

Findings from the feedback event - “Optimizing patient decision-making”

The following key messages may help to optimize patient decision-making:

Messages directly to the patient:

- a. BOTH types of surgery are COMMONLY used in the NHS to treat this injury. Neither are NEW treatments. Both WORK, but surgeons [across the United Kingdom] genuinely don't know which surgery is better than the other, or if they are just alternatives.
- b. Taking part in this study is an opportunity to improve the future care of patients.
- c. Your surgeon thinks you are suitable for the study and is happy for you to have either surgery.
- d. Your best interests are important to us, and if you take part you will have surgery that is suitable for you.
- e. Regardless of what treatment you receive, the surgeon carrying out the operation is an expert.

Messages for the benefit of the recruiter:

- i. Recognize that a patient may have preferences; if so, try to understand why the patient has that preference, explain both treatment options and encourage the patient to keep an open mind.
- ii. Recognise you may have your own preferences and be careful not to provide your personal or other team members' preferences.
- iii. Choice of words is important. Avoid using the word 'trial' and use 'study' instead. Don't use the word 'random' for treatment allocation as patients have stated this suggests that 'staff don't really care'. Terms such as 'flipping a coin' or the 'computer choosing' are not helpful. Instead, explain that treatments will be allocated 'fairly' to give us 'comparable' groups of patients.

Please see overleaf.



Tips from the qualitative work		
<i>Conveying clinical equipoise</i>	<i>Describing randomisation</i>	<i>Patient preferences</i>
<ul style="list-style-type: none"> • Acknowledge uncertainty • Explain the advantages and disadvantages of both treatments • Think 'balance' 	<ul style="list-style-type: none"> • Focus on the process and purpose of randomisation • Avoid gambling metaphors • Caution around referring to computers 	<ul style="list-style-type: none"> • Ask patient to keep an open mind • Understand their preference(s) • Balance views, tailored to concerns

Examples of how to convey clinical equipoise have been provided. Below is an example of **how to present randomisation**:

If you agree to take part in the study you will be allocated to a treatment group by a process called randomisation. This is the fairest method to produce two groups of patients who are similar in every respect – for example age and gender. I can't choose and you can't choose your treatment, so there will be no bias. One group gets the external frame and the other group gets internal plates. Because the groups will be 'balanced', at the end of the study we can fairly compare them to see whether one treatment is better than the other without worrying that other factors (such as age or gender) have influenced the outcome.

Examples below are how to **manage patient preferences**:

- *I know you're not keen on the frame. Is this because you have a fear of needles or are there other things that you're concerned about and would like to discuss?*
- *I understand your concerns but I'd like you to keep an open mind whilst I run through all the options as there may be things about both treatments that you haven't considered.*
- *Without knowing exactly what injury your friend had, and which particular treatment, it might be that your treatment and recovery could be quite different to theirs. The thing is, these are both good treatments for your injury, and both are suitable for you.*

Another aid that was well received at the feedback event was a grid to support patient decision-making, and having patient advocates or a video was discussed. These suggestions will require more thought by the trial team, and will be discussed further with sites for your valuable input.