

**Study Title:** The effect of postoperative incentive spirometry on pulmonary function and pulmonary complications in bariatric surgery

**Protocol Version Number:** #3

**Protocol Date:** 7/17/15



## Research Protocol

**Principal Investigator:** Dmitry Nepomnayshy

**Sub-Investigators:** David Brams, Laura Doyon, Haddon Pantel, Thomas Schnelldorfer

**Research Objectives / Specific Aims / Outcome Measures:** The primary objective of this study is to evaluate the impact of incentive spirometry on postoperative respiratory status in bariatric surgery. The secondary objective is to evaluate the impact of incentive spirometry on postoperative respiratory complications in bariatric surgery. We hypothesize that the use of postoperative incentive spirometry in bariatric surgery has no impact on postoperative respiratory status or rates of pulmonary complications. The primary outcome measure of postoperative respiratory status is defined as the percent of subjects with oxygen saturation less than 92% at 6, 12 and 24 hours after their operation. This threshold is being used, as it is a clinically significant point at which if patients fall below this value they are placed on supplemental oxygen. At the request of the IRB a pilot study was conducted to evaluate the occurrence rate of the primary outcome measure of oxygen desaturation below 92%. A retrospective analysis was performed on all patients who underwent bariatric surgery, from the implementation of EPIC on 3/31/2015 to the submission of this project on 4/24/15. Of those 23 patients 34.7% (8/23) had oxygen saturations below 92% at 6 hours postoperatively. At 12 hours postoperatively, 30% (7/23) had oxygen saturations below 92%. At 24 hours postoperatively there were no patients with oxygen saturations below 92%. These findings are consistent with our previous review of the literature (Zoremba 2009, Sucandy 2013). Based on these pilot study findings we concluded that postoperative oxygen saturation below 92% is a commonly occurring event, the occurrence at Lahey is similar to previously reported rates, and that this proposed study is adequately powered.

The secondary outcome measures will include postoperative respiratory complications (atelectasis found on chest imaging, pneumonia, or re intubation) up to 30 days postoperatively. Additionally time to wean off supplemental oxygen, oxygen saturation comparison between groups, and respiratory rate will all be secondary outcome measures.

**Background Information / Significance / Scientific Rationale:** An incentive spirometer is a device in which a patient inspires slowly and as deeply as possible, and then holds their breath for 2–6 seconds. Use of these devices is speculated to improve pulmonary function in the postoperative period, though data to support this is lacking (Cochrane Database 2014). Patients at risk for postoperative decline in respiratory function and postoperative respiratory complications are the morbidly obese and patients undergoing foregut surgery. Thus bariatric surgery provides a cohort with both of these risk factors. While currently all bariatric surgery patients at Lahey receive these devices and they are cited in the literature as part of enhanced recovery protocols for bariatric surgery, no data has supported their benefit in bariatric surgery. Data has shown that their use preoperatively has no benefit on postoperative lung function (Cattano 2010). Additionally the CDC states that their use is not associated with significant improvements of inspiratory capacity prior to laparoscopic bariatric surgery and may not be useful to prevent postoperative decrease in lung function (Restrepo 2011).

Despite the lack of evidence supporting the efficacy of these devices Lahey Clinic and bariatric surgery centers across the country continue to use these devices. Lahey Burlington spent \$33,491.13 on purchasing these devices in the 2013-2014 fiscal year. In addition to this monetary cost, time is spent in the preoperative bariatric clinic by MD or advanced practitioners in teaching about the use of incentive spirometers. Once patients arrive on the surgical floor, nurses are ordered to have the patients use the

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device every 6 minutes for a total of 10 times per hour while awake. This frequency of device use is recommended by the Cleveland Clinic, however the National Institute of Health via their MedlinePlus website recommends using the device once every 1 to 2 hours after surgery. Regardless of frequency this still requires significant nursing time and thus resources in the early postoperative period. At the request of the IRB, patient compliance with the standard order of device use every 6 minutes was evaluated. As the current order is to be the control, having a baseline assessment of actual use provides for a better control. Currently the spirometer has a paper log included in the package provided for by the manufacturer for patients to record how often and at what volumes they are using the device. We had our nursing colleagues provide these logs to 10 sequential postoperative bariatric patients. These were then collected at the time of discharge. Of the 10 logs distributed 5 were returned for analysis. Results from these indicate that the actual mean compliance was 5 times per day (range 3 to 7) on postoperative day 1, on postoperative day 2 patients on average used the device 12 times per day (range 9 to 16). While this is significantly less than the current order of 10 times per hour, it is in line with the National Institute of Health recommendations of once every 1 to 2 hours. From this data we conclude that the current actual use of incentive spirometer is adequate, and thus serves as an appropriate control and is in line with the standard of care.

By demonstrating the lack of benefit of postoperative incentive spirometry, this study would eliminate the monetary and time resources consumed by this unnecessary device. Additionally, this study would add to the knowledge base and help to replace surgical dogma with evidence-based practice.

**Participant Selection / Eligibility:** All patients cleared for bariatric surgery will be potential subjects. There are no exclusion criteria.

**Subject Enrollment / Consent Process / Screening / Randomization:** Subjects will be approached regarding interest in study participation in the bariatric clinic once they have been cleared to undergo bariatric surgery per the usual screening process.

