Supplementary File 5: Individual comments providing rationale for ratings of each domain

ROUND ONE

Core Area: Life Impact

Is the domain 'Overall Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
While chronic pain literature points to asking about pain to be counter productive, subjectively I find less psychosocial factors in shoulder pain compared to say lumbar pain patients.
Pain restricts activity
Pain one of the most limiting factors for patients
But depends on type of patient. If patient is an chronic pain patient, pain is less important than in regular orthopedic problems.
Because its such an important measure for the patient- often the only thing they actually care about
This is a common patient complaint
Night pain is important to patients. Resting pain and pain With Activity also.
Need to capture average daily, nocturnal and activity related pain
From patients:
Pain directly relates to an individual's quality of life.
If you are experiencing overall pain, you are more likely not to use your shoulder to the fullest extent. I had frozen shoulder, so pain can be a critical issue.
The time period between initial injury and 6 weeks post surgery, the pain was excruciating.
Ongoing pain is distracting, all consuming, and affects ones ability to function in other areas of your life that don't even involve use of the shoulder; like concentrating on mental tasks
Shoulder hurts daily while getting dress, putting arm through bra and through sleeves of shirts, sweaters, etc.
Pain is a very important factor in quality of life
I experience periodic pain with different movements/activities. It is not a constant pain.

Is the domain 'Overall Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Do you mean before or after surgery (or both)? However, I believe that anything that has to do with a patient's pain level would be important/helpful for a physician to know. I don't mean any disrespect, but I believe you misspelled the word, "standardised" (see above.) I believe it is spelled, "standardized."
Shoulder pain affects quality of life, function, sleep. It can trigger muscle pain and muscle spasm around the shoulders and neck. Although there is no scientific proof I think the nearer the brain the worse the pain!
Does this mean that the pain is continuous - if so "yes"
The pain is almost constant and very wearing as a result. Sleep is interrupted. I have a high pain tolerance but the nature and severity of this pain in addition to the way is takes several minutes to resolve even after I correct the position has made it particularly unpleasant.
Comments provided for "no" are as below:
From Clinicians/scientists:
Need to be specific about timeframe and location
From patients:
Seldom have any problems
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Not sure if overall pain intensity is easy to score for people or best reflects the impact of shoulder pain
From patients:
If so, for acute conditions

Is the domain 'Temporal Aspects of Pain' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Important especially for tendon involvement
Pain localization can be important but often patients cannot localize with any level of accuracy
But depends on type of patient. If patient is an chronic pain patient, pain is less important than in regular orthopedic problems.
See above

Is the domain 'Temporal Aspects of Pain' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Most interested in pain at its worst
From patients:
When you experience pain, you are less likely to use your shoulder. The less you use it, the more you may have pain and the more likely you will experience decreased function.
Certain sleep positions and movements greatly increase the pain.
Temporal pain in both shoulders continually ranges from minimal to severe.
Shoulder hurts with sudden movements.
Pain can subside or come and go.
Same as stated above.
Once again, do you mean before or after surgery (or both)? I believe that anything that has to do with a patient's pain level would be important/helpful for a physician to know.
Does this mean episodes of pain above the continuous - if so "yes"
To find patterns or abnormalities in patterns
Activity, even walking, exacerbates the pain. Sitting quietly eases it. Certain movements cause very significant pain. Pain and the limits it places on movement are the key hallmarks of my condition.
Comments provided for "no" are as below:
From Clinicians/scientists:
Generally the pain is either there or not
From patients:
Seldom have any problems
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Would need to be too many questions to be core e.g. do you get intensity and duration of every single little episode - or come up with one over-arching question that captures intermittent versus persistent versus single episode.
Most/all patients experience this.
From patients:
I would need to consider this aspect and discuss it before possibly recommending it to be included in a core set of symptoms.

Is the domain 'Rest Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Might be helpful from point of view of tendon but most importantly query sinister pathology.
The presence of rest pain is important but the absolute intensity less so
But this element of pain should be distinguished from night or sleeping pain.
But depends on type of patient. If patient is a chronic pain patient, pain is less important than in regular orthopedic problems.
If this includes night pain
Although this is an infrequent event and may have lots with zero at baseline.
Gives an impression of the impact of pain.
Separate daytime versus nocturnal
From patients:
If there is no time that pain can be eliminated (resting) then a person may choose a more aggressive treatment
Pain at rest, can impact the quality of rest periods or sleep. This can have compounded impact on the quality of your life.
When shoulder was immobile there was no pain but any muscle movement would cause pain--walking, sneezing etc.
This is especially true during sleep periods. My wife frequently relates my painful moans while I'm sleeping
I think this is important, as the pain can affect ones ability to concentrate, even when resting.
Shoulder hurts lying down on my back or my side.
I think that this is important to have as a "baseline" for questions 13 & 14.
Once again, please read my previous comments regarding pain.
Shoulder pain can intensify at night whilst 'resting'.
Yes pain is present even when resting
This is the most annoying and worrying pain
Comments provided for "no" are as below:
From Clinicians/scientists:
Applies only to OA, depends on the tool
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:

Is the domain 'Rest Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
Just because I realize we cannot have to many domains, and pain during the night/ impact on sleep may be more important...
Not sure how people will rate this, worth some cognitive testing, I wonder if it would be very close to the first one, pain overall
While this is an important clinical aspect. It may not be an important outcome
From patients:
If given that test I would probably not experience any pain, however, even during sleep I am awaken with pain during movement.
I don't think so.

Is the domain 'Intensity of Pain With Activity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Activity related pain is useful as it may help to localize the pain source
But depends on type of patient. If patient is a chronic pain patient, pain is less important than in regular orthopedic problems.
Speaks to disability
May include which Activity, People are very different.
Vas best
From patients:
Again related to quality of life
The more pain you have, the more likely you are to exclude activities that were once important to you. Conversely, you may attempt to "work through" the pain and cause more damage.
Certain movement increase the pain
Changing an overhead light bulb is painful and impossible for me
Yes, because I trouble carrying my children, and this makes me very sad, and makes me wish the pain could be resolved.
Shoulder hurts while cleaning counter tops, reaching for objects off high or low shelf, carrying grocery
This is very important as it reflects that impact of the injury on normal life activities.
Varying movements can have a range of pain from no pain to serve pain.

Is the domain 'Intensity of Pain With Activity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I can't say my shoulder hurts after performing any movement that involves the use of my shoulder, however, it does happen when reaching for an object on a high shelf.
Don't you mean, "during" an activity? Your question does not match your definition. In other words, do you mean "during" activity or "after" activity (or during and after an activity)? Regardless, I believe a doctor should find out as much as he/she can about a patient's pain level.
Do you mean does it hurt more when I use the arm - if so "yes"
Specific activities or movements seem to be key factors in diagnosing the condition.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
Shoulder function is vital for most activities of daily living. If pain intensifies when moving to perform a simple function then it impairs independence.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
None.

Is the domain 'Intensity of Pain On Resisted Movement' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Least important
From patients:
May affect types of activities
The more you hurt, the less likely you are to do things that cause resistance. However, the appropriate amount of resistance can help ease some pain and regain or maintain function.

Is the domain 'Intensity of Pain On Resisted Movement' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Would indicate where the pain is coming from and be helpful in treatment
Same as # 13
All of these "pain" questions would only be helpful if the answers would help the doctors or physical therapists in their treatments of the patients!
This is how I was diagnosed and I myself was in no doubt the physician had identified exactly what was wrong - the exam was better than any description I could provide.
Comments provided for "no" are as below:
From Clinicians/scientists:
I'm not sure what is adds to clinical reasoning only loaded movements
Perhaps not as relevant to every day activities
More important for me, pain related to functional activities
Not particularly patient focused
Will be captured in functional domains
No different enough to #17
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Difficult to objectively measure this
I prefer pain with activity. Pain on resistance could be more of a clinician reported outcome based on patient response to specific movements for testing
Depends on your intervention - I don’t think it is core
You should give exact examples; lift 5 kg, push door to open etc.
From patients:
I would imagine that might prove difficult to measure. One person might push hard, another push gently resulting in different levels of pain and discomfort.

Is the domain 'Day Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
Pain impacts all facets of your life. Shoulder pain can impact how well you are able to carry out daily activities at home or work.
I can no longer perform many of the tasks I could previously accomplish
Shoulder hurts all day, enough to be on pain medication or take extra strength Tylenol
The pain is daily but periodic not constant.
In so far as it is tied to activities.
Comments provided for "no" are as below:
From Clinicians/scientists:
Pain on activity much more informative
From patients:
Seems redundant
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Less important, dependent of activities
From patients:
I don't know how it differs from overall pain, because most of my pain is during waking hours.
Please see my response to question #14.

Is the domain 'Night Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Indication of inflammation
Related to tendon and also important for sinister pathology

Is the domain 'Night Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
But is common and so not a sensitive symptom
Certainly could be different to day pain - positioning at night and ability to sleep
Central to many patient complaints
Important in shoulders, but they might say "pain that wakes me up at night". Perhaps also consider if they are sitting up to sleep in order to support shoulder so they can sleep
Sleep is important to people
Common patient complaint
From patients:
Especially important as it relates to ability to sleep
Disrupted sleep impacts how well you are able to carry out routine daily activities.
Absolutely. My wife frequently reports on the intensity of my night pains
Shoulder hurts at night to warrant pain medication and muscle relaxer to help sleep at night.
This will assess how much the pain may be negatively affecting sleep.
Getting enough rest is very important when recovering from a shoulder condition.
The pain is periodic. I have been awoken from sleep with movement of my shoulder/arm.
Hurts more at night
When night pain impaired sleep it made me very irritable, more sensitive to day pain and overall worse physical condition
Interference with sleep is important.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
Seems redundant. Sleep position should already be included in previous questions
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
I don't really get pain when sleeping

Is the domain 'Night Pain Intensity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Please read my response to question #14.

Is the domain 'Analgesic Use' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
But not for pain but more coping style.
BUT KEPT VERY SIMPLE!
Can help quantify
From patients:
A concern if long term and if addictive
While you may need some medication to help ease pain and make daily activities easier, too much medication can be dangerous.
I take Vicodin, Flexeril, extra strength Tylenol and valium.
This will give some indication of the negative impact the shoulder injury is having on the patient. It would be good to also have a control question that would probe the patient's general tendency to use medications, OTC or not, to adjust for patients who are medication averse and those who are prone to take meds.
I take Advil in the AM to start my day and once in awhile another dose if necessary.
It just won't hurt for a doctor to know as much as possible about a patient. However, I can tell you that in my case when I was asked to fill out the questionnaires, I felt very frustrated because there were way too many questions. Also, I remember that I wanted to reply with an answer that was not provided.
OTC pain relief required at least three times or more per week
Comments provided for "no" are as below:
From Clinicians/scientists:
May be an important outcome is some studies, but not all, and may reflect behaviour more than the actual severity of the shoulder condition
Virtually meaningless. Patients will forget over the counter analgesia etc.
Patients have different levels of pain and different requirements for the use of medication. However, if the use of analgesics might interfere with healing or outcomes in another way, it would be good information to have.
Difficult measure which may depend on pain perception and personality

Is the domain 'Analgesic Use' important enough to be included in a core domain set for clinical trials of shoulder conditions?
This is often a reflection of the health care provider and not the disease intensity
From patients:
I never used pain medication for my injuries.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Could be quite variable, some may not like to take pain relief but have a relatively high level of pain
Would need to look at how well it is documented and recalled. In a trial it is used as a breakthrough type of indicator, I wouldn't think it was as important as some of other indicators of pain.
So variable as to whether people bother to take analgesics at all - unless the entry criteria is someone who is needing regular analgesics for their pain and then would be a core measure
Wide variability in patient's use of medications. Doesn't seem to consistently correlate with pain or disease severity.
From patients:
Pain can be subjective and certain meds at certain level might not be the same between patients.
I don't take painkillers, but it doesn't mean I don't have pain, or that my pain is less important than other people's pain.
Not sure if it's study worthy. Just get rid of it.
Some people can tolerate high levels of opiate-based pain relief; other people such as me can only tolerate Paracetamol. I think measuring the impact of a new drug could be affected by the impact of different pain analgesia.

