Study Protocol

PROTOCOL TITLE: Phase I Safety and Feasibility Pilot Study of Same-Day Discharge after Video-Assisted Thoracoscopic Surgery (VATS) Anatomical Lung or Wedge Resection

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PROTOCOL VERSION: 4.0

PROTOCOL DATE: 27-July -2022

1.0 BACKGROUND

Over the last decade, video-assisted thoracoscopic surgery (VATS) has become the standard of care for surgical resections of early stage lung cancers with proven benefit in terms of perioperative morbidity, length of stay and post-operative pain, while providing equivalent long-term and oncological outcomes when compared to conventional open surgery (1-5).

Enhanced recovery after surgery (ERAS) has been implemented in many surgical specialties and has shown positive outcomes. Key principles and concepts of ERAS include pre-operative counselling, nutrition optimization, standardized multimodal analgesia and early mobilization (6). Our institution has adopted enhanced recovery pathways (ERP) for a variety of surgical procedures, including esophageal and upper gastrointestinal surgeries, which led to shorter length of stay (LOS) and cost savings (7-9). For lung surgery, few studies have been published describing outcomes with ERPs (10, 11). Larger prospective trials are therefore needed.

A shorter LOS is an attractive concept with regards to hospital resource management, but moreover for improving patient factors such as recovery, function and quality of life. Our centre implemented an ERP for open and VATS lobectomy in 2012 which led to shorter LOS, lower complication rates, but no difference in readmissions or chest tube reinsertions (12). A cost analysis of this ERP was performed to evaluate the economic impact and revealed significantly reduced societal costs (average of $4396 per patient) (13).

Our institution therefore recently performed a feasibility analysis of a 23-hour enhanced recovery pathway (ERP) for VATS lobectomy by retrospectively reviewing a 10-year cohort of patients (14). This study revealed that a significant proportion of patients could be discharged safely through this ERP. Patients discharged within 23 hours had shorter chest tube duration, lower clinical stage disease, lower pathological stage lesions, fewer surgical complications and shorter operative time. However, only clinical stage and surgeon were predictive factors of a shorter length of stay. 30-day mortality for this cohort was 0% and major complication rate was 8.3%. Interestingly, even without a dedicated 23-hour recovery pathway, the proportion of patients discharged within 23 hours increased starting in 2016 compared with years prior, and became close to 25% in the later portion of the study. Furthermore, in a recently conducted trial with data from 2019, discharge rates on postoperative day 1 were as high as 68 % (Kaafarani et al, “Trending towards day surgery in anatomical lung resections”, unpublished data, *manuscript in preparation*). Therefore, we believe that by further optimizing perioperative care, same-day discharges after anatomical lung resection are feasible and safe.

With the current ERP for VATS lung surgery, the standard of care target for discharge is on post-operative day 2. This prospective observational study therefore aims to evaluate the safety and feasibility of pre-operatively enrolling patients undergoing a VATS anatomical lung or wedge resection into an ERP allowing for a same-day discharge from the hospital. By demonstrating the feasibility of same-day discharge, this can be more widely applied and could further improve patient care.

2.0 HYPOTHESIS

For patients undergoing an uncomplicated VATS anatomical lung or wedge resection and enrolled in an ERP, same-day discharge is safe and feasible, and will not result in a higher rate of adverse events as compared to patients on a same-day admission pathway with an expected length of stay of 2 days.

3.0 OBJECTIVES AND PURPOSE

The aim of this phase I study is to evaluate the safety and feasibility of same-day discharge in participants undergoing anatomical lung resection (segmentectomy or lobectomy) or wedge resection by VATS with an ERP.

Primary Outcomes

1. Adverse event rate*
2. Same-day discharge rate
3. Readmission rate
4. Rate of presentation to the emergency room after surgery

Secondary Outcomes

1. Quality of life
2. Duration of indwelling chest tube catheter
3. Rate of screen failure
4. Percent of eligible participants consented
5. Pathway adherence rate

*_Post-operative complications_: recurrent pneumothorax, subcutaneous emphysema, prolonged air leak, pneumonia, pulmonary embolism, atrial fibrillation, bleeding, uncontrolled pain, chest tube reinsertion, wound infection, pleural empyema.

Postoperative complications will be classified according to the Ottawa Thoracic Surgery Mortality and Morbidity classification (15).

Feasibility of the Pilot Study

This pilot study design will be deemed feasible for larger investigations if:

1. The sample population size can be achieved
2. Greater than fifty per cent (>50%) of consented participants are able to continue with same-day discharge post-operatively
3. There are no Serious Adverse Events (SAE) raising concerns about the safety of this ERP

4.0 PARTICIPANTS

This trial will be enrolling 20 participants from the Montreal General Hospital (MGH) at McGill University who are scheduled for an elective anatomical lung or wedge resection with suspected or confirmed pulmonary malignancy. When 20 participants are successfully consented the trial will close to accrual.

4.1 Inclusion criteria

- Signed or verbal informed consent by participant
- Male and female adults, age 18 and above
- Clinical stage I-II lung cancer (suspected, proven, unproven), or secondary pulmonary malignancy
- BMI < 35
- ECOG 0-1
- Eligible for surgery and lung cancer resection (FEV1 > 60%, DLCO > 60%)

- Elective VATS anatomic resection (segmentectomy or lobectomy), or wedge resection
- Capable caregiver for discharge home

4.2 Exclusion criteria

- Clinical stage III lung cancer
- Surgery requiring pneumonectomy
- Neoadjuvant therapy
- Active pregnancy or breastfeeding
- History of chronic pain syndromes
- History of chronic opioid use
- Concomitant major surgery indicated with current admission to hospital
- Intraoperative complication including conversion to thoracotomy, major bleeding requiring blood transfusion, extensive adhesiolysis, injury to mediastinal structures, airway injury, nerve injury (phrenic, recurrent)
- Need for epidural or patient-controlled intravenous analgesia
- Need for urinary catheter

5.0 DESIGN, METHODOLOGY AND ANALYSIS

5.1 Study Design

(a) Study phase and type: Phase I, prospective observational pilot study
(b) Study blinding: Open-label
(c) Study allocation: N/A, single-arm study
(d) Study setting: Single center, Division of Upper Gastrointestinal and Thoracic Surgery at McGill University Health Centre (Montreal General Hospital)
(e) Research intervention: Enhanced recovery pathway (ERP) for VATS anatomical lung resection or wedge resection for same-day discharge from hospital
(f) Estimated enrolment period: September 2022 to September 2023
(g) Estimated duration of trial: Up to 1 year from first participant enrolled with verbal or signed informed consent to last study-related participant follow-up.
(h) Estimated duration of trial per participant involvement: From day of consent, to surgery, through follow-up within trial terms (for 4-6 weeks) for a total of approximately 2-3 months. Further follow-up according to usual treatment plan / lung cancer follow-up.

