

Acute Phase Up To Day 3 Form

Section 1 - Participant Details

Trial Number: Initials: *First, Middle, Last* Site: _____

Section 2 - Post-Operative Ward Care

Please indicate which ward(s) patient stayed on each day by ticking the relevant boxes below

Note: Day 1 is first full calendar day (from 12 midnight) post surgery, Day 2 is second full calendar day, Day 3 is third full calendar day. If the patient was located on more than one ward type on a given day please only provide ward type patient was on at midnight going into the day

Ward Locations

	Day 1	Day 2	Day 3
General Ward	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acute Ward	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HDU Level 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ITU Level 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please confirm all above ward locations were considered and all relevant ward locations have been ticked? No Yes

Was the patient discharged from hospital within 3 days post-op? No Yes

If yes please provide date of discharge: *e.g. 31-Dec-2017* - -

Section 3 - Management of the local anaesthetic block during days 1-3

Was additional, unplanned involvement of the pain team required to address pain management? *if yes indicate if block was optimised below* No Yes

Was additional, unplanned involvement of an anaesthetist/other doctor required to address pain management? *if yes indicate reason below* No Yes

Optimise block? <i>E.g. addition of bolus, increase in rate</i> <input type="radio"/> No <input type="radio"/> Yes	Resite block? <i>E.g. reinsertion of the same block or insertion of new block. If yes complete below.</i> <input type="radio"/> No <input type="radio"/> Yes
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What was the re-sited block? *if applicable* TEB PVB Other If other, please specify _____

Date local anaesthetic infusion discontinued: <i>E.g. 31-Jan-2017</i> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u>	Time local anaesthetic infusion discontinued: <i>In 24 hour format</i> <u> </u> <u> </u> <u> </u> <u> </u>
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Was the PVB/TEB removed within 48 hours post-surgery? No Yes If yes reason why: _____

Please continue to next page.

Trial Number: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Initials: <i>First, Middle, Last</i> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>
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Section 4 - Post-operative Analgesia

Please indicate if the patient had any of the below analgesia on each day:

Day 1 No Yes

Day 2 No Yes

Day 3 No Yes

Analgesia - indicate those given each day by ticking the relevant boxes in the table below

	Day 1	Day 2	Day 3
Gabapentin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pregabalin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ketamine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PCA Opioid(s) - if yes provide doses in table on next pg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oral Opioid(s) - if yes provide doses in table on next pg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IV Opioid(s) - if yes provide doses in table on next pg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Topical Opioid(s) - if yes provide doses in table on next pg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Top-up Bolus Via Catheter (excluding PCEA top-ups)- if yes provide no. in table on next pg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please continue to next page.

Opioid Analgesia Doses		
Please provide total cumulative doses of each type given on each day (If pump reset, add up with previous dose)		
Day 1	Day 2	Day 3
<p>Opioid 1</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 1</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 1</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>
<p>Opioid 2</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 2</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 2</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>
<p>Opioid 3</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 3</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>	<p>Opioid 3</p> <p>Drug: _____</p> <p>Dose: ____ _ . ____</p> <p>Dose unit: mg <input type="checkbox"/> mcg <input type="checkbox"/></p> <p>mcg/hour <input type="checkbox"/></p> <p>Route: Oral <input type="checkbox"/> IV <input type="checkbox"/> PCA <input type="checkbox"/></p> <p>Topical <input type="checkbox"/></p>
Please specify the number of local anaesthetic top-ups via catheter (excluding PCEA top-ups) in each 24h period		
Day 1 <input style="width: 40px; height: 20px;" type="text"/>	Day 2 <input style="width: 40px; height: 20px;" type="text"/>	Day 3 <input style="width: 40px; height: 20px;" type="text"/>

Please confirm all post operative analgesia section data items were considered and all analgesia used have been ticked and recorded? No Yes

Please continue to next page.

Trial Number:

Initials: *First, Middle, Last*

Section 5 - Complications

Did the patient suffer any of the following complications in the period following surgery to the end of day 3? *Please tick all that apply and grade severity according to Thoracic Morbidity and Mortality Classification Format (refer to pages 7 to 11).*

This should cover the period from recovery up to the end of day 3

No Yes

Complications (consider if SAE)		
	Yes	TMM Grade I-V e.g. IIIa, IVb
Nausea	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Vomiting	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Post-dural Headache	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Blockade Failure	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Vascular Puncture	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Pleural Puncture	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Atelectasis	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
ARDS	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Pulmonary Aspiration	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Pulmonary Embolism	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Atrial Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Ventricular Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Myocardial Infarction	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
DVT	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Renal Failure	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Urinary Retention	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Hypotension (systolic bp <90mmHg)	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Neurological Complication	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Low Respiratory Rate (<10/minute)	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Drowsiness	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Itching	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
High Block	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Please confirm all above items in the complications section have been considered and only those ticked occurred? No Yes

Has the patient tested positive for an acute COVID19 infection in the period following surgery to end of day 3? No Yes

