### Full title of manuscript:

What do the OMERACT Shoulder Core Set candidate instruments measure? An analysis using the refined ICF linking rules

### Complete given names and surnames of all authors with ORCID ID if any:

Yngve Røe

https://orcid.org/0000-0003-2428-571X

Rachelle Buchbinder

https://orcid.org/0000-0002-0597-0933

Margreth Grotle

https://orcid.org/0000-0001-8243-1143

Samuel Whittle

https://orcid.org/0000-0001-7417-7691

Sofia Ramiro

https://orcid.org/0000-0002-8899-9087

Hsiaomin Huang

Scopus Author Identifier: 56883268800

Joel Gagnier

https://orcid.org/0000-0002-3162-3935

Arianne Verhagen

https://orcid.org/0000-0002-6195-0128

Sigrid Østensjø

https://orcid.org/0000-0002-7418-2973

### **Key Indexing Terms:**

OMERACT, Outcome assessment, ICF, Shoulder pain

### Name of department(s) and institution(s) to which the work should be attributed:

Department of Physiotherapy, Oslo Metropolitan University, Oslo, Norway

Department of Epidemiology and Preventive Medicine, Monash University, Sydney, Australia

The Queen Elizabeth Hospital, Woodville South, Australia

Department of Epidemiology and Orthopaedic Surgery, University of Michigan, USA

University of Technology, Melbourne, Australia

### The source(s) of support in the form of grants or industrial support:

None

### **Conflict of interest:**

None

### Initials, surnames, appointments, and highest academic degrees of all authors:

- Y. Røe, Associated Professor, PhD
- R. Buchbinder, Professor, PhD
- M. Grotle, Professor, PhD
- S. Whittle, MD, PhD
- S. Ramiro, MD, PhD
- H. Huang, Associated Professor, PhD
- J. Gagnier, Associated Professor, PhD
- A. Verhagen, Associated Professor, PhD
- S. Østensjø, Professor, PhD

### Name, address, and e-mail of author responsible for correspondence:

Yngve Røe

OsloMet - Oslo Metropolitan University

Department of Physiotherapy

P.O. Box 4, St. Olavs plass

N-0130 Oslo

Norway

yngveroe@oslomet.no

### **Short running head:**

Shoulder candidate instruments

### **Abstract**

Objective: to assess the content and measurement constructs of the candidate instruments for the domains of 'Pain' and 'Physical function/activity' in the OMERACT Shoulder Core Set.

The results of this ICF based analysis may inform further decisions on which instruments finally to be included in the Core Set.

Methods: The materials for the analysis were the 13 candidate measurement instruments within 'Pain' and 'Physical function/activity' in the Shoulder Core Domain Set, which either passed or received amber ratings (meaning there were some issues with the instrument) in the OMERACT filtering process. The content of the candidate instruments was extracted and linked to the International Classification of Functioning, Disability and Health (ICF), using the refined linking rules. The linking rules enhance the comparability of instruments, by providing a comprehensive overview of the content of the instruments, the context in which the measurements take place, the perspectives adopted and the types of response options.

<u>Results</u>: The ICF content analysis showed large variation in content and measurement constructs in the candidate instruments for the Shoulder Core Outcome Measurement Set.

Conclusion: Two of six 'Pain' instruments include other constructs than pain. Within 'Physical function/activity' two candidate instruments matched the domain, three included additional content and the two last instruments included meaningful concepts in the response options, suggesting that they should be omitted as candidate instruments. The analyses show that the content in most existing instruments of shoulder pain and functioning extend across Core Set domains.

# Introduction

Shoulder pain is a common musculoskeletal disorder with an incidence of 10 per 1000 in primary care and point prevalence estimates of 7-26% in the general population (1). Shoulder disorders can be long lasting; in a Dutch study in those patients presenting a new episode of shoulder pain for their general practitioner, a considerable number (41%) showed persistent symptoms after 12 months (2). The associated disability and impact in terms of earnings, missed workdays, and disability payments, is substantial (3-7).

The domains and measurement instruments reported in trials on shoulder disorders are widely diverse, therefore the development of a core outcome set for use in clinical trials across shoulder disorders, have been advocated (8). Since 2016, there has been an ongoing effort to develop a Shoulder Core Set within the Outcome Measures in Rheumatology (OMERACT) (9-12). At the OMERACT 2018 conference, a Shoulder Core Domain Set was approved by the delegates (13). It consisted of four mandatory domains for all trials of shoulder disorders: 'Pain', 'Physical function/activity', 'Patient global – shoulder', and 'Adverse events including death'; and four important but optional domains: 'Participation (recreation/work)', 'Sleep', 'Emotional wellbeing' and 'Condition-specific pathophysiological manifestations' (13). The next phase will be to recommend specific measurement instruments for a Core Outcome Measurement Set (10).

