












## PAIN

## A core outcome set of measurement instruments for assessing effectiveness and efficacy of perioperative pain management: results of the international IMI-PainCare PROMPT Delphi consensus process<sup>☆</sup>

Esther M. Pogatzki-Zahn<sup>1,\*</sup>, Sarah De Lucia<sup>1</sup>, Claudia Weinmann<sup>2</sup>, Hauke Heitkamp<sup>1</sup>, Lone Hummelshoj<sup>3</sup>, Hiltrud Liedgens<sup>4</sup>, Winfried Meissner<sup>2</sup>, Katy Vincent<sup>5</sup>, Jan Vollert<sup>1,6</sup>, Peter Zahn<sup>7</sup>, the IMI-PainCare PROMPT Consensus Panel<sup>†</sup>, Ulrike Kaiser<sup>8</sup> and Daniela C. Rosenberger<sup>1</sup>

<sup>1</sup>Department of Anesthesiology, Intensive Care and Pain Medicine, University Hospital Muenster, Muenster, Germany, <sup>2</sup>Department of Anesthesiology and Intensive Care Medicine, Jena University Hospital, Friedrich Schiller University Jena, Germany, <sup>3</sup>Endometriosis.org, London, UK, <sup>4</sup>Grunenthal GmbH, Aachen, Germany, <sup>5</sup>Nuffield Department of Women's and Reproductive Health, University of Oxford, Oxford, UK, <sup>6</sup>Department of Clinical and Biomedical Sciences, Faculty of Health and Life Sciences, University of Exeter, Exeter, UK, <sup>7</sup>Department of Anesthesiology, Intensive Care Medicine, and Pain Management, Berufsgenossenschaftliches Universitätsklinikum Bergmannsheil GmbH Bochum, Ruhr University Bochum, Bochum, Germany and <sup>8</sup>University Hospital Schleswig-Holstein, Campus Luebeck, Germany

\*Corresponding author. E-mail: [pogatzki@anit.uni-muenster.de](mailto:pogatzki@anit.uni-muenster.de)

<sup>†</sup>The full list of collaborator names appears in [Appendix 1](#).

<sup>☆</sup>Preliminary results have been presented as a poster during the IASP World Congress on Pain 2024 in Amsterdam, the Netherlands.

### Abstract

**Background:** Effective perioperative pain management is crucial to prevent patient suffering, delayed recovery, chronic postsurgical pain, and long-term opioid use. However, the heterogeneous use of outcomes in studies complicates evidence synthesis and might not accurately reflect the experiences of individual patients. We initiated a consensus process to establish a core outcome set (COS) of patient-reported outcome measures (PROMs) in postoperative pain, building upon the earlier consensus on a COS of domains.

**Methods:** Potential PROMs were identified via systematic literature searches for the domains pain intensity (with sub-domains at rest and during activity), physical function, self-efficacy, and adverse events, followed by appraisal of psychometric properties according to the CONsensus-based Standards for the selection of health Measurement INstruments methodology. Then, a consensus meeting was convened, followed by a Delphi process with an international, multi-professional panel of stakeholders, including those with lived experience. A conclusive consensus meeting approved the final COS of PROMs.

**Results:** The final COS consists of one unidimensional numerical rating scale for assessing pain intensity on average, worst pain intensity, pain intensity at rest, and procedure-specific pain intensity during activity; one unidimensional scale for pain interfering with activities in bed; one procedure-specific scale for assessing physical function; the IMI-PainCare PROMPT adaptation of the Arthritis Self-Efficacy Scale for assessing self-efficacy; and the IMI-PainCare PROMPT adaptation of the Opioid-Related Symptom Distress Scale for assessing adverse events.

**Conclusions:** Comprehensive use of a core outcome set will help harmonise outcome assessment, facilitate comparisons between studies, promote patient-centred research, and improve postoperative pain care.

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**Keywords:** consensus process; core outcome set; Delphi approach; patient-reported outcome measure; postoperative pain; psychometric properties; questionnaire

### Editor's key points

- Use of heterogeneous outcomes in studies of perioperative pain management complicates evidence synthesis and might not accurately reflect the experiences of individual patients.
- A consensus process was performed to establish a core outcome set of patient-reported outcome measures (PROMs) in postoperative pain following systematic reviews.
- The IMI-PainCare PROMPT core outcome set of PROMs for assessing the effectiveness and efficacy of perioperative pain management enables a comprehensive assessment of postoperative pain beyond common pain intensity scales.
- Comprehensive use of this core outcome set will help harmonise outcome assessments, facilitate comparisons between studies, promote patient-centred research, and improve postoperative pain care.