5.2 Participant accrual

(a) Estimated enrolment: 20 participants
(b) Surgeons:
    - Dr. Jonathan Spicer
    - Dr. Lorenzo Ferri
    - Dr. Jonathan Cools-Lartigue
    - Dr. Sara Najmeh
(c) Study estimated start date: October 2022
(d) Study estimated completion date: October 2023

5.3 Description of procedures

SOC - Standard of care; RP – Research procedure

(a) Pre-operative ERP:

- Participant education: Tailored preoperative education protocol with information booklet that includes daily goals. [SOC]
- Participant education: Addendum to the information booklet "VATS Guide Addendum" with specifics regarding this research protocol. [RP]
- Participants will be booked as first case of the day. [RP]
- All standard COVID-19 mitigation strategies for thoracic surgery patients will be employed. [SOC]
- Proposed perioperative anesthesia care pathway consensus [See Appendix 1 for more details]. [SOC and RP]
    - All participants will be booked as the first case of the day to allow for a prolonged PACU stay, if needed. [RP]

(b) Intraoperative ERP:

- Proposed perioperative anesthesia care pathway consensus [See Appendix 1 for more details]. [SOC and RP]
- Extubation: In the operating room. [SOC]

(c) Lung resection: Patients will be placed under General Anesthesia and intubated with a double-lumen endotracheal tube. Patient will be rotated in lateral decubitus so as to elevate the surgical side (16). Standard sterilization and draping will be performed. A 3-5 cm incision will be performed in the fifth or fourth intercostal space and a 1cm incision in the eighth intercostal space. Some surgeons might choose to place a third access port that is 1-3 cm. The pleural cavity will be inspected and the site of tumor, identified. A segmentectomy or lobectomy will be performed in standard protocol. A 20F or 24F tube will be advanced to the thoracic apex and connected to Mini-Atrium dry seal drainage system (Mini-Atrium 500, Atrium, USA). Skin incisions will be closed in standard fashion. The procedures will be performed by staff surgeons from the Division of Upper Gastrointestinal and Thoracic Surgery. [SOC]

(d) Post-operative ERP:

- Proposed perioperative anesthesia care pathway [See Appendix 1 for more details].[SOC]
- Urinary catheter: None, avoid. [SOC]
- Chest tube: Will be connected to a small portable dry seal drainage system (Mini-Atrium 500, Atrium, USA) with which the participants will be discharged. Chest tube will be removed upon the absence of an air-leak and a drainage of less than 800 ml of non-bloody, non-chylous fluid. [*Note*: Chest tube insertion is SOC, and patients can be discharged with or without tube if they fit removal criteria. Usually, if they are discharged home with the tube, they are seen between post-operative days 5 and 7 in follow-up and removal of chest tube. As part of RP, because participants will be discharged on the same day as surgery, they will all keep the tube and been seen on post-operative day 2 or no later than day POD 7.
- Short-term follow-up: Participants will be seen on post-operative day (POD) 2, and on POD 5 if the chest tube was not removed on POD 2 after surgery. Upon arrival in the outpatient clinic, the participant's chest tube will be clamped and a chest x-ray will be performed 2 hours later. Moreover, participants will be called daily until chest tube removal or POD 5. Further follow-up will be tailored to participants' needs. [RP]

(e) Criteria for safe discharge on the day of surgery [SOC]:

- Pain well controlled (VAS <3 at rest and <5 when moving)

- Non-bloody chest tube drainage quality, of no more than 100 cc/h over last 4 hours before planned discharge
- No subcutaneous emphysema, clinically and on post-operative x-ray
- Participant independently ambulating to bathroom
- No oxygen requirement and oxygen saturation (SpO2) > 92% on room air at rest
- Stable vital signs (match vitals before surgery) and no documented perioperative tachyarrhythmia
- Dry dressings for the last 4 hours prior to planned discharge
- Participant awake, oriented and cooperative (Glasgow Coma Scale (GCS) 15)
- Bedside swallowing assessment performed by surgeon or thoracic surgery fellow; participant must be able to drink clear liquids without clinical signs of aspiration
- Capable caregiver for discharge home

(f) Quality of life:

Quality of life will be assessed using the Functional Assessment of Cancer Therapy - Lung (FACT-L) and the Edmonton Symptom Assessment System (ESAS) questionnaires at the following time points [RP]:

- At the time of consent
- On the day of surgery
- After removal of the chest tube
- 30 days after surgery

5.4 Description of outcomes

Primary Outcomes

1. Adverse event rate: Proportion of participants experiencing complications related to surgery (classified per type of complication).
2. Same-day discharge rate: Proportion of participants enrolled in the trial that go home on the day of the surgery.
3. Readmission rate: Proportion of participants requiring hospitalization due to complications or conditions related to the surgery.
4. Rate of presentation to the emergency room after surgery: Proportion of participants presenting to the emergency room due to complications or conditions related to surgery.

Secondary Outcomes

1. Quality of life: Assessed using the Functional Assessment of Cancer Therapy - Lung (FACT-L) and the Edmonton Symptom Assessment System (ESAS) questionnaires. [See Appendix 2, 3]
    a. FACT-L: Rating questions regarding physical, social/family, emotion and function well-being as well as general questions regarding medical health, on a scale of 0-4 (from ‘Not at all’ to ‘Very much’).
    b. ESAS: Rating pain, fatigue, nausea, depression, anxiety, drowsiness, appetite, well-being and shortness of breath, on a scale of 1 to 10.
2. Duration of indwelling chest tube catheter: In days, from insertion until removal of chest tube catheter.
3. Rate of screen failure: Proportion of participants who were screened, but did not meet one or more inclusion or exclusion criteria that was required for participation in the study.
4. Percent of eligible patients consented: Proportion of participants enrolled vs. not enrolled who meet all inclusion and exclusion criteria.

5. Pathway adherence rate: Proportion of participants enrolled that remained on the enhanced recovery pathway and followed all measures for same-day discharge vs. those that did not.

5.5 Statistical analysis

Participants that meet criteria (inclusion and exclusion) will be prospectively enrolled into this trial. Clinical data will be prospectively collected according to the Thoracic Surgery Quality monitoring, Information management, and Clinical documentation (TSQIC) software data management system and subsequently extracted for analysis; https://tsqic.org/tsqic/. [See Appendix 4]

Demographic characteristics (sex, age), baseline characteristics (past medical and surgical history, smoking status, occupational exposure), diagnostic data (pulmonary function [FEV1, FVC, DLCO], diagnosis, clinical staging), pathological data (pathological stage, margin status, lymphovascular invasion, pleural visceral invasion) and operative data (operative time, timing of surgery, morbidity and mortality including post-operative complications and major complications) will be collected.