Is the domain 'Physical Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Outcomes related to function are helpful
Knowing what a patient can do and not do is essential information and will also aid discussing patient expectation
Most important!
AGAIN SHORT AND SWEET!
Again - central to patient complaints
From patients:

Is the domain 'Physical Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Simple, basic daily activities are important to a person's sense of wellbeing. No one likes needing assistance with any of the above situations.
Again, pain would be triggered by muscle movements
This goes along with questions 13 & 14.
Intense shoulder pain affects every aspect of the day. The inability to perform basic grooming tasks as well as routine activities because of pain/loss of function severely debilitates ones quality of life.
I can carry out daily physical activities on my own, however, they too, are not always without pain.
Only ask the questions that would be helpful for a doctor to know to be able to treat the patient. Once again, I felt that there were more questions than necessary.
Affects all the above listed
Helps to localize the functional problems pain is causing.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
For me it is more interesting what I really do, more in the term of activity
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
None.

Is the domain 'Health-Related Quality of Life' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Having an overall idea about general status is required as co-morbidities, social factors all will affect outcome
Complicated but well recognized concept for clinicians

Is the domain 'Health-Related Quality of Life' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I like how you have designed this survey with the definitions that are very clear right beside the question. Well done
Needed for all now as a comparator across conditions
Should be specified that the question is about the shoulder. It is a lot of comorbidities.
From patients:
Your overall health can have a huge impact on your psychosocial well-being. Pain or chronic health issues may lead to depression and decreased social interaction.
I'd much rather not have to deal with the pain and the limitations on my life
Comments provided for "no" are as below:
From Clinicians/scientists:
HR QOL is not only one domain, it needs to be explored in physical, mental and social aspect of life separately
I think that HRQOL is something difficult to define, although you presented a definition. Furthermore, HRQOL is influenced from to many aspects and thus probably not able to measure appropriately (I know that this survey is at the level of measurement Instruments). There is no consensus on HRQOL, and I think it is too broad from the definition and we do not know what really will be measured, thus I would not include this domain in a COS.
From patients:
At this time I would say this issue has not affected my overall Quality of Life. I make a concerted effort not to let anything stop me.
I answered "no" to this question because I felt that once the physical pain is lessened or gone, then the psychological and social aspects will go away!
This is too global
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
This seems too broad to be specifically helpful in assessing the shoulder status.

Is the domain 'Social Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:

Is the domain 'Social Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
There is an association between (shoulder) pain, depression and coping
Anxiety and depression are common
Insight on impact of complaints is important
Likely will be a secondary outcome pointing to quality of life or social support
It needs to be taken in context with anxiety and depressive scores
From patients:
Chronic pain or illness can impact a person's ability and/or willingness to interact with others. Chronic illness can lead to isolation.
It affects my ability to love and care for my children.
I miss a lot of social gathering due to shoulder pain and the medication I have to take to prevent the pain will make me sleepy.
Comments provided for "no" are as below:
From Clinicians/scientists:
It may be applicable only to chronic conditions such as OA
TOO DIFFICULT TO MEASURE- THE QUESTIONS USUALLY END UP JUST SOUNDING VERY WAFFELY
From patients:
I go to the gym 3 days a week, I play cards 3 nights a week and when not performing those acts I shop for charitable organization.
Please see my response to questions # 19.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Yes, if this includes a broad domain that can also cover recreation ad leisure activity.
If we are sure the shoulder is the main issue
From patients:
Pain can cause or aggravate depression, cause social withdrawal.

Is the domain 'Recreation and Leisure Activity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Many older persons now expect to be able to have a lot of recreational time and activities; again managing expectations
If relevant
From patients:
Not as important as need to perform activities of daily living
Chronic pain or illness can impact a person's ability to interact in recreational activities. This is especially important if a person was very active in a particular sport or activity and now experiences a decline in their ability to engage in that activity.
As a ceramist, it has become difficult to throw with very heavy amounts of clay.
I use to ballroom and belly dance, but due to shoulder pain I don't because it hurt to lift my arm above my head when I do the turns.
To the extent that should injury would limit the patient's ability to take part in such activities.
This was critical to me since I am very active, playing hockey, skiing, and golf.
As stated above I stay active and attend social events.
I have to limit my hobby activities
When this part is impaired by the condition and the patient is not willing to accept it can cause great distress and frustration
Ability to exercise
Comments provided for "no" are as below:
From Clinicians/scientists:
May be in instability related conditions
Perhaps not relevant to all, and can perhaps be covered by other questions (social activities)
Daily functioning is much more important. This is difficult to compare between subjects
A/A
From patients:
Please see my response to question #19.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Highly variable tasks, important as an indicator of engagement in life, and often leisure is given up first. But I would not use it as an indicator of function because the numbers won't be comparable across a wide variety of tasks being considered by respondents

Is the domain 'Recreation and Leisure Activity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
For some people this is important
Maybe this domain should be captured within the domain 'Social functioning'. I find it difficult to define which is more important, but from my experience the number of domains included in a COS should be at the possible minimum
From patients:
None.

Is the domain 'Work Ability' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Contribution to society is important
Shoulder surgery has an important effect on different types of work so we need to know whether the patient can work / return to work / workers compensation
Key for younger patients
If being conducted in a working age population
Best if you can subset work type
From patients:
Being able to completely fulfill your work obligations is important. If unable to engage fully in your line of work can mean loss of job and income and a sense of psychosocial wellbeing.
Again, a critical life function that may be negatively affected by the shoulder injury.
I am retired, however, if I were working I would make every effort to avoid letting the pain affect my performance.
Limits daily tasks
Yes - many of us work on keyboards.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:

Is the domain 'Work Ability' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I think the limitations of shoulder dysfunction/pain on a person's ability to perform their job in order to sustain financial viability are obvious and not study worthy.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
Some work is very physical which would be difficult with shoulder pain. Other work is cerebral which might be difficult with shoulder pain (the nearer the brain the worse the pain!). Some people no longer or have never participated in paid work.

Is the domain 'Psychological Functioning: Depression' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Would be interesting to assess impact of psychological factors in shoulder pain compared to other areas
Any pain condition will be affected by this so must know it
Anxiety and depression are common
This can affect outcomes
Important predictor
Strongly related to outcomes
From patients:
Decreased ability to function due to depression, loss of self-confidence, etc. can lead to loss of job, decreased interaction with peers and family.
Not a factor for me with my injuries.
Negative mood and lack of sleep
I was feeling dragged down by the experience.
Comments provided for "no" are as below:
From Clinicians/scientists:
General health related questionnaires have this aspect of health. This does not need to be included in a shoulder-specific instrument

Is the domain 'Psychological Functioning: Depression' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Depression can be a relevant determinant or outcome, but the association is less strong in shoulder pain compared to other MSK conditions (e.g. back pain) - so important in some studies, but not in all - does not have to be a core domain.
Secondary at best, certainly could be important for some studies, but not core for all studies
Certainly a modifying factor but would want to distinguish from shoulder outcome if possible
Why should 'depression' be a possible outcome for shoulder trials? Depressive patients need other treatment than shoulder treatment (whether conservative or surgical treatment). If shoulder treatment fails patients may become depressive, but this surely does not justify to include this domain in a COS.
From patients:
It has not affected my mood, or caused loss of self-confidence or motivation and enjoyment.
Depression is not the sole issue of emotional distress which occurs during a limitation such as shoulder pain related impairment
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
No depression but general psychological function. How good are healthcare providers and patients able to determine this?
From patients:
It is hard to assess this. It would seem not to be important; however, I can imagine that if a patient had a chronic shoulder injury and associated pain and restricted movement for a long period of time it may very well have psychological effects.

Is the domain 'Psychological Functioning: Anxiety' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Would be interesting to assess impact of psychological factors in shoulder pain compared to other areas
Again will significantly influence reporting of pain
As above
Try to get a combined scale for anxiety and depression
Tools such as the GAD 7 would be helpful
From patients:

Is the domain 'Psychological Functioning: Anxiety' important enough to be included in a core domain set for clinical trials of shoulder conditions?
If the person's chronic pain or illness causes anxiety this could lead to a decreased social interaction.
Have had professional counseling
Sometimes
Comments provided for "no" are as below:
From Clinicians/scientists:
General health related questionnaires have this aspect of health. This does not need to be included in a shoulder-specific instrument
As above, anxiety can be a relevant determinant or outcome, but the association is less strong in shoulder pain compared to other MSK conditions (e.g. back pain) - so important in some studies, but not in all - does not have to be a core domain.
As with depression, an important issue for people with shoulder problems, but not in the core set, I would put in the middle ring.
From patients:
No, again, I will not allow this injury to stop me from enjoying life.
See above for Depression. Not all patients suffer from depressive or anxious symptoms. Anger and grief are associated, too.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
General psychological function.
Most likely an important predictor, but not documented in the literature.
From patients:
Same as question 23
Not a factor for me with my injuries.
Possibly

Is the domain 'Psychological Functioning: Fear avoidance beliefs' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Would be interesting to assess impact of psychological factors in shoulder pain compared to other areas
Again critical to outcome for patient and will influence all other variables

Is the domain 'Psychological Functioning: Fear avoidance beliefs' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Useful to know if a patient does not appear to be recovering
From patients:
Fear could directly effect ability to heal and achieve hugest level of function
Following my shoulder surgery, I wanted to avoid things that caused pain. However, with therapy, I was able to regain nearly full functioning without pain. Avoidance would only have cause complete dysfunction.
This seems to be important as the fear of pain or further injury would limit the patient's activities.
Comments provided for "no" are as below:
From Clinicians/scientists:
This does not need to be included in a shoulder-specific instrument
There is some evidence for the role of fear avoidance beliefs in shoulder pain, but this measure is perhaps more important as a determinant (or secondary outcome) rather than a core outcome.
Middle ring with careful monitoring of the scale. The concept is important, but I think the scales are weak. Injured workers all look fear avoidant.
From patients:
I will not let it stop me. I deal with the pain and move on.
If pain were involved, wouldn't a patient naturally avoid that type of movement? I think someone has too much time on their hands to be thinking up some of these questions.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
General
Only for certain conditions such as instability
From patients:
Not a factor for me with my injuries.

