

Longitudinal Assessment of Bariatric Surgery (LABS)

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

The Longitudinal Assessment of Bariatric Surgery (LABS) 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 **significant** health benefits, such as reversal of type 2 diabetes or improvements in sleep apnea, but the procedures 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 estimates that 220,000 people in the United States had bariatric surgery in 2008.

Why did the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) establish 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, many of these benefits are lost.
- Because weight loss is so difficult to sustain over the long term, especially in those who are extremely obese, doctors need effective methods for weight loss and weight maintenance in this population.
- Currently, the most effective way for people with extreme obesity to lose substantial amounts of weight and improve their weight-related health conditions 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 psychiatric illness and quality of life.

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 evaluated 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 began patient enrollment in March 2005. The study was completed in December 2007 and published in the July 30, 2009 issue of *The New England Journal of Medicine*. To review study results, visit <http://content.nejm.org/cgi/content/short/361/5/445>.

The consortium followed 4,776 adults who underwent bariatric surgery for the first time. Researchers evaluated complications and death rates within the first 30 days after surgery. Listed here are some of the key findings:

- Within 30 days of surgery, 4.1 percent of the patients had at least one major adverse outcome. Adverse outcomes were defined as death, development of blood clots, repeat surgeries, or failure to be discharged from the hospital within 30 days of surgery.
- Mortality rates at 30 days were low: 2.1 percent among the small percentage of participants who underwent open Roux-en-Y gastric bypass, and 0.2 percent among patients who underwent laparoscopic Roux-en-Y gastric bypass. No deaths occurred among patients who underwent laparoscopic adjustable gastric banding.
- Complications varied by procedure, but researchers noted that patients who underwent open Roux-en-Y gastric bypass tended to be heavier and sicker than others in the study. After adjusting data for patient and medical center characteristics, no significant differences in complication risk could be attributed to the type of Roux-en-Y procedure.
- Patient factors can increase risk for complications. For example, patients with a BMI of 75 had a 61-percent higher risk of complications than patients with a BMI of 53. Other factors identified to increase complication risk were a history of deep vein blood clots and a diagnosis of sleep apnea.

LABS 2 has recruited more than 2,400 patients since beginning in February 2006. Enrollment into LABS was completed in April 2009. The patients enrolled in LABS 2 will be followed up at 6 months, 1 year, and then yearly after surgery. Researchers will assess multiple areas before and after surgery to help determine longer-term medical, psychosocial, and economic risks and benefits.

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 a subset of patients with type 2 diabetes mellitus following gastric bypass surgery.

The LABS 3 psychosocial study began recruiting patients in April 2007 and includes an in-depth assessment of current and prior psychological functioning and eating problems in a subset of LABS 2 subjects who have had bariatric surgery.

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, NIDDK extended LABS for an additional 5 years to allow researchers to continue to collect data yearly in LABS participants.

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>.

Is recruitment for LABS still ongoing?

No, enrollment in LABS is now complete, although current participants continue to be followed yearly.

How can I get more information about 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.gsph.pitt.edu/labs/>.

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For Further Information

For additional assistance with media queries, including a list of LABS investigators with specific expertise in topics related to bariatric surgery, contact: Ms. Leslie L. Curtis, M.A. (301) 496-3585, NIDDK Office of Communications and Public Liaison, (301) 496-3583, curtisl@extra.niddk.nih.gov. For more information about LABS, see <http://www.niddklabs.org>.

For general information about bariatric surgery, obesity, and related topics, contact:

The Weight-control Information Network (WIN)
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Bethesda, MD 20892-3665
Phone: (202) 828-1025; Toll-free: 1-877-946-4627
<http://www.win.niddk.nih.gov>

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American Society for Metabolic and Bariatric Surgery
<http://www.asbs.org> (*This site is not affiliated with NIH.*)

For information about obesity research at NIH, see:

NIH Obesity Research
<http://www.obesityresearch.nih.gov>

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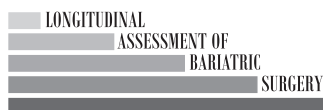
The Weight-control Information Network (WIN) is a national information service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health, which is the Federal Government's lead agency responsible for biomedical research on nutrition and obesity. 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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