

Entered: __/__/20__

Initials: _____

Verified: __/__/20__

Initials: _____

For office use only.

Post-Operative Evaluation Form (POST2) – Version - 08/28/2006

Patient ID _____

Form Completion Date __/__/20__
mm dd yy

Certification number: _____

Date of Surgery __/__/20__
mm dd yy

- | | | | |
|------------------------------|--------------------------|--------------------------|------------------------------|
| | No | Yes | Date of most recent contact: |
| 1. Source(s) of information: | <input type="checkbox"/> | <input type="checkbox"/> | ____/____/20__ |
| (check all that apply) | <input type="checkbox"/> | <input type="checkbox"/> | ____/____/20__ |
| | <input type="checkbox"/> | <input type="checkbox"/> | ____/____/20__ |
| | <input type="checkbox"/> | <input type="checkbox"/> | ____/____/20__ |
| | <input type="checkbox"/> | <input type="checkbox"/> | ____/____/20__ |

- | | | | |
|---|------------------------|---|--|
| 2. Length of hospital stay
for obesity surgery: _____ (days) | 3. Discharge location: | <input type="checkbox"/> 1. Home | <input type="checkbox"/> 3. Skilled nursing facility |
| | | <input type="checkbox"/> 2. Rehabilitation facility | <input type="checkbox"/> 4. Other hospital |
| | | | <input type="checkbox"/> 5. Was not discharged |

4. Did the patient die? 0. No 1. Yes → Date of death: __/__/20__
mm dd yy

If No,

4.1 Status Date: __/__/20__ (Most recent date participant known to be alive)

5. Was the patient re-hospitalized after initial discharge? 0. No 1. Yes

If yes,

- 5.1 Number of times rehospitalized: # ____
- 5.2 Date of first re-hospitalization: __/__/20__
mm dd yy
- 5.3 Were any of these related to a cardiac event? 0. No 1. Yes

6. Did the patient have any post-discharge complications? 0. No 1. Yes

If yes,

6.1. Wound infection	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes
6.2. Fascial dehiscence	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes
If yes,		
6.2.1 Did the wound edges open within 30 days following surgery? <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes		
6.2.2 Did the wound edges separate within 30 days following surgery requiring packing or bandage? <input type="checkbox"/> 0. No <input type="checkbox"/> 1. Yes		
6.3. Small bowel obstruction	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes
If yes,		
6.11.1 Specify obstruction:		
<input type="checkbox"/> 1. Partial obstruction	6.11.2 Specify cause:	
<input type="checkbox"/> 2. Complete obstruction	<input type="checkbox"/> 1. Internal hernia	<input type="checkbox"/> 4. obstructed JJ Anastomosis
	<input type="checkbox"/> 2. Adhesions	<input type="checkbox"/> 5. Unknown
	<input type="checkbox"/> 3. Anastomotic anatomy	<input type="checkbox"/> 6. Other (Specify: _____)
6.4. Incisional/ventral hernia	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes
6.5. Acute cholecystitis/biliary colic	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes
6.6. Common bowel duct stones/cholangitis	<input type="checkbox"/> 0. No	<input type="checkbox"/> 1. Yes

7. Did the patient have any post-bariatric surgical operations or undergo unplanned post-discharge anticoagulation therapy? 0. No 1. Yes
 If yes, specify all of the bariatric surgical operations or anticoagulation therapies below:

No	Yes	Event	Date first performed after surgery (mm/dd/20yy)	Suspected reason for intervention (see codes on next page)	Was the reason for the intervention confirmed?	
					No	Yes
<input type="checkbox"/>	<input type="checkbox"/>	7.1 Abdominal re-operation 7.1.1. Specify approach: <input type="checkbox"/> 1. Laparoscopic <input type="checkbox"/> 2. Laparoscopic converted to Open <input type="checkbox"/> 3. Open 7.1.2. Specify procedure: No Yes <input type="checkbox"/> <input type="checkbox"/> a. Operative drain placement <input type="checkbox"/> <input type="checkbox"/> b. Gastrostomy <input type="checkbox"/> <input type="checkbox"/> c. Anastomotic revision Specify revision: → <input type="checkbox"/> GJ <input type="checkbox"/> JJ <input type="checkbox"/> DJ <input type="checkbox"/> <input type="checkbox"/> d. Band replacement <input type="checkbox"/> <input type="checkbox"/> e. Band/port revision <input type="checkbox"/> <input type="checkbox"/> f. Wound revision or evisceration <input type="checkbox"/> <input type="checkbox"/> g. Re-exploration <input type="checkbox"/> <input type="checkbox"/> h. Other (Specify: _____)	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.2 Tracheal reintubation	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.3 Tracheostomy	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.4 Endoscopy	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.5 Placement of percutaneous drain	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.6 Anticoagulation therapy for presumed/confirmed DVT	n/a	n/a	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.7 Anticoagulation therapy for presumed/confirmed PE	n/a	n/a	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.8 Readmission (other) 1 (Specify: _____)	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.9 Readmission (other) 2 (Specify: _____)	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	7.10 Readmission (other) 3 (Specify: _____)	____/____/20__	_____	<input type="checkbox"/>	<input type="checkbox"/>