Preliminary work has investigated instruments within two of the mandatory domains, 'Pain' and 'Physical function/activity', identified from a systematic review of outcome domains and measurement instruments reported across randomized trials of any interventions for various shoulder disorders (8). Pain was defined 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)" and physical function/activity as "A person's ability to carry out daily physical activities,

ranging from self-care (e.g. bathing, combing hair) to more complex activities that require a combination of skills (e.g. driving a car)" (13). Thirty-eight instruments within the pain domain and 45 within the physical function/activity domain, were further investigated with the Truth Part 1 and Feasibility filters of the Outcome Measures in Rheumatology (OMERACT) (11, 12). Altogether, six instruments in the pain domain and seven within the physical function/activity domain, passed both filters and are candidates for further assessment (14, 15). However five in the 'Pain' domain and three in the 'Physical function/activity' domain received 'amber' ratings for content validity, indicating potential limitations in their utility (14, 15).

The International Classification of Functioning, Disability and Health (ICF) is the WHO framework for measuring health and disability (16). Since its publication in 2001, the ICF has been used to describe and compare health information. To establish a standardized procedure to translate the content of measurement instruments into ICF concepts, a set of ten linking rules were published in 2002, and updated in 2005 (17, 18). Since their introduction, a number of instruments has been linked to the ICF (19-21). To enhance the comparability of instruments, and ultimately to be able to aggregate information gathered with various instruments, it does not only require content comparability of items, but also a reflection on the perspective they have adopted, and the categorization of their response options.

In 2016, the linking rules were refined to account for these aspects offering a more transparent tool to assess the content of measurement instruments and the context in which the measurements take place (22). Thus, content linking of outcome measure instruments based on the refined ICF linking rules provide information on important aspects of content validity. Content validity is considered to be the most important measurement property of an outcome measure instrument, because if it is unclear what an instrument is actually measuring, the assessment of other measurement properties may be irrelevant (23).

The aim of the present study was to assess the content and measurement constructs of the candidate instruments for the domains of 'Pain' and 'Physical function/activity' in the OMERACT Shoulder Core Set, using the refined ICF linking rules. The results of this ICF based analysis may inform further decisions on which instruments finally to be included in the Core Set.

### **Materials and Methods**

The materials for the analysis were the 13 candidate measurement instruments within 'Pain' and 'Physical function/activity' in the Shoulder Core Domain Set, which either passed or received amber ratings (meaning there were some issues with the instrument) in the Outcome Measures in Rheumatology (OMERACT) filtering process (14, 15). The six candidate instruments within the pain domain and the seven within the physical function/activity domain are presented in Table 1. These instruments are widely used in clinical and epidemiological research of shoulder pain conditions (8).

Please insert Table 1, about here

### Analysis of content and measurement constructs

The International Classification of Functioning, Disability and Health (ICF) is based on an integrative model of health that classifies functioning within the components of 'Body Functions' (b), 'Body Structures' (s), 'Activities and Participation' (d) and 'Environmental factors' (e) and 'Personal Factors' (not classified) (16). The ICF provides four sub-

classification (b, s, d, e) where categories of functioning and environmental factors are arranged hierarchically, using an alphanumeric coding system. At the first level the initial letters is followed by a numeric code (one-digit) (e.g., d4 Mobility), two more digits for the second level (e.g., d445 Hand and arm use) and a total of 4 digits for third level categories (e.g., d4452 Reaching). A fourth level is also available, when appropriate. An overview of the chapter structure of the components 'Body Functions' and 'Activities and Participation', is shown in Table 2.

Please insert Table 2, about here

The content from each item in the measurement instruments was linked to the ICF according to the 10 refined linking rules (22). Linking rules #1–3 specify how to get familiar with the ICF, identifying the purpose of an instrument and concepts to be linked to the ICF. Both the researchers who conducted the analyses (YR & SØ) had previously linked the content of shoulder pain instruments to the ICF (21).

First, the actual meaning (main and additional concepts) of the information to be linked was identified, consistent with rules #2 and 3 (22). When identifying the concepts, both the item text and the text that set premises for the interpretation of the item content were taken into consideration. For most items it was straightforward to identify main and additional concepts. Such as for the item "How severe is your pain: pushing with the involved arm? "Pain" was identified as the main concept and "pushing with the arm", as an additional concept. In this item, the additional concept defines the context in which pain is assessed. Sometimes more than one activity was listed in the same item. When this was the case, all the listed activities

were recognized as main concepts. In a few cases, the item was framed in general terms, while specific activities were included in the response options, such as in the "Function subscale" of the UCLA and the "Activities of daily living subscale" of the SFA (32, 34). Then the naming of the item was identified as the main concept and the specific activities as additional concepts.

The next step was to document the perspectives from which the information was collected (linking rule # 4). The most common perspectives included in measurement instruments are the descriptive, appraisal and the needs or dependency perspectives (22). The descriptive perspective refers to a person's function of the body, ability to perform a task in a standardized environment (capacity), or actual performance of certain task or activities in the natural environment. According to linking rule #5, the categorisation of the response option in every measurement instrument was identified and documented.

Finally, all main and additional concepts identified during steps #2 and 3 were linked to the most precise ICF category (linking rules #6-10). For concepts not sufficiently specified to be linked, the 'not definable' option, was used. If a concept was not covered by any of the ICF classifications, the option 'not covered', was used.

All instruments were independently assessed by two researchers (YR and SØ). In case of differences in linking, this was solved by discussion. There were no cases of disagreement in the identification and documentation of perspectives and response options.

