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**Delphi process for Core Domain Set for Tendinopathy: Survey data.****Context:**

1. Synthesising research findings from clinical trials of human tendinopathy is currently difficult for a number of reasons, one of them being a lack of agreed upon core set of outcome measures (that are valid, responsive and feasible).
2. A critical and primary consideration of an outcome measure is that it targets/measures a health domain of the condition (tendinopathy in this case).
3. There are currently no core health domains for tendinopathy that are agreed upon.
4. Once there is an agreed Core Domain Set for Tendinopathy, then the task of agreeing to the outcome measures for each specific tendinopathy can commence.

**Methods:**

The development of the Core Domain Set is being developed as per the following process:

1. Literature review of domains and instruments previously used in tendinopathy (note that the instruments/measures used were only included in the survey to help put in context the domain. The survey was not about the measures, but rather the domains)
2. Structured enquiry with stakeholders on their views on domains of importance – survey and then meeting
3. Full participation of all stakeholders (including patients) in a consensus process to determine agreement on what should be – the Core Domain Set

**Results:**

The results of the expert survey are shown herein in Table 1 and 2. Table 1 shows the characteristics of the experts responding to the survey. Table 2 reports the % agreement, disagreement and unsure, the comments aligned to these responder levels, followed by a brief overview made by the committee and a proposal for the meeting.

In summary, there are two domains that are above the 70% agreement threshold:

- Pain on Activity or Loading (a rating of pain when the patient is doing an activity or under load)
- Disability (this is a patient rating of the disability, or ability depending on anchors and wording/orientation, on a multi-item questionnaire)

There was one domain that was above the 70% disagreement threshold:

- Range of Motion

There were a number of domains in the 50-70% agreement range, which will need consideration, and they are:

Agreement: Function, Patient rating of status, QoL, Physical Function, Sports Participation, Medication use\*, Physical Activity\*.

Disagreement: pain on clinical stress test, sensory modality specificity, pain without specific context.

*\*note that medication use and physical activity were 79% and 86% agreement, respective, in the minimal reporting standards, which will need to be reconciled at the meeting. The issue that comes into consideration is that minimal reporting standards will require valid and feasible measures, which are in common with the outcome measures for the domains. This ought be discussed.*

In addition, a cohort of patients in Australia were also surveyed on the Domains questionnaire. A summary of the patient responses to the survey is included in Table 3 (pages 33- & 34).

**Table 1: Participant characteristics of the health professionals completing the survey. 28 of the 30 contacted responded (93% response rate)**

Characteristic	N (%)
Sex Male (%)	18 (64%)
Role:	
Clinician only	0
Researcher/Scientist only	5 (18%)
Clinician and Researcher	23 (82%)
Cases per month:	
0 (I am a clinician/scientist)	5 (18%)
At least 4	1 (4%)
Between 5 and 10	2 (7%)
Between 11 and 15	7 (25%)
More than 16	13 (46%)
Years managing tendon problem:	/27
At least 4	0
Between 5 and 10	2 (4%)
Between 11 and 15	6 (22%)
More than 16	19 (70%)
Highest academic qualification (/26):	
Master	1 (4%)
PhD	23 (88%)
Clinical Doctorate	2 (8%)
Health care profession (some cited more than one~):	
Physiotherapy	13
Sports physician	5
Orthopaedic surgery~	4
Rheumatology~	3
Sport and Exercise Medicine~	3
Radiology	1
Human movement scientist~	1
Epidemiology~	1
Surgery	1
Currently have tendon problem:	8 (29%)
Past history of tendon problem:	19 (68%)
Country (where work):	
Australia	8 (29%)
United Kingdom	5 (18%)
Netherlands	5 (18%)
Canada	2 (7%)
USA	2 (7%)
Denmark	2 (7%)
Qatar	1 (4%)
Sweden	1 (4%)
Hong Kong	1 (4%)
Norway	1 (4%)

Core Domain Set for Tendinopathy: Survey Data

**Table 2: Survey data.**

<p>Order of agree or disagree: 1. Percent Agree / Disagree / Unsure: 93% / 0% / 7%</p> <p><b>Domain as on survey: Pain on Activity or Loading</b></p> <p><i>The domain as listed on the survey and EXAMPLE measures for context: The domain as listed on the survey: This domain was reported on 60 occasions in 45 papers (37%), as some authors used multiple loading tests (e.g.; often the hop, jump and squat). *The types of outcome measures used by authors for this domain were usually a 10cm line (Visual Analogue Scale) and a 11 point Numerical Rating Scales (0 to 10) by which the participant (patients or controls) reported the level of pain on certain tasks that are known to aggravate tendons. Some example of tasks are hopping, jumping, squatting, gripping, lifting.</i></p> <p>Committee's comments: Strongly support with no disagreement.</p> <p>Comments of Agree responders:</p> <ol style="list-style-type: none"> <li>1. A critical part of assessment</li> <li>2. Certainly a mainstay in lower limb and elbow tendinopathy. Less sure of the universality in shoulder tendinopathy beyond activities of daily living.</li> <li>3. Differences between upper and lower limb may cause problems</li> <li>4. I agree that pain on activity and loading should be included as one of the core domain set for tendinopathy. However, the intensity of activity and loading might differ in subjects with different level of participation. To standardize the magnitude of habitual loading is essential but difficult. e.g. the training intensity / competition time needed to be recorded and included as co-variate. To standardize the intensity of loading during certain provocative test may be possible. In this connection, single-legged declined test is being used as a provocative test for individual with patellar tendinopathy. The intensity of pain is quantify when subject performs single-legged squatt to a pre-set angle. Nevertheless, not all subject would have pain being produced at the pre-set angle. Hence, I agree that pain on activity/pain under pre-defined loading should be included as one of the core domain set.</li> <li>5. I think it is important, as I frequently use it as measure for progression in the clinical setting. However, it might be more important whether a patient thinks this is relevant.</li> <li>6. In general I agree - for tendons such as achilles and patellar tendinopathy and also tennis elbow (grip), tests for pain on activity or loading is already fairly well defined and very useful. For other tendons, such tests may need further development and standardisation to be able to recommend. The severity of the condition will also influence ability to reproduce pain during a functional test in clinic - sometimes the pain is cumulative and only reproducible after a long run or a hill running session (e.g. for proximal hamstring tendinopathy), but as we use multiple domains in examination, this one is useful as a severity guide.</li> <li>7. Pain is what patients present to us with! One has to be very careful with pain in trials - because tendon pain is relapsing and remitting to a degree (i.e. if you train more there is more pain and if you rest there is less). Also pain can stay static whilst function improves (or disability recedes) although there is an improvement.</li> <li>8. Seems more sensitive to change and patient understands the domain</li> <li>9. Tendinopathy usually and mostly presents as a pain related to loading musculoskeletal condition, so this is an important domain. It relates directly to what might be viewed as the current clinical 'diagnosis' of tendinopathy (ie, tendon localised pain related to/associated with loading)</li> <li>10. The clinical definition of tendinopathy should include pain, local changes, and decreased levels of ability (i.e. disability) induced by the condition</li> <li>11. This type of injury is related to loading and many have no pain at rest.</li> <li>12. Very important info. Pain during a soecific type of loading-like pain during walki g, running and jumping.</li> <li>13. Very important measure - and the main reason that patients see sports physicians</li> <li>14. VERY important. This is a core complaint of patients.</li> <li>15. Yes - once the loading tests are appropriate loading tests as deemed at a later date following further work.</li> </ol> <p>Comments of Disagree responders: none</p> <p>Comments of Unsure responders:</p> <ol style="list-style-type: none"> <li>16. Not sure of this is relevant for ALL subjects with tendinopathy or only for patients with specific activities such as athletes.</li> </ol>
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## Core Domain Set for Tendinopathy: Survey Data

Order of agree or disagree: 2.

Percent Agree / Disagree / Unsure: 86% / 7% / 7%

**Domain as on survey: Disability**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 75 papers (/122; 62%). \*The types of outcome measures that are used by authors for this domain are: (a) all patient rated (completed by the patient); (b) ask a series of questions about how the tendon problem affects a range of activities (e.g., day to day activities, sport, recreation) to score disability (or the limits to function/doing things); and (c) give one number to represent the patient's problem. Some of the measures that are used are VISA-A,-P,-G; Disability of the Arm, Shoulder and Hand (DASH and quickDASH); Patient Rated Tennis Elbow Evaluation (PRTEE); Foot and Ankle Outcome Score (FAOS); Western Ontario and McMaster University OA Index (WOMAC); Roles Maudsley Score.*

Committee's comments:

Strong support for the concept of disability, with some comments surrounding aspects of terminology (ability, function, disability) and issues of measurement (specific to a tendon, or sport etc, validity?)

