

The Delphi Technique: Developing a Consensus on Indications, Timing and Core Outcome Measures for Rib Fracture Surgical Fixation

Consent

This question confirms your consent to participate in the study.

The decision to complete this consensus questionnaire is voluntary. If you do complete the questionnaire, information you provide will be included in our analysis along with anonymised direct quotes.

- I confirm I have read an understood the information provided above and in the participant information sheet – click <u>here</u>
- I understand that the completion of this questionnaire is voluntary
- I agree to the use of anonymised quotes in publications
- I agree that my data gathered in this study will be kept and stored confidentially
- I understand I can drop out at anytime

It is encouraged that you complete all rounds as the reliability of the results could be compromised if you drop out. Even if you feel your views are in the minority compared to others within the group it is important to continue as the final results may overestimate the degree of consensus.

Do you agree with all of these statements and agree to take part in this study?

Yes

No

Are you an allied health professional, clinician, patient or carer? – Drop down box

Patient or Carer (takes the participant only to the outcome questions)

Allied Health Professional (takes the participant only to the outcome questions)

Clinician (takes participant through the full survey)

Appendix F 04/12/2017 Version 2.0

If clinician box is selected a further question will be asked

What is your **specialty?**

Emergency Medicine

Cardiothoracic Surgery

Trauma and Orthopaedics

General Surgery

Intensive Care Medicine

Other with free text box

Medical panel only

In your **own words**, list up to **five INDICATIONS** in which you would offer surgery to fix any type of adult rib fracture. (Could include a certain injury pattern, patient demographic or a particular sign or symptom)

- Indication 1
- Indication 2
- Indication 3
- Indication 4
- Indication 5

In your **own words**, what would be the **EARLIEST** you would operate on adult patient?

- Earliest Timing 1
- Earliest Timing 2
- Earliest Timing 3

In your **own words**, what would be the **LATEST** you would operate on adult patient?

- Latest Timing 1
- Latest Timing 2
- Latest Timing 3

In your **own words**, how long would you **TRIAL WEANING** from a ventilator before considering rib fracture fixation?

- Wean Time 1
- Wean Time 2
- Wean Time 3

Appendix F 04/12/2017 Version 2.0

All participants will answer this question

In your **own words**, what do you believe are the most important **OUTCOMES** to measure following rib fracture surgery in adults? Please list up to **five** outcome measures.

- Outcome 1
- Outcome 2
- Outcome 3
- Outcome 4
- Outcome 5

Please click <u>here</u> to access the information leaflet

Medical panel only

The second part of the questionnaire will ask you to rate the importance of each statement based on your experience. Statements are in three groups including indications for surgery, timing of surgery and outcome measures.

Indications for surgery

In this section, each statement describes an indication for surgical fixation of rib fractures. We would like you to rate, which you feel are important and should inform a list of recommendations on rib fracture surgery.

If you feel unable to comment based on your experience, please select 'unable to score'. Please rate on the scale

- 1-3 Not important
- 4 6 Important but not critical
- 7 9 Critically important.

If you would like clarification on any of the statements or further instructions, please click the link <u>here</u>

A list of the statements is provided but will be formatted as below with a rating scale for each statement.

Figure 1 Preview of questionnaire format with rating scale and comments box

A patient should be routinely offered surgical rib fixation for the following injury patterns

	Not Important 1-3				tant but ritical 4-6	Critical 7-9				
	1	2	3	4	5	6	7	8	9	Unable to comment
Any flail segment	0	0	0	0	0	0	0	0	0	0
Any flail segment with paradoxical movement (flail chest)	0	0	0	0	0	0	0	0	0	0
Flail chest with respiratory compromise	0	0	0	0	0	0	0	0	0	0
Flail chest and patient requiring invasive ventilation	0	0	0	0	0	0	0	0	0	0
Please write any comr you think that a staten needs further explanat feedback on items suc round.	nent is ion, ex	alread pansic	y cove on or c	ered wit larity. V	hin and /e wou	other o	r if you ngly re	feel th	e state end yo	ement u provide

Definitions

Flail SEGMENT – A radiological diagnosis of a segmental rib fracture in 2 or more adjacent ribs

Flail CHEST – A clinical diagnosis of a flail segment with paradoxical movement

A patient should be **routinely offered** surgical rib fixation for the following injury patterns:

Segmental fractures

- 1. Any Flail SEGMENT no paradoxical movement
- 2. Any **Flail SEGMENT** with paradoxical movement (flail chest)
- 3. Flail CHEST with respiratory compromise
- 4. Flail CHEST and patient requiring invasive ventilation
- 5. Flail CHEST and intractable pain despite regional and epidural anaestheia
- 6. Flail CHEST and failure to wean from ventilation within 48 hours
- 7. Flail CHEST with deformity
- 8. Flail CHEST requiring tracheostomy placement
- 9. Flail CHEST and haemodynamic instability

- 10. Flail CHEST and pulmonary contusion
- 11. Flail CHEST and traumatic brain injury
- 12. Flail CHEST and underlying chronic lung disease

Simple Rib Fractures

- 13. **FOUR** or more **unilateral** adjacent rib fractures (non-flail chest)
- 14. **TWO** or **THREE unilateral** adjacent rib fractures (non-flail chest)
- 15. **ONE unilateral** rib fracture (non-flail chest)
- 16. MULTIPLE adjacent rib fractures with displacement of more than 1 rib width
- 17. **MULTIPLE** adjacent rib fractures with paradoxical movement
- 18. MULTIPLE adjacent rib fractures with respiratory compromise
- 19. MULTIPLE adjacent rib fractures and patient requiring invasive ventilation
- 20. **MULTIPLE** adjacent rib fractures and intractable pain despite regional and epidural anaestheia
- 21. **MULTIPLE** adjacent rib fractures and failure to wean from ventilation within 48 hours
- 22. MULTIPLE adjacent rib fractures with deformity
- 23. **MULTIPLE** adjacent rib fractures requiring tracheostomy placement
- 24. **MULTIPLE** adjacent rib fractures and haemodynamic instability
- 25. **MULTIPLE** adjacent rib fractures and pulmonary contusion
- 26. MULTIPLE adjacent rib fractures and traumatic brain injury
- 27. MULTIPLE adjacent rib fractures and underlying chronic lung disease

Other indications

- 28. **ANY chest wall injury** requiring a thoracic operation for another indication (fix on retreat)
- 29. ANY chest wall injury with more than 30% volume loss of hemithorax
- 30. ANY rib fracture with anticipated non-union

Please write any comments you have on the above statements. Comments could include if you think that a statement is already covered within another or if you feel the statement needs further explanation, expansion or clarity. We would **strongly recommend** you provide feedback on items such that we can incorporate your thoughts and ideas into the second round.

Timing of surgery

In this section, each statement describes a scenario in which you are asked on your opinion on the timing of surgical fixation of rib fractures. We would like you to rate, which you feel are important and should inform a list of recommendations on timing of rib fracture surgery.

If you feel unable to comment based on your experience, please select 'unable to score'. Please rate on the scale

- 1 3 Not important
- 4 6 Important but not critical
- 7 9 Critically important.

If you would like clarification on any of the statements or further instructions, please click the link <u>here</u>

In the **first** scenario, your patient satisfies the indications for surgery. Having decided that your patient **requires surgery** in your opinion what would be the **EARLIEST** you would surgically fix any patient regardless of the **ventilation state** or **the injury morphology**?

- 1. The **EARLIEST** time a patient (independent of ventilation status or injury morphology) should have fracture fixation is **within 24 hours** after injury
- The EARLIEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 24 and 48 hours after injury
- The EARLIEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 48 and 72 hours after injury
- The EARLIEST time a patient (independent of ventilation status or injury morphology should have fracture fixation is between 3 and 5 days after injury

- The EARLIEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 5 and 7 days after injury
- The EARLIEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 7 and 14 days after injury
- 7. The **EARLIEST** time a patient (independent of ventilation status or injury morphology) should have fracture fixation **is more than 14 days** after injury

In the **second** scenario, your patient satisfies the indications for surgery. Having decided that your patient **requires surgery** in your opinion what would be the **LATEST** you would surgically fix any patient regardless of the **ventilation state** or **the injury morphology**?

- 8. The **LATEST** time a patient (independent of ventilation status or injury morphology) should have fracture fixation is **within 24 hours** after injury
- The LATEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 24 and 48 hours after injury
- 10. The LATEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 48 and 72 hours after injury
- 11. The LATEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 3 and 5 days after injury
- 12. The LATEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 5 and 7 days after injury
- 13. The LATEST time a patient (independent of ventilation status or injury morphology) should have fracture fixation is between 7 and 14 days after injury
- 14. The **LATEST** time a patient (independent of ventilation status or injury morphology) should have fracture fixation is **more than 14 days** after injury

For a rib fracture patient who is **ventilated**, the **ABILITY TO WEAN** from a ventilator may influence decision making.

