

Developing a Core Outcome Set and a Consensus Statement on Indications and Timing for Surgical Rib Fracture Fixation Trials

A Delphi Study Participant Information Sheet

What is a Delphi Consensus? – A general overview of the process

A consensus on the **indications** and **timing of surgical fixation** of rib fractures is not well established or evidenced and has not been undertaken with a consensus panel of multiple clinical specialties. If considering further trial work on rib fracture surgical fixation then clear evidence for the indication and timing of surgery needs agreement.

How are health care treatments developed?

To help patients, doctors and other health professionals make decisions about treatments, we need evidence about what works best. Treatments are developed and tested by researchers to make sure they work and are safe. To do this researchers need to look at the effects those treatments have on patients. Researchers do this by measuring an '**outcome**'. For example, in a study of how well rib fracture surgery treatment works, 'outcomes' might include:

- A measure of how fast you can blow air out of your lungs
- How long you stayed in hospital
- Quality of life measure

How do researchers decide on the indications for surgery and what outcomes are important to measure in research studies?

When researchers design research studies to investigate treatments for health conditions they need to know what are the indications for that health intervention and what outcome measures are important and relevant to those people affected by the condition. To decide which outcomes are important researchers need to get everyone's opinion and try to reach agreement, or “consensus”, on the most important outcomes. In order to do this, researchers carry out a 'consensus exercise'. One way of doing this is by using something called a 'Delphi' study. In a Delphi study researchers identify groups of people who are “experts” in the health condition they are interested in. “Experts” are:

- People with personal experience of the condition, for example, patients, carers and service users (it doesn't matter how long the person has had the condition for, their opinion is incredibly valuable).
- Health professionals with expertise in treating and caring for people with the condition.

Experts taking part in a Delphi study are asked to give their opinion on what outcomes are most important. The study is anonymous to make sure everyone has an equal say. Patients and allied health professionals will be asked their opinions on outcomes however only clinicians will be asked to rate statements on indications and timing of surgical fixation to a consensus statement.

What happens early on in a Delphi Study?

The research team has developed a long list of possible outcomes that they want to ask the experts about. This list has been created after looking at research papers.

What happens next?

You have been sent the list in the form of a questionnaire by email link and asked to score the importance of each statement and outcome. If, in your opinion, there are key outcomes or statements missing from the list, they you are encouraged to add these to the list. We refer to this as “Round 1” of the Delphi study. Your ratings will be returned back to the research team, we will then summarise the responses from the group as a whole and send this summary back to each expert in what we refer to

as Round 2 of the Delphi process. At this stage each expert is given the range of scores of the rest of the group. No-one in the group can see your score; and you can only see the overall results for the group as a whole. Using this information you are asked to reflect on your own view and on the view of the group and to decide whether you stick with your original rating or change it. Through the whole process no-one is under any pressure to change their rating if they don't want to. It is perfectly fine for you to stick with your original rating even if you rated the outcome or statement differently to the rest of the group. Your responses are then sent back again to the research team who again collate the information.

Every time the researchers ask the experts for their opinions we call this a 'round' of the Delphi. Each time the idea is that the experts review their previous score based on what the group rated in their last round. At the end of this process the research team produce a report on what the experts have agreed as the most important outcomes. These are called the 'core outcomes' for a particular health condition.

Aim of this study

The aim of the study is to develop a consensus on the **indications** and **timing of fixation** of rib fractures which will undertaken by **clinicians**. In addition a consensus will be undertaken to develop a **core outcome set** for surgical rib fracture fixation this part of the Delphi consensus will bring together **clinicians** in the field of rib fracture surgery and chest trauma care with **allied health professionals** and **patients**. The consensus process will follow the Delphi method and will be completed as anonymous online questionnaires with up to three rounds. Each round will be open for four weeks at a time.

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 consensus.

Who is doing the study?

The Chief Investigator is Dr Helen Ingoe who is an Orthopaedic Surgeon in Training based at the University of York Trials Unit. The York Trials Unit is sponsored by the British Orthopaedic Association to develop and expand the portfolio of trials in the

UK related to trauma and orthopaedics. This work is being completed as part of an MD project and is sponsored by Orthopaedic Research UK.



Who is being asked to participate? *or* Why have I been asked to participate?

You are being asked to participate, as you have experienced a blunt chest trauma injury with rib fractures or you care for someone who has had this injury.

Do I have to take part?

The questionnaires are voluntary, you will be asked to consent to take part by accepting the terms at the beginning of the questionnaire.

What will be involved if I take part in this study?

The study will involve up to three online questionnaires each will take 15 minutes to complete online.

