

Supplementary File 4: Feedback report for round two participants

**Development of a core outcome measurement set for clinical trials  
of shoulder conditions**

**Responses to the 1<sup>st</sup> Round of the Delphi study**

**Table 1. Characteristics of participants**

<b>Characteristic</b>	<b>Number (%)<sup>a</sup></b>
<b><i>General characteristics</i></b>	
<b><i>n = 91</i></b>	
Gender	
Male	42 (46)
Female	49 (54)
Age	
Median (IQR)	51 (40-58)
Highest education	
Postgraduate degree (MSc, PhD)	56 (62)
Graduated from College/University	18 (20)
Graduated from High School	10 (11)
Graduated from Primary School	1 (1)
Other	6 (7)
Stakeholder group	
Health care provider	19 (21)
Health care researcher	13 (14)
Health care provider and researcher	18 (20)
Patient	41 (45)
<b><i>Clinician/scientist characteristics</i></b>	
<b><i>n = 50</i></b>	
Country of work	
United Kingdom	11 (22)
The Netherlands	8 (16)
Australia	7 (14)
USA	7 (14)
Canada	6 (12)
Sweden	2 (4)
Ireland	2 (4)
Turkey	2 (4)

<b>Characteristic</b>	<b>Number (%)<sup>a</sup></b>
Brazil	1 (2)
Finland	1 (2)
Germany	1 (2)
Italy	1 (2)
Norway	1 (2)
Field of work	
Orthopaedics	17 (34)
Physiotherapy	15 (30)
Rheumatology	5 (10)
Epidemiology	4 (8)
General practice/family medicine	3 (6)
Other (emergency medicine, physical medicine and rehabilitation)	6 (12)
Have conducted at least one clinical trial for shoulder conditions	40 (80)
Median (IQR) number of clinical trials	3 (2-6)
Have conducted at least one systematic review for shoulder conditions	23 (46)
Median (IQR) number of systematic reviews	2 (1-6)
Have conducted at least one study to develop or test a measurement instrument for shoulder conditions	15 (30)
Median (IQR) number of measurement instrument studies	3 (2-5)
Have participated in the development of a core outcome set	20 (40)
Median (IQR) number of core outcome set studies	2 (1-3)
<b><i>Patient characteristics</i></b>	<b><i>n= 41</i></b>
<i>Country of residence</i>	
USA	18 (44)
United Kingdom	6 (15)
The Netherlands	4 (10)
Austria	3 (7)
Australia	2 (5)
Germany	2 (5)
Other (Belgium, Canada, Poland, Slovakia)	4 (10)
<i>Shoulder disorder history</i>	
Have sought health care for a shoulder disorder at least once	36 (88)
Currently have a shoulder disorder	27 (66)
<i>Duration of current shoulder disorder</i>	
Less than 6 weeks	2 (7) <sup>a</sup>
Between 6 and 12 weeks	3 (11) <sup>a</sup>
More than 3 months	15 (56) <sup>a</sup>
Not stated	7 (26) <sup>a</sup>

<sup>a</sup>Denominator is the number of patients who currently have a shoulder disorder (n=27)