In the **third** scenario, your rib fracture patient is ventilated. How long would you use a **TRIAL OF WEANING** from a ventilator **BEFORE** considering surgical fixation?

- 15. In a patient that requires invasive ventilation, they should **NOT** have a **TRIAL OF WEANING** from a ventilator before considering surgical fixation
- 16. In a patient that requires invasive ventilation, they should have a **TRIAL OF WEANING** from a ventilator for **at least 24 hours** before considering surgical fixation
- 17. In a patient that requires invasive ventilation, they should have a **TRIAL OF WEANING** from a ventilator **between 24 and 48 hours** before considering surgical fixation
- 18. In a patient that requires invasive ventilation they should have a TRIAL OF WEANING from a ventilator between 48 hours and 72 hours before considering surgical fixation
- 19. In a patient that requires invasive ventilation they should have a TRIAL OF WEANING from a ventilator between 3 and 5 days before considering surgical fixation
- 20. In a patient that requires invasive ventilation they should have a TRIAL OF WEANING from a ventilator between 5 and 7 days before considering surgical fixation
- 21. In a patient that requires invasive ventilation should have a **TRIAL OF WEANING** from a ventilator **between 7 and 14 days** before considering surgical fixation
- 22. In a patient that requires invasive ventilation should have **A TRIAL OF**WEANING from a ventilator more than 14 days before considering surgical fixation

The **forth** scenario describes in what time frame after a **decision** has been made on treatment should patients be **transferred**, **referred** or **operated** on.

- 23. Patients should be **REFERRED** to a **multidisciplinary trauma unit** within **24 hours** for consideration of surgical rib fracture fixation
- 24. Patients should be **REFERRED** to a **multidisciplinary trauma unit** within **48 hours** for consideration of surgical rib fracture fixation
- 25. Patients should be **TRANSFERRED** to a **multidisciplinary trauma unit** for rib fracture fixation within **24 hours** of the decision to transfer or the patient becoming fit for transfer.
- 26. Patients should be **TRANSFERRED** to a **multidisciplinary trauma unit** for rib fracture fixation within **48 hours** of the decision to transfer or the patient becoming fit for transfer.
- 27. Patients with rib fractures (independent of ventilation status or type of injury) should have surgical fixation within 24 hours of the DECISION to operate unless patient becomes unwell or there are complications
- 28. Patients with rib fractures (independent of ventilation status or type of injury) should have surgical fixation **within 48 hours** of the **DECISION to operate** unless patient becomes unwell or there are complications

Please write any comments you have on the above statements. Comments could include if you think that a statement is already covered within another or if you feel the statement needs further explanation, expansion or clarity. We would strongly recommend you provide feedback on items such that we can incorporate your thoughts and ideas into the second round.

All participants will answer the following questions

Outcomes

In this section, each statement describes a type of outcome. We would like you to rate, which you feel are important and should inform a list of recommendations for a core outcome set on rib fracture surgery.

It is the expectation that the core outcome set will always be collected and reported as a minimum within future trials making it easier for trials to be compared and contrasted. Other particular outcomes of relevance may be included within trial but may not form part of the 'core' outcome set.

If you feel unable to comment based on your experience, please select 'unable to score'. Please rate on the scale

- 1-3 Not important
- 4 6 Important but not critical
- 7 9 Critically important.

If you would like clarification on any of the statements or further instructions, please click the link <u>here</u>

Adverse events

How important are the following **adverse events** (a complication) for the evaluation rib fracture surgery effectiveness?

- 1. Overall adverse events (a complication)
 - a. Acute Respiratory Distress Syndrome (not able to get enough oxygen into the body due to inflammation in the lungs in critically ill patients)
 - b. Barotrauma (pressure damage to lungs following using a machine to help you breathe)
 - c. **Empyema** (a collection of pus in the lining of the lung and the lining or the ribcage)
 - d. **Mediastinitis** (inflammation or infection of the lining surrounding the heart)
 - e. **Metal work failure** (broken metal plates within the body)