Comments of Agree responders:

1. Disability - in terms of whether or not you are able to complete your sport / activity is probably second only to pain in importance
2. Disability being a composite measure that associates the level of ability/function of the individual with their condition (pain state).
3. disability is a key factor in the condition
4. Disability is defined as: a physical or mental condition that limits a person's movements, senses, or activities. our shoulder research <https://bjsm.bmj.com/content/52/4/269> <https://www.ncbi.nlm.nih.gov/pubmed/28106306> has identified that bio and psychosocial factors are important to measure
5. Disability is one of the most important indicators of the impact of tendinopathy on a variety of activities.
6. I don't think that tendinopathy is disabling - rather, annoying and functionally difficult. However, I recognize that outcomes measurements use this term and its definition is somewhat fluid.
7. It is how the injury affects the patient that is the core of patient centered treatments.
8. It would be good to have consistent measures used in the future as well as develop more if there is a gap
9. Limitation of function is one of the primary reasons a person with tendon related issues presents to a health professional for assistance.
10. Main reason for presentation in most cases.
11. PROMS important. The outcome measures listed are valuable (declared interest, I was part of VISA-P and VISA-A teams)
12. Tendinopathy is clinically relevant, and does cause disability
13. Tendon, is the key component of the muscle-tendon-bone unit, and is the controller of the local motion system. Tendinopathy is a disease that causes great impact on individual's ability. This disease is not associated with life-or-death but essentially is a disease that link to individual's ability on motion.
14. Vital information along with pain on specified circumstances

Comments of Disagree responders:

15. I rather focus on exactly what type of exercise/loading the patient cannot tolerate.
16. Relevant as a domain but not sensitive nor reliable to measure. Patients struggle with rating it, and tools are often not sensitive to many patients symptoms nor change

Comments of Unsure responders:

none

Order of agree or disagree: 3.

Percent Agree / Disagree / Unsure: 11% / 75% / 14%

**Domain as on survey: Range of Motion**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 19 papers (16%).*

*\*This was usually measured with a special instrument (goniometer, inclinometer, or dynamometer), but also visually in a few reports. Note that this is a sole domain here. In another domain ('clinical examination findings') it is included in a combined score.*

Committee's comments:

Comments and responses are consistent with ROM not being core

Comments of Agree responders:

1. as above
2. Based primarily on an elite athlete population, where objective measures of function are important outcomes of treatment.
3. tendinopathy, in and of itself, does not BLOCK range of motion, but pain related decreases occur.

Comments of Disagree responders:

4. Again, usually poor correlation with outcome and function.
5. Generally not, yet there may be a case in the shoulder.
6. I see ROM as I see strength + imaging - its a nice to have - but not a must have domain. For the same reasons - I think you can have a well set up and useful study without ROM measures.
7. Limits to range of motion are not a common feature to all tendon complaints - I feel response to loading is more tendon specific and hence feel that range of motion should not be included in a core domain set
8. Often low inter observer reliability, tells me nothing about impact or consequences of the disability for a specific person.
9. often not relevant
10. Patients do not complain about their restricted (or increased) ROM.
11. Please see qualification to question 11.
12. Related to pain and swelling of paratenon.
13. ROM has not been consistently related to tendinopathy injury.
14. ROM not relevant in most tendons, although decreased DF associated with tendon pain
15. Too many other variables

Comments of Unsure responders:

16. Also, it depends on the aim of the paper. It may not be required under the inclusion /exclusion criteria. It can be used as an outcomes in certain tendinopathic tendon. However, which joint range to be included is sport-specific aside from tendon specific . E.g, knee flexion / extension and ankle dorsiflexion range might be important for volleyball players with patellar tendinopathy. However, badminton requires good range of hip range (IR/ER) for appropriate alignment of the knee during forward /backward lunging.
17. Hardly ever an issue for people in the lower limb, but may be in the shoulder. Depends on the scope of this.
18. see above.

Order of agree or disagree: 4.

Percent Agree / Disagree / Unsure: 68% / 11% / 21%

**Domain as on survey: Function**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 8 papers (7 %). \*This domain is specifically about the participant rating their level of function in one score (e.g., Patient Specific Function Scale, wherein 100% is full function and 0% is unable to use the limb such as in a sling for the arm and not weight bearing on a leg). It does not ask about the pain, just about the function.*

Committee's comments:

Nine (/14) comments from the agree responders (approx 70% agreement here, third highest agreed to domain) for Function, with many of the comments for disagree and unsure (and some in the agree) indicating the focus was more on tendon related pain, which as some point out is covered in disability. This domain is just function - that is, what is the level of functioning (disregarding pain) as in how much can they do.

Comments of Agree responders:

1. Full return to function is generally a main goal both for treating MD/PT and patient.
2. If it is well specified it adds value for sure- especially in athletes
3. If related to certs in tendon
4. Key reason patients present.
5. Overlaps with disability. One or the other.
6. Part of the triad as described in Arthroscopy. 1998 Nov-Dec;14(8):840-3. Overuse tendon conditions: time to change a confusing terminology. Maffulli N1, Khan KM, Puddu G.
7. tailored to each tendon
8. The level of function an individual is able to attain is a part of the ICF framework and should be captured for a load related condition like tendinopathy.
9. Yes because we aim to rehabilitate function

Comments of Disagree responders:

10. I consider the domain 'disability' to provide synergistic information.
11. I think this is only relevant when the pain is taken into account (like in all VISA scores for example). Someone can have a perfect function with a lot of pain, so as isolated measure it is less valuable.

Comments of Unsure responders:

12. Markedly less specific than the more tendon-related instruments that have been developed over the last 2 decades or so.
13. The PSFS can be useful for tracking change in a specific function for one individual, but there are difficulties as patients often find it very difficult to separate pain and function as most often the reason for their inability to perform a task is the pain. Also, it is important to question regarding the same particular function/s over time, as given a blank PSFS to rate at different time points, patients will often fill in different tasks, resulting in difficulties with comparability.
14. tricky. Good questions. Will rule out many studies. Is a one number score valid?

Order of agree or disagree: 5.

Percent Agree / Disagree / Unsure: 61% / 14% / 25%

**Domain as on survey: Patient perception of condition status**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 37 papers (30 %).*

*\*Two examples of the types of outcome measures reported by authors were: global rating of change (e.g., are you better, same or worse than immediately before treatment), and patient perception of status of condition (e.g., is your current condition satisfactory, when you take your general functioning and current pain into consideration).*

Committee's comments:

This has the 4th highest agreement, 7th highest of unsure and among the lowest of the disagree (20th /24). There were many comments (11) by those who agreed to the effect that this measure reflected the patient's overall perception of their condition, as opposed to 2 comments by those who did not agree who indicated the measure is too subjective or the term is difficult to understand, while the 4 comments from the unsure responses that tended to mirror the disagree comments. The domain could be reworded to 'patient overall assessment of condition' as this might accommodate comments herein - as it more clearly describes the overall rating by the patient of their condition and leaves silent at this conceptual level if this is a change over time or a global rating of the condition (considering we are working towards a parsimonious core domain set).

Comments of Agree responders:

1. A single numerical/categorical assessment of the patient's status (with their tendinopathy) provides an overall assessment from their perspective. They will inherently apportion different aspects of their condition a value in coming to a single assessment number or category. In our patient consultation meetings (focus groups) where we discuss outcome measures - patients favour the GROC - ie how are you now compared to before treatment (eg, better, same, worse - across several categories).
2. A subject may show changes at imaging, and not manifest any symptoms. In these days of patients based outcomes, the perception of the patient is of capital importance
3. Also usefull for resposiveness studies
4. as above
5. as long as it is not used in isolation
6. Embraces patient response to all domains of management...
7. I think a GROC is useful - i can be used to compare accross many diseases and conditions throughout the whole of medicine and is easy in interpret for both clinicians and patients. It is however an item that only really has use at follow up moments and not during a baseline measure
8. Patient efficacy or recovery expectations is an important consideration.
9. Strongly agree - these are often the sort of questions that patients seem to find easiest to relate to.
10. This is a definite for me. Although we may think we know what is important to patients ie disability, pain, etc, we cannot know this for all patients. This measure therefore in my opinion is patient centered and important.
11. This is essential

Comments of Disagree responders:

12. I don't understand the term, honestly. How the patient perceives their condition? Thinking on this further, I am assuming this is coming from some of the work stating that patients who have a tendency to catastrophize are those who present for care. I still don't think this should be included.
13. patient perception is too subjective. There are unknown elements that might influence the outcome / changes in this outcome. the unknown element include personality, mood etc

Comments of Unsure responders:

14. Depends. The first example is very different than the second. Rating of change on a likert scale / similar is seemingly more reliable and than others. The second sample is more difficult for patients to answer
15. I believe that the (perceived) rating of change is important when assessing therapy. Not sure whether the perceived status of condition is of added value to other scores. It may be important to check whether there is an overlap of this question with other questions e.g. on coping strategies.
16. I'm not convinced of this because it is not particularly objective
17. Maybe not important. More important to know if remaining pain after treatment during walking, running or jumping.