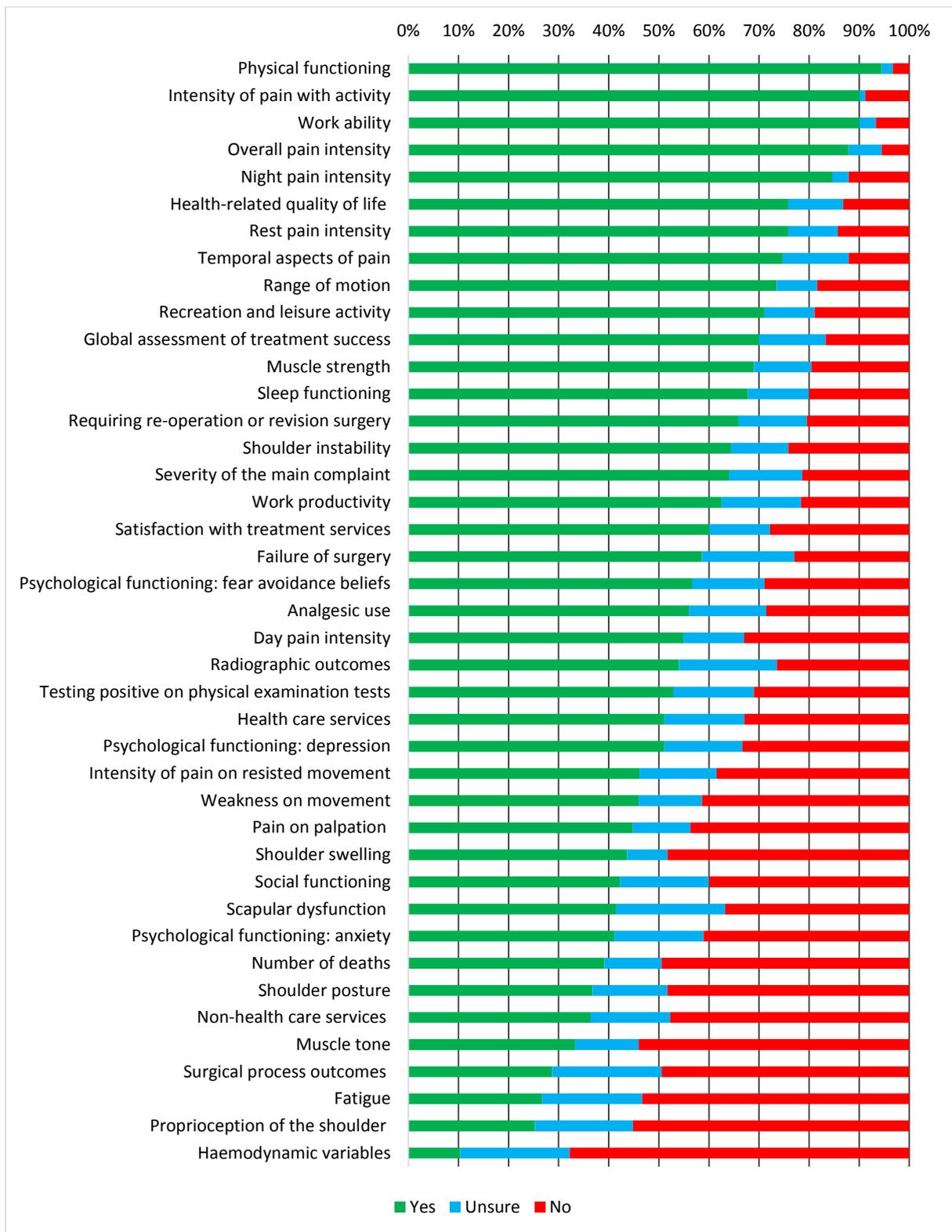


Figure 1. Ratings by total panel (n=91) of potential core domains in the first Delphi round