> **Post-operative complications*: recurrent pneumothorax, subcutaneous emphysema, prolonged air leak, pneumonia, pulmonary embolism, atrial fibrillation, bleeding, uncontrolled pain, chest tube reinsertion, wound infection, pleural empyema.

Complications will be scored using the Ottawa Thoracic Morbidity and Mortality classification system (15); https://ottawatmm.org/.

Clinical and pathological staging will be performed according to AJCC TNM 8th edition.

Specific research data, such as admission/discharge/emergency visit/readmission dates and secondary outcomes data, will be collected in a password-protected document behind the firewall of the MUHC. Only principal investigators and members of the research team will have access to the password.

Descriptive and observational sample analyses will be performed using proportions for categorical variables, means with standard deviations for normally distributed variables and medians with interquartile ranges (IQRs) for skewed distribution variables.

5.6 Benefits and risks

Benefits

Participants may or may not personally benefit from their participation in this research study. The safety and feasibility information collected during the research will help guide future decisions with regards to implementing a same-day discharge ERP for patients undergoing VATS lung surgery.

Risks

Although this protocol is designed and optimized to minimize any harm to the participants, there are possible risks related to the research procedures:

- ERP: unrecognized and more severe surgical complications (bleeding, urinary retention, arrhythmias, pneumothorax) requiring revisit to hospital
- Quality of life questionnaire: discomfort, distress
- Chest tube: inconvenience of returning for following on post-operative day 2, chest tube fall-out, wound care issues or infection

6.0 ETHICAL CONSIDERATIONS

6.1 Consent

Participants will be approached for consent during their pre-procedure (pre-op) visit. A detailed explanation of the study will be discussed including its purpose in regards to assessing the safety and feasibility of this enhanced recovery pathway. While the treating surgeon will be the one explaining the standard of care procedures in detail, the study details will be provided and consent obtained by the study's research coordinator. Consent will be documented by the participant's signed or verbal dated consent along with the signature of the person conducting the consent process and a witness, if applicable. A witness will be present for a verbal consent. The consent statement will be read aloud and participants will be given time to ask their questions. After verbal consent is given, the participants name, witness' name, and name of who is obtaining consent will be put on the informed consent document. No signatures will be collected for verbal consent. Verbal consent shall be collected if the participant has a reading disability or inability to read, communicates in a foreign language requiring an interpreter, or they are capable of consenting but unable to write. A copy of the consent form will be provided to the participant prior to participation in the study. A copy of the signed consent form should be given to the participant, or mailed to the participant's home address, if signature is required. For remote consent (over the phone), participants will receive a copy to sign when they arrive on site for their scheduled procedure.

The consent process will adhere to REB requirements, applicable laws and regulations including Health Canada's guidance on consent during the COVID-19 pandemic.

Should remote consent be required or requested, a digital copy of a signed consent form (photo or PDF) that has been emailed to the clinic will be accepted.

The total period of study for participant involvement will be approximately 2-3 months (surgical procedure + ERP + follow-up). The procedures and concepts included in the enhanced recovery pathway will be described and explained to the participant.

General participant information collected will include participants' demographic, diagnostic and pathological data. Information collected that is specific to this study will consist of adverse events and feasibility measures. All information will be de-identified to maintain participant confidentiality.

Study participation is completely voluntary. Patients may refuse participation or consent can be withdrawn at any time at the request of the participant without any consequence to their care.

6.2 Confidentiality

This study will be conducted in accord with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018), as well as in respect of the requirements set out in the applicable standard operation procedures of the Research Institute of the McGill University Health Centre Research Institute and of the McGill University Health Centre Research Ethics Board. The McGill University Health Centre Research Ethics Board will review this study and will be responsible for monitoring it.

Only data relevant to this study as outlined in this protocol will be collected by the research team. All information collected during the research project will remain confidential to the extent required

and provided by law. Participant data will be de-identified and coded. The code will be kept by the Principal Investigator in a password-protected digital file behind the MUHC firewall.

Data may be published or shared during scientific meetings, however all participant identifying information will be excluded.

6.3 Maintenance of study records

To enable evaluations and/or audits from regulatory authorities, the Principal Investigator agrees to keep records, including the identity of all participants, all original signed informed consent forms, source documents, and detailed records of treatment disposition.

The data will be entered in an electronic secure database (TSQIC) and file, which will be maintained with up-to-date information by the Principal Investigator or their team. It is the Principal Investigator's responsibility to ensure the accuracy of the data entered.

The clinical data extracted from TSQIC and research data collected will be de-identified and coded in a password protected file behind the MUHC firewall.

The data will be kept for a total of 7 years.

6.4 Compensation and reimbursement

Participants will be compensated 50$ for the additional follow-up visit after surgery, during which they will undergo removal of their chest tube. This compensation is provided by the Division of Thoracic Surgery Account.

6.5 Reporting Serious Adverse Events

In compliance with SOP 405A.001 Serious Adverse Events (SAE) must be reported to the REB through NAGANO. Follow the guidelines below:

Local Serious Adverse Events:

- The Researcher must report to the REB any local serious adverse event that, in the opinion of the Researcher, meets all of the following criteria:
    - Unexpected;
    - Related or possibly related to participation in the research; and
    - Suggests that the research places research participants or others at a greater risk of harm than previously identified at time of review and approval.

Non-Local (External) Serious Adverse Events

- The Researcher must report to the REB, any non-local serious adverse event that, in the opinion of the Researcher, meets all of the following criteria:
    - Unexpected;
    - Related or possibly related to participation in the research; and
    - Suggests that the research places research participants or others at a greater risk of harm than previously identified at time of review and approval.
      AND
    - Requires a change to the research and/or informed consent form and/or requires immediate notification to participants for safety reasons.

Report to the REB

- The report submitted to the REB must include all of the following information:
    - The description of the adverse event;
    - Previous safety reports concerning similar events, if available;
    - An analysis of the significance of the current adverse event; and
    - If applicable, the proposed modifications to the conduct of the research project and/or to the informed consent form and/or a list of corrective actions to be taken in response to the event;
    - A copy of the sponsor's report, if available.
- Any applicable form completed/required by the sponsor, if any, (e.g. SAE form), must be uploaded to NAGANO
- Subsequent, important follow-up reports related to the SAE should be submitted as soon as available.