**Core Domain Set for Tendinopathy: Survey Data**

Order of agree or disagree: 6.

Percent Agree / Disagree / Unsure: 57% / 11% / 32%

**Domain as on survey: Quality of Life**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported by 21 authors (17%).*

*\*The types of outcome measures reported: EQ-5D, AQoL, SF-36, international Hip Outcome Tool (iHOT-33), SF-36, Western Ontario Rotator Cuff Index (WORC), Foot & Ankle Outcome Score (FAOS).*

Committee's comments:

Approx 60% agree and 30% unsure having comments that essentially agree with QoL, but many stipulating the need for specificity of measures for the tendinopathy population. 5th and 4th highest proportion of agreement and unsure as opposed to 21/24 for disagree, tends to support this domain as core.

Comments of Agree responders:

1. Absolutely important.
2. Although not commonly utilised, it does generally reflect a patient's status against their normal level of function. Some instruments above are less specific to tendon-related limitations to function or performance.
3. as above
4. Comparison to other disabilities possible
5. especially for demonstrating the impact of tp on ADL/QOL important to get tp 'on the agenda'
6. How the injury is affecting the individual is of importance since patients have different goals, activity requirements and expectations.
7. In most cases not very specific and hard to complete for this patient group, but important for funding
8. QoL is an important outcome measure for evaluation (cost-effectiveness) research when appropriate outcome measures are used. In addition to the general QoL questionnaires it is necessary to have a more specific anatomy/lesion based score. I am too unfamiliar with the WORC, IHOT-33, and FAOS to judge these.
9. Really important and has not been done well in the past
10. ultimately it is the value a person places on their quality of life that determines the impact of the condition
11. Yes - but need to create more specific tendon specific quality of life measures?
12. Yes, it might be of importance to show how some tendon conditions affects daily life.

Comments of Disagree responders:

13. Not in the core.
14. Too subjective and difficult to assess

Comments of Unsure responders:

15. Depends on the patient population. My responses are mainly based on the population I work with, (elite) athletes. For athletes, I do not think the general QoL instruments are appropriate (and therefore athletes find them irrelevant and cumbersome).
16. depends on the tendon, reduction of activity in an Achilles may result in an OK QoL, same not true in glut tendon
17. Depends on which tendon. Overall not sensitive in many patients
18. QoL is an important domain but is perhaps reflected in other domains such as function and questions such as the GROC. I would be happy to include if the majority decides to include.
19. Quality of life may be affected
20. Yes in places - I like the EQ5D because it is a quick easy to measure assessment. SF36 becomes more difficult but possible; as do some of the others mentioned.

Order of agree or disagree: 7.

Percent Agree / Disagree / Unsure: 18% / 61% / 21%

**Domain as on survey: Pain elicited with clinician applied stress test**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 9 papers (7 %).*

*\*Clinicians applied a special stress or orthopaedic test and the participant (patient or control) report the intensity of pain they feel on a 10cm line or 11 point scale. This is not the participant doing the test as would be the case when they hop or jump or squat in the domain item 'pain on activity or loading' above.*

Committee's comments:

With 60% disagree and 20% unsure, there does not appear to be sufficient substance for this in a core domain set.

Comments of Agree responders:

1. Obvious.
2. This is how I measure physical exam signs

Comments of Disagree responders:

3. I dont see this being "universal" enough to go in core set - which special test would i do for patella/achilles for example.
4. No. Perhaps only relevant if the 'stress' could be quantified.
5. Not an important outcome for patients.
6. not reliable
7. Please see question 13.
8. unlikely to load the tendon enough
9. Unreliable and tendon specific

Comments of Unsure responders:

10. Is part of clinical examination
11. Not sure how this differs from pain on palpation.
12. This might provide a reasonably objective measure of elicited pain for comparison between individuals ?
13. Yes - But not sure we have the appropriate knowledge or consensus on what the best "stress" tests are for the relevant tendons

Order of agree or disagree: 8.

Percent Agree / Disagree / Unsure: 11% / 54% / 36%

**Domain as on survey: Sensory-modality specific pain**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 8 papers (7%). \*The amount of a stimulus (such as pressure, heat, cold) that elicits pain is measured with an instrument (an algometer) for this domain. So it is not the level of pain that is the focus but how much stimulus elicits the pain, and the stimulus is a sensory one.*

Committee's comments:

Comments of the unsure align strongly with the disagree response and do not support sensory modality specific pain as a core domain.

Comments of Agree responders:

1. Any way to quantify pain is welcome. It should be noted, however, that pain on palpation may not correspond to pain on use of the limb
2. Optional depending on equipment available and expertise

Comments of Disagree responders:

3. As per imaging/rom/strength/cost analysis - great if you can do but not "core"
4. Difficult to adequately evaluate
5. Interesting explorative measure, but not a C-TOM.
6. May be useful for research studies, but not a core domain that would be widely clinically applicable.
7. More a research/mechanisms application for me.
8. Not critical and not reported enough.
9. Too variable

Comments of Unsure responders:

10. Although I think this is a very important metric - I am not sure we are at the point where we know enough about Quantitative sensory testing in tendon complaints to make it a core domain set
11. how valid are these measurements and what do they ad?
12. important in studies directed at this, but for clinical studies no, will be done badly unless good equipment and this is too expensive for many researchers
13. Maybe not a core domain, but very useful in further investigation into the greater challenge of pain generation and modulation.

Order of agree or disagree: 9.

Percent Agree / Disagree / Unsure: 57% / 21% / 21%

**Domain as on survey: Physical function**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 6 papers (5 %). \*The types of measures used for this domain were: distance jumped, height hopped, number of single heel raises. That is, how much of a task the participant (patient or control) was willing to perform.*

Committee's comments:

The physical function domain aligns reasonably well with the loading tests in the baseline reporting recommendation survey (61% agree there). Some of the comments in here need to be explored at the meeting to ensure that there is a difference between 'function' and 'disability' domains, as well as physical activity possibly. Otherwise there appears to be support for this as a stand alone core domain.

Comments of Agree responders:

1. as a load related condition, tendinopathy ought be described in terms of the physical function of the individual
2. As above, overlaps with function, disability. My preference from all of these would be physical function.
3. definitely key.
4. Especially for physically active individuals the return of function (to at least reaching the uninjured side) is of importance for full recovery.
5. for studies in the more active definitely and again more specific for some tendons, such as walking distance for glut med
6. This can be measured alongside the pain measurements during these tasks so does not take additional time.
7. Yes Please refer to Arthroscopy. 1998 Nov-Dec;14(8):840-3. Overuse tendon conditions: time to change a confusing terminology. Maffulli N1, Khan KM, Puddu G.
8. Yes but not in addition to Q18

Comments of Disagree responders:

9. combine with above?
10. Interesting explorative outcome measure, but it is very depended on patient's motivation. As a sports physician, I am not using it in the clinical setting. So for me, this is not a C-TOM.
11. Is that proven to be reliable and repeatable and sensitive? I doubt it.
12. While such measures are useful for assessing impairments within an individual which might provide some treatment direction in clinical practice for that individual, correlation with outcomes esp imposing a single measure across a group of individuals as an indicator of outcomes is likely to be poor.

Comments of Unsure responders:

13. Could be very useful but how to define which tests to do accross the age ranges and ability ranges u see in practice. In Achilles I may have 65 yr old grandma who cant hop once - but never needs to - or 20 year old runner who can nail 5 hops but cant run 21 km at burning pace - so passes the test but is still restricted. So as a principle - would be great - but may be challenging in practice
14. Perhaps not a core domain as the application would be cohort-specific. In Achilles tendinopathy for example, normalisation of height or distance hop could be an important global parameter in a high functioning group, yet it must be acknowledged this could not be applied universally.

Order of agree or disagree: 10.

Percent Agree / Disagree / Unsure: 25% / 57% / 18%

**Domain as on survey: Pain', without any further specification**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 36 papers (30 %).*

*\*The unique feature of this domain (Pain) is that the authors only state they reported pain of the participants. That is, they did not specify if it was under loading (e.g., activity, hop or walk) or specific circumstances (e.g., first step) or in a particular time frame or at a specific time (e.g., morning). So this item in this survey is asking you to consider if pain should be further specified, as in some of the other items in this survey.*

Committee's comments:

Comments by agree responders look like they did not understand the domain and would likely disagree with this domain. The comments from the unsure responders also tend to mirror those from the disagree. The approx 60% disagreement places it h'as the 3rd highest disagreement proportion. Given comments here and response rates for other pain related items, pain needs to be specified in context (eg with loading).

Comments of Agree responders:

1. as above
2. I recommend pain being a domain on its own AND having specifications listed.
3. this is the reason patients present. It is a critical domain.