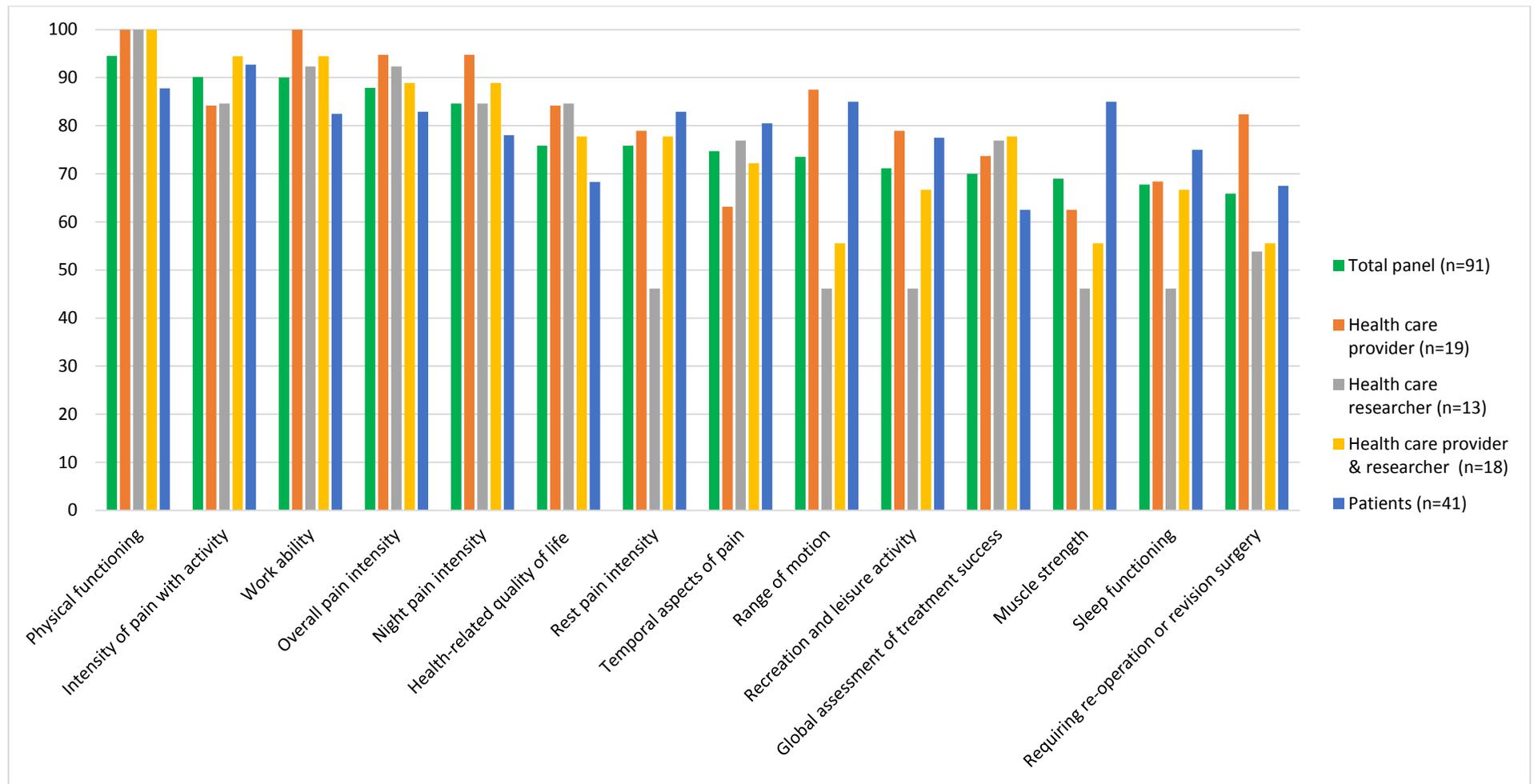


Fig 2. Ratings of core domains stratified by stakeholder group (top 14 ranked domains). The percentage of people rating a domain as important to include is presented.