6.6 Stop Criteria

This pilot study will be halted if any of following criteria is met:

- >15% Grade 3 or 4 complications
- Any Grade 5 complications
- >10% readmission rate after 10 patients is discharged on same day

Grading of Complications (17):

- Grade I: Any deviation from normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions.
- Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are included
- Grade III: Requiring surgical, endoscopic or radiological intervention
- Grade IV: Life-threatening complications requiring IC/ICU management
- Grade V: Death of Patient

7.0 APPENDICES

Appendix 1

Perioperative anesthesia care pathway for same-day discharge anatomical lung or wedge resection feasibility study

SOC - Standard of care; RP – Research procedure

A) PREOPERATIVE

- All participants will be booked as the first case of the day to allow for a prolonged PACU stay, if needed. [RP]
- All participants will be flagged by a thoracic surgeon, and seen in the MGH preoperative clinic by an anesthetist. [SOC]
- All standard COVID-19 mitigation strategies for thoracic surgery patients will be employed. [SOC]
- Upon being called to OR, the participant will receive acetaminophen 1000 mg and celecoxib 200 mg PO with a sip of water. [SOC]
- Avoid routine use of midazolam. [SOC]

B) INTRAOPERATIVE

- Upon arrival to the operating room, preoperative checklist and consent will be verified. [SOC]
- Vascular access will be established and Ringer's Lactate will be started at 6 ml/kg/hour. [SOC]

Antibiotic prophylaxis:

- As per standard of care thoracic pathway. [SOC]

Monitoring:

- Standard monitoring will include ECG, arterial line, peripheral saturation, temperature, neuromuscular blockade at the adductor pollicis, lung mechanics and gas analyzer. [SOC]

Anesthesia:

- Inhalation anesthesia (sevoflurane or desflurane), or total intravenous anaesthesia (TIVA). [SOC]

Opioid-sparing analgesia (one or more of the following techniques):

- A preoperative single shot erector spinae plane nerve block will be performed at the T5 level with 20 ml of bupivacaine 0.375% with epinephrine 1:200 000, and dexamethasone 5 mg. [SOC]
- Magnesium sulfate 2.5 g IV will be given as co-analgesic over the course of the surgery. [SOC]
- Lidocaine 1.5 ml/kg following 2mg/kg/h. [SOC]
- Ketamine 0.5 mg/kg. [SOC]

Ventilation:

- Lung isolation will be performed with a left-sided double lumen endotracheal tube, or a bronchial blocker through a single-lumen tube. [SOC]

- Tidal volumes will be maintained at 6 ml/kg of PBW on 2 lungs and 4 ml/kg of PBW on one lung. PEEP and FiO2 will be adjusted to maintain SpO2 above 92%. Aim for driving pressure below 15 cmH_2O. [SOC]

Temperature control:
- Normothermia will be maintained with an underbody heated water blanket on the operating table and a surgical access forced air warmer on the participant. [SOC]

Post-operative nausea and vomiting (PONV) prophylaxis:
- Dexamethasone 6 mg IV will be given at induction unless contraindicated. [SOC]
- Ondansetron 4 mg IV will be given 30 minutes before emergence of anesthesia. [SOC]
- Consider giving metoclopramide 10mg IV 30 minutes before emergence or use of TIVA if high PONV risk. [SOC]

End of surgery analgesia:
- At the end of the surgery, intercostal blocks will be performed by the surgeon, under direct visualization. A total a 20 ml of bupivacaine 0.25% with epinephrine 1:200,000 will be injected from T3 to T6. [SOC]

Extubation:
- At surgery completion, reverse neuromuscular blockade before extubating with suggamadex or neostigmine to achieve and document a ToF T4/T1 ratio > 0.9. [SOC]
- Participants will be extubated in the operating room and transferred to PACU. [SOC]

C) POST-OPERATIVE (IN PACU)

Post-operative nausea and vomiting (PONV):
- Avoid dimenhydrinate IV/PO. [SOC]
- If nausea or vomiting occurs within 6 hours after surgery, participants should not receive a repeat dose of the prophylactic antiemetic received intra-operatively. Treat with one of the following instead: [SOC]
    - Ondansetron 4 mg IV
    - Metoclopramide 10 mg IV
    - Haloperidol 0.5-1 mg IV/IM

Fluids:
- Clear fluids PO as tolerated. [SOC]
- Ringer's Lactate IV at 10 mL/h ("Keep Vein Open" - KVO). [SOC]

Analgesia:
- Fentanyl 25 mcg IV to a maximum of 250 mcg. [SOC]
- Non-IV analgesia as per pathway. [SOC]
- Oxycodone 5mg PO q2h PRN or Dilaudid 1mg PO q2h PRN (to be standardized). [SOC]
- Acetaminophen 1000 mg PO/PR q6h regular to be started 6h after the first dose. [SOC]

Respiratory support:
- Incentive spirometry in PACU. [SOC]
- Possible physiotherapy in PACU. [SOC]

Appendix 2

Example of Functional Assessment of Cancer Therapy - Lung (FACT-L) questionnaire in English and French

FACT-L (Version 4)

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.**

	<u>PHYSICAL WELL-BEING</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	<u>SOCIAL/FAMILY WELL-BEING</u>	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-L (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

	EMOTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

FACT-L (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the <u>past 7 days</u>.

	ADDITIONAL CONCERNS	**Not at all**	**A little bit**	**Some-what**	**Quite a bit**	**Very much**
B1	I have been short of breath	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4
L1	My thinking is clear	0	1	2	3	4
L2	I have been coughing	0	1	2	3	4
B5	I am bothered by hair loss	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
L3	I feel tightness in my chest	0	1	2	3	4
L4	Breathing is easy for me	0	1	2	3	4
Q3	Have you ever smoked? No ___ Yes ___ If yes:					
L5	I regret my smoking	0	1	2	3	4

