

Longitudinal Assessment of Bariatric Surgery (LABS)

What is the Longitudinal Assessment of Bariatric Surgery (LABS)?

The Longitudinal Assessment of Bariatric Surgery was originally known as the Bariatric Surgery Clinical Research Consortium. LABS is a National Institutes of Health (NIH)-funded consortium of six clinical centers and a data coordinating center working in cooperation with NIH scientific staff to plan, develop, and conduct coordinated clinical, epidemiological, and behavioral research in bariatric surgery.

What is bariatric surgery?

Bariatric surgery restricts stomach size and/or leads to decreased absorption of nutrients. These procedures can have dramatic health benefits, such as improved control of blood sugar or even reversal of type 2 diabetes, but they also carry substantial risks, including death.

How many people have had bariatric surgery?

According to the former American Society for Bariatric Surgery (now the American Society for Metabolic and Bariatric Surgery, or ASMBS), the number of procedures increased from about 16,000 in the early 1990s to more than 103,000 in 2003. The ASMBS estimated that 205,000 people in the United States would have bariatric surgery in 2007.

Why did the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) launch LABS?

- A majority of U.S. adults are overweight or obese, with more than 30 percent of adults considered obese (Body Mass Index, or BMI, greater than 30). An increasing number of adults are considered extremely obese (BMI greater than or equal to 40).
- Numerous studies have shown that behavioral therapy to improve diet and physical activity can lead to weight loss of approximately 5 to 10 percent over 4 to 6 months.
- When a person loses weight, obesity-related conditions such as high blood pressure and type 2 diabetes improve, but if a person regains weight, these benefits are lost.
- In many cases, a person who regains weight ends up weighing more than he or she weighed before the intervention. Doctors need effective weight-loss methods for people with extreme obesity and effective ways to maintain long-term weight loss.
- Currently, the most effective way for people with extreme obesity to lose substantial weight and improve their weight-related health conditions, such as high blood pressure and type 2 diabetes, is through bariatric surgery.
- Although an increasing number of persons with extreme obesity are undergoing bariatric surgical procedures, there has been little systematic research to help determine its risks and benefits or to provide guidance on appropriate patient selection. To facilitate research in this area, NIDDK established LABS.

What is the goal of LABS?

LABS has brought together experts in bariatric surgery, obesity research, internal medicine, endocrinology, behavioral science, outcomes research, epidemiology, and other relevant fields to plan and conduct studies that will analyze the risks and benefits of bariatric surgery and its impact on the health and well-being of patients with extreme obesity, and identify the kinds of patients who are most likely to benefit.

How will LABS accomplish its goal?

The consortium has developed a database for collecting standardized information on patients undergoing bariatric surgery at the participating clinical centers. Rigorously collected information on patient characteristics, types of surgery, medical and psychosocial outcomes, and economic factors will ultimately provide science-based information on the risks and benefits of bariatric surgery. This information should lead to rational recommendations for clinical care.

LABS is also supporting two clinical studies that were proposed, designed, and approved by the Steering Committee (see below). These studies address:

- The impact of surgical procedures on insulin resistance and type 2 diabetes.
- The impact of bariatric surgery on rates of psychopathology, in particular depressive illness and quality-of-life, post-operatively.

LABS Centers also collect data and specimens for future research. These data will provide a valuable resource for the future study of obesity and its complications.

How is LABS organized?

- Through a competitive, peer-reviewed process, principal investigators at six clinical centers and a data coordinating center were funded in September 2003. These investigators are listed on page 4.

- The principal investigators at the clinical centers and data coordinating center and the NIH project scientist comprise the Steering Committee, which is the governing body for the consortium.
- The Steering Committee has met on a frequent basis to develop the database and plan the clinical protocols.
- When LABS started, the Steering Committee members organized working groups to develop the protocols. The working groups have completed most of their work, and LABS has established other subcommittees to address ancillary studies, adjudication, and publications and presentations.
- Investigators, scientists, and clinicians from the participating centers with relevant expertise participate in the committees and working groups.

What is the study timeline for LABS?