Comments of Disagree responders:

4. "Pain" provides limited information and cannot be regarded as a core domain set for tendinopathy. The intensity of pain under what "kind" of loading, what "intensity" of loading, and "time"
5. condition in which pain occurs should be specified
6. In a stimulus-response paradigm both elements should be reported for rigour and a deeper understanding. Perhaps pain at rest may be useful though in some of the upper limb tendinopathies where these affect daily function.
7. May depend on the patient population. My responses are mainly based on the population I work with, (elite) athletes. For these, it is important to use instruments that clearly separate rest/night pain with pain during and after activity (activity-related pain). Otherwise, an athlete who cannot train may report no pain, because he is not training...
8. Needs more details
9. Needs some form of clarification
10. Needs to be clear under what circumstance
11. Needs to be specified
12. not specific enough, source of poor diagnosis
13. Pain if described should be specified
14. Pain is the main reason why patients consult, yet if reported without context is has no value as you cant interpret/understand it
15. Pain should be qualified
16. Pain should be rated in a specific context.
17. Seems to vague to be valuable. Rest pain NOT a feature of most tendinopathy as u know
18. When pain is asked, it should be specified under which conditions the pain is occurring, otherwise this may be misleading.
19. Without specification it is useless imo

Comments of Unsure responders:

20. I am unsure how to answer due to the explanation. Yes I think pain questions need further explanation such as at rest, morning pain etc. But still not sure if I should answer this question yes or no.
21. Pain important only if located in a soecific tendon and related to a certain type of loading of that tendon.
22. Pain severity without further specification appears to be less useful than specified pain. Sometimes where this can be difficult however is if the most painful task or situation changes over time. So, worst pain can sometimes be useful to capture this. Pain constancy/frequency can also be a useful measure of pain - % of time over the last week a patient has experienced pain.
23. Would need to be further defined.

Order of agree or disagree: 11.

Percent Agree / Disagree / Unsure: 57% / 29% / 14%

**Domain as on survey: Sport participation**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 3 papers (2.5 %).*

*\*The sorts of measures used here were: the time to return to sport, the level of sport achieved, and a range of different scales of participation in sport (e.g., social or elite level).*

Committee's comments:

Most comments from the agree responders - but these seem to reflect the others in that it might be too restrictive for tendinopathy generally. Given the responses to the aggregate/remove items on the survey, it would seem reasonable that we discuss where this fits (eg, as part of another domain - like participation?).

Comments of Agree responders:

1. A load related condition ought to encompass participation, including sport.
2. activity rather than sport, return to their level of activity critical
3. And not just participation level, but performance related to normal performance level.
4. And not only sport participation/RTS yes or no but also the participation level (eg OSTRC questionnaire)
5. Applies to a subset. Again, will depend on tendon and scope.
6. Important for patients and something we always ask as healthcare providers during follow-up. My impression is that this type of outcome measure description in literature is very heterogeneous. Could we provide a standard for tendinopathy on this subject?
7. it may be an optional question for those actively participate in sport
8. Of importance in athletes It should be recognised, though, that many sedentary individuals suffer from tendinopathy
9. Part of VISA of course - in sports medicine I think it is :)
10. This can really vary depending on type and site of tendinopathy. Meaning is the injury mainly a sport/physical activity related injury then very important. Is the injury more work related than less important.
11. Yes - but needs to be defined - Bern consensus on RTS in BJSM would seem good place to start. Just as "pain" is useless domain without specifics - RTS does not help without context and specifics,

Comments of Disagree responders:

12. For some tendon problems, this is very important but not so useful for others that are more prevalent in older people less engaged in formal sport. If the aim is to achieve a core set applicable across all tendons, then no.
13. Most patients presenting are past the age of active sports.
14. Not everyone participates in sport
15. Unreliable

Comments of Unsure responders:

16. Again best considered a supplementary domain, as tendinopathy is not restricted to sportspeople.
17. Although this is perhaps the most significant activity for a large proportion of tendinopathy patients, this seems to overlap with previous questions on activity and disability ?

Order of agree or disagree: 12.

Percent Agree / Disagree / Unsure: 57% / 29% / 14%

**Domain as on survey: Medication use**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 3 papers (2.5 %).*

Committee's comments:

Rated at almost 60%, medication use is the 5th highest ranked on agreement of all domains. The minimal reporting of baseline features has returned a 79% agreement that this should be reported. This when considered alongside the comments, all of which are by the agree responders, it would seem that this domain is core.

Comments of Agree responders:

1. Corticosteroids and fluoroquinolones do influence the onset and course of tendinopathy
2. depends if it includes those that are used for the tendon, thinking here of the polypill etc also may give indication of systemic conditions such as diabetes that affect tendon
3. I think 'medication use' needs to be specified eg tendon injection or oral anti-inflammatory medication.
4. I think all co-medication should be reported, as it is considered an important measure that can influence primary outcome.
5. influences other measures
6. May need further consensus/agreement on what exactly we mean by medication use (i.e. What medications are relevant in tendinopathy specifically?)
7. The usage of co-interventions is always important to record.
8. this can be an extra information. But not sure whether it is commonly used or seldom use due to the chronicity nature of the disease
9. This is critical as it is a function of medicalisation of what is essentially a health related issue - ie loading associated pain state
10. Would be important to know.
11. Yes - easy to do

Comments of Disagree responders:

12. Does not link to severity

Comments of Unsure responders:

no comments

Order of agree or disagree: 13.

Percent Agree / Disagree / Unsure: 25% / 50% / 25%

**Domain as on survey: Participation**

*The domain as listed on the survey and EXAMPLE measures for context: (This domain was reported in 1 paper, but it had 4 scales (3% of all scales). \*This was measured by asking participants (patients and controls) what their level of activity was with family and at home, recreation, running or other physical activity, and social activities, using a 10cm line (0cm = no limitation, 100cm = complete limitation).*

**Committee's comments:**

Comments indicating some uncertainty about this domain generally and overall, suggesting it should be discussed in the meeting. It would seem that such a discussion would encompass the domains of participation, physical activity, sport and work related participation as separate domains.

**Comments of Agree responders:**

1. A load related condition ought to encompass participation

**Comments of Disagree responders:**

2. as above
3. Cant see how this is different from Physical activity - how physically active are you can be used for athletes and non athletes alike?
4. combined with quality of life of function scales?
5. Difficult to validate
6. I thinks it is hard to translate this outcome measure to patients.
7. needs more quantified information
8. will not add much

**Comments of Unsure responders:**

9. Overlaps greatly with other queries.
10. Participation in what? This needs to be better qualified
11. Would need to be specified and context related to add meaning

Order of agree or disagree: 14.

Percent Agree / Disagree / Unsure: 54% / 32% / 14%

**Domain as on survey: Physical activity**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in at least 5 papers (4%). \*This is about the participant (patient or control) rating overall physical activity regardless of pain or the tendinopathy.*

Committee's comments:

Physical activity is strongly supported as a baseline feature to be reported in that survey. Comments here are mainly about it being captured in other domains - we will need to look at the questions that deal with aggregation and deletion to try to come to some agreement regarding core domain for physical activity.

Comments of Agree responders:

1. A load related condition ought to encompass physical activity capacity
2. in view of the relationship between tendinopathy and intensity of exercise/activitiy
3. part of the overall perspective of the person's activity level
4. Physical activity is key but could be inferred from other domains
5. Please refer to question about sport
6. The ramifications of not being able to be physically active are serious for maintaining health.
7. work, sports, adl, hobby

Comments of Disagree responders:

8. could be captured in function
9. Doesn't change treatment or eval.
10. I think would need to be specified - as RTS above
11. If this is different from sports activity, I would say no.
12. There are so many factors that can influence general physical activity, so unlikely to be useful as a core domain.

Comments of Unsure responders:

13. Less stringent reporting element than the tendon-specific tools.

Order of agree or disagree: 15.

Percent Agree / Disagree / Unsure: 50% / 29% / 21%

**Domain as on survey: Adverse effects/events**

*The domain as listed on the survey and EXAMPLE measures for context: his domain was reported in 9 papers (7 %).*

*\*Adverse effects/events are any event that occurs to the participant (patient or control) while in the study (or being followed clinically). They need not be related to a treatment for the tendinopathy or to the study in particular, but just any event that is adverse to the health of the individual.*

Committee's comments:

The comments from the unsure responders align with supporting adverse events as a core domain, but with further qualification, possibly in the measurement of the domain. Very few comments of any substance in the disagree responders lends support to this observation.

