

Topic Guide

Public/Patient Focus Group

Tues 6th Feb 2018

The Botnar Research Centre, Room G52

Topic 1 (Post it Colour: White)

Thoughts and feelings about the use of patches, when they could be used and how their effect might be best measured.

How would you/did you feel about being offered a patch in addition to the standard rotator cuff tendon repair?

PROBES

- Would you/did you have any concerns about receiving an implant?
- Did/would the material the patch is made out of affect your decision?
- Would knowing that you are the first (or one of the first) human(s) to be given a new implant make a difference to your decision?

Bearing in mind that patients have different sized tears that surgeons categorise as small, medium, large, massive or irreparable.

- Do you have any thoughts around which situations you would expect a patch to be used?
- Would you only expect patches to be used on patients who've had a re-tear or on all tears?

If you had surgery that included a patch, what improvements would you hope or expect to see?

- How would you know if the treatment had been successful for you?
- What does a successful operation mean to you?
- Would/do you have greater expectations if/because a patch had been used?
- When seeking/undergoing treatment for shoulder problem what is it that you want to get out of it?
 - In your mind what is it that you'd like to see improvement in?
 - What is the main most important aspect?
- How do you measure improvement or deterioration in your own health?

Topic 2 (Post it Colour: **Yellow**)

The clinical trial.

How would you feel if your surgeon invited you to take part in a clinical trial designed to look at whether or not adding a patch can improve recovery from rotator cuff repair surgery?

PROBES

In a clinical trial all participants will undergo standard rotator cuff repair surgery. Some (usually around half) will have a patch implanted, the others won't.

- **How would you feel about this?**

To make sure the results of the clinical trial are fair participants will be allocated to receive a certain treatment through a process called randomisation – this is the best way to make sure that no-one, not the patient, the surgeon, nor the people running the trial have any control or influence over which participant receives which treatment. A computer program is used to 'randomise participants'.

- **How would you feel about leaving the decision about which treatment you receive to a computer programme?**

Once the treatment has been allocated participants will be kept 'blind' – which means they will not be told which treatment they will undergo. For example, depending on the design of the trial.....participants may or may not receive a patch.

- **Would you mind not knowing if a patch had been implanted or not?**
- **If you were allocated to receive a patch, how would you feel not knowing what type of patch you or the person you care for had inside of you/them?**

Clinical trials usually require participants to undergo 'extra' tests and the information collected in these tests is generally used for research purposes only.

- **How would you feel about undergoing extra tests that would mean more visits to hospital specifically for the purpose of the clinical trial?**

- **If we wanted more information from you in the form of questionnaires how would you prefer to receive it?**
 - **Is there a format that would make you less likely to complete and return it, if so why?**
 - **How do you feel about logging in to a website and entering information on a computer or mobile phone app?**

- **Is there anything that would make you more likely or less likely to saying yes to taking part in a clinical trial to assess using patches in rotator cuff repair surgery?**

Topic Guide

Public/Patient Focus Group

Wed 14th March 2018

The James Cook University Hospital, South Tees

Topic 1 (Post it Colour: White)

Thoughts and feelings about the use of patches, when they could be used and how their effect might be best measured.

How would you feel about being offered a patch in addition to the standard rotator cuff tendon repair?

PROBES

- Would you have any concerns about receiving an implant?

Describe patch materials - cards

- Would the material the patch is made out of affect your decision?
- Would knowing that you are the first (or one of the first) human(s) to be given a new implant make a difference to your decision?
 - If you were invited to receive a patch, outside of the information you were given at the hospital, what research do you think you would go and do yourselves?
 - Who do you think you would talk to?
 - Where might you go looking for further information?
 - Can you think of anything that you might find during your research that would put you off or deter you from saying yes to receiving an implant?

(Breast implants, metal on metal hip, vaginal & hernia mesh – media)

Bearing in mind that patients have different sized tears that surgeons categorise as small, medium, large, massive or irreparable.

- Do you have any thoughts around which situations you would expect a patch to be used in?

- **Would you only expect patches to be used on patients who've had a re-tear or would you expect them to be used on all types of tear?**
 - **All patients regardless?**
Age, general health (obesity, smoker), levels of activity (sports, working, retired), determined need (mobility, occupation)

If you had surgery that included a patch, what improvements would you hope or expect to see?