Please continue to next page

Trial Number: Initials: *First, Middle, Last*

Did the patient suffer an SAE as a result of a protocol defined expected event in the period from the intervention to end of day 3? *If yes indicate below* No Yes

If patient suffered an SAE that was not a protocol defined expected event an SAE form must be completed and sent to the trial office

Protocol defined expected event:

<input type="radio"/> ARDS	<input type="radio"/> Atelectasis	<input type="radio"/> Atrial arrhythmia
<input type="radio"/> Bronchopleural fistula	<input type="radio"/> DVT	<input type="radio"/> Failure of blockade
<input type="radio"/> Hypotension	<input type="radio"/> Inadequate pain relief	<input type="radio"/> Itching
<input type="radio"/> Myocardial infarct	<input type="radio"/> Nausea	<input type="radio"/> Neurological complication
<input type="radio"/> Pleural effusion	<input type="radio"/> Pleural puncture	<input type="radio"/> Pneumonia
<input type="radio"/> Pneumothorax	<input type="radio"/> Postdural puncture headache	<input type="radio"/> Post-surgical bleed
<input type="radio"/> Prolonged air leak	<input type="radio"/> Pulmonary aspiration	<input type="radio"/> Pulmonary embolism
<input type="radio"/> Renal failure	<input type="radio"/> Respiratory failure type 1	<input type="radio"/> Respiratory failure type 2
<input type="radio"/> Urinary retention	<input type="radio"/> Vascular puncture	<input type="radio"/> Ventricular arrhythmia
<input type="radio"/> Vomiting	<input type="radio"/> Surgical emphysema	<input type="radio"/> Chylothorax

Seriousness of Event (Each Yes/No question requires a response)

	No	Yes
Death	<input type="checkbox"/>	<input type="checkbox"/>
Life Threatening Event	<input type="checkbox"/>	<input type="checkbox"/>
Prolongation of Existing Hospitalisation	<input type="checkbox"/>	<input type="checkbox"/>
Persistent or Significant Disability/Incapacity	<input type="checkbox"/>	<input type="checkbox"/>
Congenital Anomaly or Birth Defect	<input type="checkbox"/>	<input type="checkbox"/>
Other Medical Reason For Reporting	<input type="checkbox"/>	<input type="checkbox"/>

Specify other medical reason: _____

If death please complete trial exit/change of status form

Event severity Mild Moderate Severe Life threatening Fatal

Date of onset - - Date became serious: - -

Date resolved - -

Section 6 - Return to theatre during days 1-3

Did the patient return to theatre? *If yes please complete below* No Yes

Bronchoscopy No Yes Redo thoracotomy No Yes Other No Yes

If other, please specify _____

Section 7 - Patient Completed Booklets

Did patient complete booklets at days 1, 2 and 3? No Yes

If no, please specify day(s) not completed and provide reason: _____

Please continue to next page

Trial Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Initials: <i>First, Middle, Last</i> <input type="text"/> <input type="text"/> <input type="text"/>
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Section 8 - Willing to Continue

Has the patient confirmed their willingness to continue? *If no complete trial exit/change of status form* No Yes

Section 9 - Form Completion

Completed By (Name): _____	Signed: _____	Date: <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u>
PI Name: _____	PI Confirmation Signature: _____	Date: <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> - <u> </u> <u> </u> <u> </u> <u> </u>

Major cardiopulmonary complications as classified by the European Society of Thoracic Surgeons

ARDS: Adult respiratory distress syndrome defined according to the American--European consensus conference. All of the following criteria should be met:

1. Acute onset
2. Arterial hypoxemia with PaO₂/FIO₂ ratio lower than 200 (regardless PEEP level)
3. Bilateral infiltrates at chest radiograph or CT scan
4. No clinical evidence of left atrial hypertension or pulmonary artery occlusive pressure <18 mmHg
5. Compatible risk factors

Atrial Arrhythmia: new onset of atrial fibrillation/flutter (AF) requiring medical treatment or cardioversion. Does not include recurrence of AF which had been present preoperatively.

Ventricular Arrhythmia: sustained ventricular tachycardia or ventricular fibrillation that has been clinically documented and treated by ablation therapy, implantable cardioverter defibrillator, permanent pacemaker, pharmacologic treatment or cardioversion.

Bronchoscopy for atelectasis: postoperative atelectasis documented clinically or radiographically that needed bronchoscopy.

Pneumonia: defined according to the last CDC criteria. Two or more serial chest radiographs with at least **one** of the following:

- New or progressive and persistent infiltrate
- Consolidation
- Cavitation

And at least **one** of the following:

- Fever (>38°C or >100.4°F) with no other recognized cause
- Leukopenia (<4000 WBC/mm³) or leukocytosis (>12,000 WBC/mm³)
- For adults >70 years old, altered mental status with no other recognized cause

and at least **two** of the following:

- New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, or dyspnea, or tachypnea
- Rales or bronchial breath sounds Worsening gas exchange (e.g. O₂ desaturations (e.g., PaO₂/FiO₂ < 240), increased oxygen requirements, or increased ventilator demand).