Comments of Agree responders:

1. Been done poorly in the past but very important to have!
2. I would like documentation or adverse events pertaining to drop outs or details on exacerbation of symptoms etc
3. important for all studies
4. Important to look for possible issues with treatment
5. The associated adverse health issues, whether related to the tendon issue or not, should be part of the overall health domain set of any musculoskeletal condition.
6. This is underreported, but very important when informing patients.
7. We need to know what adverse effects a given treatment may induce

Comments of Disagree responders:

8. Not important.
9. Not sure how this is relevant
10. provocative activity / tests are more appropriate to rule -in

Comments of Unsure responders:

11. I think it is a useful item especially in treatment trials, but I believe the nature of the adverse event needs to be specified in more detail.
12. May be event specific. If this extended to say utilisation of coach-rated performance in a professional sportsperson this would be quite useful, although may be not a core domain.
13. not in all studies I think only in intervention studies

Order of agree or disagree: 16.

Percent Agree / Disagree / Unsure: 46% / 29% / 25%

**Domain as on survey: Work participation**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 2 papers (2 %). \*This domain relates to things like how long to return to work, the level of work (how strenuous for the particular tendon).*

Committee's comments:

Comments aligning with the other participation responses.

Comments of Agree responders:

1. A load related condition ought to encompass participation, definitely work (which might be sport in professional sport)
2. But depends on the patient population. In sports, work equals return to sport.
3. for some tendons more than others, upper limb especially
4. Important as part of disability that tendinopathy induces
5. Important for funding. And not only this dichotomous outcome, but also limitations during work and days absent from work.
6. Important to determine the impact on work performance and vice versa, work load on tendon problems
7. Same answer as above to sports. It depends on site and cause of injury. If work related then yes of great importance.
8. Yes - easy to do and not been done well in past

Comments of Disagree responders:

9. Most have to work anyway. Low reporting too.
10. Not normally recorded and so we know little about this

Comments of Unsure responders:

11. condition specific. because the influence would be differ in subjects with elbow verse ankle pain associated with tendinopathy
12. Deoendant on type of work and tendon.
13. Is this relevant for every patient - effects of tendon complaints on work practices may be a small subset for it to be included as a core domain. Enough on disability/function data captured already in previous statements?
14. Maybe supplementary, only useful in those who load the affected tendon in their work.

Order of agree or disagree: 17.

Percent Agree / Disagree / Unsure: 46% / 32% / 21%

**Domain as on survey: Discontinue treatment (drop out)**

*The domain as listed on the survey and EXAMPLE measures for context: This was not extracted from the reviewed reports and is included here for consideration.*

Committee's comments:

Approximately 50% agreement and comments indicate need clarity on reasons for dis-continuing treatment.

Comments of Agree responders:

1. I think this should be part of the evaluation. It is striking that this was not done in previous trials.
2. Obvious."
3. Part of any well conducted study
4. persistent pain states, like tendinopathy in many instances, is marked by a frustrating off and on, try many treatments, cyclical pattern - so treatment adherence or lack thereof is a function of the condition
5. Yes - can have big impact on interpreting results - again like GROG - this is really a follow up measure and could be specified as being such - rather than something done at baseline and again at f/u

Comments of Disagree responders:

6. Difficult to define easily
7. No, there are many reasons why people may discontinue treatment that have nothing to do with the effect of the intervention.

Comments of Unsure responders:

8. Maybe not core but a useful supplementary question which may empirically reflect a balance of treatment burden against efficacy. Reason for dropout would also need to be recorded as it may be influenced by non-treatment related issues.
9. not sure what this means, needs context
10. Only in intervention studies

Order of agree or disagree: 18.

Percent Agree / Disagree / Unsure: 43% / 29% / 29%

**Domain as on survey: Structure**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 36 papers (30 %), as 51 different measures or 42% of all domains extracted. \*The types of outcome measures reported were: MRI, US (grey scale, Doppler), and Xray.*

Committee's comments:

Structure was the 13th most agreed and disagreed domain with the 6th highest proportion of unsure. The latter reflects the uncertainty of the relationship between structural change and symptoms, as reflected in many comments. The number of comments was almost twice as many from the agree responders (11) than the disagree (7) and unsure (6) - many of these agree comments acknowledge the issues with measurement of structure and the presenting signs and symptoms of the patient with tendinopathy, but felt it an important health domain, sufficient to be a core domain. Those in the disagree countered by means of highlighting the disconnect between structure and clinical presentation. The comments from the unsure responders largely reflect the disagree comments. This will be a domain to discuss at the meeting - we need to consider the following: Agree that it is a core domain, but not have a valid (responsive, feasible) measure - this would be based on the tendon structure (changes in tendinopathy) are core to the condition of tendinopathy. On the other hand, if we disagree that it is a core health domain of tendinopathy, it does not matter if there exists a valid, responsive and feasible measure.

Comments of Agree responders:

1. as identified in our research and reviews eg <https://bmjopensem.bmj.com/content/3/1/e000279.info> <https://www.ncbi.nlm.nih.gov/pubmed/26666736> <https://onlinelibrary.wiley.com/doi/full/10.1002/jcu.22318>
2. Function determines structure and structure influences function. There seems not a strong relationship between tendon structure, pain and function. Same as for low back pain. X-ray, MRI doesn't associate with pain or dysfunction in those with low back pain. However, imaging can further confirm clinical/physical diagnosis.
3. I agree it should be a core domain and consensus regarding the types of outcome measures is needed. However, acknowledgement that feasibility/funding etc may preclude measures of 'structure' being reported in all future studies may be worthwhile.
4. I think it is critical to look at structure in addition to symptoms and disability, since we need to understand more about the relationship between structural changes and symptoms. By looking at structure we may also identify subgroups of different tendinopathy phenotypes as well as stratify patients for specific treatments in regards to subgroups of prognosis.
5. In patients with symptoms, structure relates to symptoms. In addition many treatments are aimed at improving structure, and structure relates to function.
6. Issues are tendon specific How to handle poor correlation between structure and symptoms Some modalities eg ultrasound are investigator dependent
7. My yes is because I believe we need much more research to understand the relationship between structure and function/symptoms. But structure does not need to be core, as such.
8. Structure important-but difficult to accurately visualize. UTC is as far as I know the only objective evaluation of structure.
9. Structure referring to anatomic region affected? YES.
10. The issue of structural changes is important, but not of essential importance. Some patients may have pain and disability without evident (or with minimally evident) changes. Clinical symptoms and the clinical picture should guide in the diagnosis and management
11. Tough one and will be a source of debate. The problem with excluding it is that folks will argue that the tendon condition may have been something else, e.g, inferior pole patellar articular cartilage damage rather than patellar tendinopathy. If you include imaging as part of the core you still have the choice of including 'normal imaging' in a study cohort. (early tendinopathy). good luck with this one!

Comments of Disagree responders:

12. Due to the mismatch between pain & function and imaging, I don't believe structure should be a part of the 'core domain set'. It may still be of interest within a research environment and is an important risk factor for the development of painful tendinopathy, but usually has poor correlation with outcomes.

Core Domain Set for Tendinopathy: Survey Data

13. not a lot of evidence that this changes with intervention and/or pain
14. Not as an outcome measure as not shown to correlate with patient status
15. Poor relationship with pain, prognosis, and limited evidence that it changes with loading.
16. There is already evidence that this is not related to severity of symptoms. Not in present state during exam, nor in the future. It might be an interesting outcome measure in some cases, but not a C-TOM.
17. There seems to be no relation and actual patient contact is needed
18. This limits the possibility of studies to comply with the minimum set criteria as it makes research more expensive. I see a role for imaging studies but would not consider those that have not used imaging to have failed or be less useful.

Comments of Unsure responders:

19. Depends. Not sure what you are getting at, apart from using imaging (US) to describe grade and physiology.
20. Given the disconnect between structure and pain, I am not sure this should be included in a core domain set for tendinopathy
21. In contemporary thinking appears less/unrelated to patient outcomes. Good analogies to OA.....however in that field joint changes are still tracked and published. Perhaps useful to understand some subsets of the condition but not a core domain.
22. It depends on what the domain set is looking at. If it is essentially a clinical tool then, given that there is little relationship between structure and function / pain then structure is not too important. Structure also appears to change little, at least in the short to medium term. If it is more of a scientific assessment, or you want to link structure to tendon severity then there is more merit in this.
23. No doubt the tendon structure is an integral part of the condition, but not sure if it should be a domain - because a domain will need to be measured in clinical trials - reliably, validly, discriminatively and feasibly.
24. pain and function not related to structure on the other hand it is an objective outcome measure

Order of agree or disagree: 19.

Percent Agree / Disagree / Unsure: 32% / 43% / 25%

**Domain as on survey: Pain over 24 hours**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 23 papers (19 %).*

*\*The measures used here include asking the participant (patients or controls) to rate their pain over a specified time frame(s) (e.g., last week, last 24 hours, in the morning, at night) on a 10cm line (Visual Analogue Scale) or out of 10 (Numerical Rating Scale).*

Committee's comments:

General sense from the comments was that time frame is much less important than the loading activity (which was the most agreed upon domain of all herein). Some expressions that a timeframe over which the pain is rated was in some comments, but very much in the minority (and usually as a secondary consideration) compared to loading/activity. There were some comments elsewhere for start up pain in the morning - should we consider that is part of the 24 hour pain picture?