Agreement between the researchers in the linking of concepts at the 2<sup>nd</sup> ICF category level was calculated with the Cohen's Kappa coefficient. The 95% confidence intervals for the Kappa coefficient were calculated using the standard error of the kappa:

 $k-1.96 \times SE_k$  to  $k+1.96 \times SE_k$  (35). The calculated Kappa coefficient of the linking of main and additional concepts was 0.85 (95% CI, 0.78 - 0.91), considered as excellent (range 0.61 – 1.00) (36). The study did not include data from patients or any other sensitive material, thus ethical approval was waived

### **Results**

Descriptive information about the six candidate instruments within the 'Pain' and 'Physical function/activity' domains of the Shoulder Core Set, is shown in Table 1.

### 'Pain' candidate instruments

The analysis of the perspectives showed that the 'Descriptive-performance' perspective was adopted in all six instruments. The response options in the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS), The Oxford Shoulder Score (OSS) and the Shoulder Pain and Disability Index (SPADI) pain subscale reflect 'Intensity'. In the Verbal Rating Scale (VRS) the response options reflected 'Qualitative attributes', and in the Shoulder Pain Scale (SPS), a combination of 'Intensity' and 'Qualitative attributes'.

All instruments had main concepts linked to 'Sensory functions and pain' categories in the International Classification of Functioning, Disability and Health (ICF) (Table 3). For the three overall pain scales (VAS, NRS and VRS) and the SPADI pain subscale, all main concepts were linked to a pain ICF category. The overall pain scales only cover a single ICF pain category, while the SPADI includes five categories.

In addition to pain categories, the SPS included a main concept linked to a 'Mobility' category in the ICF. An instrument stood out from the others; in the OSS 10 of 14 main

concepts were linked to ICF categories other than pain, namely to 'Activity and Participation' categories within the 'Mobility', 'Self-care' and 'Domestic life' chapters.

The additional concepts in the pain instruments provide information about the context in which the pain is assessed. In the three overall pain scales, no additional concepts were identified. In the SPS, three additional concepts were not sufficiently specified to be classified in the ICF (at rest, in motion and nightly), whereas in the SPADI pain subscale, pain was measured in the context of four different 'Mobility' activities. Of the four main concepts in the OSS that assessed pain, two were provided without any additional concepts, one was linked to a 'Mobility' category and another was assigned to 'not definable'.

Please insert Table 3, about here

### 'Physical function/activity' candidate instruments

The analysis of perspectives in the candidate instruments showed that a 'Descriptive-performance' perspective was adopted in all seven instruments. With respect to the response options, four instruments, the Penn Shoulder Score, Function subscale (Penn), the L'Insalata Shoulder Rating Questionnaire (SRQ), the American Shoulder and Elbow Surgeons Shoulder Outcome Score (ASES) and the Shoulder Pain And Disability Index (SPADI) disability subscale, assessed 'Intensity', the Simple Shoulder Test (SST) and the University of California at Los Angeles Shoulder Score (UCLA) 'Confirmation/agreement' and the Shoulder Function Assessment scale (SFA) 'Qualitative attributes'.

The instruments varied with respect to the depth and breadth of information (see Table 4).

The additional concepts in the physical function/activity measures were often used for

specifying the content, and thus should be interpreted differently than in the 'Pain' candidate instruments. All 'Physical function/activity' candidate instruments included concepts linked to 'Self-care' ICF categories, and all except one, the SFA, included concepts linked to both 'Self-care' and 'Mobility'.

The Penn was the most wide-ranging instrument with concepts linked to categories in five chapters of the 'Activities and Participation' component of the ICF. In particular, the Penn comprehensively covers 'Mobility', 'Self-care' and 'Domestic life' (23 of 27 main concepts). It is also worth noting that the Penn included four main concepts linked to a sleep category which is classified as 'Body Functions' in the ICF, and also to work and leisure activities in the 'Activities and Participation' component of the ICF. Similarly, the ASES covered 'Mobility' and 'Self-care' comprehensively, but it also included concepts linked to sleep functions and to work and leisure activities. In the SST, 8 of 15 concepts were linked to 'Mobility' categories and the rest to work, sleep and pain categories in the ICF.

Two instruments, the SRQ and the SPADI disability subscale, covered 'Mobility' and 'Self-care' comprehensively. In the SRQ, the content was linked to three 'Mobility' categories and seven different 'Self-care' categories. In addition, two concepts were linked to 'Domestic life' activities. Another instrument, the SPADI disability subscale had concepts linked to three 'Mobility' categories and five 'Self-care' categories (of these only two unique).

In the two last instruments, the SFA and the UCLA, the meaningful concepts were identified in the response options. For the UCLA, these concepts were linked to 'Mobility', Self-care' and 'Domestic life' categories in the ICF, and for the SFA to 'Self-care' categories.

Please insert Table 4, about here

## **Discussion**

showed large variation in content and measurement constructs in the candidate instruments for 'Pain' and 'Physical function/activity' for the Shoulder Core Outcome Measurement Set.

Among the six pain candidate instruments, all included concepts linked to a pain category in the ICF. However, two of the instruments, the Shoulder Pain Score (SPS) and the Oxford Shoulder Score (OSS), also covered sleep functions, and mobility, self-care and domestic life activities. This was particularly prominent in the OSS, where more than two thirds of the items covered other concepts than pain.