Delphi Consensus

Method

Round One

The first part of the questionnaire will ask you about **your thoughts** on indications for surgery, timing of surgery and outcomes you feel are important to measure. The second part comprises of a list of outcomes that has been compiled following a review of the research studies. You will be asked to score on a scale of 1 to 9

important the statement on indications and timing or the outcome measure is, one being not important and nine being critically important. There will be a free text box for you to add any comments. Comments could include if you think that a statement or outcome is already covered within another statement or if you feel the outcome 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. If you are unable to comment on the outcome then please select unable to comment.

Scoring

Statement and outcome scores will be reviewed by the research team, outcomes that have a some level of agreement will be submitted into a second round in which you will be asked to rescore. Statements that did not have agreement will be dropped from the consensus process.

Round Two

All new statements and statements that had agreement will be rescored in the second round. You will be able to see the range of scores from each of the groups to compare. Using this information each expert is asked to reflect on their own view and on the view of the group. No one will be able to see individual scores.

Round Three

The research team will undertake another scoring process and further outcomes may be dropped. With the feedback from round two, you will rescore all the outcomes that had agreement. The aim of the third round is to finalise the core outcome set.

A maximum of 3 rounds will take place and a core outcome set will be formed after this round.

What are the advantages/benefits and disadvantages/risks of taking part?

Research into rib fracture fixation is lacking in the UK and it is vital that clinical trials in this area should be valid, robust and efficient. Providing a clear consensus

statement on the outcome measures will inform future trial work. A certificate to evidence research participation will be sent on completion of all rounds.

Can I withdraw from the study at any time?

You can withdraw at any point up until the questionnaire is submitted. It is regrettable but data can't be withdrawn following questionnaire completion as all the data is anonymised and we will not be able to identify the data to withdraw.

Will the information I give be kept confidential?

All storage and archiving will be conducted in line with the York Trials Unit Standard Operating Procedure. All study data will be stored on a secure server accessed via a password protected computer at the University of York. No identifiable data will be collected and email addresses will not be linked to the data. We will only collect your email address if you submit it within the form and only to provide you with a certificate or report of the findings.

What will happen to the results of the study?

A summary report of the study will be available. If you would like a copy of this then please enter your email within the questionnaire and a copy of the findings will be sent to you.

Who has reviewed this study?

The research has been approved by the Department of Health Sciences' Research Governance Committee at the University of York and the Research and Ethics Committee (REC) and Health Research Authority (HRA).

Who do I contact in the event of a complaint?

If you have any concerns please contact Dr Catriona McDaid (Senior Research Fellow and Research Supervisor) Tel: [+44 \(0\)1904 321371](tel:+44(0)1904321371) Email: catriona.mcdaid@york.ac.uk

If you agree to take part, would like more information or have any questions or concerns about the study please contact

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Thank you for taking the time to read this information sheet.

Appendix E



A Core Outcome Set for Surgical Rib Fracture Fixation Trials

A Delphi Study

Participant Information Sheet

What is a Delphi Consensus? – A general overview of the process

How are health care treatments developed?

To help patients, doctors and other health professionals make decisions about treatments, we need evidence about what works best. Treatments are developed and tested by researchers to make sure they work and are safe. To do this researchers need to look at the effects those treatments have on patients. Researchers do this by measuring an 'outcome'. For example, in a study of how well rib fracture surgery treatment works, 'outcomes' might include:

- A measure of how fast you can blow air out of your lungs
- How long you stayed in hospital
- Quality of life measure

How do researchers decide on what outcomes are important to measure in research studies?

When researchers design research studies to investigate treatments for health conditions they need to measure outcomes that are important and relevant to those people affected by the condition. To decide which outcomes are important researchers need to get everyone's opinion and try to reach agreement, or "consensus", on the most important outcomes. In order to do this, researchers carry out a 'consensus exercise'. One way of doing this is by using something called a 'Delphi' study. In a Delphi study researchers identify groups of people who are "experts" in the health condition they are interested in. "Experts" are:

- People with personal experience of the condition, for example, patients, carers and service users (it doesn't matter how long the person has had the condition for, their opinion is incredibly valuable).
- Health professionals with expertise in treating and caring for people with the condition.

Experts taking part in a Delphi study are asked to give their opinion on what outcomes are most important. The study is anonymous to make sure everyone has an equal say.

What happens early on in a Delphi Study?

The research team will have developed a long list of possible outcomes that they want to ask the experts about. This list is likely to have been created after looking at research papers, and sometimes after interviewing patients (see the flowchart)

What happens next?