Comments of Agree responders:

1. a key response for those with tendon pain
2. Depends on the patient population. My responses are mainly based on the population I work with, (elite) athletes. For these, it is important to use instruments that clearly separate rest/night pain with pain during and after activity (activity-related pain). Otherwise, an athlete who cannot train may report no pain, because he is not training...
3. Describing pain pattern over a 24hour period in conjunction with an appropriate pain scale is an important feature of tendinopathy
4. I agree this is important but very hard to assess in practice. Patients may be doing activities that aggravate daily, or they may not have an accurate understanding of the 24 hour response. This may be less true for some sports and tendinopathies, for example patellar tendinopathy among jumpers. Often they have a better understanding of the 24 hour response.
5. if not 24 hours then over a determined period of time

Comments of Disagree responders:

6. Depends on what patient has done in that time frame
7. I think it is important to be aware that pain in tendinopathy can fluctuate over time. My impression is that there is not so much change in 24 hours, so I don't think this is useful. However, I think that we should agree on a certain time frame when we assess subjective outcome measures (e.g. mean pain during ADL activities during the past week).
8. incidence of pain normally associated with loading but not time
9. It does not change management
10. My preference would be worst pain over last week to capture activities that are not performed on a daily basis.
11. See my answers above.
12. Small number of papers reporting; it's not how patients perceive or report pain. It also doesn't affect how we treat this problem.
13. Too restrictive
14. Without specifying what they did in last 24 hours does not really help me interpret

Comments of Unsure responders:

15. Only when connected to activity/ loading
16. Specification of the circumstances (rest vs activity) when pain is occurring may be necessary.
17. This measure of itself does assume variety and magnitude are constants in subjects. Less rigorous than other measures above. Not core but may be useful

Order of agree or disagree: 20.

Percent Agree / Disagree / Unsure: 29% / 39% / 32%

**Domain as on survey: Clinical examination findings**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 28 papers (/122; 23%). \*This domain covers measures that report a single number/score for a combination of clinical tests (e.g., combine the test results of range of motion, strength, palpation into one score). Some examples of these measures/scores are: University of California-Los Angeles (UCLA); Constant score; Liverpool elbow score.*

Committee's comments:

The comments largely concern combining a number of clinical tests into one score. The percent agreement was almost similar across all response options (agree, disagree, unsure: 30,40,30%), but the comments are largely aligned with disagree.

Comments of Agree responders:

1. as above
2. but not sure which have to be reported in different conditions
3. It will be difficult, but should be included.
4. Please refer to Arthroscopy. 1998 Nov-Dec;14(8):840-3. Overuse tendon conditions: time to change a confusing terminology. Maffulli N1, Khan KM, Puddu G.
5. Yes, but only specific tendon related tests.

Comments of Disagree responders:

6. Any time you take data and combine you loose information.
7. Clinical scores of this nature are not well enough worked out for all of the required common tendon issues
8. Clinician measures are at best surrogate.
9. I would rather have specific clinical findings reported seperatley - once you make a composite score it gets harder to interpret findings and know what the patients looked like on examination
10. Many may not change after treatment/improvement of symptoms e.g. palpation tenderness is a very good example of this.
11. Not specific enough when combined into one score, inter observer reliability is often low

Comments of Unsure responders:

12. Depends on which tendon
13. depends what these are, many clinical tests specified above will not be valid for tendon pain
14. Each tendinopathy is individual in presentation. Here, pain free shoulder ROM for example is a useful reflection of change in status, whereas in lower limb tendons this is a less useful measure. Any amalgamation of clinical findings is only as good as the rigour of each portion. That said, a single score is useful in portraying overall status.
15. I think the addition of a number of reliable clinical tests for each specific tendinopathy location can be valuable. But I am not sure whether these combination tests should be a C-TOM.
16. Not sure whether an aggregate score is very useful. I am assuming that when the combined score is available, there should also be information on the individual clinical tests, which may be more informative.
17. the use of composite may be "condition" specific. Tendinopathy in the upper limb (range of motion and muscle function are normally affected) may have different domain from the lower limb (more associated with impact loading, less associated with physical findings such range of motion / muscle strength).
18. There may be a huge variation in the number of clinical tests that may be used to create this composite score. I am not sure we are at a stage yet were we have a reliable and defined set of "tests" that could the be used to create a reliable composite score.

Order of agree or disagree: 21.

Percent Agree / Disagree / Unsure: 29% / 39% / 32%

**Domain as on survey: Economic impact: costs**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 4 papers (3 %). \*This is usually measured from medical/health records, questionnaires, diaries, or interviews.*

Committee's comments:

30/40/30% spread across agree/disagree/unsure indicates this is undecided as put in the survey. But looking at the comments the disagree has fewest comments (3/14) and these hold an element of feasibility in their wording (nice to have but not devalue study, societal not individual, difficult to analyse). The other comments in the unsure are also along these lines. There are comments elsewhere in the addition of domains item for example that indicate health care utilisation and costs should be included, and other comments that indicate issues with measuring it. If we for this stage of the process ignore the measure, then the question becomes is the costs of tendinopathy (individual and societal) a domain that ought be in the core set.

Comments of Agree responders:

1. Cost effectiveness is a necessity in the present health care environment
2. Especially when data are to be used in cost effectiveness analyses or health technology assessment.
3. Important to note
4. in our society one way we measure impact/value is through economic impacts (direct and indirect costs, lost time at work, etc)
5. this needs more attention to get tp on the agenda

Comments of Disagree responders:

6. Again here its a "nice to have" like strength/ROM/Imaging - drives up the cost of research and not having it doenst de-value a study
7. At a societal level then MSK injury can have a major burden on mortality risk - but for an individual difficult to include
8. It is difficult to analyze cost for this injury due to the slow insidious onset and since the patient often can be active during treatment. Surgery is also not a main treatment.

Comments of Unsure responders:

9. a secondary measure for most studies, but increasingly important as more people trow money at useless interventions
10. Could be useful in certain cohorts eg professional sportspersons or tradespeople. Not sure if it should be a core domain but again useful in appreciating impact of tendinopathy in certain cohorts.
11. Not sure this is feasible as a core domain set
12. Only in some studies.
13. This is important for funding, but I am not sure whether it should be a C-TOM
14. Wont that be insensitive?

Order of agree or disagree: 22.

Percent Agree / Disagree / Unsure: 36% / 29% / 36%

**Domain as on survey: Psychological impact**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 3 papers (2.5 %), accounting for 5% of all domains extracted. \*The types of outcome measures were: pain catastrophizing scale, pain self-efficacy, anxiety and depression scales.*

Committee's comments:

Based on the comments, which are largely about the measure rather than the construct, it would seem that combined the agree and disagree would meet the 70% target. There is a comment to consider if this domain should be split further into smaller domains - but no suggestion of what they might be.

Comments of Agree responders:

1. I would argue that we do not currently have appropriate tendon specific outcome metrics to quantify this - have FABQ etc been validated in a tendon population?
2. Pain is usually a main presenting feature, and not uncommonly persistently, which is associated with various levels of psychological distress.
3. Some sort of screening for psychological impact/factors may help provide early indication of treatment requirements for an individual. Pain self-efficacy can be useful in providing an indication of effect of interventions such as education and functional retraining, improving a patients confidence in their ability to engage in activity/recreation/normal lifestyle. This may be an important mechanism by which our interventions provide effect. High levels of anxiety, depression and catastrophising are not as common in those with an isolated tendon, but when they are present they may present a significant impediment to recovery. So early screening for these could be useful to direct most appropriate treatment, but as an outcome measure for the majority of those with tendon related problems, changes in these measures over time are unlikely to be a strong indicator of recovery.
4. This dimension has been sparsely studied. Personally, I believe that personality traits make a difference in treatment and impact. I am not a psychologist, though, and appropriate questionnaires need to be tested in this respect.
5. Yes! Seems to be an important factor but is not given enough attention in studies so far.

Comments of Disagree responders:

6. Difficult to define - but could be assessed e.g. via EQ5D
7. Interesting as explorative outcome measure, but not a C-TOM
8. Not reported and not important.

Comments of Unsure responders:

9. Does this differ from QOL? If so - i think we should have this as well - gives holistic view of impact
10. Evaluation only in some studies.
11. I doubt it - not sensitive nor specific
12. My be not a core domain, but a very useful supplementary domain, where ongoing limitation has more general effects on patient wellbeing.
13. specific studies on this important but not a core domain for most studies
14. Would this perhaps provide a means of controlling for coping factors in other domains?

Order of agree or disagree: 23.