Effective perioperative pain management is crucial to prevent patient suffering, delayed recovery, chronic postsurgical pain (CPSP), and long-term opioid use. Despite numerous trials attempting its improvement, acute postoperative pain management remains far from satisfactory, with inadequate outcome assessments in both clinical trials and practice identified as key contributors to this failure.<sup>1–4</sup> Reliance on pain intensity as the sole outcome in clinical practice, or the failure to assess pain at all, has been shown as one major risk of excessive and long-term opioid prescriptions.<sup>5–7</sup> Poorly defined outcome assessment in clinical trials (e.g. pain at rest vs during activity<sup>8</sup>) leads to misinterpretation of study results. This, together with pain intensity as the only outcome assessed, hinders identification of effective treatment options targeting pain-related outcomes critical to patient recovery.<sup>9–13</sup>

To harmonise outcome assessment for postoperative pain, the international Innovative Medicines Initiative (IMI)-PainCare launched the Providing Standardized Consented PROMs for Improving Pain Treatment (PROMPT) project to establish a core outcome set (COS) of patient-reported outcome measures (PROMs) for assessing effectiveness in clinical practice and efficacy in clinical studies related to acute perioperative pain (<https://www.imi-paincare.eu/PROJECT/PROMPT/>).<sup>14</sup> Core outcome sets are consensus-driven sets of minimal outcomes to be included in clinical trials and practice to improve data harmonisation, enhance the robustness and generalisability of study results, facilitate systematic reviews and meta-analyses, and reduce the risk of bias.<sup>15–19</sup> Defining the minimal yet most relevant outcome domains ensures the collection of essential data while reducing patient burden, with optional additional outcomes.<sup>17,19</sup> As recommended by Core Outcome Measures in Effectiveness Trials (COMET),

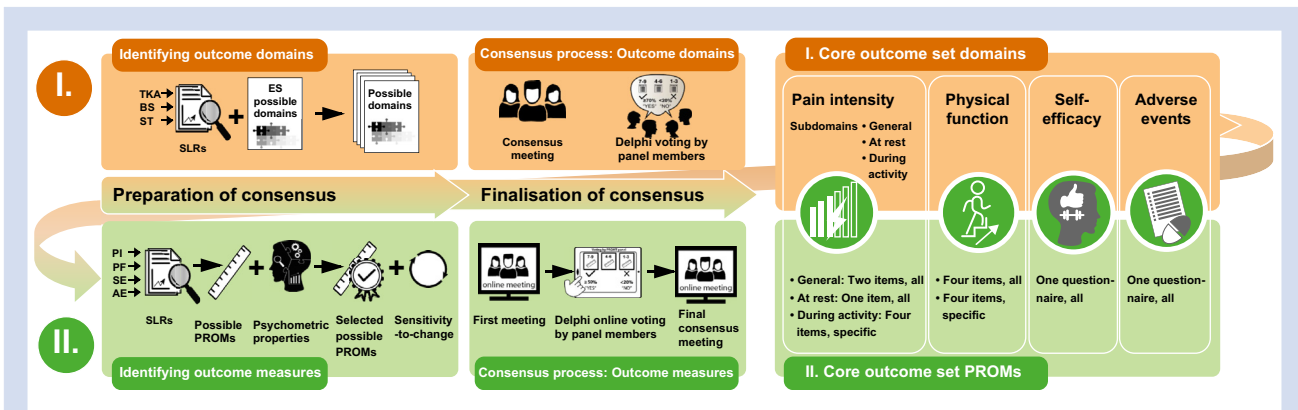
developing a COS begins with achieving consensus on the domains ('what to assess') and is completed by identifying corresponding outcome measurement instruments ('how to measure'), such as PROMs.<sup>18–20</sup>

The IMI-PainCare PROMPT project is initiated by identifying a COS of four domains (with subdomains) considered most important for assessing the effectiveness and efficacy of postoperative pain management: pain intensity (with the subdomains pain intensity in general, at rest, and during activity), physical function (for a condition-specific measurement), self-efficacy, and adverse events.<sup>21</sup> This consensus-driven approach involved a diverse, international group of stakeholders, including individuals with lived experience of pain. The next step is to identify suitable PROMs for each domain to ensure appropriate assessment.<sup>17,19</sup> Inclusion of PROMs in a COS requires high psychometric quality, based on criteria such as content validity, reliability, sensitivity to change, and feasibility.<sup>20</sup> Recommendations for a stepwise process have been outlined by the joint COMET and COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative.<sup>18,22</sup>

The primary aim of the present study was to complete the IMI-PainCare PROMPT COS by identifying corresponding PROMs for its domains through systematic literature searches, critical evaluation of identified PROMs based on current recommendations, and a consensus process including a Delphi approach, leading to a COS of PROMs for adult patients undergoing surgery and receiving perioperative pain management, intended for use in clinical practice and research trials.