Pulmonary embolism: confirmed by V/Q scan, angiogram or CT scan.

DVT: deep venous thrombosis confirmed by Doppler study, contrast study or other study and that required treatment.

Myocardial infarct: evidenced by one of the following criteria:

1. Transmural infarction diagnosed by the appearance of a new Q wave in two or more contiguous leads on ECG.
2. Subendocardial infarction (non Q wave) evidenced by clinical, angiographic electrocardiographic signs.
3. Laboratory isoenzyme evidence of myocardial necrosis.

Renal failure: defined as the onset of new renal failure in the postoperative period according to one of the following criteria:

1. Increase of serum creatinine to greater than 2.0, and 2-fold the preoperative creatinine level.
2. A new requirement for dialysis postoperatively.

Neurological complication: occurrence of one of the following central neurologic postoperative events not present preoperatively:

1. A central neurologic deficit persisting postoperatively for more than 72 hours
2. A transient neurologic deficit (transient ischemic attack or reversible ischemic neurological deficit) with recovery within 72 hours
3. A new postoperative coma persisting at least 24 hours and caused by anoxic/ischemic and/or metabolic encephalopathy, thromboembolic event or cerebral bleed.

Seeley Systematic Classification of Morbidity and Mortality After Thoracic Surgery (TM &M) Classification of Severity

Complication: Any deviation from the normal postoperative course.

Minor	
Grade I	Any complication without need for pharmacologic treatment or other intervention.
Grade II	Any complication that requires pharmacologic treatment or minor intervention only.
Major	
Grade III	Any complication that requires surgical, radiologic, endoscopic intervention, or multi-therapy.
Grade IIIa	Intervention does not require general anaesthesia.
Grade IIIb	Intervention requires general anaesthesia.
Grade IV	Any complication requiring intensive care unit management and life support.
Grade IVa	Single organ dysfunction.
Grade IVb	Multi-organ dysfunction.
Mortality	
Grade V	Any complication leading to the death of the patient.

StEP Core Outcome Measures in Perioperative and Anaesthetic Care (COMPAQ) – Post-operative Pulmonary Complications

ARDS - Berlin definition

Timing: within 1 week of a known clinical insult or new or worsening respiratory symptoms
AND...

Chest imaging: bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules **AND...**

Origin of oedema: respiratory failure not fully explained by cardiac failure or fluid overload (requires objective assessment, e.g. echocardiography, to exclude hydrostatic oedema),
AND...

Oxygenation: mild $\text{PaO}_2:\text{FiO}_2$ between 26.7 and 40.0 kPa (200-300 mm Hg) with PEEP or CPAP_5 cm H_2O ; moderate $\text{PaO}_2:\text{FiO}_2$ between 13.3 and 26.6 kPa (100-200 mm Hg) with PEEP_5 cm H_2O ; severe $\text{PaO}_2:\text{FiO}_2$ \leq 13.3 kPa (100 mm Hg) with PEEP_5 cm H_2O .

Mechanical ventilation

The need for need for tracheal re-intubation and mechanical ventilation after extubation, and within 30 days after surgery OR mechanical ventilation for more than 24 h after surgery. The inclusion of non-invasive ventilation may be considered on a study by study basis.

Post-operative Complications*

Composite of respiratory diagnoses that share common pathophysiological mechanisms including pulmonary collapse and airway contamination:

- (i) atelectasis detected on computed tomography or chest radiograph,
- (ii) pneumonia using US Centers for Disease Control criteria,
- (iii) Acute Respiratory Distress Syndrome using Berlin consensus definition,
- (iv) pulmonary aspiration (clear clinical history **AND** radiological evidence).

*Exclusions

Other diagnoses that do not share a common biological mechanism are best evaluated separately and only when clearly relevant to the treatment under investigation:

- (i) pulmonary embolism,
- (ii) pleural effusion,
- (iii) cardiogenic pulmonary oedema,
- (iv) pneumothorax,
- (v) bronchospasm.

Post-operative Pneumonia

Two or more serial chest radiographs with at least one of the following (one radiograph is sufficient for patients with no underlying pulmonary or cardiac disease):

- (i) New or progressive and persistent infiltrates, (ii) consolidation
- (iii) cavitation; **AND** at least **one** of the following:

- (a) fever ($>38^{\circ}\text{C}$) with no other recognised cause,
- (b) leucopaenia (white cell count $<4 \times 10^9$ litre⁻¹) or leucocytosis (white cell count $>12 \times 10^9$ litre⁻¹),
- c) for adults >70 yr old, altered mental status with no other recognised cause;

AND at least **two** of the following:

- (a) new onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements,
- (b) new onset or worsening cough, or dyspnoea, or tachypnoea,
- (c) rales or bronchial breath sounds,
- (d) worsening gas exchange (hypoxaemia, increased oxygen requirement, increased ventilator demand).