- **How would you know if the treatment had been successful for you**
- **What does a successful operation mean to you?**
- **Would you have greater expectations if a patch had been used?**
 - **With regards to the post-op recovery period and rehab – would you expect this to a shorter, longer or the same as a standard repair without a patch?**
 - **How important is length of time to recovery?**
- **When seeking/undergoing treatment for shoulder problem what is it that you want to get out of it?**
 - **In your mind what is it that you'd like to see improvement in?**
 - **What is the main most important aspect for you?**
- **How do you measure improvement or deterioration in your own health?**

Topic 2 (Post it Colour: **Yellow**)

The clinical trial.

How would you feel if your surgeon invited you to take part in a clinical trial designed to look at whether or not adding a patch can improve recovery from rotator cuff repair surgery?

PROBES

In a clinical trial all participants will undergo standard rotator cuff repair surgery. Some (usually around half) will have a patch implanted, the others won't.

- **How would you feel about this?**
 - **How would you feel if the final decisions about your eligibility for the clinical trial was made when you were under general anaesthetic and the surgeon was looking at your tendon?**
 - **Would this affect your willingness to take part in a clinical trial to assess the use of patches to support rotator cuff repair?**

To make sure the results of the clinical trial are fair participants will be allocated to receive a certain treatment through a process called randomisation – this is the best way to make sure that no-one, not the patient, the surgeon, nor the people running the trial have any control or influence over which participant receives which treatment. A computer program is used to 'randomise participants'.

- **How do you feel about this?**
- **What does the term randomisation mean to you?**
- **Does the involvement of a computer program give you more confidence or less confidence in the process, or does it make no difference to you?**

Once the treatment has been allocated participants will be kept 'blind' – which means they will not be told which treatment they will undergo. For example, depending on the design of the trial.....participants may or may not receive a patch.

- **Would you mind not knowing if a patch had been implanted or not?**
- **If you were allocated to receive a patch, how would you feel not knowing what type of patch you had inside of you?**

Clinical trials usually require participants to undergo 'extra' tests and the information collected in these tests is generally used for research purposes only.

- How would you feel about undergoing extra tests that would mean more visits to hospital specifically for the purpose of the clinical trial?

These can be anything such as filling out questionnaires, interviews, physical assessment, having blood taken or a biopsy of the tendon being taken while awake.

- If we wanted more information from you in the form of questionnaires how would you prefer to receive the questionnaire? (through the post, by e-mail, face to face)

Questionnaires can come in various formats such as paper, e-mail attachment, on-line

- Is there a format that would make you less likely to complete and return the questionnaire, if so why?
 - How do you feel about logging in to a website and entering information on a computer or mobile phone app?
- Is there anything that would make you more likely or less likely to saying yes to taking part in a clinical trial to assess using patches in rotator cuff repair surgery?

Topic Guide

Representatives from Industry

Wed 21st Feb 2018

The Botnar Research Centre, Room G51

Topic 1

Definition of a Patch

Do you have any thoughts or comments on how we have chosen to define a patch?

Patches and their use.

In your experience, when and how are the patches you supply being used?

PROBES

- **Does your product specify indications for use or is this left to the surgeon?**
- **Do you have any thoughts around which situations you would expect the patch to be used?**
 - **Would you expect patches to be used in primary repair or only where there's been re-tear?**
 - **What about using the patch to bridge the gap in an irreparable tear?**
- **Do your patches have other indications for use or are they designed to augment the repair of rotator cuff tendon only?**
- **What feedback do you receive from users (surgeons/patients)?**
 - **What do surgeons tell you the product is good for?**
 - **What do the users tell you they like about your product?**
- **How do you monitor product safety?**
 - **Is the recent concern about mesh products an issue?**

Topic 2

Trial Design

What would a clinical trial look like in your mind?

Potential designs.

- **What are your thoughts on the following designs?**
 - **Specific patch (make/manufacture)**
 - **Type of patch (material)**

PROBES

- **What comparisons would you like to see/do you think would be most useful/appropriate?**
 - **Refer to PowerPoint**
What would your Intervention and Comparator be?
- **Are there any ongoing/planned studies involving your product?**
- **From a commercial perspective, what would be the maximum 'time to results'?**
 - **Ideal follow-up period?**
 - **What level of post-market surveillance would you include in a clinical trial?**
- **Would your company be willing to supply product for a clinical trial?**
 - **What level of involvement would the company expect to have?**
 - **How much influence in the trial would the company expect/want?**
 - **What costs might be involved?**
 - **Willing to partially fund a clinical trial?**