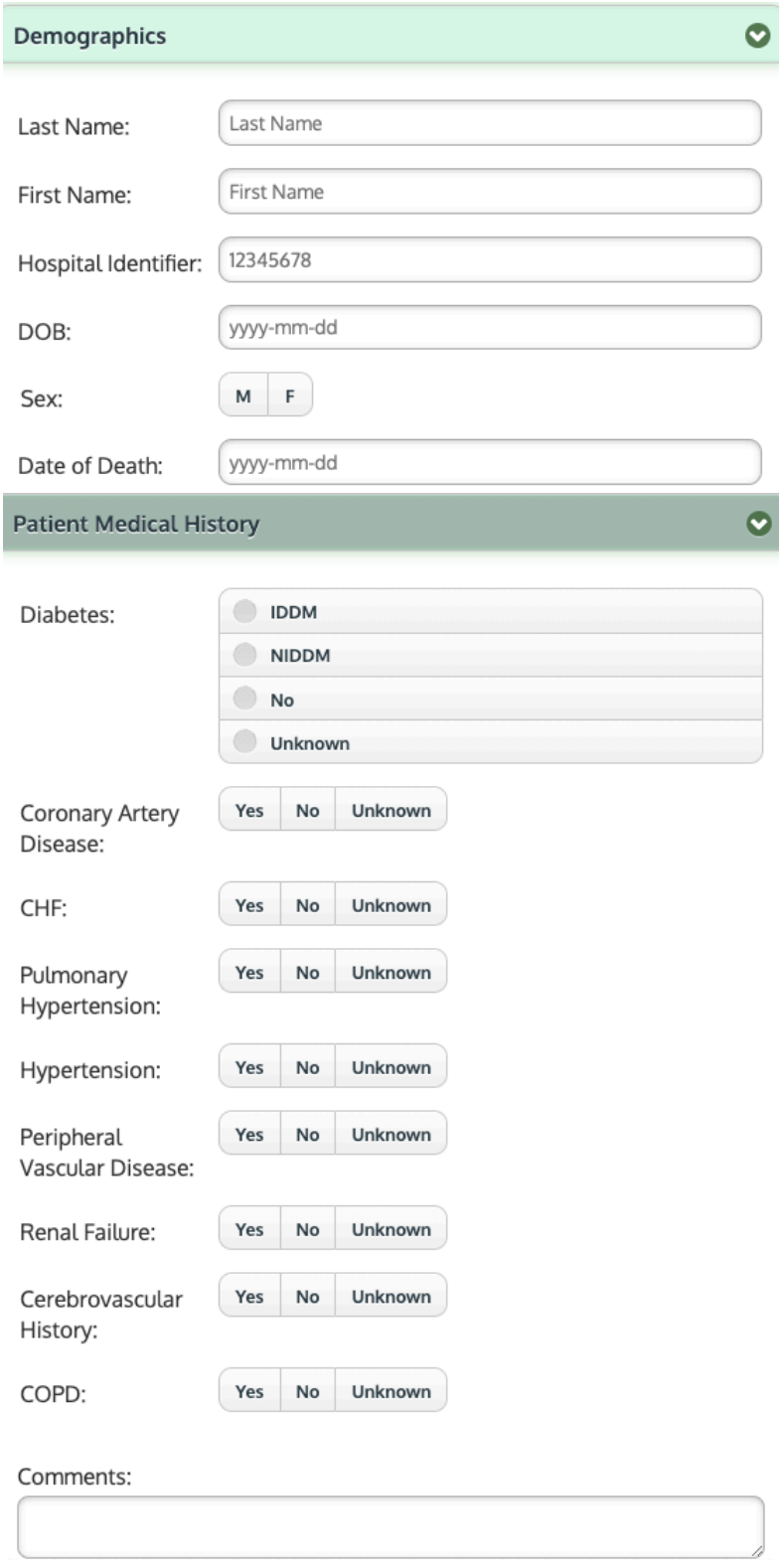
Appendix 3
Example of Edmonton Symptom Assessment System questionnaire in English