## Methods

The rationale and framework of the COS initiative, part of the EU-funded IMI-PainCare PROMPT project, were designed following COMET recommendations for COS development and the COSMIN methodology for evaluating PROMs for a COS<sup>18–20,22</sup> and reported according to Core Outcome Set -STAndards for Reporting (COS-STAR) guidelines.<sup>23</sup> The protocol for developing this COS was registered in the COMET database (<https://www.comet-initiative.org/Studies/Details/1731>) and published in detail before commencing all associated studies.<sup>14</sup> Building on the initial consensus process (Fig. 1, I. COS of domains), which established a COS of domains for evaluation of perioperative pain management across clinical trials, observational studies, and clinical practice,<sup>21</sup> this study focused on developing a COS of PROMS for the four domains. The stepwise process (Fig. 1, II. COS of PROMs) included the following: (1) systematic identification of potential PROMs by the IMI-PainCare PROMPT project steering committee, (2) extensive evaluation of their psychometric properties following COSMIN and COMET recommendations, and (3) a consensus process using a Delphi approach with an international, multiprofessional stakeholder panel, including persons with lived experience (PWLE).



**Fig 1.** Overall study design of the IMI-PainCare PROMPT development process for a core outcome set (COS) of patient-reported outcome measures (PROMs) for the assessment of acute postoperative pain in adults. The COS process began with developing a COS of domains (I, in orange),<sup>21</sup> followed by the development of a COS of PROMs (II, in green; this study). (I) Following SLRs on domains assessed in clinical postoperative pain, the IMI-PainCare PROMPT consensus panel consented on a COS of domains comprising four overarching outcome domains<sup>21</sup>: pain intensity with the subdomains ‘in general’, ‘at rest’, and ‘during activity’; physical function; adverse events; and self-efficacy. (II) Subsequently, SLRs were conducted to identify PROMs potentially suitable to assess pain intensity (in general, at rest, and during activity), physical function (physical function after TKA<sup>11</sup>), adverse events, and self-efficacy after surgery. The identified instruments were evaluated following COSMIN recommendations (e.g. regarding content validity assessment of scales). Sensitivity-to-change analysis of preselected PROMs was carried out in a prospective multicentre trial.<sup>3</sup> Results of these analyses were presented to the IMI-PainCare PROMPT consensus panel in an online meeting, followed by an online Delphi process and a concluding consensus meeting. Finally, a COS of PROMs was recommended for assessing effectiveness and efficacy of perioperative pain management. Similar to the process on domains, representative types of surgery were selected: BS, ST, TKA, and ES. The reasoning behind choosing these four types of surgery is detailed in a previous publication.<sup>3,21</sup> AE, adverse event; BS, breast surgery; COS, core outcome set; ES, surgery related to endometriosis; NIT- 1, non-interventional trial 1; PF, physical function; PI, pain intensity; PROM, patient-reported outcome measure; PROMPT, PROMs for postoperative pain treatment; SE, self-efficacy; SLR, systematic literature search; ST, sternotomy; TKA, total knee arthroplasty.

### Identification and evaluation of possible PROMs

Systematic literature reviews (SLRs) were conducted to identify potential PROMs for the predefined COS of domains,<sup>21</sup> followed by appraisal of psychometric properties according to the COSMIN methodology.<sup>18–20,22</sup> The methods for SLRs are detailed in [Supplementary material S1](#), including PRISMA flow charts ([Supplementary Figs S1–S7](#)) and PICOS criteria ([Supplementary Tables S1–S7](#)). The methods for evaluating the psychometric properties of all PROMs suggested for inclusion in the Delphi process are detailed in [Supplementary material S1](#), Chapter S2.1.

