8%). Other reasons for missed 24 month visits were: “other commitments” (n=22), “scheduled but did not show” (n=15), “refused” (n=10), “out of town” (n=4), and “other” (n=4).

There were 77 (3.2%), 85 (3.5%) and 148 (6.2%) participants who missed the 6-month, 12-month or 24-month visits, respectively. Of these, 181 participants missed only one visit, 40 participants missed two visits and only 15 participants missed all three visits. Some participants who missed visits participated in data collection at later study time points. For example, 42 participants could not be located or contacted at 6-months and data were obtained for 23 (54.7%) of them at 12 months. Similarly, 52 participants could not be located or contacted at 12 months and data were obtained for 18 (34.6%) of them at 24 months.

The research coordinators at each of the six LABS sites (some sites had two or more centers) were asked to rank the retention strategies according to effectiveness at the 24-month time point. The retention strategies were divided into two categories, tangible and intangible. We asked the site coordinators to prioritize their most effective retention strategies on a scale of 1 to 7, with 1 being the most effective and 7 the least effective. The average scores (lower is better) for the top three in the tangible category were: honoraria (1.2), travel reimbursement (2.2) and progress report (3.2); the top three average scores for the intangible category were: visit specific tracking and continual updating contact information (1.3), standardized scheduling and contact protocols (2.5) and comprehensive participant locating protocols (3.3).

Discussion

Achieving high retention rates in longitudinal and bariatric surgical research is difficult and retention rates decrease substantially with time^(7, 19-21). Attrition is unavoidable even with extensive planning and implementing a wide range of retention strategies. One goal of LABS from the start was to monitor retention and attrition and to enlist strategies to maximize retention (minimize attrition). These steps may explain why the LABS-2 retention data are superior to many published reports. Vital status and weight were available on a large majority of participants at 24 months.

Historically, long-term studies of bariatric surgery that reported high retention rates utilized methodologies that are no longer feasible or applicable in the US health care system. MacDonald et al.⁽⁹⁾ followed 837 bariatric surgical patients from 1980 – 1996 with a 95% follow-up but they provided free care to the patients and their families (now limited legally), had a van to bring patients to the medical center (now raises liability issues) and requested help from the sheriff if they could not find the patients (HIPAA violation). Sjostrom and his group⁽¹⁰⁾ had high retention due to the common record system of Swedish universal health care.

Recently, Higa et al.⁽²¹⁾ reported on gastric bypass patients with 66% two-year retention (only half of those contacts being in-person) and 25% ten-year retention with only 7% of participants being seen in person at that time point. Fifty-one percent of those seen at 10 years were reported to have a vitamin deficiency. In addition to its potential deleterious effect on scientific investigations, poor retention has safety issues since without retention, it is difficult to prevent and monitor, and impossible to treat, surgical complications.

Attrition will always occur in research and clinical practice due to participant choice and mobility, particularly in the United States since it has such a mobile society⁽¹⁹⁾. Poor retention could affect estimated measures of outcomes, e.g. complication rates, weight change, comorbidity prevalence, and quality of life all of which are measures of efficacy⁽⁵⁾.

One cannot assume that patients or participants who are evaluated post-surgery are comparable to those who are not evaluated.

The relatively good LABS retention results required a concerted effort to develop and implement a multi-faceted retention plan composed of several retention strategies focusing on many themes, modified by local sites as needed due to IRB requirements and geographic and participant characteristics. Of importance, these strategies consume significant resources of time, personnel, and money. Thus, the retention rates enjoyed by the LABS study are unlikely to be achieved in clinical practice, but some of the strategies discussed are potentially helpful.

Attrition was low due to a general policy of not inactivating participants unless they requested to withdraw and the use of successful retention strategies. From the beginning, it was very difficult to get information about why participants were requesting to withdraw. This led to developing and administering surveys of the motivations, needs, issues of inconvenience and interests of those who participated in an effort to continually modify and develop strategies to prevent withdrawals. In addition, LABS developed specific strategies for systematic tracking, scheduling, contacting and locating participants.

In spite of these many efforts, missed visits occurred. The most common reason for a missed visit at 24 months was “could not be contacted or located”. The phrase “could not be located” barely reflects the challenge of finding some participants. Some moved without leaving an address even for family members, military members and families may have gone on a remote assignment, some changed their names, some avoided calls to escape bill collectors, and some changed from land lines to mobile telephone equipment. The list is long and varied. However, it is important to note that the majority of those who missed visits only missed one visit. Importantly, several participants who missed one or more visits returned at a later time point for a visit. This is especially interesting because the most common reason for a missed visit was that participants could not be contacted. Therefore, missed research or clinical visits is not a reason to inactivate participants or consider them “lost to follow up”.