8. Were any planned post-discharge anticoagulation therapies received? 0. No 1. Yes
 If yes,

No	Yes		Prophylactic (preventative) Use?		# of Days	Times per day	Therapeutic (as treatment) Use?		# of Days	Times per day
			No	Yes			No	Yes		
<input type="checkbox"/>	<input type="checkbox"/>	5000 units sub-cutaneous heparin	<input type="checkbox"/>	<input type="checkbox"/>	____	____	<input type="checkbox"/>	<input type="checkbox"/>	____	____
<input type="checkbox"/>	<input type="checkbox"/>	Other dose heparin (Dose: _____ units)	<input type="checkbox"/>	<input type="checkbox"/>	____	____	<input type="checkbox"/>	<input type="checkbox"/>	____	____
<input type="checkbox"/>	<input type="checkbox"/>	Low molecular weight heparin If yes, Specify dose: <input type="checkbox"/> 20 mg <input type="checkbox"/> 40 mg <input type="checkbox"/> 60 mg <input type="checkbox"/> Other (Specify: _____ mg)	<input type="checkbox"/>	<input type="checkbox"/>	____	____	<input type="checkbox"/>	<input type="checkbox"/>	____	____
<input type="checkbox"/>	<input type="checkbox"/>	Other Anticoagulant If yes, Specify name: _____ Specify dose: _____ <input type="checkbox"/> 1.mg <input type="checkbox"/> 2. units	<input type="checkbox"/>	<input type="checkbox"/>	____	____	<input type="checkbox"/>	<input type="checkbox"/>	____	____

**Table of codes for
suspected reason for an intervention**

Code	Suspected reason for an intervention	Code	Suspected reason for an intervention
1	Anastomotic leak	8	Wound infection/evisceration
2	Other abdominal sepsis	9	Fluid or electrolyte depletion
3	Intestinal obstruction	10	Vomiting or poor intake
4	DVT	11	Gastric distension
5	Pulmonary embolism	12	Strictures
6	Pneumonia	13	Bleeding
7	Other respiratory failure	14	Infection/fever
		15	Other

POST-OPERATIVE EVALUATION (POST2):

<p>PURPOSE:</p>	<p>To identify short-term adverse outcomes (within 30 days) of bariatric surgery. <i>NOTE: LABS-2 defines "undergoing bariatric surgery," as undergoing anesthesia induction for bariatric surgery. Therefore, patients whose surgery was cancelled after anesthesia induction must complete the 30-day follow-up form.</i></p>
<p>PERSON(S) RESPONSIBLE:</p>	<p>Clinician, Coordinator</p>
<p>SOURCE(S) OF INFORMATION:</p>	<p>Patient, patient representative, medical chart</p>
<p>TIME OF ADMINISTERING FORM:</p>	<p>This form is to be administered between day 30 and 55 after the date that bariatric surgery was performed. Note that all information/activity reported on this form must have transpired from the time of anesthesia induction until 11:59 PM on the 30th day following surgery.</p>
<p>GENERAL INSTRUCTIONS: (Patient)</p>	<p>Instruct the patients that all questions only pertain to the time period starting with their obesity surgery and ending 30 days after their obesity surgery (give the patient the exact date and day of the week that the time period ends).</p>
<p>GENERAL INSTRUCTIONS: (Clinician)</p>	<p>This form must be administered by a LABS certified Coordinator or Clinician. This form can be administered to the patient over the phone or in person. The source of the information collected can be from chart review, patient response or a representative for the patient (as identified on the informed consent).</p>
<p>SCORING ALGORITHM:</p>	<p>N/A</p>