Is the domain 'Sleep Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:

Is the domain 'Sleep Functioning' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Sleep is very important healing and recovery for the body
Loss of sleep will have a major effect
Important in relation to recovery
From patients:
It's important to know if sleep disruption is due to pain or the fear of pain.
I can no longer raise my left arm high enough to enjoy sleeping on my left side
Pain definitely negatively impacts the quality and duration of sleep, which is critical for health.
It does affect my sleep functions, however, I cannot say, it affects my ability to function through any given day.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
Not as important as simple ability to sleep
Obvious dysfunction/pain. I don't feel it's study worthy.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
There are many overlapping domains that are being asked. I think sleep function is important but so is night pain. I don't think they both need to be included, but one should be
May be captured in nocturnal pain domain. Many other causes for sleep problems unrelated to the shoulder
From patients:
If a patient were having difficulty sleeping due to pain, I would think that he/she would have enough sense to tell the doctor. I don't mean to sound grumpy with my answers on this survey, but there should be a limit to how many questions should be asked. Allow the patient to bring up some issues. If they don't, then they are not an issue.

Is the domain 'Fatigue' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:

Is the domain 'Fatigue' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Important in relation to recovery
From patients:
Decreased sleep can cause disruptions in social interactions, ability to continue to work, etc.
I am fatigued every day. I feel I never get enough sleep.
Comments provided for "no" are as below:
From Clinicians/scientists:
Fatigue is really important, just don't think it needs to be a core outcome in every study... Impact on sleep and measures of function & participation may also cover this.
This will be better captured by sleep and depression
Neurogenic fatigue might be useful but general fatigue is not specific for shoulder conditions
Depends on different circumstances
From patients:
It has not come to causing exhaustion or the inability to perform my daily routine,
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
May not necessarily be related to shoulder pain
Sleep is definitely an issue, I don't know if the fatigue is a lack of sleep type of tiredness rather than the systemic fatigue of a person with IA. Would like to hear from patients discussing with persons with IA. I know that they are tired from disrupted sleep.
Would be guided on patients for this one - I am not aware that it is a major feature of shoulder problems in isolation.
From patients:
Seems somewhat redundant to previous questions
Not a factor for me with my injuries.
Any fatigue might be due to an underlying illness.

Is the domain 'Satisfaction with Treatment Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:

Is the domain 'Satisfaction with Treatment Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
If looking at treatment, otherwise no.
Potentially interesting outcome
Satisfaction scores are useful and may show a different result to standard PROMs
From patients:
Satisfaction is key and is directly related to an individual's expectations which could vary greatly
It's important to know if current treatments are effective or if there is room for improvement in treatment services.
Although my treatment was very good, no one paid attention to the pain in my right shoulder, also injured in my accident
One potential concern is that the quality of treatment services in a clinical trial may exceed the typical quality of treatment that one would receive in a normal health care system. If the quality of treatment services significantly affects the treatment outcome, this could be an issue.
Domino Farms and their staff are what got me on the road to recovery. Though I still experience pain it is not so that I feel surgery is required at this time.
This is a good one. I believe feedback can help doctors learn from their patients' comments after surgery and during follow-up treatments.
Given limitations that I am informed the condition is not necessarily successfully operable
It's useful to provide feedback - I benefited greatly from a steroid injection.
Comments provided for "no" are as below:
From Clinicians/scientists:
Important for shared decision making and expectancy management
Process indicator not an outcome in my mind.
Even though we're at the domain and not measurement instrument level: this will be influenced from many factors which cannot be adequately controlled and thus measured
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Satisfaction is often rated quite highly (regardless of improvement in the health condition). I am not convinced it should be a core outcome.

Is the domain 'Satisfaction with Treatment Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
We use this in our clinic to monitor patients satisfaction, I don't think it should be a part of a questionnaire
People are often happy with their provider even with a poor outcome. Best to separate out if possible.
From patients:
If the treatment is e.g. physiotherapy then this domain might be relevant.

Is the domain 'Global assessment of treatment success' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
I would rename this into: global assessment of improvement (not necessarily due to treatment)
This is often the best way of subjectively evaluating treatment outcome in the office
Similar to satisfaction
This is critical
Yes, I think an assessment of recovery is important from the patient's perspective.
This sounds better. VAS
From patients:
This allows you to know if treatments are effective.
As long as the patient has a realistic expectation of the treatment outcome.
How else can progress be tracked?
This question appears to be the same as questions # 28. Therefore, I checked off "No."
A person’s self-efficacy can be measured (RASE scale). A persons belief in an intervention can, I think, affect their perception of levels of improvement.
See above
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:

Is the domain 'Global assessment of treatment success' important enough to be included in a core domain set for clinical trials of shoulder conditions?
No I am not satisfied with my recovery. I feel that I had surgery and it improved my condition only 50%.
I'd ask about physical therapy specifically.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Global perceived change could be an important domain - don't think it should be worded as 'global assessment of treatment success', as this would ask for an extra level of interpretation related to the extent to which the treatment has led to improvement. Would rather ask directly about change in symptoms in all treatment arms of a trial, and it would make the measure suitable for all types of studies.
Same as above mentioned
Even though were are at the domain and not measurement instrument level: Maybe if this is measured using a PROM
From patients:
Similar to 28
Most of my patients don't even know what factors to base this on except pain level

Is the domain 'Severity of the Main Complaint' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
It may be helpful
Helps separate shoulder problems from everything else
This is great to have an individualized patient centered main activity etc. that they can focus on - more should go this way
This is what we ask of our patients in clinic to direct treatment
From patients:
Not every person is alike. We all can have very different opinions of how limited our function may be. Knowing this information may help to develop a specific treatment program.
I feel that as far as the questions regarding pain, that this questionnaire is being very redundant. My suggestion is to consolidate most of these questions into one question.
Comments provided for "no" are as below:

Is the domain 'Severity of the Main Complaint' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
Unclear
Overall functional capacity of the whole person is often more important
OVERALL PAIN SHOULD HAVE GIVEN A GOOD IDEA OF THIS
Is repeating
From patients:
I don't know how to define the "main complaint" when the shoulder is used for so many things.
Seems like this is captured in other questions.
I believe if I don't use my shoulder/arm regardless of the pain I will lose total movement, thus, I will not stop trying.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Like the measure as it is relevant to people and very responsive, but can cause difficulties in assessment and analysis (especially if people list activities that may shift in terms of importance (different complaints are important at different stages of the shoulder condition).
May be overlap with other areas
From patients:
None.

Core Area: Resource use/economical impact

Is the domain 'Work Productivity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Good outcomes if actually at work to start with
Policy makers need this information
Likely as a secondary but even with shoulder fractures ~30% are employed ps. this takes back my last comment re where are other domains...they are here (I thought that was end of survey)

Is the domain 'Work Productivity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
You already asked this
Maybe a single VAS on how much impact on time lost from work productivity, absentee and lost intensity together?
From patients:
When there is a high degree of pain, there will be some decline in a person's ability to complete all tasks asked of them in a job or volunteer position. Even if you are at work daily, you may not be fully present due to pain.
Tough question. Different professions have different demands on shoulder functionality. The higher the demand, the longer the off-work recovery, the greater the financial impact. Job security is certainly a consideration in terms of course of action. A person with high shoulder demands could be left with a choice of either risk losing their job, or losing their profession. Depending on the age of the person, retraining for a new profession that has a favorable employment outlook may be rather dismal. If the person is not in a financial position to absorb the risk, the resulting "choice" would seem to be masking the symptoms as opposed to fixing the problem. Then there is the loss of income, compounded by the cost of care. Some people don't have the option of "choice". So they continue to work at a less than optimal productivity level, if possible.
Early retirement was outcome
Possibly, for research purposes. I'm not sure how prevalent these conditions are and how they might impact society.
Comments provided for "no" are as below:
From Clinicians/scientists:
Difficult to measure
The problem with putting work questions into a core set is that unless the trial is focused only on working population, a considerable % of participants wont be able to answer it, so it cannot be part of a core set?
Important but does not relate to large segment of population...so yes if a working population...this not core
From patients:
I am retired.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Would certainly support work absence as a core outcome domain. Economic impact in terms of both absenteeism and presenteeism is not always easy to measure - may be a hard ask to include as a core domain.
From patients:
Presenteeism??? Important to be able to perform job related activity

Is the domain 'Work Productivity' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I continue to work, as my job is not physically active, so not sure how you would capture that when people have different jobs.
I am not sure what you mean, but anything that helps, is of course worthwhile.
What about those who are retired?

Is the domain 'Health Care Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Again critical moving forward to collect this information in trials to compare cost effectiveness
But only if relevant, and it would be great to define a common set of "costs" to be included
From patients:
The more you know about your particular shoulder issues, the better it can be treated.
If you want feedback to improve services.
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on the research question
Definitely important, but perhaps not in all trials (think of pilot trials or efficacy studies), and very dependent on the healthcare system, setting, country. So perhaps not as a core domain for all trials.
It is really interesting to assess in trials but I do not think it has much relevance as part of a clinical outcome measure.
More important to know why some patients seek not to get treatment
Health care services may not reflect the type of intervention being tested in a trial, e.g. prevention interventions or self management interventions or occupational interventions, hence cannot be part of a core set?
This will vary widely between the different health care systems/countries in which the patient is being treated. Thus it will not be comparable, and should not be included in a COS.
From patients:
I have not sought any further medical treatment regarding shoulder/arm.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:

Is the domain 'Health Care Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Only if including a health economic analysis
Hard to lump it all together
From patients:
May be important as it relates to ability to seek and obtain care related to insurance coverage or ability to pay for care

Is the domain 'Non-health Care Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Useful but not as important as above
Agree, these are often important expenses. Out of pocket for rehab would be picked up here for many people where physio is not covered by insurance
From patients:
Some alternative health sources such as yoga, general exercise may be helpful in reducing pain. Some OTC pain medications may be as effective as prescription meds. I'm not as convinced that other OTC meds are as effective.
General information about massage therapy, or acupuncture treatments would be helpful
OTC medication, chiropractic, and travel expenses
Possibly, for research purposes.
Comments provided for "no" are as below:
From Clinicians/scientists:
In some societies this may be important but not in a general core set
Interesting but ? relevance
Same response as to 38
As above - important for health economics but not necessarily for all studies
Examples not non-health do you mean non-medical
From patients:
I go to the gym three days a week.

Is the domain 'Non-health Care Services' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
None.