### Consensus process including Delphi voting

The methods of the Delphi process adhered to the ethical principles of the Declaration of Helsinki and Good Epidemiological Practice. The planned consensus process was submitted to the Ethics Committees of Dresden and Muenster, who determined that IRB approval and, consequently, obtaining informed consent, were unnecessary (EK 261052019; 2019-151-b-S, amended 26.08.2022).

### IMI-PainCare-PROMPT consensus panel

The PROMPT consensus panel consisted of 40 members, including clinicians, researchers, and stakeholders from pharmaceutical companies, health technology assessment agencies, regulatory bodies, and PWLE, treated equally alongside the experts. Four members were invited per stakeholder

group, including those with lived experience. Details on the panel composition and recruitment process are provided in [Supplementary material S1](#), Chapter S3.1, and in our previous publication.<sup>2,21</sup>

Thirty-nine panel members agreed to participate in the IMI-PainCare PROMPT Delphi consensus process on PROMs, with 36 voting in any of the Delphi rounds. A total of 33 participants voted in round 1 (including four PWLE), 31 voted in round 2 (including three PWLE), and 33 (including three PWLE) attended the final consensus meeting. Participant characteristics, including age, sex, experience with consensus processes, profession, and other variables, are presented in [Table 1](#).

### Initial consensus meeting and supporting materials

To facilitate informed decision-making from the beginning, an initial meeting was held (November 2, 2022). Supporting information materials were disseminated, providing comprehensive details on the aim, scope, Delphi methodology, relevant terminology (notably the concept of PROMs), specified domains and subdomains, and information about the candidate PROMs derived from the SLRs, covering content validity and sensitivity to change,<sup>3</sup> aligned with COSMIN recommendations for evaluating PROMs<sup>18</sup> ([Supplementary material S1](#), Chapters S1.1–S1.4 and S2.1–S2.3).

### Delphi voting process

During an anonymous online survey conducted via a REDCap interface<sup>24</sup> hosted by the University of Muenster, stakeholders

**Table 1** Participant characteristics. Self-reported participant characteristics and classifications for voters in the Delphi process: HP, including PR, HCP, and HTA, and PWLE\*. Total counts can be less than actual *n* because voters were not required to answer all participant characteristic questions. HCP, clinicians/healthcare professionals; HP, healthcare professionals; HTA, healthcare technology assessment experts; PR, pain researchers; PWLE, persons with lived experience of pain. \*We retained the abbreviation 'PWLE' for the tables to facilitate readability and because it is commonly used in publication including patient representatives; however, upon request from participating individuals who have experienced pain, we refer to them as 'those with lived experience' throughout the text. †Previous round: For the first round, this question refers to the previous Delphi process on domains.<sup>21</sup> ‡Although experts were invited to represent specific roles, many of them held multiple positions, such as being both clinicians and researchers or anaesthesiologists and pain specialists.

	Round 1			Round 2		
	Overall (n=33)	HP (n=29)	PWLE (n=4)	Overall (n=31)	HP (n=28)	PWLE (n=3)
<b>Sex</b>						
Female	15	11	4	15	12	3
Male	17	17	0	16	16	0
Unknown	0	0	0	0	0	0
Prefer not to answer	1	1	0	1	1	0
Other	0	0	0	0	0	0
<b>Voted in previous round<sup>†</sup></b>						
Yes	22	19	3	28	25	3
No	9	8	1	4	4	0
Do not remember	2	2	0	0	0	0
<b>Invited as<sup>‡</sup></b>						
PR	17	17	0	19	18	0
HCP	8	8	0	7	7	0
HTA	2	2	0	3	3	0
<b>Professions (self-reported)<sup>‡</sup></b>						
Anaesthesiologists	8			7		
Pain specialists	7			4		
Surgeons	2			3		
Physiotherapist	3			4		
Nurses	4			2		
Psychologists	3			4		
Gynaecologists	0			1		
Health economists	1			1		
Neurologists	0			1		
Clinical development scientist	0			1		
Clinical researcher	1			1		
Preclinical scientist	1			0		
PWLE	4	0	4	3	0	3
Other	2	2	0	0	0	0
<b>Years of clinical experience</b>						
<1	5	7	4	8	5	3
1–5	6	2	0	2	2	0
6–10	5	3	0	2	2	0
>10	16	16	0	19	19	0
<b>Years of research experience</b>						
<1	1	0	1	1	0	1
1–5	2	1	1	1	1	0
6–10	5	4	1	4	4	0
>10	25	24	1	26	24	2
<b>Years of COS experience</b>						
None	4	4	0	2	2	0
<1	1	1	0	3	3	0
1–5	6	4	2	5	4	1
6–10	5	5	0	6	6	0
>10	16	14	2	16	14	2
<b>Region of residence</b>						
Belgium	3	3	0	2	2	0
France	1	1	0	1	1	0
Germany	11	5	2	8	7	1
Greece	1	1	0	1	0	0
Iceland	1	1	0	0	0	0
The Netherlands	3	3	0	2	2	0
New Zealand	0	0	0	1	1	0
UK	4	2	2	5	4	1