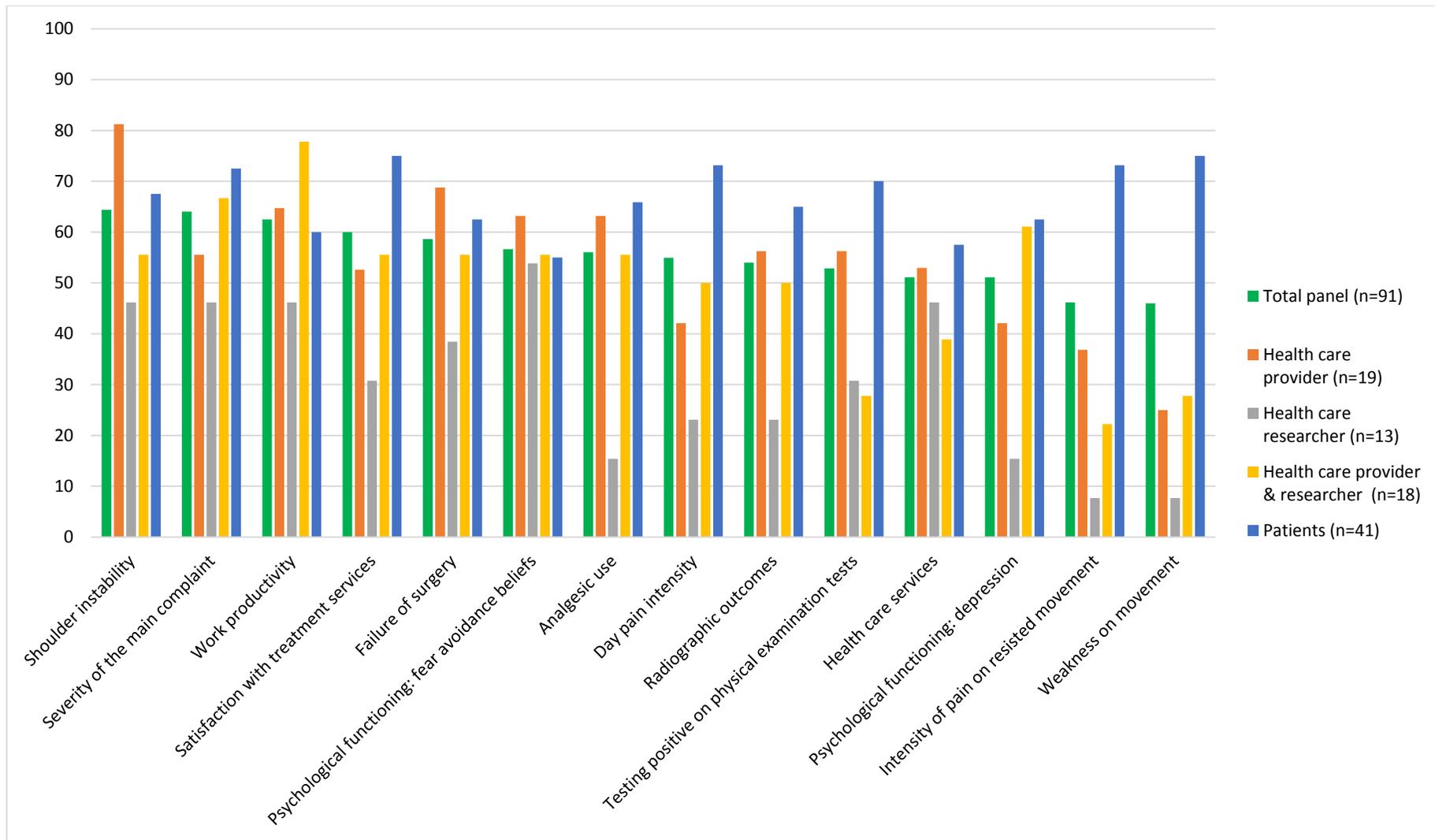


Fig 3. Ratings of core domains stratified by stakeholder group (middle 14 ranked domains). The percentage of people rating a domain as important to include is presented.