Percent Agree / Disagree / Unsure: 39% / 43% / 18%

**Domain as on survey: Palpation (pain or tenderness)**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 11 papers (9 %).*

*\*The clinician presses on the tendon with a thumb or finger and elicits pain (or not in controls) and the participant (patient or control) reports this pain or tenderness in a variety of ways (e.g., on a 10cm line, out of a 11 point rating scale (0 to 10), bespoke nominal/ordinal scales, or in some cases not stated in the paper).*

Committee's comments:

Even though agree and disagree were selected about the same proportions (40% each), the comments affirming palpation are largely about clinical examination and in the main most comments do not support palpation as a core domain.

Comments of Agree responders:

1. I still place clinical value on palpation and find it useful - its quick, universally accessible and easy to understand for patients and clinicians. Am however happy to be voted down here - i know it has drawbacks too - standardising pressures etc
2. It is important, but it should be again better qualified. Algometry should be employed
3. It is very hard to standardize, so this measure has a lot of limitations. It is, however, one of the main diagnostic criteria for tendinopathy and most healthcare providers use it in the clinical setting. From that perspective, it is important to know more about its clinical value.
4. Pain on palpation is one of the clinical tests in defining tendon-related problem.
5. This is part of the diagnosis but not actually sure how that would differentiate from core domain.
6. Very important for at least Achilles. Also to localuse where pain is located-superficial, deep, medial or lateral side.

Comments of Disagree responders:

7. for the tendons of my area of interest it is not possible to accurately identify the structure the relationship between palpation and pain remains uncertain
8. Hardly ever useful, aside from ruling out a tendon issue in the diagnostic process.
9. It is difficult to palpate many tendons e.g. supraspinatus
10. Not diagnostic or a good outcome measure, in fact leads most people astray
11. Palpation is often most useful as a negative predictor of the presence of painful tendinopathy but is not a good indicator of outcome. Tenderness on palpation often remains in the presence of substantial improvements in outcome/function.
12. Palpation pain changes appear poorly correlated to functional outcomes
13. Too prone to errors

Comments of Unsure responders:

14. As a inclusion criteria or as an outcome measure?
15. Depends on tendon. Overall, no

Order of agree or disagree: 24.

Percent Agree / Disagree / Unsure: 36% / 39% / 25%

**Domain as on survey: Strength**

*The domain as listed on the survey and EXAMPLE measures for context: This domain was reported in 19 papers (16 %).*

*\*Strength being measured by an instrument such as: a dynamometers or force transducers.*

Committee's comments:

On balance the comments indicate that strength might not be a core domain, with many comments in the agree responders not favouring it as core - which would likely indicate that 70% would be reached on further discussion.

Comments of Agree responders:

1. as above
2. Based primarily on an elite athlete population, where objective measures of function are important outcomes of treatment.
3. Not as an inner core domain. As an outer domain.
4. Often a perceived issue; function impacted by decreased strength
5. Strength changes are less commonly investigated in much of the literature as perhaps over the decades there has been too much focus on the tendon in isolation. More recent papers have identified strength changes that appear to have some relation to overall outcome, yet more work is required in the area.
6. tendons join muscle to bone - and strength testing is of the muscle - a critical impairment to capture
7. This is important, since the injury is an overloading injury and treatment is often aimed at improving strength
8. Yes because strength is fundamental to function and many of our rehabilitation techniques

Comments of Disagree responders:

9. A limb can be strong and still not function. While it is an interesting variable to know, strength in and by itself does not carry much clinical relevance
10. Feasibility and reproducibility issues
11. I dont think strength necessarily needs to be evaluated. Pain very much affects strength, and I have seen that after local anesthesia the strength values are completely different and not seldom normal.
12. I see strength as I see imaging - its a nice to have - but not a must have domain. For the same reasons - I think you can have a well set up and useful study without strength measures.
13. Interesting explorative outcome measure, but not a C-TOM.
14. Need for specific measurement apparatus
15. not the core - will rule out too many investigators
16. Strength seems to be a poor indicator of outcome and function in a painful population.

Comments of Unsure responders:

17. if theses were relevant and standardised possibly, but hard to do across studies and could be too expensive to do for some investigators
18. No need under the inclusion /exclusion part. But can be regarded as one of the outcome measures However, it should include muscle in the kinetic chain. e.g. for patellar / achilles tendinopathy, muscle strength of the hip should be included as well; supraspinatus /ECRL/ECRB tendinopathy, muscle strength of the scapular muscle should be included.
19. Not sure i agree with the term strength as this has various interpretations - i would favour function. Although I think function is an important core domain set I am not sure we are in a position that we appropriate knowledge of what the correct functional tests are.
20. This overlaps with the question on clinical examination. I am too unfamiliar with this topic to judge the differences in strength assessments with and without instruments.

**The following items were about deleting, aggregating, adding or splitting the domains previously presented above in the survey: provided here to help with decisions on each domain at the meeting.**

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Core Domain Set for Tendinopathy: Survey Data

Order of agree or disagree: .

Percent Agree / Disagree / Unsure: 36% / 43% / 21%

**Domain as on survey: Add domains?**

*The domain as listed on the survey and EXAMPLE measures for context: Are there any other domains that you consider important enough to be included in a core domain set for tendinopathy?*

Committee's comments:

Some new domains to consider are: (i) co-morbidities (other conditions, other areas of pain), (ii) Family history, (iii) some domain that covers persistency - previous tendinopathy, and treatments, (iv) pain constancy as opposed to intensity, (v) bothersomeness/impact of interference of pain, (vi) duration of symptoms. Many of the other suggestions are already included in the domains. For example healthcare consumption is covered under econ costs and medication use; and patient satisfaction is similar to patient status as a generic overall domain, as opposed to a measure of that domain. Then the following are directly included: participation (sports level, performance, sports specific), imaging/structure, and start up pain in morning (ie, 24 hour pain).

Comments of Agree responders:

1. healthcare consumption before the start of a trial and during the trial (other treatments / visits to healthcare providers). This could also be important in terms of economic analysis and finally for funding purposes - patient satisfaction (excellent/good/moderate/poor) is not explicitly mentioned. While it has some disadvantages as outcome measure, it is helpful for patient information before starting a treatment. - there is no information regarding the recommended timepoints when C-TOMs should be taken, but it is certainly important to discuss this as well
2. As mentioned above, in the sports setting, our past measures have been crude (professional/amateur level, division level, etc.). I believe we need to try to measure/grade performance level (compared to normal performance, teammate performance, etc).
3. Family history Previous treatments
4. family history of tendon conditions and other systemic conditions
5. Length of time of symptoms. The data on self-limited vs persistent nature of tendinopathy is controversial. It would be important to gather these data.
6. long term impact recurrence level of participation confidence for short medium and long term participation
7. One question I ask is what does your tendon pain stop you doing. This is not necessarily linked to sport but adds to my assessment clinically
8. Pain constancy/frequency - the pain domains mentioned already appeared to be primarily related to severity or intensity of pain. In clinical practice patients may note that although the pain severity is similar, there may have been a substantial reduction in the amount of time their pain is present. I believe this is a useful pain domain.
9. Pain in other bodily areas, either individual areas (eg neck) or sum of areas. Bothersomeness/ impact or interference of pain Duration of symptoms
10. start up pain on rising in morning (likert)night pain

Comments of Disagree responders:

(no comments)

Comments of Unsure responders:

11. As an imager, I am wondering whether any features relating to tendinopathy from imaging (US or MRI) may be useful to add IF available.
12. I alluded to the utilisation in specific cohorts of independently rated sports performance, which would also be a useful supplementary rating in professional sport only.
13. None that currently come to mind - it would be good to start with aforementioned domains and work from there
14. sports-specific and tendon-specific may need to be consider in a core domain set for tendinopathy.

Core Domain Set for Tendinopathy: Survey Data

Order of agree or disagree: .

Percent Agree / Disagree / Unsure: 21% / 43% / 36%

**Domain as on survey: Remove domains?**

*The domain as listed on the survey and EXAMPLE measures for context: Are there any domains that you consider are NOT important enough to be included in a core domain set for tendinopathy? That is, they should be removed from this list of domains.*

Committee's comments:

Domains suggested for removal: 1 discontinue treatemtn/drop out, 2 sensory modality tests (x2), 3 palpation (x3), 4 pain with clinical applied stress (x2), 4 structure/imaging (x4), 5 pain without context specified (x2), 6 clin examination findings as a combined score, 7 p over 24 hour period, 8 strength, 9 ROM (x2), 10 Function, 11 physical function, 12 Psychological impact, 13 participation life,

Comments of Agree responders:

1. as answered !
2. Discontinue treatment Sensory modality tests Palpation Pain with clinician applied stress Structure
3. Imaging - again given the the inconsistent relationship between structure and pain I am not sure we can justify as a core domain set. Also if a core domain set does that mean all HCP's must train in imaging modalities to include this domain?
4. Structure Pain without context specified Clinician examination findings as a combined score Pain over a 24 hour period Strength (muscle) Range of motion Sensory modality tests Function Physical Function Psychological impact Participation (life)
5. The domains that are not context specific or mainly involve a rating by the clinician (i.e, Pain without context specified, Clinician examination findings as a combined score, Range of motion Palpation, Pain with clinician applied stress)

Comments of Disagree responders:

6. Possibly palpation because not all can be palpated easily
7. They are worthy of consideration. Answers above re which would seem most important.