The International Classification of Functioning, Disability and Health (ICF) content analysis

In pain assessments, it is important to take into account the context in which the pain is experienced. This is consistent with the definition of pain in the Shoulder Core Set, relating pain experiences to a given context ("i.e. at rest, during and after activity") (13). The only candidate instrument where all main concepts cover pain and at the same time refer to a specific context, was the Shoulder Pain And Disability Index (SPADI pain). It should, however, be noted that all except one SPADI items measure pain in the context of performing hand and arm 'Mobility' activities. In addition, a single item requests pain at its worst. Thus, one of its items measure pain in relation to self-care or domestic life activities, nor pain at rest.

The overall pain candidate scales, the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS) and the Verbal Rating Scale (VRS), measure the magnitude of the pain, regardless of any contextual information. Due to the vagueness in construct definition, it has

been recommended that such scales can only complement and not replace genuine, validated pain scales (37).

Based on our ICF analysis, no single candidate instrument completely matches the magnitude of the pain experience, as defined in the Shoulder Core Outcome Set (13). However, the use of the SPADI pain in combination with an overall pain scale (VAS, NRS or VRS), might provide an acceptable coverage of the 'Pain' domain. Moreover, the documented inconsistencies in content of the SPS and OSS should be considered in the further discussions on which 'Pain' instruments to be included in the Core Set

Seven candidate instruments in the 'Physical function/activity' domain were included in the ICF content analysis. As defined in the Core Set, this domain covers functions ranging from self-care (e.g. bathing, combing hair) to more complex activities (e.g. driving a car) (13). Our analysis showed that a majority of the candidate instruments cover 'Mobility' and 'Self-care' activities, which matches the domain definition of the Core Set (13, 16). Nevertheless, a majority of the candidate instruments also cover content that falls outside the domain definition. In particular one instrument, the Penn Shoulder Score (Penn), included content from five of nine chapters within the 'Activities and Participation' component and content that was linked to the 'Body functions' component of the ICF. A similar content coverage was found in the Simple Shoulder Test (SST) and the American Shoulder and Elbow Surgeons Shoulder Outcome Score (ASES). This wider content coverage, as provided by the Penn, SST and ASES, are supported by empirical evidence showing that patient-reported problems are frequently reported within a range of body functions and activities and participation chapters (38).

The candidate instruments that provided the best match with 'Physical function/activity', was the Shoulder Rating Questionnaire (SRQ and) the Shoulder Pain and Disability Index (SPADI disability). Both instruments covered 'Mobility' and 'Self-care' activities, and included little

additional content. Although both instruments had a similar content profile, an important difference was discovered: while the SRQ covers a range of self-care activities, the SPADI only included two such activities. It should also be noted that only 6 of the 15 items in the full version of the SRQ were selected as candidates for the Shoulder Outcome Measurement Set. From our previous content analyses of shoulder pain instruments, we learned that the full version of the SRQ covers similar ICF domains as the most wide ranging candidate instrument, the Penn (21).

The two last candidate instruments, the University of California at Los Angeles Shoulder Score (UCLA) and the Shoulder Function Assessment scale (SFA) have little or no content that address 'Mobility' activities of the hand and arm. In addition, they have a structure that imply that the meaningful concepts are included in the response options, and not in the item itself. This limitation need to be considered in the ongoing selection process.

Our ICF analysis showed that a majority of the 'Physical function/activity' candidate instruments had content that did not perfectly match the OMERACT domain definition (13). In addition to mobility and self-care activities, most of the measures covered content belonging to 'Pain' and to two 'optional' Core Set domains, 'Participation (recreation and work)' and 'Sleep' (13). There were also examples of domestic life activities (e.g. household tasks) in the instruments, that are not included in any of the recommended Core Set domains (13).

We suggest that the lack of alignment between the definition of 'Physical function/activity' in Shoulder Core Outcome Set, and the content of the candidate measures, needs further consideration by the OMERACT shoulder working group. The group could consider either adjusting the domain definition or not including instruments that do not comply with the current definition. In this work, the consensus-based guidelines for selection of outcome measurement instruments, developed as a joint initiative between the Core Outcome Measures

in Effectiveness Trials (COMET) initiative and the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) initiative, will be useful (23, 39).

A limitation of our study was that some of the measures included content that neither could not be defined, nor is covered by the ICF. Due to this, the results do not provide a complete overview of the content in the measures.

### Conclusion

The ICF based analysis of the candidate instruments within the mandatory 'Pain' and 'Physical function/activity' domains of the OMERACT Shoulder Core Outcome Set, showed large variations in the content and measurement constructs covered. Two of six 'Pain' instruments include other constructs than pain. Within 'Physical function/activity' two candidate instruments matched the domain, three included additional content and the two last instruments included meaningful concepts in the response options, suggesting that they should be omitted as candidate instruments. The analyses show that the content in most existing instruments of shoulder pain and functioning extend across Core Set domains.