Is the domain 'Requiring Re-operation or Revision Surgery' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Revision etc. yes but the reasons why need to be recorded
From patients:
Also as it relates to surgery after decision to not have surgery initially
However, I would hope that all other modalities would be tried first before a second surgery is considered. Also, some people may not be willing to experience a second surgery.
Of course this is important. Perhaps the revision surgery could have been avoided if the original surgery was done differently.
Good to know the incidence, gather information.
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on the research question
The far majority of patients are treated in primary care, and a small minority of those will be considered for surgery. It will be an important measure in people attending secondary care / hospital settings, but not as a core domain for all trials.
Relevant to surgical trials not all trials though
This will apply only to surgical trials so cannot be part of a core set for all trials
Re-operation is very seldom indicated even if patients put forward a need for operation.
From patients:
I have had 2 already

Is the domain 'Requiring Re-operation or Revision Surgery' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I have not had surgery.
No surgery as advised condition not necessarily successfully operable
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on whether surgery has been provided in the first place
Yes if it is a surgical intervention
Won't make sense for trials including patients without previous surgery (especially if conservative therapy is being evaluated).
From patients:
This might apply if the intervention is surgery or if the intervention has not been effective resulting in shoulder damage which is now too late for surgery.

Core Area: Pathophysiological Manifestations

Is the domain 'Range of Motion' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Depends on pathology
Active versus passive; failure to recover (stiffness or pain)
This can be determined by the patient as there are now three studies that demonstrate reasonable agreement between patient perception of ROM and physician exam of ROM
From patients:
To have full range of motion is important to complete many daily tasks. Personally, I was interested in being able to reach top shelves in my kitchen and complete routine ADL tasks. It's important to know what each person's goal is.
My range of motion in both shoulders has become severely limited
Again, for me the most important thing is pain, but range of movement does also affect my ability to do stuff, with or without pain.
Range of motion is very important in day-to-day life and an important factor in the perception of how well the recovery is progressing.
I go to the gym to improve range of motion.
Yes, but only if the doctors or physical therapists can use the results to help the patients.

Is the domain 'Range of Motion' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Limits to motion in all directions
But more in a general way as in "is ROM sufficient for ADL or participation in sports"
Critical symptom is loss of range of motion.
Comments provided for "no" are as below:
From Clinicians/scientists:
Research has highlighted poor reliability, validity, and responsiveness of physical examination tests, and perhaps more importantly, the main outcomes of relevance to patients are related to pain, function, and quality of life. Many trials therefore only include (postal/online) questionnaires as outcome measures. Adding physical examination as a core outcome would make all trials (especially large, community-based trials) a lot more expensive and less feasible.
Function is more important.
Any variable that requires objective assessment such as ROM or strength or tone will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Doesn't matter, captured in function and is always age dependent also
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on the condition being studied
Depends on clinical context
Very subjective really even though supposedly objective and difficult to reproduce - and labour intensive functional items probably better e.g. do up your bra, wipe your bottom
Stiffness is important for people when it is severe. Especially in Frozen shoulder and osteoarthritis
From patients:
None.

Is the domain 'Muscle Strength' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:

Is the domain 'Muscle Strength' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
Depends on pathology
But difficult to test with simple manual techniques
But difficult to quantify or even estimate in the context of pain
Difficult, most people mix pain and strength. But it is important in paralysis and large ruptures
Not MRC grading though, more granularity needed i.e. VAS 10 point?
Might just use term strength and leave the term muscle out of the definition
Shoulder depends on muscle function more than any other joint
From patients:
Muscle strength can impact basic daily tasks such as lifting or carrying heavy items.
I go to the gym to improve muscle strength
Please see my answer to question #39.
Particularly limiting as it is my dominant hand
Comments provided for "no" are as below:
From Clinicians/scientists:
Any variable that requires objective assessment such as ROM or strength or tone will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
For same reasons above
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Very difficult to measure properly, even with dynamometer
Depends on clinical context
Muscle strength seldom changes in the most trials I have read until now.
From patients:
I feel weak, but I don't know if it is weakness or pain.

Is the domain 'Muscle Tone' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
Muscle tone and strength impact daily tasks and mobility.
I go to the gym to improve muscle tone.
Please see my answer to question #39.
If it can be measured.
Comments provided for "no" are as below:
From Clinicians/scientists:
Only in neurogenic causes
Any variable that requires objective assessment such as ROM or strength or tone will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Too difficult to reproduce and measure
Unreliable not related to function
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on clinical context
From patients:
None.

Is the domain 'Pain on Palpation' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:

Is the domain 'Pain on Palpation' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Can help to localize the problem
From patients:
As it relates to treatment decisions by professionals
This information may lead to more specific treatment.
Please see my answer to question #39.
Comments provided for "no" are as below:
From Clinicians/scientists:
Too ambiguous
I think this may be vague
Any variable that requires objective assessment such as ROM or strength or tone will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Everyone has pain on palpation if you press in certain spots
Could be important in individual patients, but is an imprecise measure
Too unreliable
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on clinical context
From patients:
Most of my pain is from the biceps tendon, but I know also have pins and needles down the back of my arm, and sometimes into my forearm. None of this is painful to touch really; event the biceps region is not that painful to touch.
This may be difficult for the patient to identify

Is the domain 'Testing Positive on Specific Tests During Physical Examination' important enough to be included in a core domain set for clinical trials of shoulder conditions?

Is the domain 'Testing Positive on Specific Tests During Physical Examination' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Many studies have shown poor reliability of these tests either alone or in combination. However should be recorded
I wonder if the shoulder societies have practices for shoulder exam that they have studied. ASES, ASSET are two groups I can think of
From patients:
Pre and post tests are important for determining the effectiveness of treatment.
Post treatment assessments should be done at varying recovery intervals up to 18 months.
Please see my answer to question # 39. If nothing good can come from any of these tests, then my answers are all, "no."
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on pathology. As long as tests that have established validity and reliability are used.
Rubbish validity and reliability
Most of these physical examination tests are not reliable
This will reproduce pain if present but 'special tests' lack specificity so unsure how this could be useful as a part of an outcome tool.
Very low sensitivity/specificity. These are useful in the office, not for research
Tests are not sensitive or specific enough
In physical exam tests designed to diagnose a specific shoulder condition, those that look for pain have low +LR, and do not affect the probability of having the condition. On the other hand, those tests that reproduce symptoms (e.g. apprehension testing for instability or lag signs for cuff tears) do have high likelihood ratios.
These tests are insufficiently accurate for inclusion in a core set
Most tests are not validated and have poor predictive value
Unreliable
Especially because such tests seems to lack sufficient reliability and validity
From patients:
If there is too much specificity you will lose useful information
Very unreliable especially when based on pain experience
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:

Is the domain 'Testing Positive on Specific Tests During Physical Examination' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Depends on quality of test and context
Would like to see evidence that these are valid and reproducible and sensitive to change with intervention before commenting
From patients:
This could be of value but I have no experience in this domain.

Is the domain 'Shoulder Instability' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
However, this depends on the disease that is being evaluated
Instability is complex and there needs to be a detailed assessment and comparison with the contralateral shoulder
Depends on the condition being studied. Would be important in labral tears.
Defining instability is a challenge. Many authors consider a painful labral tear without a sensation of laxity or looseness as instability
Glenohumeral instability
From patients:
Often related to other conditions, often in combination with decreased coordination of muscle groups and thus decreased stability in ADL movements
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on pathology
As above
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Have you considered defining instability from the perspective of the patient rather than the 'black and white' anatomical perspective?
Unreliable, only relevant in certain cases
From patients:
May be more important to physician than patients

Is the domain 'Shoulder Instability' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on clinical context
Could ask this as a self-report in the function questions
Seldom instability, patients mix a lot
Is likely very important to measure in patients with shoulder instability, but definitely not all shoulder conditions
From patients:
Yes, if it could lead to specific treatments.
Sorry, but if I were a doctor, I would be in a better position to answer these types of specific questions. Therefore, I feel more comfortable answering, "Unsure/I do not know."

Is the domain 'Scapular Dysfunction' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Again needs definition and precise assessment to be useful
Although this would only be helpful if diagnosed by a physician. Patients cannot perceive the presence of scapular dysfunction
Yes/no - not specific answers
From patients:
Scapular dysfunction must not be underestimated! Causes trouble moving the shoulder and the (wrong) moving pattern is very hard to change / train.
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on research question
The idea of scapular dysfunction as a distinct clinical entity is really losing traction as it cannot be made certain whether it is causal or acquired as a result of something else. Not useful in my opinion for outcome.
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of

Is the domain 'Scapular Dysfunction' important enough to be included in a core domain set for clinical trials of shoulder conditions?
the size of the trial
From patients:
For professionals
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on clinical context. Do you have valid tests?
Poor consistency in assessment, therefore might be good for one clinician, but not for a clinical trial
Certain injuries and interventions this may be important but surely not core
Hard to settle on a definition
Ideally yes, but reliable methods???
From patients:
Perhaps this should be a separate study.
Please see previous comments.

Is the domain 'Proprioception' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
To help with the development of therapies.
Often seen in my patients: the better the feel for movements of the body, the better the overall active recovery
Comments provided for "no" are as below:
From Clinicians/scientists:
Applies only to rare cases
If measured properly yes but difficult to do
Depends on clinical context. Do you have valid tests?

Is the domain 'Proprioception' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Again may be ok for certain nerve injuries but not core
Not sufficient data YET to support
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
Please see previous comments.

Is the domain 'Weakness on Movement' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Same as muscle strength important but difficult to assess
From patients:
To develop specific therapies.
Yes, but only if it will be helpful for the doctor or physical therapist to remedy weakness.
Comments provided for "no" are as below:
From Clinicians/scientists:
Not reliable, often limited by pain
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Too subjective
Vague, better to have actual measures of strength

Is the domain 'Weakness on Movement' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From patients:
No weakness experienced..
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on clinical context. Do you have valid tests?
The definition is a perception, which is interesting about effort. But not core
Seems like strength
From patients:
None.

Is the domain 'Shoulder swelling' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Must be recorded
From patients:
This will cause problems with participating in therapies.
Sorry, but now I feel that a doctor or a physical therapist should be answering these types of questions . . . not previous patients!
Comments provided for "no" are as below:
From Clinicians/scientists:
Applies only to rare cases such as RA
Cannot reliably detect
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
Not a common complaint or concern
Reliable??
From patients:

Is the domain 'Shoulder swelling' important enough to be included in a core domain set for clinical trials of shoulder conditions?
No swelling.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Only if an arthritis intervention and swollen at baseline - too specialized to be core
From patients:
It seems that a short answer would give patients the opportunity to give you all this information

Is the domain 'Shoulder Posture' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
Good posture can reduce pain.
Cannot hold single position for long
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on pathology
Too may variations between subjects
Not a core set item but may be informative
"Good posture" is difficult to define
Not measured well enough to be used as a core outcome in a clinical trial. Perhaps research this, see if it helps. Along with scapular dysfunction.
Any variable that requires objective assessment will mean it is challenging to implement as part of a core set, my view is that a core set most likely needs to be information that can be gathered through self report and therefore collected on all participants, irrespective of the size of the trial
From patients:
It seems as though you already know the answer.
Comments provided for "Unsure/I do not know" are as below:

Is the domain 'Shoulder Posture' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
Do you mean scapular posture or shoulder posture?
Would like to see data - I do not think would be reproducible
Maybe if defined in a clear and useful way... but doubt that w
From patients:
See previous comments.

