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Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS): Methodologic Features of the First Prospective Multicenter Study of Adolescent Bariatric Surgery

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More than 20 million adults and 2 million children and teenagers in the USA have extreme obesity (body mass index $\geq$ 40 kg/m^2), a condition associated with premature morbidity and mortality (1,2). In adults, bariatric surgery results in prolonged weight control and improvement in serious obesity comorbidities (3). Bariatric surgery performed late in the course of comorbid conditions may not be as effective as surgery performed earlier. Based on these factors, we proposed that surgery for extreme adolescent obesity may be a beneficial option for highly selected teenagers (4), but large-scale prospective studies using reliable and valid measures that are systematic assessed are still lacking.

To facilitate and accelerate data collection and research in bariatric surgery, the National Institute of Diabetes & Digestive, and Kidney Diseases established the Longitudinal Assessment of Bariatric Surgery (LABS) consortium, a prospective observational study of adults undergoing bariatric surgery. *Teen*-LABS, an ancillary study to LABS, is also a prospective observational cohort study with the goal of collecting coordinated clinical, epidemiological and behavioral data in adolescent bariatric surgical patients (5). The design of Teen-LABS is patterned from the second phase of LABS, using similar research methodology and data collection instruments. The detailed methodology of the LABS study is now published (6) and available in a public access domain (7). The LABS and Teen-LABS studies will afford the first opportunity to understand broad ranging outcomes of bariatric

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surgery using duration of obesity as the moderating variable. Such an analysis will permit a realistic estimate of the risks and benefits of bariatric surgery in adolescent years and will lead to a better understanding of the plasticity of important medical and psychosocial obesity-related comorbidities.

More specifically, Teen LABS will determine whether health significantly differs between adolescents and adults seeking bariatric surgery, identify early (30 day) and intermediate term (1-2 year) health risks for adolescents and adults undergoing bariatric surgery, and compare the psychosocial status of adolescents and adults with extreme obesity undergoing surgery. Psychosocial status will be examined in three domains: eating behaviors, depressive symptoms, and health related quality of life.

Design Summary

A prospective, observational cohort design will be used to collect data during standard clinical care of 200 adolescent bariatric patients (age ≤ 19), most of whom will be undergoing roux en Y gastric bypass between 2007 and 2009. Data regarding family environment will also be obtained from caregivers of these adolescent patients. Adolescent subjects will be recruited from 4 centers: Cincinnati Children's Hospital Medical Center, Texas Children's Hospital, Children's Hospital of Alabama, and University of Pittsburgh Medical Center. The demographic profile of anticipated enrollment for adolescents is shown in Table 2 in the online supplementary materials. In addition, a comparison group of 200 adults with history of obesity by age 18 years will be selected from Phase 2 of LABS. Adult comparitors will be recruited within the context of the LABS study at 5 centers: University of Washington, Oregon Health Sciences University, University of Pittsburgh Medical Center, East Carolina University, and the Neuropsychiatric Research Institute. Teen-LABS assessments are shown in Table 2. Teen-LABS subjects will provide biospecimens to address hypotheses relevant to this study and to provide a resource for future biological studies. If liver biopsies are performed as standard care at participating clinical centers, slides will be obtained for research purposes and analyzed by a central NIDDK hepatopathologist.

As with other major NIH-sponsored clinical studies (8), Teen-LABS encourages ancillary study proposals which propose questions and test hypotheses that are relevant to the goals and purposes of Teen-LABS but are not specifically addressed by the Teen-LABS-funded core or any other sub-study protocols within Teen-LABS. An ancillary study, by definition, derives its financial support from sources other than the funds awarded for support of the Teen-LABS consortium. Ancillary studies will generally utilize information about, or specimens obtained from patients already enrolled in the Teen-LABS core database. However, they may also involve additional study sites, investigators, specimens and data collection, procedures, cohorts, or other interventions provided that the proposed study does not interfere with the observational nature of Teen-LABS. Well-defined ancillary protocol submission guidelines can be found on our study website, www.cincinnatichildrens.org/teen-LABS, and the design of ancillary proposals should take into consideration details of LABS design (6,7), as Teen-LABS was patterned closely after these clinical research methods.

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Table 1

Demographics of Anticipated Adolescent Enrollment

	Female	Hispanic	Black	White	Multi/other race
TCH	65%	29%	35%	35%	0%
CCHMC	68%	0%	12%	86%	2%
UPMC	20%	0%	20%	80%	0%
UAB	63%	0%	38%	63%	0%
Overall	64%	6%	19%	74%	1%

Table 2

Baseline, 6, 12, 24 month postoperative data elements. Asterisk (*) indicates items which will only be obtained at baseline (before operation).

- Adolescent's month and year of birth, gender, height, weight, race, ethnicity *
- Weight history*
- Preoperative weight loss program characteristics*
- Smoking history, other conditions possibly affecting outcomes
- Primary caregiver demographics, weight, height
- Assessment of obesity-related comorbidities
- Medication usage
- Anthropometrics and vital signs
- Study laboratory values: vitamin A, parathyroid hormone, 25-OH vitamin D, ferritin, vitamin B12 / folate, high sensitivity CRP, glucose, serum and urine albumin, insulin, vitamin B1, calcium, lipids, HbA1c, serum and urine creatinine, cystatin C, and transferrin
- DNA*, serum, plasma, and urine collection and banking for future studies
- Fitness (400 meter corridor walk, physical activity monitoring)
- Psychosocial assessments: Beck Depression Inventory, SF-36, IWQOL-Kids, and Questionnaire of Eating and Weight Patterns-Revised
- Nutritional supplements prescribed for postoperative period
- Nutritional supplement adherence
- Postoperative healthcare utilization

Operative data elements. These elements are collected by the surgeon immediately after the surgical procedure.

- Anesthesia risk-derived classification
- Planned procedure, planned approach, previous obesity surgery
- Procedure(s) and concurrent procedures performed
- Method of surgical procedure and anastomosis testing, if applicable
- Deep vein thrombosis prophylaxis before and after surgery
- Adverse intra-operative events

30-day post-operative outcome elements. These data will be collected within a desired window of 30-55 days. If patient cannot be reached within this window, the objective elements of the form which can be completed by chart review without patient input will be collected by coordinator.

- Length of hospital stay
- Discharge location
- Major complications, re-hospitalization(s), unanticipated surgical, endoscopic, radiologic or pharmacologic interventions, wound status
- Nutritional supplement adherence