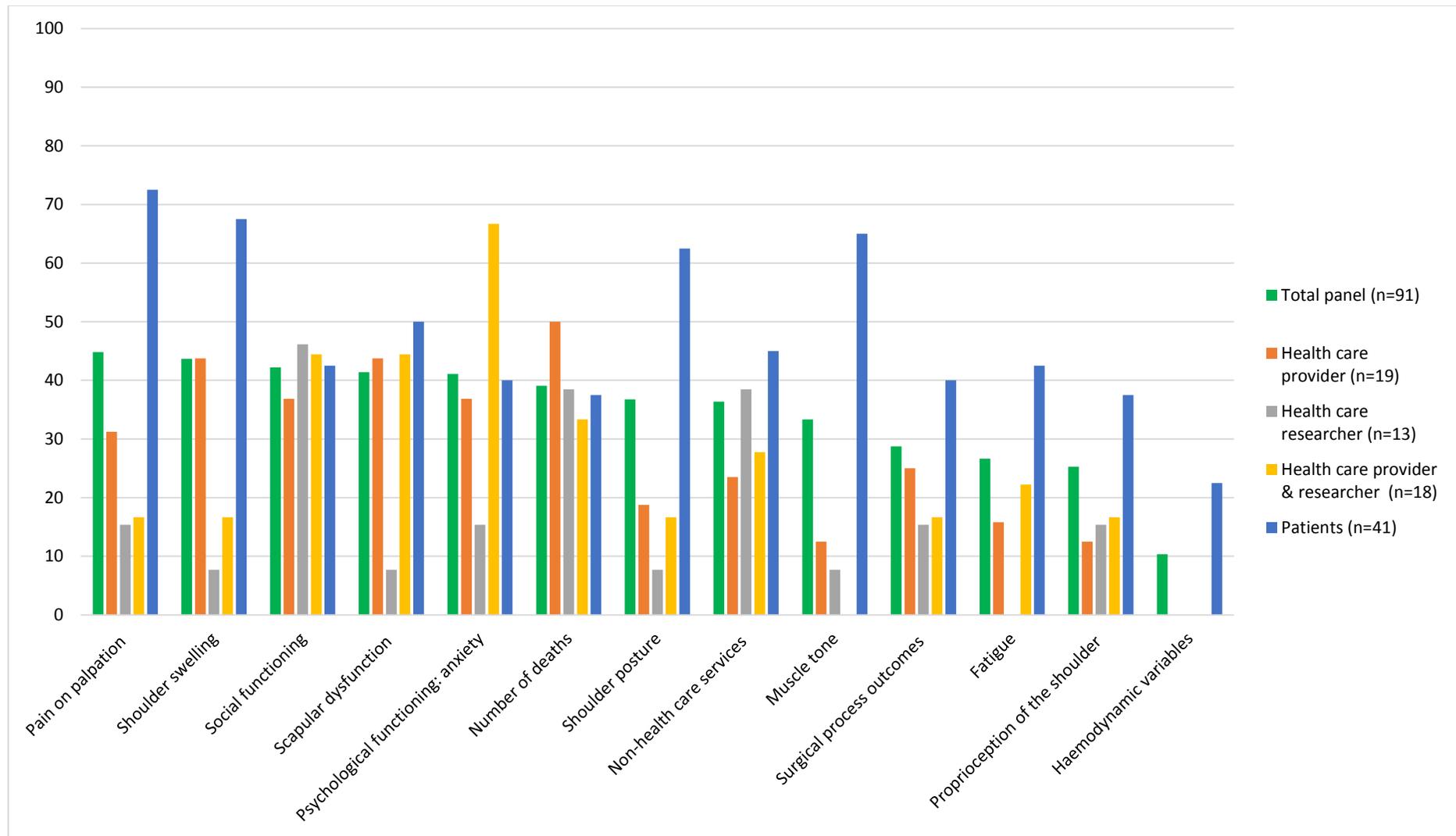


Fig 4. Ratings of core domains stratified by stakeholder group (bottom 13 ranked domains). The percentage of people rating a domain as important to include is presented.

Based on comments from respondents, the Steering Group considered the following domains as not important to include in a core domain set for **all** trials of shoulder conditions, as they are only applicable to certain trials (e.g. surgical trials).

- **Require re-operation or revision surgery**, defined as the utilization of additional surgical procedures following the failure of the first attempt. The Steering Group considered it potentially important to measure this domain only in trials of surgical interventions.
- **Radiographic outcomes**, defined as any measure of the structure of the bones/joints/tendons measured via imaging (e.g. x-ray, MRI or ultrasound to measure anterior subluxations, acromiohumeral distance reduction success, tendon thickness). The Steering Group considered it potentially important to measure this domain only in trials of particular interventions or conditions (e.g. full thickness rotator cuff tear).
- **Failure of surgery**, defined as the failure of the surgery to correct a specific structural problem (e.g. malunion of a fracture after surgery). The Steering Group considered it potentially important to measure this domain only in trials of surgical interventions.
- **Surgical process outcomes**, defined as measures of the implementation of a surgical intervention (e.g. length of time of the surgery, reduction manoeuvre time, number of reduction attempts). The Steering Group considered it potentially important to measure this domain only in trials of surgical interventions.
- **Severity of the main complaint**, defined as an unavoidable painful or limited functional activity during daily life in which the shoulder is chiefly involved. It is a person-specific individualized approach for measuring limitation of shoulder function during daily activities. The Steering Group considered it potentially important to measure this domain only in the clinical setting or in pragmatic trials (which reflect real world settings rather than highly controlled experimental environments).
- **Shoulder instability**, defined as the loosening of connective tissue surrounding the shoulder joint which enables the bones forming the joint to move excessively on each other. In some cases the upper arm bone (humerus) may move partially or completely out of the socket during certain arm movements (i.e. subluxation or dislocation). The Steering Group considered it potentially important to measure this domain only in trials of people with a diagnosis of shoulder instability.