Is the domain 'Radiographic Outcomes' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Useful additional information
Again the relevance of the findings can be difficult to interpret as many asymptomatic patients have MRI and even radiographic changes.
If relevant
Particularly for fractures. Also would like to see BMD if it is a shoulder fracture perhaps as a covariate of a good fracture healing or not
Diagnostic important for osteoarthritis and a few seldom conditions
For certain procedures, TSA, fracture
From patients:
Diagnosis by ultrasound includes torn tendon
Comments provided for "no" are as below:
From Clinicians/scientists:
There are lots of questions regarding the role of imaging (e.g. false positive rate) in the diagnosis of shoulder conditions, I am not sure what the evidence is for imaging as an outcome measure - perhaps only of relevance in certain surgical procedures....
The lack of association between clinical symptoms of pain and disability with radiographic findings means that the latter would be unhelpful as part of a core set of outcomes for trials of interventions for shoulder problems
From patients:
For professionals

Is the domain 'Radiographic Outcomes' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Maybe
MRI outcomes may be meaningless; some may have no symptoms but tendon damage on MRI.
Only for limited interventions? But I cant think of any
Perhaps but clear definitions would be needed
Condition specific so not core
From patients:
They may help determine results of therapies.
Every person is different. A favorable surgical outcome would seem to be determined by the individual patients claims of pain and function and not a radiology outcome, so no. If the radiology exams are preformed to evaluate common observations based upon "the patients" claims, then yes.
See previous comments.

Is the domain 'Failure of Surgery' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
If relevant
But with detail for the possible reason(s)
If relevant
From patients:
Could be relate R to patients and professionals
May help develop better practices.
Comments provided for "no" are as below:
From Clinicians/scientists:
Only relevant for surgical interventions, so in my opinion not relevant as a core outcome domain.
You may wish a subset of measures for tendinopathy?

Is the domain 'Failure of Surgery' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Maybe
Only if the intervention was for new technique or substance for fracture healing - would be core for that study but surely not all
As previously mentioned: Makes less sense for studies including patients without surgery
From patients:
If the intervention is surgery then yes.
No surgery

Is the domain 'Surgical Process Outcomes' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
None.
Comments provided for "no" are as below:
From Clinicians/scientists:
As above
Would not be used in all trials
Not core but useful in some studies
Unless we are getting at costs
From patients:
Only for professionals
Comments provided for "Unsure/I do not know" are as below:

Is the domain 'Surgical Process Outcomes' important enough to be included in a core domain set for clinical trials of shoulder conditions?
From Clinicians/scientists:
Maybe more related to quality of doctor/surgeon
Very intervention specific
From patients:
One can never have too little knowledge if it will improve the outcome! But only a doctor would know which of these questions you listed on this questionnaire are the most important ones. I personally feel that you are asking too many.
N/A

Is the domain 'Haemodynamic Variables' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
None.
From patients:
If such studies will help improve outcomes.
Comments provided for "no" are as below:
From Clinicians/scientists:
Too laboratory-like to be utilised by the majority of clinicians. Some studies have already showing good coordination of haemodynamic assessment with special tests for upper limb blood flow issues.
Too "systemic"
Covariates, contextual factors but not core outcome; there might be a slate of contextual factors around the surgery process
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:

Is the domain 'Haemodynamic Variables' important enough to be included in a core domain set for clinical trials of shoulder conditions?
For professionals not patients
Pleeeeeeeeeeze ask a doctor.

Core Area: Mortality

Is the domain 'Number of Deaths' important enough to be included in a core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
Shoulder fractures have an increased mortality risk; we are not considering it so we need to think about that.
This is a simple thing to include, and should be reported in all trials of treatments
Required by ethics
From patients:
It would be important to know the reason for the death. Also, deaths may change the outcomes of the study.
Comments provided for "no" are as below:
From Clinicians/scientists:
Depends on the research question
Number of cases of harm might be more suitable
Mortality in most shoulder surgery is unusual and any deaths should be recorded but also whether associated with the shoulder pathology / treatment or not
No deaths primarily from shoulder disease. Too rare to include
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Since adverse events need to be reported, this domain should maybe not be part of the COS
From patients:

Is the domain 'Number of Deaths' important enough to be included in a core domain set for clinical trials of shoulder conditions?
I assume that death will be related to another condition than the shoulder condition. If you are speaking about the anesthetic and death occurred while the patient was in the beach chair position and died because of that, it may be helpful.

Responses to open-ended questions about overlap within the core areas, general suggestions, and reporting of adverse events

In your opinion, are there any domains in the Life Impact core area that have too large conceptual overlap? 39/89 (44%) responded, "Yes". Comments were as follows:
"Social functioning" and "Leisure/recreation" could be captured under a health-related quality of life measurement instrument
18, 21 & 22 (overall pain, pain with activity, pain with resisted movement) seem to overlap in that they are all aligned with physical function limitations. I don't know if it is important to know if those are work, life or leisure related. 23 & 24 (day pain and night pain) also seem to overlap.
28 and 29 (social functioning and recreation/leisure activities); 32 and 33 (anxiety and fear avoidance beliefs)
31 and others as stated in comments
A few domains overlap in concept and they are difficult to define specifically in relation to shoulder pathology
All concepts referring to psychological terms
Anxiety & depression; perhaps some of the physical function ones
Definitely!!! Holy cow! It's a relief to know that someone beside myself realized this, ha-ha.
Depends on the core areas that come out of this study...?
For example, overall pain, and daytime pain. Also something the activities of daily living and the social interaction pain.
Health related quality of life covers the domains of social function, recreation & leisure activity, work ability & psychological functions of depression, anxiety & fear avoidance beliefs
However, there are overlaps. But these overlaps seem to be trying to gain slightly different pieces of information.
HRQOL was mentioned but then many of the domains within HRQOL were then mentioned separately. Similarly with some of the depression / anxiety domain questions
I selected only some of the domains because of the overlap issue –e.g. work versus sport etc.
I would think that the primary reasons a person seeks treatment is pain/dysfunction. When these factors limit essential daily activities it seems obvious that there is going to be psychological/social frustrations. Fix the problem, fix the by-products of the problem.
Long questionnaires such as the Western University outcome measures (WORC, WOOS, WOSI) have not proven to be superior to short questionnaires such as ASES. The shortcomings of these measures are mixing emotional and psychosocial questions with pain and function. Items contributing to the total or sub-scale score should display similar change trajectories and these areas are not changing in a similar fashion. In addition these questions add too much variability to the questionnaires and reduce sensitivity of the measurement.
Many of the pain measures overlap
Many of the pain questions overlap and so I have chosen only some for consideration for a core set, the same for function questions

In your opinion, are there any domains in the <u>Life Impact</u> core area that have too large conceptual overlap? 39/89 (44%) responded, "Yes". Comments were as follows:
Maybe – I'd imagine the overlap of what helps a clinician in reasoning and what are useful outcomes from a trial on effectiveness often are not the same thing.
Maybe: Social functioning and Leisure/sport activities
Night pain & resting pain, in general all the questions about pain are somewhat important but maybe they should be summed up in two or three domains? Pain is not the most important indicator in most conditions especially when chronic severity of main complaint basically includes quality of life and impact on daily life activities,
No overlap, but several domains are influencing each other, such as night pain influences sleep quality, sleep quality influences probably work performance/quality of life etc.
Overlap across all domains
Pain during the night & sleep; potentially pain at rest & pain during the night
Pain is the dominating problem for most patients. Many of these questions relate to pain.
Psychological/ social
Psychological: I would suggest a general indication of psychological function; Pain: pain can be measured in several ways. I would choose 1 or 2 options.
Several of the pain assessment and psychological function domains appear to overlap
Severity of main complaint may have overlap with pain related to activities, sleep or day pain
Sleep quality and pain sleeping
Sleep results in fatigue. Question about fatigue is already answered by answering the "sleep" questions.
Social functioning with recreation and leisure; sleep function with night pain intensity
Social functioning and leisure activity
Some relating to function seem to overlap but I can't remember the specific question numbers. I would like to see questions about the range of shoulder movement (both with and also without pain) and subsequent improvement.
The pain questions
There is some redundancy
They are all interrelated
We need to explore sleep and fatigue and understand experiences of this population.

Are there any additional suggestions that you would like to make about the wording of terms and definitions of domains within the Life Impact core area?
After a while, people in general, will lose interest in long questionnaires and begin to put down any answers just to be finished.
Allowing respondents to answer in short answer form might give you the most information as opposed to multiple choice.
I think the most important outcome domains are: shoulder pain and functionality. Secondary measures should include: general quality of life, depression/anxiety, expectations, and satisfaction. However these domains should not be mixed with the primary outcome domains.
If you are looking for something to measure outcomes as a performance measure, a global rating of change is important, as is some measure of patient expectations-which have been shown to highly influence outcomes
Interested to know the level of patient involvement in development thus far and how this has influenced development of the questionnaire
Keeping the number of questions to a reasonable level is important
Perhaps work related items that could influence recovery like work related stress/ergonomy etc., good luck with the trial.
References for the definitions would be good; where did you get the definitions?
Satisfaction is common measure... but not a useful measure- often relates to process.. avoid confusing predictors of outcome and outcome measures... need to keep core small
See above: wording of the domain related to global perceived change: would not word this in relation to treatment success
Strength measurement ROM measurement
The wording of the whole questionnaire is bad and not in plain English
Try and not overlap too many questions
Using specific and relevant questions will improve the accuracy of measurement. Distinction between QOL and disability is important. DO NOT use HRQOL unless the question is properly worded.
We have found that depression and anxiety are not as common in shoulder problems than for example back problems, but fear of moving the shoulder is likely to be more relevant as a psychological obstacle to recovery
Would be good to know what patients overall level of pain is and then separately what their shoulder specific level if pain is...gets around confounders of other causes of pain
Yes. Please use plain English
Your focus here is mainly on PRO, which is lacking in this area. What will happen to other domains (resource use, pathophysiological manifestations)? I am agreeing with you that this patient perspective is key. And is worthy of focus like this. Perhaps other areas are already clear. The recovery definition...I wonder if that domain could be called "recovery"

In your opinion, are there any domains in the Resource Use core area that have too large conceptual overlap? 14/88 (16%) responded, "Yes". Comments were as follows:
37-38 (global assessment of treatment success, severity of main complaint)
All of these domains appear to be there to illicit different pieces of information.
As above, overlap across all domains; inter-related issues. Theoretical exploration required along with patient input.
Health care services covers requiring re-operation or revision surgery
I didn't think any were important anyway!
I suggest an open question "history"?
Lots of reasons for repeat surgery, but still a good measure. Must watch for surgery to other shoulder, done mix up in outcome
Pain is important for patients and a lot of these questions rely on pain
Perhaps watch work ability and work productivity and whether there would be a chance to do them together while playing the two roles. The items are often similar to respondents.
Potentially: work productivity & impact on work in the previous section - would make sure to include work absence.
There could be a domain on services of health in general asking for the time invested in rehabilitation instead of breaking it down to health care and non-health care
Yes, even this question. I believe that you already asked a similar question.