Comments of Unsure responders:

8. From a practical point of view it would be important to keep any questionnaire manageable/limited
9. Important here to also consider both core and supplementary domains. I consider palpation, imaging (generally) and the less specific activity domains candidates for removal.
10. see reponse in 1st section
11. some could be combined eg the activity ones

Order of agree or disagree: .

Percent Agree / Disagree / Unsure: 46% / 7% / 46%

**Domain as on survey: Aggregate any domains**

*The domain as listed on the survey and EXAMPLE measures for context: Should any of the domains listed above be aggregated (combined into one or fewer domains) before being included in a core domain set for tendinopathy?*

**Committee's comments:**

Some discussion around what the domains mean (rather than the measures) in terms of the condition appears necessary as there is conflation between the two apparent here. For example pain and disability, are they actually one domain or two? Function, disability, participation also appear to be in need of some consideration here, as is disability, QoL and psychological. Perhaps best considered for each domain as they are individually considered.

**Comments of Agree responders:**

1. Aggregation in to the next groups History Activity & Load Pain Function Clinical examination Imaging Impact (Disability, psycholol, QOL, costs)
2. cant remember exactly what they were called some of the clinical examination and clinical stress tests seem to overlap
3. Disability, function, physical function Participation, work/sport participation, physical activity
4. Palpation and pain with stress. Pain questions could be combined.
5. Quite a few. Disability, QoL, psychological effect - could be covered by EQ5D for example
6. ROM combined into clinical examination.
7. Several of the pain and activity domains are highly overlapping and could perhaps be aggregated.
8. Some of physical activity & participation domains may be aggregated and possibly loading/stress test related statements also
9. Sports participation and physical activity Function should include work, strength
10. There should be one functional capacity domain that encompasses (a) function, and (b) physical function. How this is measured is another matter, but there should be a domain for function, which is different to disability - there should be a distinction between function and disability. Function being ability and capacity. There should be consideration for one participation domain that encompasses (a) 'general life' participation (life), (b) sport participation, and (c) work participation. The reason being that measures that capture this 'participation' domain to be valid, discriminating and feasible will need to capture the overall participation relevant for the individual, regardless (or encompassing) if they are elite athletes, non-athletic workers or otherwise. These (function and participation) ought to be different to physical activity level.
11. Where applicable, I favor combining pain function and sports participation (as in VISA scores)

**Comments of Disagree responders:**

(no comments)

**Comments of Unsure responders:**

12. Aggregating less specific domains achieves little (garbage in- garbage out!) That said, if some of the more rigorous instruments can be combined for a global effect I would support this, however because of the significantly different cohorts encountered, (tendon affected, activity level) applying this universally may be challenging.
13. I think this is the perfect topic for meeting Things that come to mind would be QOL - psychology Participation-sports Various pain measures
14. needs discussion
15. tendinopathy is the "failure" on multiple factors that may be tendon-specific, sport-specific and gender-specific. I am not sure whether we can find aggregated domains

**Core Domain Set for Tendinopathy: Survey Data**

Order of agree or disagree: .

Percent Agree / Disagree / Unsure: 14% / 43% / 43%

**Domain as on survey: Splitting domains**

*The domain as listed on the survey and EXAMPLE measures for context: Should any of the domains listed above be further split up or divided into two or more domains before being included in a core domain set for tendinopathy?*

Committee's comments:

Comments from the agree responders to consider are (i) splitting up psychological just as pain has been, and (ii) strength, endurance, power for different functions of muscle.

Comments of Agree responders:

1. As pain is split up into several domains, the domain psychological impact can also be split up
2. I consider strength and endurance both measure of muscle. I do not think heel-rise test should be considered a function the same way as jumping etc.
3. The demand on a tendon is sport / activity -specific. It may be worth in consider splitting the domain according to different sport group. e.g. jumping/landing sport (volleyball and basketball); lunging sport (badminton/fencing) for the lower limb. throwing sports (cricket, volleyball); racket sports (badminton, tennis); crawling sports (swimming) for the upper limb. The domains can be designed involving the kinetic chain according to sport-specific requirement

Comments of Disagree responders:

4. Enough already
5. I feel they are pretty specific now

Comments of Unsure responders:

6. ditto, too hard to consider based on the survey to date
7. I'm not quite sure what an example of this might be. Pain on loading and disability/function would have a number of tendon-specific tasks as sub-questions, but I wouldn't consider these separate domains.
8. There is a case at times for mining the tendon specific instruments for effect of an intervention. ie in VISA X, sport participation did not change over 6 -12 weeks but other parameters did...

**Patient survey:**

In Brisbane and Melbourne (Australia), 219 patient participants on the database lists of three research centers were asked to complete the Domains survey (i.e., emailed with the link to the Domains survey). 56 participants (26%) went to the link and 32 (57%) then provided consent to complete the survey. Only the domains survey was sent to these participants. The responses of the patients is summarized in Table 3, and their characteristics are in Table 3a.

The green coding in Table 3 highlight the items reaching 70% agreement. Note that there are no disagreements reaching the 70% threshold.

These data are provided for clinicians to consider when reviewing the clinician data and in preparation for the consensus meeting in Groningen.

**Table 3: Summary statistics of patient\* responses to the Domains Survey (n=56)**

Item	Domain	Responses (rate%)	Agree N (%)	Disagree N (%)	Unsure N (%)
4	Pain on Activity or loading*	32 (57%)	31 (97%)	0 (0%)	1 (3%)
11	Strength	32 (57%)	29 (91%)	0 (0%)	3 (9%)
10	QoL	32 (57%)	29 (91%)	1 (3%)	2 (6%)
5	Patient perception of condition status	32 (57%)	29 (91%)	2 (6%)	1 (3%)
18	Function	31 (55%)	27 (87%)	2 (6%)	2 (6%)
12	ROM <sup>^</sup>	32 (57%)	27 (84%)	2 (6%)	3 (9%)
24	Physical activity	32 (57%)	25 (81%)	3 (10%)	3 (10%)
20	Psychological impact	32 (57%)	24 (77%)	6 (19%)	1 (3%)
8	Clinical exam findings	32 (57%)	24 (75%)	4 (13%)	4 (13%)
21	Sport participation	32 (57%)	23 (74%)	5 (16%)	3 (10%)
22	Medication use	32 (57%)	23 (74%)	4 (13%)	4 (3%)
3	Disability*	32 (57%)	22 (69%)	3 (9%)	7 (22%)
9	Pain over 24 hours	32 (57%)	22 (69%)	7 (22%)	3 (9%)
13	Palpation	32 (57%)	21 (68%)	5 (16%)	5 (16%)
19	Physical function	32 (57%)	21 (68%)	5 (16%)	5 (16%)
23	Work participation	32 (57%)	20 (65%)	6 (19%)	5 (16%)
25	Participation	32 (57%)	20 (65%)	8 (26%)	3 (10%)
7	Pain without further specification	32 (57%)	20 (63%)	8 (25%)	4 (13%)
14	Pain elicited with clinician applied stress test	32 (57%)	19 (61%)	3 (10%)	9 (29%)
26	Discontinue treatment	32 (57%)	19 (61%)	5 (16%)	7 (23%)
15	Adverse effects/events	32 (57%)	18 (58%)	6 (19%)	7 (23%)
16	Economic impact: costs	32 (57%)	17 (55%)	7 (23%)	7 (23%)
17	Sensory modality specific pain	32 (57%)	13 (42%)	7 (23%)	11 (35%)
6	Structure	32 (57%)	11 (34%)	4 (13%)	17 (53%)

\* These items reached 70% agreement in the clinician survey (i.e., clinicians indicated these to be a core domain

<sup>^</sup> This item reached 70% disagreement in the clinician survey (i.e., clinicians did not think it a core domain)

**Table 3a: Patient participant characteristics of the completing the survey.**

Characteristic	N (%)
Sex Female (%)	24 (77%)
Role:	
Clinician	1 (3%)
Neither Clinician nor Researcher/Scientist	28 (90%)
Other	2 (6%)
Cases per month:	
0 (I am a patient)	29 (94%)
At least 4	1 (3%)
Between 11 and 15	1 (3%)
Highest academic qualification:	
Undergraduate Diploma/Certificate	5 (16%)
Bachelor	14 (45%)
Master	4 (13%)
PhD	5 (16%)
Other	3 (10%)
Currently have tendon problem:	26 (84%)
Past history of tendon problem:	21 (68%)