# Acknowledgement

Not applicable

# **Funding**

None

# **Competing interests**

The authors have no competing interests to declare

### References

- 1. Luime JJ, Koes BW, Hendriksen IJ, Burdorf A, Verhagen AP, Miedema HS, et al. Prevalence and incidence of shoulder pain in the general population; a systematic review. Scand J Rheumatol 2004;33:73-81.
- 2. van der Windt DA, Koes BW, Boeke AJ, Deville W, De Jong BA, Bouter LM. Shoulder disorders in general practice: Prognostic indicators of outcome. Br J Gen Pract 1996;46:519-23.
- 3. Largacha M, Parsons IMt, Campbell B, Titelman RM, Smith KL, Matsen F, 3rd. Deficits in shoulder function and general health associated with sixteen common shoulder diagnoses: A study of 2674 patients. J Shoulder Elbow Surg 2006;15:30-9.
- 4. Mather RC, 3rd, Koenig L, Acevedo D, Dall TM, Gallo P, Romeo A, et al. The societal and economic value of rotator cuff repair. J Bone Joint Surg Am 2013;95:1993-2000.
- 5. Page MJ, Voshaar MJH, Shea B, Verhagen AP, Whittle SL, van der Windt DA, et al. Patients' experience of shoulder disorders: A systematic review of qualitative studies for the omeract shoulder core domain set. Rheumatology (Oxford) 2019;58:1410-21.
- 6. van der Windt DA, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: Incidence, patient characteristics, and management. Ann Rheum Dis 1995;54:959-64.
- 7. Virta L, Joranger P, Brox JI, Eriksson R. Costs of shoulder pain and resource use in primary health care: A cost-of-illness study in sweden. BMC Musculoskelet Disord 2012;13:17.

- 8. Page MJ, Huang H, Verhagen AP, Gagnier JJ, Buchbinder R. Outcome reporting in randomized trials for shoulder disorders: Literature review to inform the development of a core outcome set. Arthritis Care Res 2018;70:252-9.
- 9. Buchbinder R, Page MJ, Huang H, Verhagen AP, Beaton D, Kopkow C, et al. A preliminary core domain set for clinical trials of shoulder disorders: A report from the omeract 2016 shoulder core outcome set special interest group. J Rheumatol 2017;44:1880-83.
- 10. Gagnier JJ, Page MJ, Huang H, Verhagen AP, Buchbinder R. Creation of a core outcome set for clinical trials of people with shoulder pain: A study protocol. Trials 2017;18:336-45.
- 11. Boers M, Beaton DE, Shea BJ, Maxwell LJ, Bartlett SJ, Bingham CO, et al. Omeract filter 2.1: Elaboration of the conceptual framework for outcome measurement in health intervention studies. J Rheumatol 2019;46:1021-27.
- 12. Boers M, Kirwan JR, Wells G, Beaton D, Gossec L, d'Agostino MA, et al. Developing core outcome measurement sets for clinical trials: Omeract filter 2.0. J Clin Epidemiol 2014;67:745-53.
- 13. Ramiro S, Page MJ, Whittle SL, Huang H, Verhagen AP, Beaton D, et al. The omeract core domain set for clinical trials of shoulder disorders. J Rheumatol 2019;01:01.
- 14. Huang H, editor. Omeract filter 2.1 item 1 and 2: Truth and feasibility test. Domain of interest physical function/activity. OMERACT Outcome Measures in Rheumatology Conference; 2018; New South Wales, Australia.
- 15. Whittle S, editor. Assessment of pain in clinical trials of shoulder disorders.

  OMERACT Outcome Measures in Rheumatology Conference; 2018; New South Wales,
  Australia.

- 16. World Health Organization (WHO). International classification of functioning, disability and health (icf). WHO, Geneva (Switzerland); 2001.
- 17. Cieza A, Brockow T, Ewert T, Amman E, Kollerits B, Chatterji S, et al. Linking health-status measurements to the international classification of functioning, disability and health. J Rehabil Med 2002;34:205-10.
- 18. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustun B, Stucki G. Icf linking rules: An update based on lessons learned. J Rehabil Med 2005;37:212-8.
- 19. Brockow T, Cieza A, Kuhlow H, Sigl T, Franke T, Harder M, et al. Identifying the concepts contained in outcome measures of clinical trials on musculoskeletal disorders and chronic widespread pain using the international classification of functioning, disability and health as a reference. J Rehabil Med 2004:30-6.
- 20. Grotle M, Brox JI, Vollestad NK. Functional status and disability questionnaires: What do they assess? A systematic review of back-specific outcome questionnaires. Spine 2005;30:130-40.
- 21. Roe Y, Østensjø S. Conceptualization and assessment of disability in shoulder-specific measures with reference to the international classification of functioning, disability and health. J Rehabil Med 2016;48:325-32.
- 22. Cieza A, Fayed N, Bickenbach J, Prodinger B. Refinements of the icf linking rules to strengthen their potential for establishing comparability of health information. Disabil Rehabil 2016:1-10.
- 23. Prinsen CAC, Vohra S, Rose MR, Boers M, Tugwell P, Clarke M, et al. How to select outcome measurement instruments for outcomes included in a "core outcome set" a practical guideline. Trials 2016;17:449.
- 24. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. J Bone Joint Surg Br 1996;78:593-600.