The following domains did **not** meet our pre-specified cut-point for inclusion in the core domain set. Moreover, no substantial arguments were presented for the inclusion of these domains.

- **Testing positive on physical examination tests**, defined as in some clinical trials, tests are used for diagnostic purposes to decide if the person is eligible for the trial (e.g. 'painful arc test' or 'Neer impingement test' or 'empty can test' for rotator cuff disease; 'apprehension test' or 'relocation test' for shoulder instability). In some trials, these examinations are repeated post-treatment to assess whether or not the test is still positive, which suggests that the shoulder condition is still present. An example of an examination is presented here: [http://www.physio-pedia.com/Painful\\_Arc](http://www.physio-pedia.com/Painful_Arc)
- **Social functioning**, defined as a person's ability to interact with people in a contextually and socially appropriate manner (e.g. showing consideration and esteem when appropriate, responding to the feeling of others), to create and maintain close relationships with others (excluding members of the family), to engage in desired aspects of community social life (e.g. charitable organizations, service clubs or professional social organizations)
- **Health care services**, defined as utilization of health care services within the formal health care system for treating shoulder conditions, including: visits, laboratory tests, imaging, days of admission to a hospital, medications
- **Non-health care services**, defined as utilization of health care services not included in the formal health care system for treating shoulder conditions, including for example: visits to professionals of alternative medicine, over-the-counter medications, patient's time and travel expenses
- **Satisfaction with treatment services**, defined as a person's satisfaction with care received, including treatment and care providers
- **Weakness on movement**, defined as the person's sense that more effort than normal is required to move the shoulder
- **Pain on palpation**, defined as pain following palpation of muscle, tendon and bony prominences of the shoulder region, where patients are instructed to say 'yes' at the moment when they start to feel pain or discomfort
- **Shoulder swelling**, defined as abnormal enlargement of an area of the shoulder that is caused by accumulation of fluid in the shoulder joint
- **Scapular dysfunction**, defined as problems with rotating the scapular (the two wing shaped bones on the upper back) or poor motor control of the scapular
- **Shoulder posture**, defined as the position in which the shoulder is held upright against gravity while standing, sitting or lying down. Good posture places the least strain on supporting muscles and ligaments during movement

- **Muscle tone**, defined as a slight tension or firmness present in the resting muscles (i.e. a slight resistance offered when trying to move them passively) of the shoulder and/or of other adjacent body parts
- **Fatigue**, defined as ranging from mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that it is likely to decrease one's ability to carry out daily activities (including work activities) and to function at one's usual levels in family or social roles
- **Proprioception of the shoulder**, defined as the person's sense of the position and movement of the shoulder and/or of other adjacent body parts
- **Haemodynamic variables**, defined as any measure of blood flow, such as blood pressure or heart rate. Such outcomes are sometimes measured in trials of surgical interventions for shoulder conditions

### **Adverse events**

We asked participants about different approaches to measuring adverse events. There was support for the OMERACT recommendation that a measured adverse event would only be defined as an adverse event if it belongs to a different domain than one of the core domains (only 16% disagreed with this approach). Considerations noted repeatedly by respondents were that there should be a distinction between serious and non-serious adverse events, and that the severity of adverse events should be recorded. Following OMERACT guidance and respondents' suggestions, we will recommend that adverse events be measured in all trials of shoulder conditions.