Are there any additional suggestions that you would like to make about the wording of terms and definitions of domains within the Resource Use core area?
Looking at the timing of assessment and treatment. If a person with shoulder pain / injury is left too long they may develop too much damage for surgery to rectify.
No questions on primary surgical intervention
Persons who seek help often do this because their coping strategies are insufficient. A coping question should be included. An important negative predictor is catastrophizing. A question about this should be included.
The denominator for the treatment effect should be the money spent. This requires the knowledge on the true monetary input, including individual and societal costs.
This area other than health care service will not apply to all patients

In your opinion, are there any domains in the Pathophysiological Manifestations core area that have too large conceptual overlap? 10/87 (11%) responded, "Yes". Comments were as follows:
53, 57 (scapular dysfunction, shoulder posture)
Concomitant neck complaints
Failure of surgery & surgical process outcomes
I think there too many questions in general. Patients are going to get bored answering all of these at the same time. Perhaps 3 or 4 different surveys for different issues.
Strength and weakness are the same concept
Surgical outcome and failure of surgery
The domains need to focus on either patient focused or professional focused
These 'physical' or biomechanics' domains have limited value
Yes, however, I am not a doctor, so unfortunately I cannot help you.

Are there any additional suggestions that you would like to make about the wording of terms and definitions of domains within the Pathophysiological Manifestations core area?
I have missed the painful arc. I think that might be relevant
Need separate surgical subset
The clinical and radiographic findings can be used as secondary measures, but these should not be mixed with the true outcome domains: pain and functionality.
Very likely, but I'm pooped now. Answering these questions took a lot out of me.

In your opinion, are there any domains that should be added to the list presented in this survey? If yes, please mention them in the space provided below.
1) Treatments received prior to this treatment episode and their success. 2) Treatment received during this episode of care. 3) Is this episode a first time shoulder disorder, persistent issue (never fully settled) or a recurrent issue (occurred, treated, resolved and now re-occurred)?
As mentioned above, patient expectations with treatment would be critical

In your opinion, are there any domains that should be added to the list presented in this survey? If yes, please mention them in the space provided below.
BMD in shoulder fractures, AE
Can only be judged from a summary
Could consider "reaching" rather than ROM, lots of complaints with getting dressed,
Effective pain control methods.
Harm
I didn’t see anything concerning patient satisfaction with outcomes or treatment.
Intensity of pain depending on shoulder/arm position (e.g., arm at side, overhead, across chest, shoulder bent forward). Some of this would have to do with how the person lays down when sleeping (e.g., on their side versus back).
It might it be relevant to consider the relationship between shoulder pain / damage and developing neck pain? Also the possible impact on cognitive functioning and perhaps lack of patience because of the pain.
No (apart perhaps from global perceived change)
Overall posture/body composition
Pain with activities of daily living.
Physical therapy, intensity etc. The physical therapy is very important for the outcome / result of the recovery.
Return to sport
Sex/gender considerations; work consider unpaid and paid work
Should determine what initial patient expectation is in order to relate outcomes to expectation
The amount and type of physical activity used to get back to normal activity.
There are too many already :-)
You could consider value for money or cost-effectiveness
You have too many already

If you have experienced a shoulder condition, are there any considerations that you would like to make about the domains included in this survey? For example, you may wish to suggest some domains that, according to your opinion, should absolutely be included in this core domain set.
Activity

If you have experienced a shoulder condition, are there any considerations that you would like to make about the domains included in this survey? For example, you may wish to suggest some domains that, according to your opinion, should absolutely be included in this core domain set.
Comorbidities smoking etc.
Effective pain control
For surgery: would you recommend the operation to your closest friend?
Function is more important than pain experience
I don't know how you would capture it, but my shoulder pain varies quite a bit in nature. If can be sharp and very localized, or a searing pain after a certain activity. A question about the pain might try to separate those, or others. The searing pain continues after the action and doesn't settle for a period of time. The sharp pain might be different if I move out of that position it will stop...but searing might continue. We might want to explore - similar was found in hip OA in the ICOAP work. Also thinking about the shoulder fractures and link to OP, whether in shoulder fractures we should have a sense of this through BMD? Also AE's – i.e., not tolerating NSAIDs, reaction to stitches, burns from hot packs etc.
Like said above, physical therapy has a key role and is not included yet separately.
Pain and function are the most important; time to recovery is also important to patients - they want to get better as quickly as possible
Pain and limitations that affect your life negatively (due to shoulder problems), such as sleep, social life, work
Pain during day, night, sleep. Work impact
Pain, function (e.g. getting dressed), range of movement, sleep, quality of life, X-rays.
Range of motion
Role and benefits of physical therapy.
These seem to be critical: 11-14, 16-18, 26, 36, 39, 42-44, 48, 51

Are there any other considerations that you would like to make about the domains included in this survey?
I am not sure about the type of survey you are developing but mixing too many concepts together weakens the usefulness of the instrument and adds a burden on the patient and examiner. Clinical trials should use the tools that are suitable based on the research questions. I am not in favour of generalized cookbook recipes. There are already many valid and reliable tools that measure general wellbeing, depression, surgical success and so on.
If muscle strength is included than please consider thoughtfully the way you measure strength
Only some of the domains in the survey should be included as true outcome domains. The other domains are important secondary

Are there any other considerations that you would like to make about the domains included in this survey?
measurement.
Probably most areas covered
Sometimes you cannot divide domains from each other, because they can be connected (pain, bad sleep quality, less work productivity)
The tolerance of pain by the patient.
They might be too much for a COS
We need to think carefully which domains are core domain relevant to all patients with shoulder pain, and relevant to all trials, regardless of setting. Feasibility of measures to be included implemented in all types of trials will also need consideration.

Are there any general considerations that you would like to make about this survey?
Agree with most and they apply with my experience with shoulder surgery performed.
Everything depends on context. In my opinion it important to determine if a patient has acute, subacute or chronic shoulder complaints or is it a chronic pain patient with shoulder complaints
I am very interested to learn about your results.
I have done focus groups with patients with shoulder pain and the conclusion is that they should not have to answer to more than 70 questions. After that, they don't read or pay attention.
I wonder how patients decide about all the biological indicators, for me it was hard to decide
It needs to be specific to each condition e.g. rotator cuff tear, labral pathology, etc.
Language is inappropriate for patients
Reasonably well structured
References for the definitions given would be good
The wording of the survey needs to be put in plain English. It might be ok if you are medically trained but it could be made much more clear.
This was a VERY WELL designed survey. I hope you might let others in OMERACT learn from this. I think you will get informative responses.
Very long

Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey and specify why.
2

Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey and specify why.
2
3
4
4
4
4
5
5
5
6
6
7
8
8
10
10
10
10
10
10
10
10
12
12
15
20
20
20

Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey and specify why.
25
1 primary domain & 4 secondary domains
10- as more feasible to collect well
15 enough to handle
15-20
20. Enough details, not too long
3 major with subtypes of 3-5 allowed in each; Symptoms, Function, Process of Care
30 to 40 questions max length of time to complete should not exceed 30 minutes
3-post injury, immediately post-surgery, 6 months post-surgery
4, maybe 5 (a core set should be limited to a small set which are applicable to all shoulder studies). These could of course be supplemented with other outcome measures which are specific for the study at issue
6 core domains: Function, mental/psychological aspects, pain, health care, mortality, positive or negative outcome of surgery/treatment
8 - but I don't think there is an easy answer!
A maximum of 5, ideally 3 (since then they are likely to be used by trial teams)
All
All domains presented appear to be important.
All of them
Almost everything. You need to know what is going to happen. But they must not scare you for doing it.
AS FEW AS POSSIBLE
As few as possible. Max 10 questions
As many as needed to increase positive outcome as determined by the patient.
Depends on the burden really. I would say 5-7 but not firm on that. Pain and function are what matter to patients, ultimately impact of that on QoL. Then mortality, some structure (motion), and we are at five.
Don't know
Don't make it too long
I believe most of them should be included to obtain an accurate & effective outcome.
I find it hard to say. I think that many of the domains are important but to control the "trial placebo" it maybe would me wiser not to use too

Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey and specify why.
many questionnaires, patients could be biased because of the amount of questions they are asked.
I think the domains were adequately covered
I would not specify a specific number. In part it would depend on the research question driving the trial
Max 20; in order not to irritate participants with too many questions
Max 4
Max 5 (pain, function, sleep, work, QoL - or another combination): in order to stimulate wide adoption of the core domains, it needs to be a set that is feasible and important to all patients and all trials.
Max. 9 to keep it feasible for patients and researchers
Maximum 7
Most.
Need a second phase to judge
Need for parsimony - maybe 10 max?
No idea
No idea
No more than 10, too many questions are too hard to answer
No more than 5 - too long otherwise
No strong preference as long as the final set is parsimonious.
Not my expertise
Not really sure...enough to be thorough though--maybe 25.
Pain, function, range, social impact, psychological impact, radiology
Pain, work, social, psychological, recreational
Related concepts so one underpinning 'domain' would be ideal from both a clinical and research perspective
Six key domains: pain, function (shoulder specific and including work productivity), function (health including depression and anxiety), harm, satisfaction/global perceived change, cost
Ten is a nice reasonable number. After a while, people lose interest.
Ten maximum.
They seem to be repetitive. Need to be reduced.

Ideally, how many domains would you include in this core domain set for clinical trials of shoulder conditions? Please try to answer this question regardless of your rating during this survey and specify why.
Two domains: pain and function. The function domain should document impact on work (household chores and paid employment)

The presence (or not) of adverse events should always be reported in all clinical trials. Following OMERACT guidance, a recommendation for the reporting of adverse events should be included in every core outcome set. For this core outcome set, we propose an approach that demands a conceptual separation between adverse events and core domains. This means that a measured adverse event would only be defined as an adverse event if belongs to a different domain than one of the core domains. The following hypothetical example is provided for illustrative purposes. Suppose that this core domain set has already been defined and "Pain Intensity", "Physical Functioning" and "Work Productivity" are the core domains included. In this case a patient with an increase in pain intensity due to treatment cannot be defined as an adverse event because it belongs to one of the core domains (i.e. Pain Intensity). In fact, this increase in pain intensity would be summarized within the group results for that domain. However, people who report symptoms such as dizziness or nausea (or any other bad event or outcome following treatment would be defined as adverse events. Do you agree with this approach to defining adverse events? **49/87 (56%) responded "Yes", 14/87 (16%) responded "No", and 24/87 (28%) responded "Not my expertise".** **Reasons for responding "No" were as follows:**
A patient may get temporarily worse in a core domain like pain intensity during the treatment, but if by the end of the treatment they are worse, I would consider that an adverse effect.
Any increase in complaints whether it is pain, dizziness, nausea etc. is an adverse event AND most serious when an event cannot be explained.
I think an increase in pain during a clinical trial can never be the scope of the trial and should be registered.
If pain increases purely due to the intervention then that is an unintended consequence of the treatment and therefore an adverse event. If nausea is an adverse event which affects work productivity then decreased work productivity is an adverse event caused by another adverse event i.e. nausea.
If you get a septic arthritis or haematoma from a procedure then this will manifest as an increase in pain. Surely these adverse events should be considered separately even though they will overlap with the patient's core domain symptoms.
If you get pain because of an adverse event, it would not be caught in the pain intensity domain, in there it is interpreted as the health state, not attributed to an AE.
Increasing pain in order to some therapy approach IS per definition an adverse effect and needs to be reported
It depends if you included certain domains e.g. mortality. You would certainly define death from a shoulder procedure as an adverse event!