- f. **Multi Organ Failure** (a life threatening illness that causes the organs (lungs, liver, kidneys, heart) of the body to stop working)
- g. **Pleural effusion** (fluid between the lining of the lung and the lining or the ribcage)
- h. **Pneumonia** (an infection within the lung)
- i. Pulmonary embolism (clot of material (an embolus) that blocks blood from getting to the lungs)
- Reintubation or Failed extubation (having a tube reinserted into the windpipe to help breathing after removal of a previous tube)
- k. **Re-operation** (needing a further operation)
- I. **Respiratory failure** (not able to get enough oxygen into the body)
- m. **Retained Haemothorax** (blood that stays between the lining of the lung and the lining or the ribcage)
- n. **Sepsis** (a life-threatening illness that can occur when the whole body reacts to an infection)
- o. **Wound Infection** (redness and pain over the surgical site)
- 2. Overall perioperative adverse events (a complication during surgery)
 - a. latrogenic mediastinal injury (an injury to the cavity containing the heart during surgery)
 - b. **latrogenic nerve injury** (an injury to a nerve caused by surgery)
 - c. latrogenic thoracic injury (an injury to the cavity containing the lungs during surgery)
 - d. **latrogenic vascular injury** (an injury to a blood vessel caused by surgery)
- 3. Rib fracture non-union (rib fractures that do not heal)

Death

How important is the following **mortality** outcome for the evaluation rib fracture surgery effectiveness?

4. Mortality

Physiological or clinical

How important are the following **physiological and clinical** outcomes for the evaluation rib fracture surgery effectiveness?

- 5. Acute pain (sudden pain)
- 6. **Breathing movements** (the movement of the rib cage during breathing)
- 7. Chest discomfort/ tightness
- 8. Chest wall deformity (the shape of the rib cage)
- 9. Chronic Pain (ongoing pain)
- 10. **Dysopnea** (shortness of breath)
- 11. Fracture healing (how much the fracture has healed or united)
- 12. Kinesiophobia (fear of moving)
- 13. Lung Function (how well air is blow out of the lungs)
- 14. **Movement of the thorax** (how well the rib cage moves)
- 15. Oxygen saturations (how much oxygen in the blood)
- 16. **Scoliosis** (curvature of the spine)
- 17. **Shoulder function** (how well the shoulder works)
- 18. **Ventilation** (how well air can move between the lungs and outside the body)

Life impact

How important are the following **life impact** outcomes for the evaluation rib fracture surgery effectiveness?

- 19. **Disability** (a limit to a person's movements, senses, or activities)
- 20. **Discharge Destination** (where a patient lives after leaving hospital)
- 21. **Home Oxygen Therapy** (using a mask connected to a cylinder of oxygen to help with breathing)
- 22. Mental health (person's emotional well-being)
- 23. **Physical function** (performing tasks)
- 24. **Quality of life** (the standard of health, comfort, and happiness experienced by an individual)
- 25. Return to Activities
- 26. Return to Work
- 27. **Satisfaction** (whether the service met your requirements)

Resource use

How important are the following **resource use** outcomes for the evaluation rib fracture surgery effectiveness?

- 28. **Antibiotic requirements** (whether antibiotic medicine is needed)
- 29. Chest drain (a tube that is inserted into the chest to get rid of air or fluid)
- 30. Cost of treatment
- 31. **Epidural** (an injection in the back to stop feeling pain in a part of the body)
- 32. **Hospital readmission** (If you need to come back to hospital after leaving the hospital following your treatment)
- 33. Hospital stay (how long someone stays in hospital)
- 34. Intensive care unit (ICU) stay (a specialised ward in a hospital that cares for patients who are critically ill and requires specialist medical equipment and nursing care)
- 35. Intensive care unit (ICU) readmission (the need to come back to ICU after leaving the ICU following treatment)
- 36. **Invasive mechanical ventilation** (a tube inserted into the windpipe and attached to a machine that assists breathing)
- 37. **Non-invasive ventilation** (through a mask or a hood a machine helps supports a patient's own breathing)
- 38. **Plasma Transfusion requirements** (receiving the part of the blood that contains factors that help the blood clot and take away used products from a donor by injection)
- 39. **Red Cell Transfusion requirements** (receiving the part of the blood that contain red cells (red cells carry oxygen) from a donor by injection
- 40. **Tracheostomy** (a cut in the wind pipe replaced with a tube that helps reduce the work of breathing)

Please write any comments you have on the above statements. Comments could include if you think that a statement is already covered within another or if you feel the statement needs further explanation, expansion or clarity. We would strongly recommend you provide feedback on items such that we can incorporate your thoughts and ideas into the second round.

Are there any statements relating to indications for rib fracture fixation surgery that							
you think have not been covered in this questionnaire?							
Are there any statements relating to timing of surgery for rib fracture fixation that you							
think have not been covered in this questionnaire?							
Are there any statements on outcome measures for rib fracture fixation that you think							
have not been covered in this questionnaire?							