- 25. Dawson J, Rogers K, Fitzpatrick R, Carr A. The oxford shoulder score revisited. Arch Orthop Trauma Surg 2009;129:119-23.
- 26. Roach KE, Budiman-Mak E, Songsiridej N, Lertratanakul Y. Development of a shoulder pain and disability index. Arthritis Care Res 1991;4:143-9.
- 27. Williams JW, Jr., Holleman DR, Jr., Simel DL. Measuring shoulder function with the shoulder pain and disability index. J Rheumatol 1995;22:727-32.
- 28. Winters JC, Sobel JS, Groenier KH, Arendzen JH, Meyboom-De Jong B. A shoulder pain score: A comprehensive questionnaire for assessing pain in patients with shoulder complaints. Scand J Of Rehabil Med 1996;28:163-7.
- 29. Leggin BG, Michener LA, Shaffer MA, Brenneman SK, Iannotti JP, Williams GR, Jr. The penn shoulder score: Reliability and validity. J Orthop Sports Phys Ther 2006;36:138-51.
- 30. L'Insalata JC, Warren RF, Cohen SB, Altchek DW, Peterson MG. A self-administered questionnaire for assessment of symptoms and function of the shoulder. J Bone Joint Surg Am 1997;79:738-48.
- 31. Lippitt SB, Harryman DTII. A practical tool for evaluation of function: The simple shoulder test. In: Matsen FI, Fu F, Hawkins R, editors. The shoulder: A balance of mobility and stability. Rosemont, Illinois: The American Academy of Orthopedic Surgeons; 1993. p. 501-18.
- 32. Richards RR, An K-N, Bigliani LU, Friedman RJ, Gartsman GM, Gristina AG, et al. A standardized method for the assessment of shoulder function. J Shoulder Elbow Surg 1994;3:347-52.
- 33. Ellman H, Hanker G, Bayer M. Repair of the rotator cuff. End-result study of factors influencing reconstruction. J Bone Joint Surg Am 1986;68:1136-44.

- 34. van Den Ende CH, Rozing PM, Dijkmans BA, Verhoef JA, Voogt-van der Harst EM, Hazes JM. Assessment of shoulder function in rheumatoid arthritis. Journal Rheumatol 1996;23:2043-8.
- 35. McHugh ML. Interrater reliability: The kappa statistic. Biochem Med 2012;22:276-82.
- 36. Cicchetti DV, Sparrow SA. Developing criteria for establishing interrater reliability of specific items: Applications to assessment of adaptive behavior. Am J Ment Defic 1981;86:127-37.
- 37. Franchignoni F, Salaffi F, Tesio L. How should we use the visual analogue scale (vas) in rehabilitation outcomes? I: How much of what? The seductive vas numbers are not true measures. J Rehabil Med 2012;44:798-9.
- 38. Roe Y, Bautz-Holter E, Juel NG, Soberg HL. Identification of relevant international classification of functioning, disability and health categories in patients with shoulder pain: A cross-sectional study. J Rehabil Med 2013;45:662-9.
- 39. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The comet handbook: Version 1.0. Trials 2017;18:280.

Table 1: Candidate instruments for the Shoulder Core Domain Set within 'Pain' and 'Physical function/activity'

|   | Abbrev. | Items | Response scales (range score)  |
|---|---------|-------|--|
| Pain instruments  |         |       |  |
| Visual Analogue Scale   | VAS     | 1     | Visual analogue scale (0-100)  |
| Numerical Rating Scale  | NRS     | 1     | Ordinal scale (0-10)   |
| Verbal Rating Scale   | VRS     | 1     | Categorical scale with optional response formats   |
| Oxford Shoulder Score (24, 25)  | OSS     | 12    | 5-point ordinal scale (0-48)   |
| Shoulder Pain And Disability Index, Pain subscale (26, 27)  | SPADI   | 5     | Visual analogue pain scale or 10-point ordinal scale (0-100)   |
| Shoulder Pain Score (28)  | SPS     | 7     | Item 1-5, 4-point ordinal scale. Item 6: Visual analogue pain scale (0-100). Item 7: Categorical scale, response formats indicating degree of pain radiation |
| Physical function/activity instruments  |         |       |  |
| Penn Shoulder Score, Function subscale (29)   | Penn    | 20    | 4-point ordinal scale (0-60)   |
| L'Insalata Shoulder Rating Questionnaire, Daily activities subscale (30)                                    | SRQ     | 6*    | 5-point ordinal scale  |
| Simple Shoulder Test (31)   | SST     | 12    | Categorical with yes/no (0-12)   |
| American Shoulder and Elbow Surgeons Shoulder<br>Outcome Score, Activities of daily living subscale<br>(32) | ASES    | 10    | 4-point ordinal scale (0-40)   |
| University of California at Los Angeles Shoulder<br>Score, Function subscale (33)                           | UCLA    | 1     | Intensity or categorical (1-10)  |
| Shoulder Pain and Disability Index, Disability subscale (26, 27)  | SPADI   | 8     | Visual analogue pain scale or 10-point ordinal scale (0-100)   |
| Shoulder Function Assessment scale, Activities of daily living subscale (34)                                | SFA     | 3     | Intensity or categorical (0-20)  |

This accepted article is protected by copyright. All rights reserved.