The presence (or not) of adverse events should always be reported in all clinical trials. Following OMERACT guidance, a recommendation for the reporting of adverse events should be included in every core outcome set. For this core outcome set, we propose an approach that demands a conceptual separation between adverse events and core domains. This means that a measured adverse event would only be defined as an adverse event if belongs to a different domain than one of the core domains. The following hypothetical example is provided for illustrative purposes. Suppose that this core domain set has already been defined and "Pain Intensity", "Physical Functioning" and "Work Productivity" are the core domains included. In this case a patient with an increase in pain intensity due to treatment cannot be defined as an adverse event because it belongs to one of the core domains (i.e. Pain Intensity). In fact, this increase in pain intensity would be summarized within the group results for that domain. However, people who report symptoms such as dizziness or nausea (or any other bad event or outcome following treatment would be defined as adverse events. Do you agree with this approach to defining adverse events? **49/87 (56%) responded "Yes", 14/87 (16%) responded "No", and 24/87 (28%) responded "Not my expertise".** **Reasons for responding "No" were as follows:**
May these symptoms be relevant outcome of injected or orally ingested treatments? Or may indicate other co-morbidity which may have impacted on treatment compliance.
Referring to the example, if a pain response is beyond that deemed acceptable by the patient then that should be deemed an adverse event. I disagree the conceptual framework as currently suggested.
There should not be a conceptual separation between adverse events and core domains. All adverse events should always be summarized regardless whether being part of the core domains or not.
Use WHO definitions? Core measure so broad may capture adverse agree that symptoms and functional level not adverse events but CRPS is and falls under pain
Yes mostly but an adverse event may be something that is unexpected in the core domain such as sudden onset of severe pain and it is important to recognise this as a AE

Different aspects should be taken into account when reporting the presence of adverse events. Examples of these aspects are: distinction between serious and non-serious adverse events, adverse events that can be intervention-specific, adverse events that can be treatment-related or not. Do you have any suggestion on how adverse events should be reported in shoulder condition clinical trials?
Adverse events can be related to all the core domains mentioned in 62, so maybe for each core domain adverse events should be allowed to be named
Adverse events intervention-specific
Adverse events should be reported to the safety officer

Different aspects should be taken into account when reporting the presence of adverse events. Examples of these aspects are: distinction between serious and non-serious adverse events, adverse events that can be intervention-specific, adverse events that can be treatment-related or not. Do you have any suggestion on how adverse events should be reported in shoulder condition clinical trials?
Agree with SAE and AE, defined as GCP standards define, so it is clear for reporting in trials
Any increase in complaints whether it is pain, dizziness, nausea etc. is an adverse event AND most serious when an event cannot be explained
Best to distinguish serious from non-serious adverse events
Brief description of injury
Cast a wide net and computerize the process.
Checklist and severity
Common treatable (e.g. treating nausea with effective anti-emetic). Common, non-serious untreatable (e.g. skin rash / purpura). Rare non-serious treatable, rare serious untreatable.
Disease related or not
Events that change diagnoses or change prescribed treatment plan
Fracture, tendon rupture, nerve injury
Given my answer to 63, I would separate adverse effects that involve increases of pre-existing symptoms from adverse effects that involve new symptoms. The distinctions listed in the question seem reasonable.
I agree that the level of intensity should be considered
I have used the Clavien-Dindo classification for treatment related complications.
I think SAEs versus AEs is primary
I would suggest a registration of adverse events that is duration depending (only short time after treatment increase of pain or longer than for instance 2 days?) and register if the increase in pain is treatment-related. In my study two patients had car-accidents during the trial, their pain got worse but this was certainly not treatment specific
I would support the above
Limiting ADLS versus not
MAYBE A SEVERITY SCALE 1-10??
Maybe life changing levels e.g. stroke,
Need to report in advance expected adverse events from the interventions being tested, and be clear on whether the trial will capture and report on expected as well as unexpected adverse events, and whether the trial will capture and report on ALL adverse events or only those that are deemed to possibly or probably related to the treatments being tested
No, all AEs should be evaluated for severity and attribution.

Different aspects should be taken into account when reporting the presence of adverse events. Examples of these aspects are: distinction between serious and non-serious adverse events, adverse events that can be intervention-specific, adverse events that can be treatment-related or not. Do you have any suggestion on how adverse events should be reported in shoulder condition clinical trials?
On a case report form
Only those related to the interventions
Report all but still necessary to identify those that may have a serious consequence
Report all patient reported adverse events
Separate: personal, work
Serious adverse events must be reported and it should be stated if caused by the intervention or by other reasons.
Serious and non-serious
Serious versus non-serious
Serious, non-serious and related to intervention
Severe and minor
The way you suggested seems to be comprehensive enough for me
These distinctions are important, and required for trials of medical interventions - so hard to avoid. There is guidance for how to classify serious (or not), and whether or not adverse effects can be related to the intervention needs to be specified in each individual trial. So hard to give general guidance...(but important to make these distinctions, especially for CTiMPs).
This not my field of expertise but I think that the three categories listed above seem sensible.
Those requiring intervention, transient vs. permanent
Treatment-related events
Using the British NIHR reporting method of serious/non-serious adverse events or reactions.
We have to report way too many adverse events that are unrelated to the core problem
Why should it be any different to the conditions?

ROUND TWO

Question 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)'.
Comments provided for "yes" are as below:
From Clinicians/scientists:
As sleep is so important (as an anti-oxidant, immune system, mental health, etc) I think shoulder pain effecting night and sleep is an important subdomain that need be considered
Qualifying the activity when and amount of pain is important
Maybe night pain should stay separate item Although less prevalent is often the key tipping point for clinical decision making because of patient impact
Night pain might still be one that should separate out Although less prevalent it is often an important discriminator for clinical decision making because of impact on patient
most patients seek treatment for the pain so pain needs to be a core domain for all clinical trials
Differentiation between pain at rest and pain with movement is important here.
principle patient complaint 80% of all presentations
a spcification as to intensity of pain ie. pain at worst over last 24 hours etc
From patients:
A critically important factor
My pain is not constant. It just happens during rest or activity making a "wrong" move.
pain is a determinate of physical capacity
Fundamental to survey
But give parameters for time of day, movements, persons overall pain tolerance, etc.
Pain is usually an indicator of a problem.
pain is the usual indication of a problem
I am not clear on what you are asking. Post surgery there was only minor pain, and after recovery there is no pain or discomfort. surgery was successful.
The intensity and duration of chronic and acute pain is very important in the study
Pain main reason for surgery and lack of it postoperative is goal for the surgery.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Each concept should be measures separately. pain in activity is different than pain intensity or frequency. They would not belong in the same scale, are you intending on having a pain intensity score, and a scale for analgesic use?
From patients:
None.

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 (e.g. driving a car), recreational/leisure activities (e.g. sports) and work tasks.
Comments provided for "yes" are as below:
From Clinicians/scientists:
Happy with combo
This is often the primary complaint of patients, i.e. it hurts when I...
Does this include tools such as the patient specific functional score where individual patients get to select thier own functional problems?
the only one I am concerned about is the inclusion of work tasks in here. I am fine with person ability to do work tasks, but would be concerned if this is trying to capture work productivity etc. These are so dependent on job situation > person ability that it might throw off your scaling properties if they are in same scale.
From patients:
Various moves, generally above the head moves, like showering setting my hair, etc.
ability to perform lifestyle activities
Poor physical functioning may lead to a poor sense of well-being and/or independence.
restriction of normal activities is important in assessing a problem
All activities are normal except for tossing a baseball. The strength is not what it once was. Distance is down, and my release has the ball going into the ground more often.
It is very important to determine physical limitations resulting from shoulder pain
My responses are post op with a good result but preop totally different responses were present.
Comments provided for "no" are as below:
From Clinicians/scientists:
They have to be differentiated as some functional activities might be possible and others not
These represent two very different levels of functioning (adl's vs sports) and it seems like an aggregate score that includes both will not serve to differentiate these.
From patients:
Ability to perform daily duties is an important feature of this study
Need to distinguish basic needs from more complex activities from recreation/leisure and work.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
None.
From patients:
None.

Question 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.
Comments provided for "yes" are as below:
From Clinicians/scientists:
we have just finished a trial with a large number of participants with shoulder pain, pyscho social domains where bigger predictors of outcome than bio factors
Happy with combo
there is a lot of overlap in psychological constructs and measures, psychological distress is likely a better term than psychological functioning?
From patients:
I know how much I struggled with this area, because of th duration of my condition. My new physiotherapist had to know how much my condition did with my mental wellbeing
determines attitude and thus activity
Anxiety about pain and anxiety about performance (like throw a ball uncontrollably or unable to lift something above shoulder because of limited strength)
Continued pain and/or decline in functional may lead to increased anxiety or drpression. This will lead to a decline in a sense of well-being.
impacts on motivation towards activity
Chronic shoulder pain can have a severely negative impact on emotional well being
Depression and anxiety has a very important impact on a persons ability to function.
some times
Comments provided for "no" are as below:
From Clinicians/scientists:
Psychological Functioning is predominantly determined by conditions other than the shoulder problem so would be a poor domain to reflect shoulder outcomes.
may be relevant in subacute and chronic conditions
Psychological functioning might not be sensitive enough for acute and towards healing oriented approaches when you define clinical relevant diagnosis such as Depression or exreme worrying! There are other subdomains in the area of PF such as anger which is frequently not considered (as well as you have not considered anger, subclinical forms of psychological distress and impairment). Your definition seems too strong for your condition. You define clinical forms and diagnosis, I would expect less intensive symptoms in your condition and therefore the same problems when applying those domains to your target population as we have in the matter of chronic pain.
From patients:
Mentally there was no worry.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
It is important but I am not sure if it should be core. I would like to know what consumers think about it.

Question 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.
This seems an aggregation without sufficient refinement; there is insufficient commonality to justify aggregation here.
Impact of the shoulder problem on mental health / emotional functioning would be an important outcome measure for all trials. I am just not sure if this really broad way of formulating the domain is helpful - a lot of (different) psychologically concepts are listed here..
Core domain is by concept, and I think these are different concepts. Fear avoidance is not same as depression, therefore I wouldn't put them in same concept.
From patients:
I don't let the minimal pain I experience have much if any impact on my Psychological Functioning. II just make an effort to shake it off and move on.
It is one of the consequences that might happen due to shoulder pain, but not directly a domain that belongs in the core set, it can be placed under the next question, QoL

Question 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'.
Comments provided for "yes" are as below:
From Clinicians/scientists:
For cross condition comparisons and economic analyses met analyses etc
Enables health economic and cross condition comparisons
From patients:
Quality of life issues must start with quality of health
quality of life is important
in contrast to the last question 4, this is broader
It's important to know how physical issues impact quality of life and a person's ability to participate in life.
if health problem diminishes life enjoyment is is an indicator
Shoulder pain definitely impacts the quality of life
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:

Question 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'.
Inclusion of this domain is topical but what does it add over previously collected data?
I am not sure if you deal with rather acute conditions or rather chronic. When assuming resting impairment or handicapp I would prefer HrQL, when not, I would think it is to global to be sensitive enough in follow ups.
Health-Related Quality of Life questionnaires are often very similar to physical functioning questionnaires. Therefore, it depends on the Health-Related Quality of Life questions that would be asked.
From patients:
None.