You have been sent the list in the form of a questionnaire by email link and asked to score the importance of each statement and outcome. If, in your opinion, there are key outcomes or statements missing from the list, they you are encouraged to add these to the list. We refer to this as “**Round 1**” of the Delphi study. Your ratings will be returned back to the research team, we will then summarise the responses from the group as a whole and send this summary back to each expert in what we refer to as **Round 2** of the Delphi process. At this stage each expert is given the range of scores of the rest of the group. No-one in the group can see your score; and you can only see the overall results for the group as a whole. Using this information you are asked to reflect on your own view and on the view of the group and to decide whether you stick with your original rating or change it. Through the whole process, you are not under any pressure to change your rating if you do not want to. It is perfectly fine for you to stick with your original rating even if you rated the outcome or statement differently to the rest of the group. Your responses are then sent back again to the research team who again collate the information.

Every time the researchers ask the experts for their opinions we call this a 'round' of the Delphi. Each time the idea is that the experts review their previous score based on what the group rated in their last round. At the end of this process the research team produce a report on what the experts have agreed as the most important outcomes. These are called the ‘core outcomes’ for a particular health condition.

Aim of this study

The aim of the study is to develop a core outcome set for surgical rib fracture fixation a clinical study. The Delphi consensus in will bring together doctors, allied health professionals, patients and carers. The consensus process will follow the ‘Delphi method’ completed as an anonymous online survey with up to three rounds. Each round will be open for four weeks at a time.

It is important 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 consensus.

Who is doing the study?

The Chief Investigator is Dr Helen Ingoe who is an Orthopaedic Surgeon in Training based at the University of York Trials Unit. The York Trials Unit is sponsored by the British Orthopaedic Association to develop and expand the portfolio of trials in the

UK related to trauma and orthopaedics. This work is being completed as part of an MD project.

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You are being asked to participate, as you have experienced a blunt chest trauma injury with rib fractures or you care for someone who has had this injury.

Do I have to take part?

The questionnaires are voluntary, you will be asked to consent to take part by accepting the terms at the beginning of the questionnaire.

What will be involved if I take part in this study?

The study will involve up to three online questionnaires each will take less than 30 minutes to complete online.

Delphi Consensus Method

Round One

The first part of the questionnaire will ask you about **your thoughts** on what outcomes you feel are important to measure. The second part comprises of a list of outcomes that has been compiled following a review of the research studies. You will be asked to score on a scale of 1 to 9 how important is the outcome, one being not important and nine being critically important. There will be a free text box for you to add any comments. Comments could include if you think that an outcome is already covered within another statement or if you feel the outcome needs further explanation, expansion or clarity. We would strongly recommend you provide feedback on items such that we can take your thoughts and ideas into the second round. If you are unable to comment on the outcome then please select unable to comment.

Scoring

Outcome scores will be reviewed by the research team, outcomes that have a high level of agreement will be submitted into a second round in which you will be asked to rescore. Statements that did not have agreement will be dropped from the consensus process.

Round Two

All new statements and statements that had agreement will be rescored in the second round. You will be able to see the range of scores from the rest of the groups to compare. Using this information each expert is asked to reflect on their own view and on the view of the group. No one will be able to see individual scores.

Round Three

The research team will undertake another scoring process and further outcomes may be dropped. With the feedback from round two, you will rescore all the outcomes that had agreement. The aim of the third round is to finalise the core outcome set.

A maximum of 3 rounds will take place and a core outcome set will be formed after this round.

What are the advantages/benefits and disadvantages/risks of taking part?

Research into rib fracture fixation is lacking in the UK and it is vital that clinical trials in this area should be valid, robust and efficient. Providing a clear consensus statement on the outcome measures will inform future trial work.

Can I withdraw from the study at any time?

You can withdraw at any point up until the questionnaire is submitted. It is regrettable but data can't be withdrawn following questionnaire completion as all the data is anonymised and we will not be able to identify the data to withdraw.

Will the information I give be kept confidential?

All storage and archiving will be conducted in line with the York Trials Unit Standard Operating Procedure. All study data will be stored on a secure server accessed via a password protected computer at the University of York. No identifiable data will be collected and email addresses will not be linked to the data. We will only collect your email address if you submit it within the form and only to provide you with a certificate or report of the findings.

What will happen to the results of the study?

A summary report of the study will be available. If you would like a copy of this then please enter your email within the questionnaire and a copy of the findings will be sent to you.

Who has reviewed this study?

The research has been approved by the Department of Health Sciences' Research Governance Committee at the University of York.

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If you agree to take part, would like more information or have any questions or concerns about the study please contact

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