<sup>\*</sup> Only item 6-11 were selected as candidates for the OMERACT core measurement instrument set

# Table 2: Overview of the ICF domain (chapter) structure within the sub-classifications of 'Body Functions' and 'Activities and Participation'

| Body  | Func  | ctions |
|-------|-------|--------|
| Chant | or h1 | Mont   |

Chapter b1 Mental functions

Chapter b2 Sensory functions and pain

<u>Chapter b3</u> Voice and speech functions

<u>Chapter b4</u> Functions of the cardiovascular,

haematological, immunological and respiratory systems

<u>Chapter b5</u> Functions of the digestive, metabolic and endocrine systems

<u>Chapter b6</u> Genitourinary and reproductive functions

<u>Chapter b7</u> Neuromusculoskeletal and movement-related functions

<u>Chapter b8</u> Functions of the skin and related structures

# **Activities and Participation**

Chapter d1 Learning and applying

knowledge

<u>Chapter d2</u> General tasks and demands

Chapter d3 Communication

**Chapter d4** Mobility

Chapter d5 Self-care

Chapter d6 Domestic life

<u>Chapter d7</u> Interpersonal interactions

and relationships

Chapter d8 Major life areas

<u>Chapter d9</u> Community, social and civic life

# Table 3: Overview of linked ICF categories in the six candidate instruments of the 'Pain' domain

|                              |  | VAS  | NRS   | VRS     | SPS     | SPADI pain | OSS  |
|------------------------------|--|------|-------|---------|---------|------------|------|
|                              |  | Mair | and a | ddition | al cond | cepts (I   | M/A) |
|                              |  | M/A  | M/A   | M/A     | M/A     | M/A        | M/A  |
| S                            | b1 Mental functions                          |      |       |         |         |            |      |
| <b>Body Functions</b>        | b1349 Sleep functions, unspecified           |      |       |         | 1       |            |      |
| nıc                          | b2 Sensory functions and pain                |      |       |         |         |            |      |
| <u>۲</u>                     | b2801 Pain in body part                      |      |       |         | 1       |            |      |
| þog                          | b28016 Pain in joints                        | 1    | 1     | 1       | 4 1     | 5          | 4 2  |
| _                            | b2804 Radiating pain in a segment or region  |      |       |         | 1       |            |      |
|                              | d4 Mobility                                  |      |       |         |         |            |      |
|                              | d4150 Maintaining a lying position           |      |       |         | 1       | 1          |      |
|                              | d4301 Carrying in the hands                  |      |       |         |         |            | 1    |
|                              | d4451 Pushing                                |      |       |         |         | 1          |      |
|                              | d4452 Reaching                               |      |       |         |         | 1          |      |
| _                            | d4453 Turning or twisting the hands or arms  |      |       |         |         |            | 1    |
| ţį                           | d4458 Hand and arm use, other specified      |      |       |         |         | 1          |      |
| ipa                          | d4701 Using private motorized transportation |      |       |         |         |            | 1    |
| ΞĒ                           | d4702 Using public motorized transportation  |      |       |         |         |            | 1    |
| Pa                           | d5 Self-care                                 |      |       |         |         |            |      |
| and                          | d5100 Washing body parts                     |      |       |         |         |            | 1    |
| es :                         | d5102 Drying oneself                         |      |       |         |         |            | 1    |
| Activities and Participation | d5202 Caring for hair                        |      |       |         |         |            | 1    |
| Acti                         | d5409 Dressing, unspecified                  |      |       |         |         |            | 1    |
|                              | d6 Domestic life                             |      |       |         |         |            |      |
|                              | d6200 Shopping                               |      |       |         |         |            | 1    |
|                              | d6408 Doing housework, other specified       |      |       |         |         |            | 1    |
|                              | d6409 Doing housework, unspecified           |      |       |         |         |            | 1    |
|                              | d8 Major life areas                          |      |       |         |         |            |      |
|                              | d8509 Remunerative employment, unspecified   |      |       |         |         |            | 1    |
|                              | Not definable (nd)                           |      |       |         | 1       |            | 2    |
|                              | Not covered by the ICF (nc)                  |      |       |         | 2       | 1          |      |
|                              | Sum of linked ICF categories                 | 1    | 1     | 1       | 12      | 10         | 20   |

Visiual Analogue Scale (VAS), Numerical Rating Scale (NRS), Vocal Rating Scale (VRS), Shoulder Pain Scale (SPS), Shoulder Pain and Disability Scale pain subscale (SPADI pain), Oxford Shoulder Score (OSS)

This accepted article is protected by copyright. All rights reserved.