Question 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'.
Comments provided for "yes" are as below:
From Clinicians/scientists:
I like this
in trials comparing treatments, it seems a very good idea to include a patients view of whether the treatment has been successful for their shoulder problem. Be clear this is about assessment of the success of the outcome from treatment, rather than satisfaction with treatment per se - as the latter is often rated highly even when the outcomes from treatment are not good
Simple, but possibly the most important component of outcome assessment.
Agree with the definition, not quite sure if I would label the domain as 'treatment success'
From patients:
An individual's optimistic or pessimistic beliefs regarding recovery must be included in the study
review os progress is helpful in validating success of treatment
The better a person recovers the better they can participate in life. Their sense of well-being will improve.
leads to continuing motivation
An individual's assessment of possible or probable shoulder recovery is an important factor in treatment program
This is the reason for undergoing the procedure so very important.
Comments provided for "no" are as below:
From Clinicians/scientists:
None.
From patients:
I have seen other doctors to see if they could fix my problem with my shoulder and they said they wanted to do another surgery and I feel that if I have already had two surgeries then they would want to do another one I feel if this was fixed I wont of had two or even 3.....
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:

Question 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'.
None.
From patients:
Is interesting to measure in CTs, but not sure if it is directly related to measure shoulder pain
If the surgery has not improved function etc, or has perhaps resulted in an infection which causes long-term problems, the patient's assessment would be important. However, the success of a treatment e.g. surgery, may be improved or hindered by the patient's adherence to physiotherapy, which may be difficult to measure.

Question 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'.
Comments provided for "yes" are as below:
From Clinicians/scientists:
yes see previous
This is the second commonest patient concern in my opinion - after pain
However, this should be limited to one or two questions
From patients:
Adaquate sleep is a critical part of psychological and physical health
perhaps ask what sleep position cause pain or anxiety
You can't function well without a good night's sleep.
sleep deprivation reduces quality of life and is an important factor
The first night after surgery I was sleeping in a bed. Most everyone I spoke with said they slept in a chair for at least a week. Other the ice pump arrangement the sleeping wasn't a real issue.
The quality of sleep with shoulder pain is also diminished by sleep partners in the same room
Symptoms do affect the quality and overall ability to sleep comfortably.
Comments provided for "no" are as below:
From Clinicians/scientists:
Very common complaint in older population Not a discriminator
Such a common problem in older age groups unlikely to be a discriminator asked in this way
sleep is an important outcome for shoulder patients but I do not feel it should be a core domain, because a) we need to keep the core set brief enough for all trialists to use and b) sleep function is often already included in measures of physical function for shoulder problems
From patients:
None.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
It is a common complaint for shoulder problems but may not apply universally to all shoulder disorders

Question 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'.
Many factors effect sleep other than shoulder pain
Not everyone has their sleep affected by shoulder pain
From patients:
like question 4, it can be placed under QoL, and should maybe not be measured in all CT. Unless it has been researched that this is a major complaint in many patients.

Question 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. Is the domain **'Number of Deaths'** important enough to be included in a core domain set for all clinical trials of shoulder conditions? 'Number of Deaths' is defined here as: 'reporting of the number of deaths that occurred within a clinical trial'.
Comments provided for "yes" are as below:
From Clinicians/scientists:
Is a must do for all trialsl As basic as saying loss to follow up Perhaps we are being silly to even ask this question
I think deaths should be reported in all trials, of course the team can also say that the deaths were unrelated (or believed to be unrelated) to the treatments in the trial
From patients:
All possible outcomes should be presented to the patient.
Comments provided for "no" are as below:
From Clinicians/scientists:
adverse and serious effects must be reported
Should be reported as adverse events, but not be included in the COS
This might be part of reporting quality and therefore included into study sample description.
Harm probably more useful than death statistics
It seems unnecessary to collect death as a separate domain in ALL shoulder trials. Perhaps it would be better to measure it as a serious adverse event?
Not for all trials.
From patients:
Not a relaxant factor to shoulder pain
Not when what you're looking for is functional status.
If so few, not necessary to detail.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
It should be reported if it occurs but not sure it needs to be 'core' as most often it won't occur.

Question 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. Is the domain **'Number of Deaths'** important enough to be included in a core domain set for all clinical trials of shoulder conditions? 'Number of Deaths' is defined here as: 'reporting of the number of deaths that occurred within a clinical trial'.
Only for studies looking at surgery/drugs and death occurs because of the surgery/drugs. For studies looking at the effects of rehab interventions, there is no need to add a death question
From patients:
only if related to shoulder injury - also depression could lead to suicide.
if you are giving this survey to patients-- clearly they are alive.

Question 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. Do you agree that **'Range of Motion'** and **'Strength'** should be **excluded** from the core domain set for clinical trials of shoulder conditions?
Comments provided for "yes" are as below:
From Clinicians/scientists:
This may be answered poorly Not good to change to exclude at this point...
any objective measures will mean its very difficult for trialists to use them as CORE for all trials, it would be unrealistic for very large trials to measure ROM and strength for all participants.
Lack of reliability and association with patient reports make it difficult to justify these components in a core set
I agree that it is part of physical function.
From patients:
Both factors contribute to well being
For me, it was important to improve range of motion. Increased ROM improved my functional status and psychosocial well-being.
In PT the range was measured, but no one followed up at a year post surgery. It would be good to know the real success of the surgery.
I agree, could be a component of "Physical Function."
Comments provided for "no" are as below:
From Clinicians/scientists:
ROM should be included as it is objective. Strength is difficult to measure so inclusion will not be helpful.
Each patient has an individual physical function, as such from an individual perspective ROM and Strength may fit under his or her physical functioning domain, however when studying populations, it would be important to have ROM and Strength data-particularly for rotator cuff tears as strength seems to drive the slightly better outcome with successful surgery.

I have never seen a study showing strong correlations between 'range of Motion' or 'Muscle Strength' and functional limitation as measured with a self-reported questionnaire. Therefore, for me it is two different constructs.
From patients:
Asking questions about shoulder function will provide specific information that more general questions will not elicit. I am able to function very well overall but I under use my non-dominant left arm to avoid discomfort. When I have to use it I have pain and experience limitations I don't otherwise experience.
range etc is a function of ability to have normal activities
because this question is about quality of life.
No, I feel these are important enough to be INCLUDED in the core domain. They are individually huge factors when measuring the outcome of a shoulder repair.
range and strength are important in the overall functioning. I can function normally below shoulder height but not above. thus some activities are removed from my range
ROM too important for success of the surgery and should be addressed.
Range of motion should be measured separately from physical functioning because a person might use gadgets, aids and adaptations to carry out their activities of daily living. For example, using a long-handled hair brush enables them to brush their hair without full shoulder movement. If the question was, 'are you able to brush your hair' then the improvement or lack of improvement in range of motion / movement may not be captured. I am not sure if muscle strength needs to be included in the core set though.
I think that it is important to monitor these two aspects of physical functioning as they are related but distinct.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
Depends on what you want to do with the result?
Need correct/same measurement to use
depends on the nature of the interventions. In some situations it is correction of specific pathology - ie, stabilizing the shoulder joint. so strength of ER might be very important. Function could be achieved by adaptive techniques and aids. That is great, but might weaken ability of physical function to capture the concept of range. The same instrument might be excluded in next phase of measurement properties (poor interrater reliability of ROM and strength testing), but at a concept level I am not sure I would want to exclude it. I can see groups not including it, ie, in my survey work. so perhaps we could have it as optional depending on focus of the study.
From patients:
None.

Question 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. Do you agree that **all of the following domains** should be **excluded** from the core domain set for all clinical trials of shoulder conditions? (Definitions of each of the following are provided on page 8-9 of Round 1 Results attached to the invitation email) **- 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** **- 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**
Comments provided for "yes" are as below:
From Clinicians/scientists:
did we get sent the feedback report?
some of these will be important for different trials, but I agree they should not be core ie. for ALL trials
Happy for these not to be assessed in all trials.
From patients:
None.
Comments provided for "no" are as below:
From Clinicians/scientists:
I think that rate of reoperations should be included
i think shoulder posture, proprioception and scapular dysfunction are essential for the overall functioning of the shoulder in almost all pathologies, so i would include them somehow in the core domain
Failure of surgery would be important, as would Satisfaction of treatment,
Satisfaction with treatment services important. Mandated by FDA for surgical interventions in many countries
Re-operation can be considered
revision should be included
From patients:

Satisfaction with treatment services should always be included preferable with an open-ended question and a scale.
Retain items 3,4,5,7,11,12,17,18
Shoulder instability / laxity and scapular disfunction can have a major impact on the shoulder injury and should, in my opinion, be included.
I definitely would want to know the percentages of "failures of surgeries" and "re operation and revision surgeries". Why did you group all of these areas into one question?
There are some very relative questions that should NOT be excluded.
Comments provided for "Unsure/I do not know" are as below:
From Clinicians/scientists:
I think failure of surgery and require resurgent/surgery
It depends on the intervention and duration of study Many of these would be primary outcomes of certain types of studies
From patients:
Too many issues to consider a yes or no response
radiographic outcomes should be included, this might be not realistic in CTs but is important in clinical practice
Some of the above more important and should be addressed.
Require re-operation or revision surgery' and 'Failure of surgery' should be captured somewhere but not necessarily as part of a core set of outcomes.

Question 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?
From Clinicians/scientists:
no
good work, congratulations
I think the important ones have been covered as they impact the most on people. I am not sure about number of deaths.
Good luck!
I really miss discussion on that issues and I miss clearity in Domain concepts. It is not only the definition as you provided but also what intensity of symptoms we expect (especially in psychological diagnosis- do we Need diagnosis here or should we assess just symptoms of distress, anger, fear, etc.). I am not convinced that this set is a reliable decision.
Thanks for this - hopefully useful
this will need to correlate (or at least not conflict)with the arthoplasty group outcomes if shoulder replacement is considered one of the trials relevant to shoulders (which I think it is)
No, just what was in the comment boxes above.
From patients:
No
Much easier this time!
na
no
no
no
No
No
no
Thank you asking me to participate.
No
I am pleased to be participating in the development of this study. I believe it to be a positive step forward in patient inclusion
I FIND THIS FORMAT DOES NOT HAVE ENOUGH FLEXIBILITY TO ALLOW ONE TO LOOK BACK AT EARLIER INFORMATION MUCH TO M Y CONCERN.
A lot of thought put into the survey.
No
I think that you are focusing in on a good core set. It might be worthwhile to articulate one or more secondary sets of questions that could be use din clinical trials depending on the nature of the trail. E.g., for trials involving surgery, some or all of the surgery -related questions could be grouped into a secondary set.
not at this time