DATA SECTION	COMPLETION INSTRUCTIONS
PATIENT ID:	Record the patient's ID number. The ID number is assigned via the ID Registration application of the MATRIX Web Data Management System (MATRIX). Instructions on using this application are included in the MATRIX Manual.
FORM COMPLETION DATE:	Record the date that the form was completed.
CERTIFICATION CODE:	Record the certification number of the person completing the form. Only LABS certified personnel can complete this form. The certification number is assigned after the LABS-1 Protocol Certification process is completed.
DATE OF SURGERY	Record the date that anesthesia for bariatric surgery was induced.
Source of information	1. <u>Source(s) of information:</u> Record whether the patient was contacted in person, by telephone, whether the representative of the patient was contacted, an other medical professional/other physician was contacted, the patient's chart was reviewed.
Length of hospital stay	2. <u>Length of hospital stay for obesity surgery:</u> Record, the number of days between the patient leaving the operating room and hospital discharge. To compute the number of days, the day the surgery ended is Day Zero (0). Thus, for example, if surgery ended on a Monday and the patient was discharged on the next Wednesday, the length of stay would be 2 days (Monday=day 0, Tuesday=day 1, Wednesday=day 2).
Discharge location	3. <u>Discharge Location:</u> Record the location to which the patient was discharged from the hospital. <u>Home</u> = patient's primary residence or other residence not equipped with specialty healthcare facilities, such as home of parent, child or friend; <u>Rehabilitation facility</u> = any licensed rehabilitation facility; <u>Skilled nursing facility</u> = An institution or a distinct part of an institution that is licensed or approved under state or local law, and which is primarily engaged in providing skilled nursing care and related services as a Skilled Nursing Facility, extended care facility, or nursing care facility approved by the Joint Commission on Accreditation of Health Care Organizations or the Bureau of Hospitals of the American Osteopathic Association, or as otherwise determined by the health plan to meet the reasonable standards applied by any of the aforesaid authorities; <u>Other Hospital</u> = a hospital other than the one where the patient underwent initial bariatric surgery; <u>Was not discharged</u> = was not discharged from the hospital where surgery was performed. 4. <u>Did the patient die:</u> Record whether or not the patient died. If so, record the date of death. If no, specify the status date.
Re-hospitalizations	4.1 <u>Record the status date</u> as the last known date that the participant was known to be alive. 5. <u>Was the patient re-hospitalized after initial discharge:</u> Record whether or not the patient was re-hospitalized following initial hospital discharge. If "Yes", record the number of times that the patient was re-hospitalized (question 5.1), the date of the first re-hospitalization after initial hospital discharge (question 5.2) and whether or not any of the hospitalizations were related to a cardiac event (question 5.3).
Post-discharge complications	6. Did the patient have any post-discharge complications? If yes, specify "no" or "yes" to each complication listed below. 6.1 Wound infection

6.2 Fascial dehiscence

6.2.1 Did the wound edges open within 30 days following surgery. Record whether or not the surgical wound edges opened within 30 days following the surgery.

6.2.2 Did the wound edges separate within 30 days following surgery requiring packing or bandage. Record whether or not the wound edges separate within 30 days following surgery requiring packing or bandage.

6.3 Small bowel obstruction

6.3.1 Specify whether the small bowel obstruction is partial or complete.
6.3.1 Cause of small bowel obstruction: Specify whether the small bowel obstruction was caused by internal hernia, adhesions, anastomotic anatomy, obstructed JJ anastomosis or an other reason. If other, then specify.

6.4 Incisional/Ventral hernia - defined as an abdominal hernia occurring through a surgical incision or scar.

6.5 Digestive: Acute Cholecystitis/biloric colic- defined as inflammation and/or hemorrhagic necrosis, with variable infection, ulceration, and neutrophilic infiltration of the gallbladder wall; usually due to impaction of a stone in the cystic duct or intense spasmodic pain felt in the right upper quadrant of the abdomen from impaction of a gallstone in the cystic duct.

6.6 Digestive: Common bowel stones/cholangitis- defined as bowel stones/ Inflammation of a bile duct or the entire biliary tree.

6.7 Stomal/gastric outlet obstruction- defined as pyloric stenosis is a narrowing of the outlet from the stomach to the small intestine (called the pylorus).

6.8 Stapleline breakdown- defined as breakdown in the stapleline.

6.9 Anastomotic stricture: GJ - defined as Narrowing, usually by scarring, of an anastomotic suture line.

6.10 Anastomotic stricture: JJ - defined as Narrowing, usually by scarring, of an anastomotic suture line.

6.11 Gastric band Stenosis- defined as scaring of the gastric tissue related to the band.

6.12 Gastric band erosion - defined as penetration of the stomach wall by the band.

6.13 Gastric band slippage - defined as mal-positioning of the band over time.

6.14 Gastric band leakage- defined as inappropriate loss of fluid from the gastric band reservoir

6.15 Port or tube problems- defined as problems with any port or tube.

6.16 Gastric prolapse- defined as a sinking of the stomach or relating to the stomach, especially its appearance at a natural or artificial orifice.