**Table 2** Results of Delphi round voting. Overall voting results of both rounds (in % of panel members participating) for considering the specific PROMs as appropriate (7–9) for all panel members (All), for health professionals (HPs; i.e. HTA specialists, researchers, and clinicians) and those with lived experience (PWLE). Type of surgery: breast surgery (BS), sternotomy (ST), total knee arthroplasty (TKA), and endometriosis-related surgery (ES), all procedures (All). PROMs: physical functioning: BBUSQ-22, Birmingham Bowel and Urinary Symptoms Questionnaire; DASH, Disabilities of the Arm, Shoulder and Hand; FDQ, Functional Difficulties Questionnaire; OKS, Oxford Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index. Self-efficacy: ASES, Arthritis Self-Efficacy Scale; ASES-8, Arthritis Self-Efficacy Scale- Short Form; K-SES, Knee Self-Efficacy Scale; RASE, Rheumatoid Arthritis Self-Efficacy Scale; ASES IMI-PainCare PROMPT adaptation. Adverse event: OR-SDS, Opioid Related Symptom Distress Scale. \*POD1 (for POD3 and all later time points ‘since your surgery’ are replaced with ‘during the last 24 h’).

(a) Results for the pain intensity domain				
Instrument	Type of surgery	Voted ‘appropriate’ (7–9)		
		All	HP	PWLE
<b>Round 1: pain intensity domain</b>				
How intense is your pain currently while <b>taking a deep breath?</b>	ST	84.85	82.76	100.00
How intense is your pain currently <b>at rest</b> while lying in bed?	All	81.82	82.76	75.00
How intense is your pain currently while <b>bending</b> your operated knee?	TKA	81.82	82.76	75.00
How intense was your pain <b>on average</b> during the last 24 h?	All	75.76	75.86	75.00
How intense is your pain currently while <b>lifting</b> your extended arm sideways on the operated side?	BS	75.76	75.86	75.00
How intense is your pain currently while changing from the lying position to <b>sitting upright?</b>	ES	75.76	75.86	75.00
How intense was your <b>worst pain</b> experienced during the last 24 h?	All	69.70	68.97	75.00
How intense was your worst pain while doing <b>physiotherapy?</b>	TKA	63.64	65.52	50.00
How intense was your worst pain while doing <b>physiotherapy?</b>	BS	60.61	62.07	50.00
How intense was your worst pain while doing <b>physiotherapy?</b>	ST	57.58	55.17	75.00
How intense was your worst pain while doing <b>physiotherapy?</b>	ES	51.52	51.72	50.00
<b>Round 2: pain intensity domain</b>				
How intense is your pain currently while <b>taking a deep breath?</b>	ST	96.77	96.43	100
How intense is your pain currently while <b>bending</b> your operated knee?	TKA	93.55	92.86	100
How intense is your pain currently while <b>lifting</b> your extended arm sideways on the operated side?	BS	90.32	89.29	100
How intense is your pain currently <b>at rest</b> while lying in bed?	All	87.10	85.71	100
How intense is your pain currently while changing from the lying position to <b>sitting upright?</b>	ES	87.10	85.71	100
How intense was your pain <b>on average</b> during the last 24 h?	All	83.87	82.14	100
How intense was your <b>worst pain</b> experienced during the last 24 h?	All	83.87	85.71	66.67
How intense was your worst pain while doing <b>physiotherapy?</b>	TKA	54.84	53.57	66.67
How intense was your worst pain while doing <b>physiotherapy?</b>	BS	48.39	46.43	66.67
How intense was your worst pain while doing <b>physiotherapy?</b>	ST	48.39	46.43	66.67
How intense was your worst pain while doing <b>physiotherapy?</b>	ES	41.94	39.29	66.67
<b>(b) Results for the physical function domain</b>				
Instrument	Type of surgery	Voted ‘appropriate’ (7–9)		
		All	HP	PWLE
<b>Round 1: physical function domain</b>				
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>deep breathing:</b>	ST	84.85	86.21	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>lifting your extended arm sideways on the operated side:</b>	BS	84.85	82.76	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	TKA	78.79	75.86	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>bending your knee:</b>	TKA	78.79	75.86	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	ES	72.73	72.41	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	ST	69.70	68.97	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	BS	69.70	68.97	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>changing from the lying position to sitting upright:</b>	ES	69.70	68.97	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	TKA	66.67	65.52	75.00
