

Supplementary File 3: Round two survey

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Question	Response option
1. Which of the following best describes you? Please select only one option.	Health Care Provider Health Care Researcher Health Care Provider & Researcher Person who has a shoulder condition at the moment, or who has had a shoulder condition in the past

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The following questions ask you to consider whether certain outcome domains (e.g. pain, physical functioning) should be included in a ‘core domain set’ for clinical trials of shoulder conditions. A core domain set represents the **minimum** that should be measured and reported in **all clinical trials of shoulder conditions**. That is, there is an expectation that the core domains will always be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate; while researchers continue to explore other domains as well.

The comments in the Round 1 survey indicated that some domains overlap or might be a part of another domain. We have created some combined domains and would like you to rate the importance of each.

Question	Response option
2. We have combined the domains related to pain (which includes, overall pain intensity, intensity of pain with activity, temporal aspects of pain, analgesic use) under one domain called ‘ Pain ’. Is the new combined domain ‘ Pain ’ important enough to be included in a core domain set for all clinical trials of shoulder conditions? ‘Pain’ is defined here as: ‘how much a person’s shoulder hurts, reflecting the overall magnitude of the pain experience (i.e. at rest, during and after activity, at night)’.	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question
3. We have combined the domains relating to physical activities (which includes, daily living activities such as bathing and combing hair, recreational/leisure activities and work ability) under one domain called ‘ Physical Functioning ’. Is the new domain ‘ Physical Functioning ’ important enough to be included in a core domain set for all clinical trials of shoulder conditions? ‘Physical Functioning’ is defined here as: ‘a person’s ability to carry out daily physical activities required to meet basic needs (e.g. bathing, combing hair), more complex activities that require a combination of skills	Yes No Unsure/I do not know Please provide any comments you wish to justify your response to the above question

Question	Response option
(e.g. driving a car), recreational/leisure activities (e.g. sports) and work tasks.	
<p>4. We have combined the three domains relating to psychological functioning (depression, anxiety, fear avoidance beliefs) under one domain called ‘Psychological Functioning’. Is the new domain ‘Psychological Functioning’ important enough to be included in a core domain set for all clinical trials of shoulder conditions? ‘Psychological Functioning’ is defined here as: ‘impact on patient’s levels of depression, anxiety, fear avoidance beliefs, or other types of psychological distress. Depression refers to negative mood, loss of self-confidence, loss of motivation and enjoyment. Anxiety refers to fear, extreme worrying and hyperarousal symptoms. Fear avoidance beliefs refers to the belief that any shoulder movements that result in pain need to be avoided.</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>

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The Steering Group considered all the responses and comments and found that ‘Health-Related Quality of Life’, ‘Global Assessment of Treatment Success’ and ‘Sleep Functioning’ were considered by over 2/3rds of respondents as core domains to include in **all** trials. We used a cut-point of 67% that was used in a previous Delphi study (<http://www.ncbi.nlm.nih.gov/pubmed/25841358>).

<p>5. Do you agree that the domain ‘Health-Related Quality of Life’ should be included in a core domain set for all clinical trials of shoulder conditions? ‘Health-Related Quality of Life’ is defined here as: ‘the physical, psychological and social domains of health, taken together, seen as distinct areas that are influenced by a person’s experiences, beliefs, expectations and perceptions’.</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>
<p>6. Do you agree that the domain ‘Global Assessment of Treatment Success’ should be included in a core domain set for all clinical trials of shoulder conditions? ‘Global assessment of treatment success’ is defined here as: ‘a person’s assessment of their recovery or degree of improvement’.</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>
<p>7. Do you agree that the domain ‘Sleep Functioning’ should be included in a core domain set for all clinical trials of shoulder conditions? ‘Sleep Functioning’ is defined here as: ‘sleep functions like onset, maintenance, quality, amount of sleep, and functions involving the sleep cycle. This domain also includes the impact on perceptions of alertness and sleepiness during usual waking hours’.</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>

<p>8. Only 39% of respondents thought it was important to include ‘Number of Deaths’ in the core domain set for clinical trials of shoulder conditions. Deaths very rarely occur in shoulder trials, however, if occurring they would be relevant outcomes. We have presented this domain here again for this reason.</p> <p>Is the domain ‘Number of Deaths’ important enough to be included in a core domain set for all clinical trials of shoulder conditions?</p> <p>‘Number of Deaths’ is defined here as: ‘reporting of the number of deaths that occurred within a clinical trial’.</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>
<p>9. The majority of respondents (>67%) thought it was important to include ‘Range of Motion’ and ‘Muscle Strength’ in a core domain set for clinical trials of shoulder conditions. However, the Steering Group believe these could be considered components of the ‘Physical Functioning’ domain, since physical activities may depend on the distance and direction that the shoulder is able to move, and the strength of shoulder muscles.</p> <p>Do you agree that ‘Range of Motion’ and ‘Strength’ should be excluded from the core domain set for clinical trials of shoulder conditions?</p>	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>
<p>10. The following domains were not rated highly by the majority of people, or comments indicated that they might not be relevant to all trials (e.g. failure of surgery). Therefore, the Steering Committee would like to exclude the following from the core domain set, although we acknowledge that in some circumstances (for example, depending on the clinical research question) they could be measured in addition to the core set.</p> <p>Do you agree that all of the following domains should be excluded from the core domain set for all clinical trials of shoulder conditions?</p> <p><i>(Definitions of each of the following are provided on page 8-9 of Round 1 Results attached to the invitation email)</i></p> <ul style="list-style-type: none"> – Require re-operation or revision surgery – Radiographic outcomes – Failure of surgery – Surgical process outcomes – Severity of the main complaint – Shoulder instability – Testing positive on physical examination tests – Social functioning – Health care services 	<p>Yes No Unsure/I do not know</p> <p>Please provide any comments you wish to justify your response to the above question</p>

<ul style="list-style-type: none"> - Non-health care services - Satisfaction with treatment services - Weakness on movement - Pain on palpation - Shoulder swelling - Scapular dysfunction - Shoulder posture - Muscle tone - Fatigue - Proprioception of the shoulder - Haemodynamic variables 	
<p>11. Are there any other comments that you would like to make about the domains included in this survey, or any general comments that you would like to make about this survey?</p>	<p>[Free text]</p>