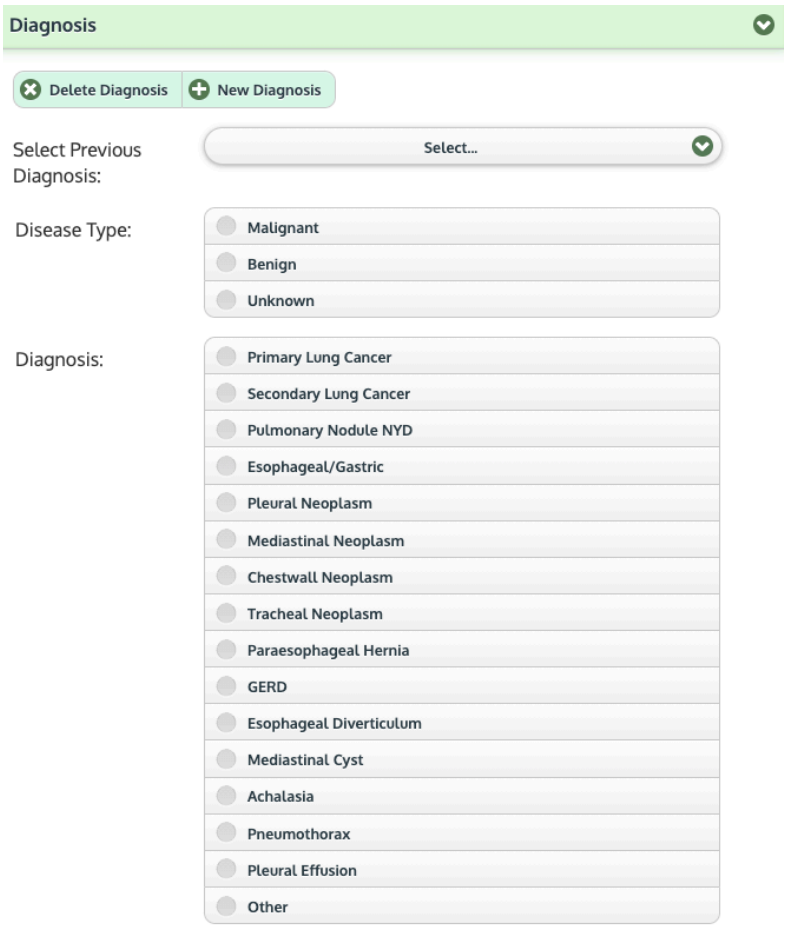
Participant code: _____

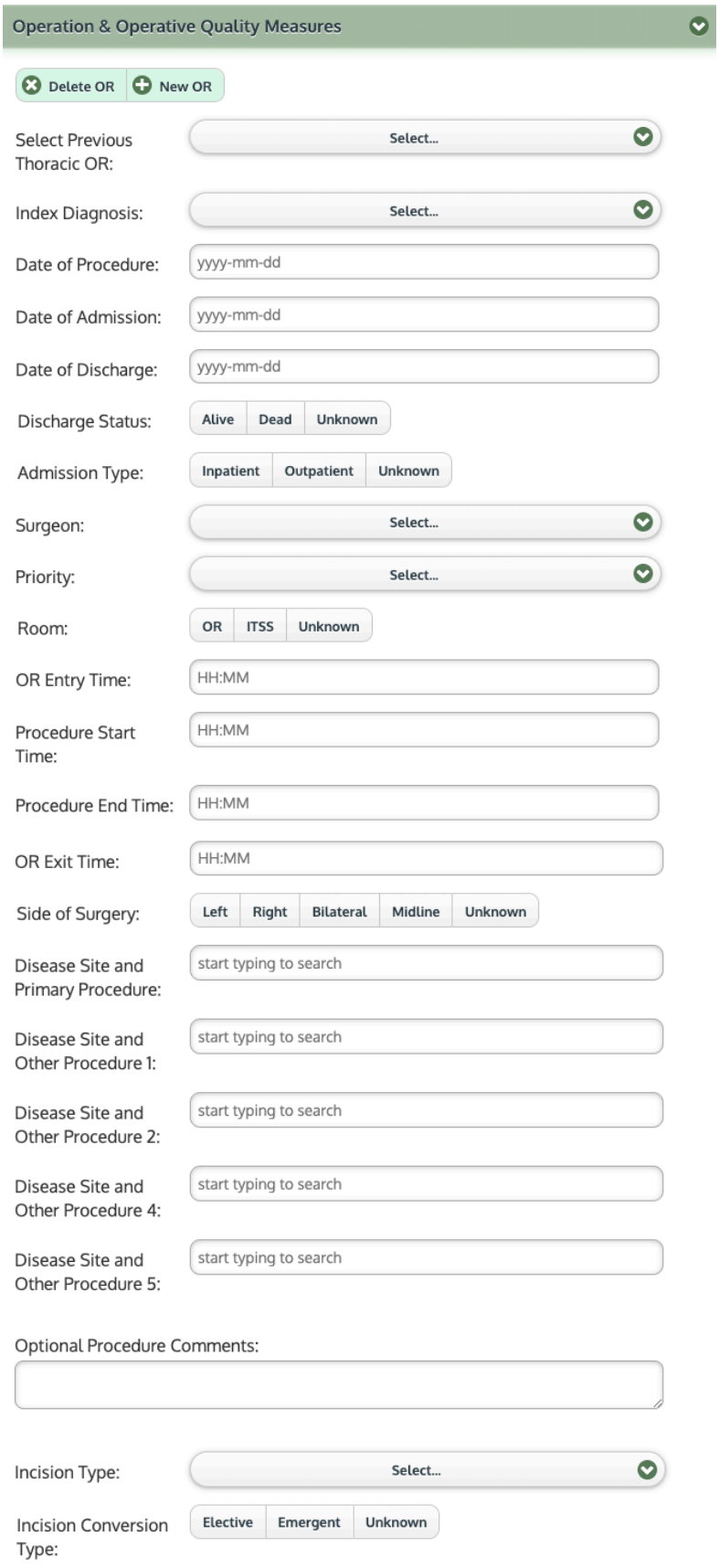
Date (AAAA/MM/DD): _____

For each of the following items, please circle the number that best describes your health during THE LAST 24 HOURS.												
No pain	0	1	2	3	4	5	6	7	8	9	10	*Worst possible pain*
Not tired	0	1	2	3	4	5	6	7	8	9	10	*Worst possible tiredness*
Not nauseated	0	1	2	3	4	5	6	7	8	9	10	*Worst possible nausea*
Not depressed	0	1	2	3	4	5	6	7	8	9	10	*Worst possible depression*
Not anxious	0	1	2	3	4	5	6	7	8	9	10	*Worst possible anxiety*
Not drowsy	0	1	2	3	4	5	6	7	8	9	10	*Worst possible drowsiness*
Best appetite	0	1	2	3	4	5	6	7	8	9	10	*Worst possible appetite*
Best feeling of well-being	0	1	2	3	4	5	6	7	8	9	10	*Worst possible feeling of well-being*
No shortness of breath	0	1	2	3	4	5	6	7	8	9	10	*Worst possible shortness of breath*
Other problem	0	1	2	3	4	5	6	7	8	9	10	
Would you like to receive some help for one or the other problem you may have mentioned above ☐ *Yes* ☐ *No*												

Appendix 4
Examples of Thoracic Surgery Quality monitoring, Information management, and Clinical documentation (TSQIC) software forms




Diagnosis
Delete Diagnosis
New Diagnosis
Select Previous Diagnosis:
Select...
Disease Type:
Malignant
Benign
Unknown
Diagnosis:
Primary Lung Cancer
Secondary Lung Cancer
Pulmonary Nodule NYD
Esophageal/Gastric
Pleural Neoplasm
Mediastinal Neoplasm
Chestwall Neoplasm
Tracheal Neoplasm
Paraesophageal Hernia
GERD
Esophageal Diverticulum
Mediastinal Cyst
Achalasia
Pneumothorax
Pleural Effusion
Other


Operation & Operative Quality Measures
Delete OR
New OR
Select Previous Thoracic OR:
Select...
Index Diagnosis:
Select...
Date of Procedure:
yyyy-mm-dd
Date of Admission:
yyyy-mm-dd
Date of Discharge:
yyyy-mm-dd
Discharge Status:
Alive
Dead
Unknown
Admission Type:
Inpatient
Outpatient
Unknown
Surgeon:
Select...
Priority:
Select...
Room:
OR
ITSS
Unknown
OR Entry Time:
HH:MM
Procedure Start Time:
HH:MM
Procedure End Time:
HH:MM
OR Exit Time:
HH:MM
Side of Surgery:
Left
Right
Bilateral
Midline
Unknown
Disease Site and Primary Procedure:
start typing to search
Disease Site and Other Procedure 1:
start typing to search
Disease Site and Other Procedure 2:
start typing to search
Disease Site and Other Procedure 4:
start typing to search
Disease Site and Other Procedure 5:
start typing to search
Optional Procedure Comments:
Incision Type:
Select...
Incision Conversion Type:
Elective
Emergent
Unknown

Incision Conversion Reason: Vascular | Anatomy | Lymph Nodes | Technical | Unknown

Optional Incision Comments:

Intra-Op Concerns:

- [ ] None
- [ ] CVA
- [ ] Clinically Significant Bleeding
- [ ] Clinically Significant Bleeding - Requiring Transfusion
- [ ] Myocardial Ischemia
- [ ] Staple Misfire
- [ ] Unstable Arrhythmia
- [ ] Arrest
- [ ] Death
- [ ] Vascular Injury
- [ ] Injury to Airway
- [ ] Injury to Esophagus
- [ ] Loss of Normal Thermia (< 35°)

Other Intra-Op Concerns:

Surgical Safety Check: performed | not performed | Unknown

Appropriate Pre-Op Antibiotics Given?: yes | no | unknown | unnecessary

Intraoperative DVT Prophylaxis

- [ ] none
- [ ] not indicated
- [ ] TED Stockings
- [ ] sequential calf compression device
- [ ] unfractionated heparin
- [ ] LMW heparin

Regional Pain Control:

- [ ] none
- [ ] epidural catheter
- [ ] paravertebral catheter
- [ ] intercostal block
- [ ] wound infiltration
- [ ] paravertebral block

Perception of Oncologic Resection:

- ( ) R0
- ( ) R1 Microscopic Involvement
- ( ) R2 Gross Involvement
- ( ) NotApplicable

Lymph Node Sampling:

1 - Low Cervical	Not Done	Sampled	Resected	Unknown
1 - Supraclavicular	Not Done	Sampled	Resected	Unknown
1 - Sternal Notch	Not Done	Sampled	Resected	Unknown
2R - Upper Paratracheal	Not Done	Sampled	Resected	Unknown
2L - Upper Paratracheal	Not Done	Sampled	Resected	Unknown
3A - Pre-vascular	Not Done	Sampled	Resected	Unknown
3P - Retrotracheal	Not Done	Sampled	Resected	Unknown
4R - Lower Paratracheal	Not Done	Sampled	Resected	Unknown
4L - Lower Paratracheal	Not Done	Sampled	Resected	Unknown
5 - Subaortic	Not Done	Sampled	Resected	Unknown
6 - Paraaortic	Not Done	Sampled	Resected	Unknown
7 - Subcarinal	Not Done	Sampled	Resected	Unknown
8 - Paraesophageal	Not Done	Sampled	Resected	Unknown
9 - Pulmonary Ligament	Not Done	Sampled	Resected	Unknown
10R - Hilar	Not Done	Sampled	Resected	Unknown
10L - Hilar	Not Done	Sampled	Resected	Unknown
11 - Intralobar	Not Done	Sampled	Resected	Unknown
12 - Lobar	Not Done	Sampled	Resected	Unknown
13 - Segmental	Not Done	Sampled	Resected	Unknown
14 - Subsegmental	Not Done	Sampled	Resected	Unknown