The attending surgeon or bariatric fellow or the primary investigator will perform the informed consent process (see designated co-investigators). This process may occur in the General Surgery clinic when potential subjects have their 30 minute scheduled preoperative appointment prior to going to the operating room., or subjects will be provided with a copy of the informed consent document to take home and review at their leisure. Subjects who chose to take the consent form to review, will be asked to sign consent on the day of their procedure, while they are awaiting surgery. The nature of their condition will be discussed; the potential risks and benefits of the study will be explained to subjects before signing the research informed consent. The options including not enrolling, enrolling now, and the option to withdraw from the study at any time for any reason will be explained to subjects as well. Once they have consented a consent form will be signed and the subject provided a copy.

Randomization will occur at the time a patient is enrolled in the study. Subjects will be randomized with simple randomization from a randomly generated number list to ensure equal number of subjects in each group.

**Study Design / Procedures:** Once a subject is enrolled they will be randomized at that time to either the control or the study group. Subjects in the control group will receive the current bariatric postoperative order set which includes the nursing order for "Incentive spirometry 10 times every hour while awake". Additionally these control subjects will be provided with the paper log included in the package produced by the manufacturer for patients to record how often and at what volumes they are using the device. Subjects randomized to the study group will receive a modified postoperative orders set where this line will be removed. Education and information about the study and the order not to provide patients in the study group with the device will be provided to Nurses and Nursing Assistant in both the Post Anesthesia Care Unit and on the surgical floor. This will be the only difference between the groups. Biometric data will be used to establish baseline characteristics of subjects. This will be obtained from the medical record and include subject's gender, age, BMI, smoking status, history of obstructive sleep apnea, and the operation they are undergoing. Baseline pulmonary data will be collected from the already established protocol of measuring preoperative oxygen saturation on room air and respiratory rate in the OR hold area. Postoperative data routinely collected on oxygen saturation and respiratory rate will be used. The primary outcome oxygen saturation will be measured with subjects off of supplemental oxygen for 5 minutes with head of bed at 30° at 6, 12 and 24 hours postoperatively. Education will be provided to Nurses and Nurse Assistants on standardizing timing and measuring these vitals. Additionally, secondary outcomes will be measured through

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review of subject's medical record looking for: respiratory rate, time to wean off supplemental oxygen, and postoperative respiratory complications (atelectasis found on chest imaging, pneumonia, or re intubation).

**Study Calendar / Schematic / Schedule:** Please see attached schematic. Enrollment will start once IRB approval is obtained. Subjects will be enrolled in the study for their entire inpatient stay following bariatric surgery. This is on average 2 to 3 days but can be up to 1 week. If subjects are readmitted within 30 days of their surgery any pulmonary complications at time of admission will be included as well.

**Potential Risks and Discomforts:** Potential risks include atelectasis, pneumonia, re-intubation. These are risks inherent to the operation and there is no data to support that incentive spirometry reduces the risks of these events following bariatric surgery. Thus there is minimal risk to subjects in taking away a device which has no proven benefit.

**Potential Benefits:** There is no potential benefit to subjects. This study will benefit Lahey by reducing financial and time costs associated with these devices. Additionally it will help to replace surgical dogma with evidence-based practice.

**Statistical Analysis:** The creation of the statistical plan was made with recommendations and advice from the Tufts CTSI. Sample size and power was calculated using a 2% difference between groups as acceptable, with a 90% power using a one-sided T-test with alpha of 0.05 (this is a non-inferiority test and there is no concern about the other side of the distribution). In order to power this study 18 subjects per group are needed to evaluate the continuous outcome of difference in O<sub>2</sub> saturation means between groups.

To look at a binary outcome (and possibly more clinically relevant outcome) of what % subjects in each group have O<sub>2</sub> saturations < 92%, I am assuming < 30% of persons getting IS will have O<sub>2</sub> saturation < 92%. This gives a delta of 10% (i.e. up to 40% of persons not getting IS have saturations < 92%) and thus a power of 112 subjects per group to show this at 80% power with an alpha of 0.05 is needed. This is why I have chosen to include 120 subjects per group.

Randomization will occur at the time a patient is enrolled in the study. Subjects will be randomized with simple randomization from a randomly generated number list.

Once data has been collected on baseline characteristics (gender, age, BMI, smoking status, history of obstructive sleep apnea, operation), groups will be compared via a two-sided T-test with alpha of 0.05. The primary outcome of O<sub>2</sub> saturation at each time point will be compared between groups with a two-sided T-test with alpha of 0.05. To look at what % subjects in each group have O<sub>2</sub> saturations < 92% postoperatively, a chi square test with delta of 10% and alpha of 0.05 will be used.

**Data Management:** Data will be managed by Haddon Pantel on a secure spread sheet in a password protected folder on the Lahey General Surgery shared drive. Subjects will be assigned a number and there will be no identifying information on this spreadsheet.

**Data and Safety Monitoring and Quality Assurance:** Again data will be stored on a secure Lahey server in a password protected folder. There will be no quality assurance, data will be eventually submitted for peer review publication and that will ensure the quality of the work.

## References:

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