6.17 Esophageal motility disorder or dilation - defined as disorder causing difficulty in swallowing, regurgitation of food, and, in some people, a spasm-type pain.

6.18 Gastroesophageal reflux - defined as the return of stomach contents back up into the oesophagus

6.18.1 If yes, specify how it was identified by either checking symptoms or pH probe. If pH probe, specify the number measured.

6.19 Primary dumping syndrome including nausea, bloating, diarrhea, colic.

- 6.20 Late-dumping symptoms including light-headedness, palpitations, sweating.
- 6.21 Nausea or vomiting – If nausea or vomiting, specify the severity level and frequency level:
 Severity level definitions:
none = does not have this complication
mild = not influencing usual activities
moderate = diverting from, but not urging modification
severe = influencing usual activities, severely enough to urge modifications
extremely severe = requiring hospitalization or bed rest
- Frequency Definitions:
None = does not have this complication
Rare = 1 time per week
Occasional = 2 or 3 times per week
Frequent = 4 to 6 times per week
Extremely frequent = 7 or more times per week
- 6.22 Flatulence – defined as excessive interference with lifestyle
- 6.23 Persistent diarrhea – defined as excessive interference with lifestyle
- 6.24 Constipation – defined as excessive interference with lifestyle
- 6.25 Dehydration – defined as requiring hospitalization
- 6.26 Acute renal failure – Defined as sudden loss of the ability of kidneys to excrete wastes, concentrate urine, and to conserve electrolytes.
- 6.27 Liver failure – Severe deterioration in the liver function
- 6.28 Myocardial infarction – Defined as heart muscle dies or is permanently damaged because of an inadequate supply of oxygen to that area
- 6.29 Cardiac arrest – Defined as abrupt cessation of heartbeat requiring medical intervention (resuscitation).
- 6.30 Other – Defined as any other event that resulted in an unexpected course of action.
7. Did the patient have any post-bariatric surgical operations or undergo unplanned post-discharge anticoagulation therapy?: Record whether or not the patient underwent any additional surgical operations (for any reason) or any **unplanned** post-discharge anticoagulation therapy. **NOTE:** “*Unplanned post-discharge anticoagulation therapy*” is not part of routine discharge plan. If “Yes” to this question, check “no” or “yes” to each of the questions 7.1 – 7.10. If “No”, all other items on this form are “Not applicable”.

Instructions for Recording Post-Bariatric Surgical Operations and Anticoagulation Therapy

Event: Check “no” or “yes” for each event

Date First Performed After Surgery: Record the date on which the (first) event occurred. For example, if the patient had 2 abdominal re-operations within 30 days of bariatric surgery, record the date that the first abdominal re-operation was performed.

Suspected Reason for Intervention: From the codes listed on page 2, record the suspected reason for the intervention. If the intervention was performed for multiple suspected reasons, record the one considered to be the primary reason.

Note: The check boxes for “Anticoagulation Therapy” already list the Suspected Reasons and thus no entry is required for these events. (See Appendix A for intervention/suspected reason associations.)

Was the reason for Intervention Confirmed: Record whether or not the suspected reason for the intervention was confirmed. Confirmation can be documented through visual ascertainment from the procedure performed or laboratory or diagnostic results (see Appendix B for definitions of intervention confirmation). Unconfirmed interventions will be referred to the Adjudication Committee. Selected interventions (e.g., tracheal reintubation) always require adjudication.

Definitions of Events:

7.1 **Abdominal Re-Operation:** One or more incisions to the abdomen for the purpose of exploration or surgical treatment. If “Yes”, complete the remaining items.

7.1.1 Check whether the abdominal procedure was Laparoscopic, Laparoscopic converted to Open, or Open.

7.1.2 Record the procedure that was performed. Check “no” or “yes” for each procedure:

Operative drain placement: Surgical placement of a drain for the purpose of controlling intestinal or anastomotic leakage.

Gastrostomy: Surgical creation of a communication between the stomach and the abdominal wall.

Anastomotic Revision: Repair of a previously constructed anastomosis by use of sutures, glue, or other methods to assure the integrity of the anastomosis. If “Yes”, check whether the revision was performed on the gastrojejunostomy (GJ) or jejunostomy (JJ), distal jejunostomy (DJ), or a combination.

Band Replacement: Removal and replacement of the band previously used to restrict the pouch opening.

Band/Port Revision: Any procedure that involves a surgical adjustment of the band around the stomach or a surgical adjustment of the port site

Wound revision or Evisceration: Revision of a wound induced from the index bariatric surgery with fascial disruption.

Re-exploration: Surgical entry into the abdomen for the purpose of investigating potential or suspected complications.