Comments on Lymph Node Sampling

Post Op Analgesia:

- [ ] Epidural
- [ ] PCA
- [ ] Intercostal Nerve Block
- [ ] Extrapleural Intercostal Analgesia
- [ ] Wound Infiltration
- [ ] Oral Analgesia

Wound Class:

- Clean
- Clean Contaminated
- Contaminated
- Dirty Infected
- Unknown

Transferred To: PACU | ICU | Unknown

Procedure Specific Medical History

Delete History | New History

Index Procedure: Select...

*all values below must come from within 30 days of the procedure

Smoking History:

- Active
- Past
- Second Hand
- Never
- Unknown

Total Exposure: (pack-years)

Dyspnea: No | Yes | Unknown

Disseminated Cancer: No | Yes | Unknown

Systemic Sepsis: No | Yes | Unknown

Ascites: No | Yes | Unknown

Dialysis: No | Yes | Unknown

Preop Steroid Use for Chronic Condition: No | Yes | Unknown

Preop Chemo: No | Yes | Unknown

When was the chemotherapy?

- Less than 6 months before surgery
- Greater than 6 months before surgery

Preop Radiation: No | Yes | Unknown

When was the radiation therapy?

- Less than 6 months before surgery
- Greater than 6 months before surgery

The radiation therapy was for:

- Related Disease
- Unrelated Disease

Previous Surgery in similar region relevant to existing surgery: No | Yes | Unknown

Functional Status:
- Independent
- Partially Dependent
- Totally Dependent
- Unknown

Height (cm):

Weight (kg):

BMI:

FEV1 (%predicted):

DLCO (%predicted):

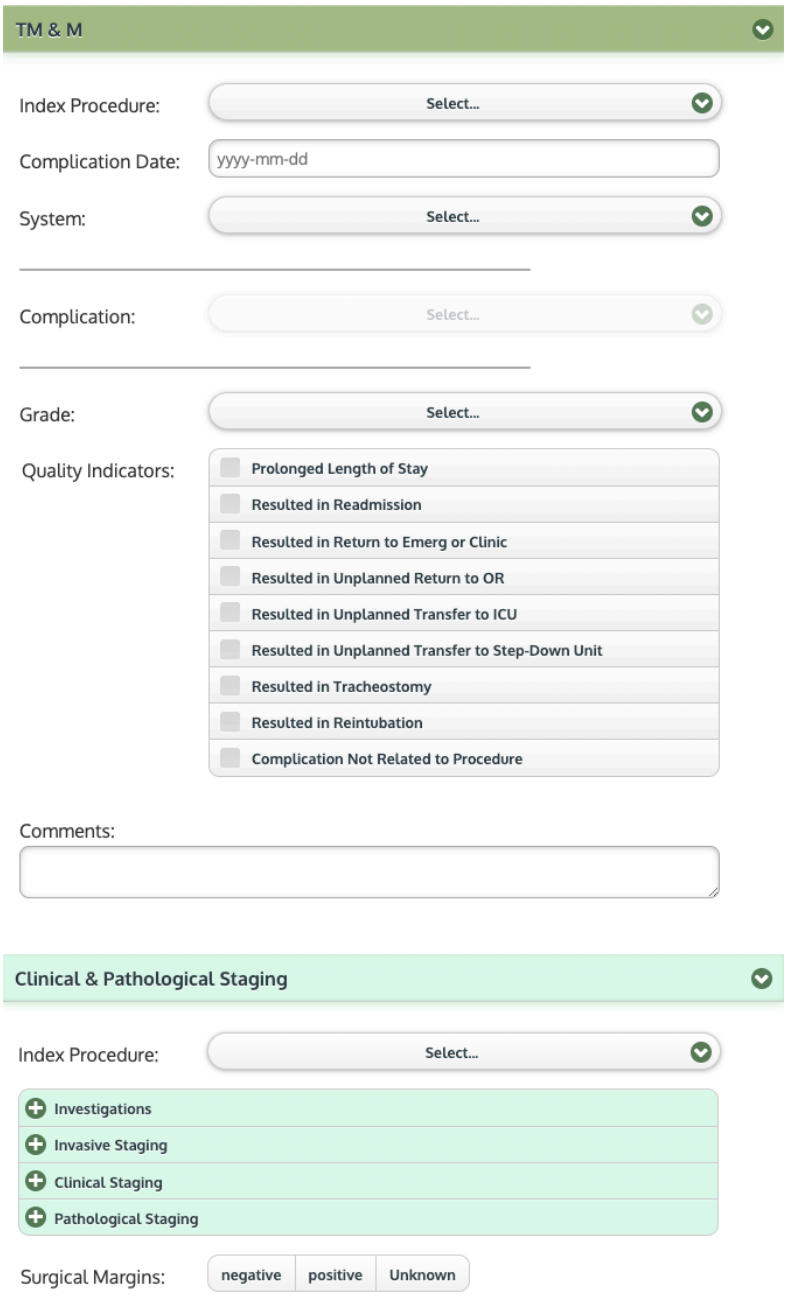
Reason for not performing PFTs:
- not a major lung resection
- never smoked and no lung dx
- tracheostomy or ventilator
- patient unable to perform
- urgent or emergent status
- Unknown