Participant retention is important, but equally important is “data” retention which is the amount of data collected relative to the amount of data requested of participants ⁽²²⁾. In LABS, the percentage of visits that were in-person, which were necessary to collect some of the data, decreased from 12 to 24 months. There is no established standard for longitudinal studies with regard to data retention ^(23, 24), but LABS investigators were proactive concerning this important study parameter. For a limited time, LABS offers home study visits utilizing a national study data collection service in an effort to capture some of the data that would otherwise be lost without an in-person visit.

In many reports of bariatric surgical research, details about retention methods and long-term follow-up rates are lacking ⁽⁷⁾. In the spirit of the CONSORT (Consolidated Standards of Reporting Trials) ⁽²⁵⁾ and the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) ⁽²⁶⁾ research reporting guidelines, we have presented the retention strategies and provided a description of participants who were inactivated and who missed visits as well as a range of retention data. We hope that others will present similar retention data in reporting future long-term studies and possibly add to this list as the science of retention in bariatric surgical research develops.

Retention strategies are rarely discussed in the bariatric surgery research literature. A systematic review of the literature seeking research retention strategies found only 21 articles that identified retention strategies and outcomes, none in the bariatric surgery literature ⁽⁸⁾. These studies reported on retention strategies from the “lessons learned”

aspect. LABS did not attempt to quantitatively evaluate the efficacy or cost effectiveness of specific retention strategies. However, similar to the Behavior Change Consortium, which explored strategies used to retain participants in NIH behavior interventional trials⁽²⁷⁾, we did offer a subjective ranking of the retention strategies. This report offers some guidance to bariatric researchers and bariatric clinicians in the allocation of their resources for retention strategies in their retention plans.

Factors that have been shown in other studies to be associated with retention include participant characteristics as well as strategies^(8, 28-34). In this paper, we focus on strategies and reporting the relatively high rates of retention that LABS was able to achieve implementing these strategies. Future work will attempt to identify participant and procedure factors that may be associated with retention.

Though LABS does have extensive retention strategies and means to collect data, we have not exhausted all possibilities. For example, the National Death Index is a resource that we are exploring to obtain vital status for those who cannot be located or contacted. To maximize its cost-effectiveness, we may utilize it in the future.

It is important to recognize that LABS is a research study and data collection was separate from clinical care so the retention data reported here cannot be directly extrapolated to bariatric surgical clinical practice. We know that some participants came regularly for research visits but did not attend follow up clinical visits, and vice versa. In other cases, participants found it convenient to have their research visit in conjunction with a clinical visit so would attend both if these could be coordinated. We did not include in our data collection the assessment of the number of participants who were following up with the bariatric surgical team in addition to the research study. We have since added this to our data collection as well as assessing those who present for research follow-up and clinical bariatric surgical follow-up on the same day.

Conclusions

Retention in longitudinal bariatric surgical research is difficult. Attrition is unavoidable even with extensive planning and the implementation of a wide range of retention strategies. LABS systematically explored retention and attrition in bariatric surgical research and developed and implemented a retention plan involving many strategies overlapping many themes. LABS retention data are more comprehensive and are superior to many published reports, but retention requires considerable effort and resources. The retention rates achieved by LABS cannot reasonably be expected for clinical practice but the strategies discussed may be helpful.

Missing a study visit does not indicate “lost to follow-up”. Participants may return after years, having missed a number of visits. Further research is needed to identify the efficacy and cost effectiveness of specific retention strategies, and other factors that may affect participant retention.

Evaluating interventional procedures with long term, rigorously defined follow up is difficult and costly. Without such studies, however, appropriate decisions regarding risk, benefit, and value are impossible.

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Table 1
LABS Cohort Baseline Characteristics

	Total (n=2458)	
Age (yrs.), Range Mean (sd)	18.0-78.0	45.5 (11.5)
Female	1931	78.6 %
Race (29 missing)		
White	2100	86.5%
Black	254	10.5 %
Other	26	1.1 %
Multi-race	49	2.0 %
Hispanic (1 missing)	120	4.9 %
Weight (kg), Range Median (Q1, Q3)	75.0-289.5	128.6 (115.0, 147.3)
BMI (kg/m ²), Range Median (Q1, Q3)	33.0-94.3	45.93 (41.8, 51.4)

*
BMI = body mass index

Table 2
12 and 24 month LABS Retention Data

	12-Month Visit		24-Month Visit	
	N	%	N	%
Data Obtainable	2426		2405	
Inactivated Participants	22	0.9	36	1.5
Deaths	10	0.4	17	0.7
Vital Status Known	2425 [*]	98.7	2391 ^{**}	97.3
Data Obtained ^{***}	2341	96.5	2256	93.8
Weight	2309	95.2	2218	92.2
In-person Visit	1917	79.0	1591	66.2
Missed Visits	85	3.5	148	6.2

* All 2458 have passed the 12-month follow-up assessment window

** All 2458 have passed the 24-month follow-up assessment window

*** At least one data element obtained