Table 4: Overview of linked ICF categories in the seven candidate instruments of the 'Physical function/activity' domain

| )                       |   | _    |     |     | _                      |      | dis       |     |
|-------------------------|---|------|-----|-----|------------------------|------|-----------|-----|
|                         |   | Penn | SRQ | SST | ASES                   | UCLA | SPADI dis | SFA |
|                         |   | -    |     |     | •                      |      | SP/       |     |
|                         |   |      |     |     | itional concepts (M/A) |      |           |     |
| 4                       |   | M/A  | M/A | M/A | M/A                    | M/A  | M/A       | M/A |
| 7                       | b1 Mental functions                                       |      |     |     |                        |      |           |     |
| S                       | b1348 Sleep functions, other specified                    |      |     | 1   | 1                      |      |           |     |
| <u>.</u>                | b1349 Sleep functions, unspecified                        | 1    |     | 1   |                        |      |           |     |
| Body Functions          | b2 Sensory functions and pain                             |      |     |     | _                      |      |           |     |
| ₹                       | b2801 Pain in body part                                   |      |     |     | 1                      |      |           |     |
| ğ                       | b28016 Pain in joints                                     |      |     | 1 2 |                        |      |           |     |
| <u>۾</u>                | b7 Neuromusculoskeletal and movementrelated functions     |      |     |     |                        |      |           |     |
|                         | b7108 Mobility of joint functions, other specified        |      |     |     |                        |      |           |     |
|                         | b7301 Power of muscles of one limb                        |      |     |     |                        |      |           |     |
|                         | d4 Mobility   |      |     |     |                        |      |           |     |
|                         | d4300 Lifting   |      | 1   | 2   | 1                      |      |           |     |
|                         | d4301 Carrying in the hands                               | 2    | 1   | 1   |                        |      |           |     |
|                         | d4302 Carrying in the arms                                |      |     |     |                        |      | 1         |     |
|                         | d4452 Reaching  |      | 1   |     | 1                      |      |           |     |
|                         | d4454 Throwing  | 1    |     | 2   | 1                      |      |           |     |
|                         | d4458 Hand and arm use, other specified                   | 8    |     | 2   |                        |      | 2         |     |
| 7                       | d4459 Hand and arm use, unspecified                       |      |     | 1   |                        | 2    |           |     |
|                         | d4751 Driving motorized vehicles                          |      |     |     |                        | 1    |           |     |
|                         | d4759 Driving, unspecified                                |      | 1   |     |                        |      |           |     |
|                         | d5 Self-care  |      |     |     |                        |      |           |     |
| Y                       | d5100 Washing body parts                                  | 2    | 1   | 1   | 1                      | 1    | 2         | 1   |
| _                       | d5109 Washing oneself, unspecified                        |      | 1   |     |                        |      |           |     |
| 5                       | d5202 Caring for hair                                     | 1    | 1   |     | 1                      |      |           | 1   |
| ğ                       | d5308 Toileting, other specified                          |      |     |     | 1                      |      |           |     |
| ities and Participation | d5309 Toileting, unspecified                              | 1    |     |     |                        |      |           | 1   |
| T.                      | d5400 Putting on clothes                                  | 1 1  | 1   | 1   | 1                      | 1    | 3         |     |
| ב<br>ב                  | d5401 Taking off clothes                                  | 1    | 1   |     |                        |      |           |     |
| es s                    | d5409 Dressing, unspecified                               | 1    | 1   |     | 1                      |      |           | 1   |
| `                       | d599 Self-care, unspecified                               |      | 1   |     |                        |      |           |     |
| Acti                    | d6 Domestic life  |      |     |     |                        |      |           |     |
| ◂                       | d6200 Shopping  |      |     |     |                        | 1    |           |     |
|                         | d6309 Preparing meals, unspecified                        | 1    |     |     |                        |      |           |     |
|                         | d6400 Washing and drying clothes and garments             | 1    |     |     |                        |      |           |     |
|                         | d6402 Cleaning living area                                | 1    |     |     |                        |      |           |     |
|                         | d6409 Doing housework, unspecified                        | 1    |     |     |                        |      |           |     |
|                         | d649 Household tasks, other specified and unspecified     | 1    | 1   |     |                        | 2    |           |     |
|                         | d699 Domestic life, unspecified                           |      | 1   |     |                        |      |           |     |
|                         | d8 Major life areas                                       |      |     |     |                        |      |           |     |
|                         | d8509 Remunerative employment, unspecified                | 1    |     | 1   |                        |      |           |     |
|                         | d859 Work and employment, other specified and unspecified |      |     |     | 1                      |      |           |     |
|                         | d9 Community, social and civic life                       |      |     |     |                        |      |           |     |
|                         | d9201 Sports  |      |     |     | 1                      |      |           |     |
| _                       | d9204 Hobbies   | 2    |     |     |                        |      |           |     |
|                         | Not definable (nd)  |      |     |     |                        | 3    |           | 1   |
|                         | Not covered by the ICF (nc)                               | 10   |     | 2   |                        |      |           |     |
|                         | Sum of linked ICF categories                              | 38   | 13  | 18  | 12                     | 11   | 8         | 5   |

Penn Shoulder Score function subscale (Penn), L'Insalata Shoulder Rating Questionnaire daily activities subscale (SRQ), Simple Shoulder Test (SST), American Shoulder and Elbow Surgeons Shoulder Outcome Score activities of daily living subscale (ASES), University of California at Los Angeles Shoulder Score function subscale (UCLA), Shoulder Pain and Disability Index disability subscale (SPADI dis), Shoulder Function Assessment scale activities of daily living subscale (SFA)