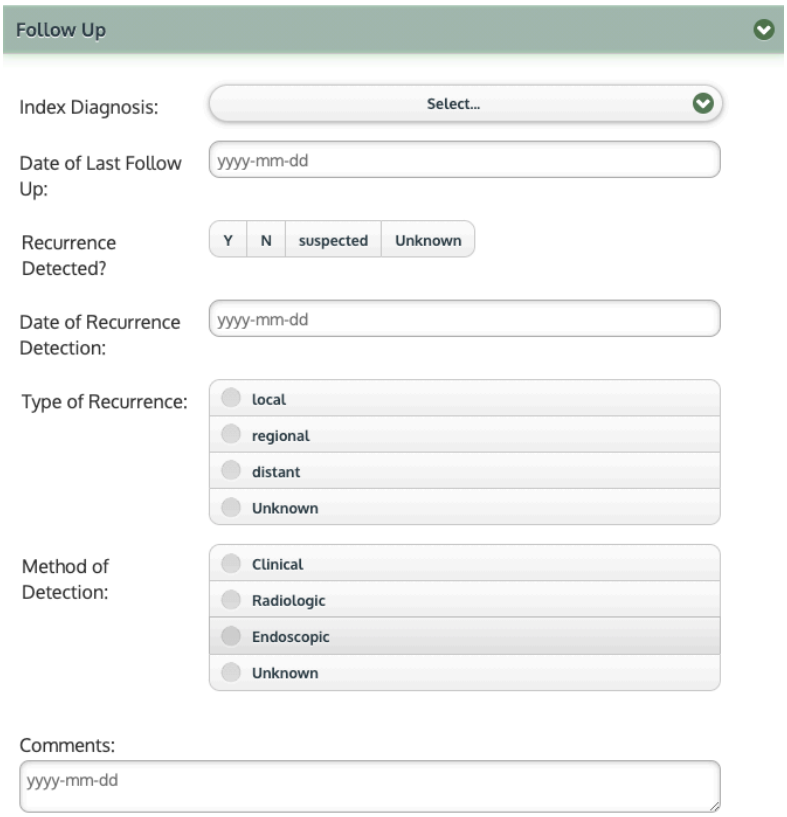
Creatinine:

Hemoglobin:

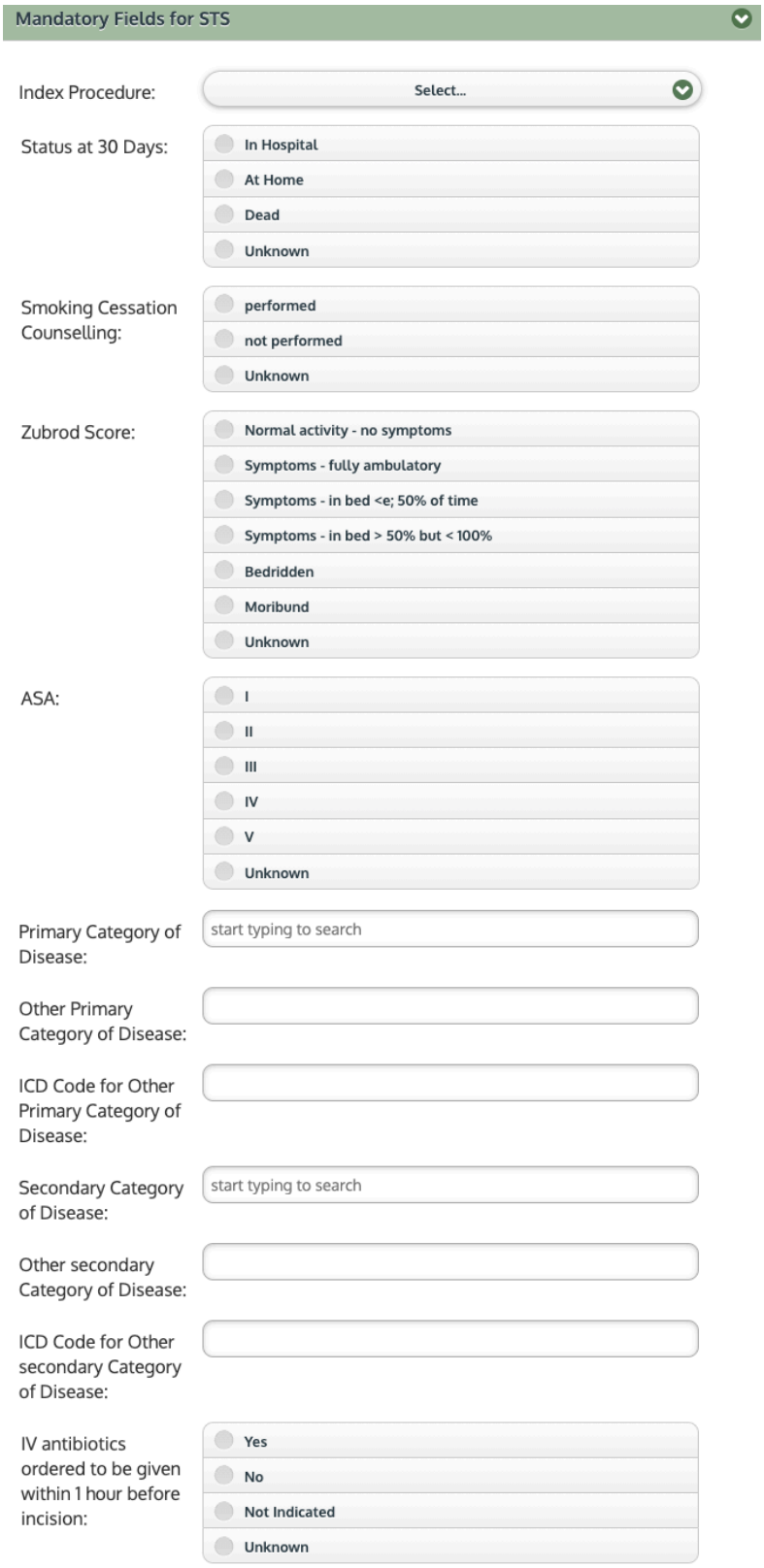
Interstitial Fibrosis: No | Yes | Unknown

Comments:


TM & M
Index Procedure:
Select...
Complication Date:
yyyy-mm-dd
System:
Select...
Complication:
Select...
Grade:
Select...
Quality Indicators:
Prolonged Length of Stay
Resulted in Readmission
Resulted in Return to Emerg or Clinic
Resulted in Unplanned Return to OR
Resulted in Unplanned Transfer to ICU
Resulted in Unplanned Transfer to Step-Down Unit
Resulted in Tracheostomy
Resulted in Reintubation
Complication Not Related to Procedure
Comments:
Clinical & Pathological Staging
Index Procedure:
Select...
Investigations
Invasive Staging
Clinical Staging
Pathological Staging
Surgical Margins:
negative
positive
Unknown


Follow Up
Index Diagnosis:
Select...
Date of Last Follow Up:
yyyy-mm-dd
Recurrence Detected?
Y
N
suspected
Unknown
Date of Recurrence Detection:
yyyy-mm-dd
Type of Recurrence:
local
regional
distant
Unknown
Method of Detection:
Clinical
Radiologic
Endoscopic
Unknown
Comments:
yyyy-mm-dd

Optional Form



IV antibiotics given within 1 hour before incision:	○ Yes ○ No ○ Not Indicated ○ Unknown
Cephalosporin Antibiotic Ordered	○ Yes ○ No ○ Not Indicated ○ Therapeutic Substitution ○ Unknown
Prophylactic Antibiotic Discontinuation Ordered within 24 hr	○ Yes ○ No ○ Not Indicated ○ No Due To Infection ○ Unknown

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