- LABS was funded in September 2003.
- During the first 18 months, investigators worked together to develop the database, plan the clinical protocols, and obtain appropriate human subjects approval. The LABS database started enrolling patients in March 2005.

What has LABS accomplished since it started?

LABS is divided into three parts:

- LABS 1, which evaluates the short-term safety of bariatric surgery for a period of 30 days.
- LABS 2, which evaluates longer-term safety and efficacy of bariatric surgery (ongoing).
- LABS 3, which includes detailed mechanistic studies in the LABS subjects.

LABS 1 started to enroll patients in March 2005. Over 5,000 subjects completed LABS 1 follow-up, which determines adverse outcomes within the first 30 days after surgery. This study is complete and the data collected is being analyzed.

LABS 2 began recruiting patients in February 2006. The goal is to recruit 2,400 patients to form a detailed description of health problems before surgery and complications after surgery. The patients in LABS 2 will be followed up at 6 months, 1 year, and then yearly after surgery. Researchers will assess multiple areas concerning surgery, including behavior, diabetes, liver function, health service delivery, and economics.

The LABS 3 diabetes study began recruiting patients in December 2007 and it will examine the physiological mechanisms that contribute to improvements of glucose homeostasis in type 2 diabetes mellitus following gastric bypass surgery in a subset of LABS 2 subjects.

The LABS 3 psychosocial study began recruiting patients in April 2007 and includes an in-depth assessment of current and prior psychopathology and eating problems in a subset of LABS 2 subjects.

What funds are available for LABS?

At the start, LABS was funded at \$3 million per year for 5 years, for a total of \$15 million. There were also opportunities for investigators to apply for additional funding for ancillary studies first through a request for applications (RFA) and currently through a Program Announcement. Information on Program Announcement PAR-07-024 is at: <http://grants.nih.gov/grants/guide/pa-files/PAR-07-024.html>.

In 2007, an expert panel recommended that NIDDK extend LABS for an additional 5 years. The extension will allow researchers to continue data collection and analysis. A limited-competition RFA proposal has been issued.

The Office of Research on Women's Health (ORWH) provided funds to be used for LABS research related to women's health issues. Information on the ORWH can be found at: <http://www4.od.nih.gov/orwh>.

Will LABS provide free bariatric surgery for study participants?

No. LABS cannot cover the costs of bariatric surgery or patient care. Study participants must be able to support the cost of their surgery and related patient care through medical insurance or other means. However, any tests or examinations done solely for research purposes rather than routine patient care will be done at no cost to participants.

How can patients get more information about enrollment in LABS?

For more information about enrollment in LABS, see: <http://www.niddklabs.org>.

In what other ways might LABS help to advance future obesity research?

- LABS may provide the preliminary data needed for future investigator-initiated research on bariatric surgery and obesity. For example, if LABS investigators are able to identify metabolic and endocrine changes that take place after bariatric surgery, this information would allow researchers to submit independent applications for full-scale clinical studies.
- LABS may encourage researchers to study the causes and treatments of obesity and its related health problems by providing access to laboratory specimens and tissues.
- The presence of coordinated obesity research efforts at participating institutions may provide opportunities for research and clinical training to students in the health professions, as well as to young investigators.
- Information on the types of data being collected in the LABS database (not individual patient information) will be available on the LABS website, so that other interested clinicians and researchers can collect similar data on their patients, facilitating additional research on bariatric surgery. See <http://www.edc.pitt.edu/labs/Public/LABS-1DescriptionPaper/>.

For information about obesity research at NIH, see:

NIH Obesity Research

<http://www.obesityresearch.nih.gov>

American Society for Metabolic and Bariatric Surgery

<http://www.asbs.org> (This site is not affiliated with NIH.)

Weight-control Information Network

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The Weight-control Information Network (WIN) is a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health, which is the Federal Government's lead agency responsible for biomedical research on nutrition and obesity. Authorized by Congress (Public Law 103–43), WIN provides the general public, health professionals, the media, and Congress with up-to-date, science-based health information on weight control, obesity, physical activity, and related nutritional issues.

Publications produced by WIN are reviewed by both NIDDK scientists and outside experts.

This fact sheet is also available at

<http://www.win.niddk.nih.gov>.

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