Other: Any other abdominal re-operation performed. If “Yes”, specify the other procedure performed.

- 7.2 Tracheal Reintubation: Placing a tube into the trachea, after having removed the tube used during the bariatric surgery, for the purpose of admitting air or fluid.
- 7.3 Tracheostomy: Construction of an artificial opening through the neck into the trachea.
- 7.4 Endoscopy: Insertion of an endoscope for the purpose of investigating or treating suspected or overt complications.
- 7.5 Placement of Percutaneous Drain: Percutaneous placement of a drain to control anastomotic leak or infection.
- 7.6 Anticoagulation Therapy for presumed/confirmed deep vein thrombosis (DVT): Anticoagulation therapy is any prescription drug used whose principle mechanism of action is to inhibit the ability of blood to clot or coagulate. DVT is blood clots or blockage that have formed in the deep veins of the legs or pelvis.
- 7.7 Anticoagulation Therapy for presumed/confirmed pulmonary embolism (PE): Anticoagulation therapy is any prescription drug used whose principle mechanism of action is to inhibit the ability of blood to clot or coagulate. PE is blockage of the pulmonary artery by foreign matter or by a blood clot.
- 7.8 - Re-admission (other 1-3): Specify any other post-discharge events that
7.10 occurred and required surgical operation or intervention.

Appendix A: Post-Operative Intervention by suspected reason for intervention

Cells marked with an ‘X’ indicate that the suspected reason can be associated with that particular intervention. Cells that are left blank (without an ‘X’) indicate that an intervention would not be performed for that particular suspected reason.

Intervention	Suspected reason for intervention						
	Anastomotic Leak	Other abdominal sepsis	Intestinal Obstruct	Deep vein thrombosis	Pulmonary embolism	Pneumonia	Other respiratory failure
Abdominal re-operation	--	--	--	--	--	--	--
Operative drain	X	X					
Gastrostomy	X	X	X			X	X
Anastomotic revision	X	X	X				
Band replacement			X				
Band/port revision			X				
Wound revision	X	X	X				
Re-exploration	X	X	X		X	X	X
Other	X	X	X	X	X	X	X
Tracheal reintubation	X	X	X	X	X	X	X
Tracheostomy	X	X	X	X	X	X	X
Endoscopy	X	X	X				
Placement of percutaneous drain	X	X					
Anticoagulation therapy for DVT				X	X		
Anticoagulation therapy for PE				X	X		
Other Readmission1	X	X	X	X	X	X	X

Continued

Intervention	Suspected reason for intervention						
	Wound infection/evisceration	Fluid or electrolyte depletion	Vomiting or poor intake	Gastric distension	Strictures	Bleeding	Infection/Fever
Abdominal re-operation	--	--	--	--	--	--	--
Operative drain	X			X		X	X
Gastrostomy		X	X	X	X	X	X
Anastomotic revision			X	X	X	X	X
Band replacement		X	X		X	X	X
Band/port revision		X	X		X	X	X
Wound revision	X					X	X
Re-exploration	X		X	X	X	X	X
Other	X	X	X	X	X	X	X
Tracheal reintubation	X	X	X	X	X	X	X
Tracheostomy	X	X	X	X	X	X	X
Endoscopy	X	X	X	X	X	X	X
Placement of percutaneous drain	X					X	X
Anticoagulation therapy for DVT							
Anticoagulation therapy for PE							
Other Readmission	X	X	X	X	X	X	X

Appendix B: LABS-2 Post Operative Definitions for Confirmation of Interventions

Event	Definition for Confirmation
Operative drain placement	Infected fluid was removed by the drain placement.
Gastrostomy	Distended gastric remnant was found, or g-tube was placed for necessary nutritional supplementation.
Anastomotic revision	Leak, obstruction, or other pathology of the anastomosis was found.
Band replacement	Malposition, erosion, or failure of band was found.
Band/port revision	Malposition, erosion, or failure of band was found.
Wound revision or evisceration	Fascial separation and wound abdominal closure failure was found.
Re-exploration	If for suspected leak; leaking intestinal contents found. If for suspected obstruction; partial or complete bowel obstruction found. If for wound evisceration; fascial separation and wound abdominal closure failure found.
Tracheal reintubation	Requires adjudication
Tracheostomy	Requires adjudication
Endoscopy	If for suspected leak, breach in anastomosis found. If for suspected obstruction,;impaired outflow found.
Placement of percutaneous drain	Infected fluid or blood at time of drain placement found
Anticoagulation therapy for presumed/confirmed DVT	Requires adjudication
Anticoagulation therapy for presumed/confirmed PE	Requires adjudication