<b>WOMAC</b>	TKA	57.58	58.62	50.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	ST	54.55	51.72	75.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	BS	54.55	55.17	50.00
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	ES	51.52	51.72	50.00
<b>OKS</b>	TKA	48.48	48.28	50.00
<b>FDQ</b>	ST	39.39	41.38	25.00
<b>DASH</b>	BS	39.39	37.93	50.00
<b>BBUSQ-22</b>	ES	15.15	13.79	25.00
<b>Round 2: physical function domain</b>				
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>deep breathing:</b>	ST	93.55	92.86	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>lifting your extended arm sideways on the operated side:</b>	BS	83.87	82.14	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	ST	80.65	78.57	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	ES	80.65	78.57	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>bending your knee:</b>	TKA	77.42	75.00	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	TKA	74.19	75.00	66.67
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>changing from the lying position to sitting upright:</b>	ES	74.19	71.43	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing activities in bed such as turning, sitting up, and changing position:</b>	BS	67.74	64.29	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	TKA	64.52	60.71	100
Interference Items from the BPI: Circle the one number below that best describes how, during the past 24 hours, pain has interfered with your: <b>general activity/ mood/ walking ability/ normal work/ relations with other people/ sleep/ enjoyment of life</b>	TKA	61.29	57.14	100
Interference Items from the BPI: Circle the one number below that best describes how, during the past 24 hours, pain has interfered with your: <b>general activity/ mood/ walking ability/ normal work/ relations with other people/ sleep/ enjoyment of life</b>	ES	61.29	57.14	100
Interference Items from the BPI: Circle the one number below that best describes how, during the past 24 hours, pain has interfered with your: <b>general activity/ mood/ walking ability/ normal work/ relations with other people/ sleep/ enjoyment of life</b>	BS	58.06	53.57	100
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	ST	51.61	50.00	66.67
Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from <b>doing physiotherapy:</b>	BS	51.61	50.00	66.67
Interference Items from the BPI: Circle the one number below that best describes how, during the past 24 hours, pain has interfered with your: <b>general activity/mood/walking ability/normal work/relations with other people/sleep/enjoyment of life</b>	ST	51.61	46.43	100

Circle the one number below that best describes how much, since your surgery*, pain interfered with or prevented you from doing physiotherapy	ES	48.39	46.43	66.67
FDQ	THT	41.94	42.86	33.33
WOMAC	TKA	38.71	42.86	0.00
DASH	BS	38.71	39.29	33.33
OKS	TKA	29.03	28.57	33.33
BBUSQ-22	ES	16.13	14.29	33.33

**(c) Results for the self-efficacy domain**  
**Round 1: self-efficacy domain**

Instrument	Type of surgery	Voted 'appropriate' (7-9)		
		All	HP	PWLE
ASES IMI-PainCare PROMPT adaptation	TKA	41.94	41.38	50.00
ASES IMI-PainCare PROMPT adaptation	ES	41.94	41.38	50.00
ASES IMI-PainCare PROMPT adaptation	ST	41.94	41.38	50.00
ASES IMI-PainCare PROMPT adaptation	BS	35.48	34.48	50.00
K-SES	TKA	22.58	20.69	50.00
ASES	TKA	19.35	17.24	50.00
RASE	TKA	16.13	13.79	50.00
ASES	ST	16.13	13.79	50.00
ASES-8	TKA	12.90	10.34	50.00
ASES	BS	12.90	10.34	50.00
RASE	BS	12.90	10.34	50.00
ASES	ES	12.90	10.34	50.00
ASES-8	ST	12.90	10.34	50.00
RASE	ST	12.90	10.34	50.00
ASES-8	BS	9.68	6.90	50.00
ASES-8	ES	9.68	6.90	50.00
RASE	ES	9.68	6.90	50.00
K-SES	ST	9.68	6.90	50.00
K-SES	BS	6.45	3.45	50.00
K-SES	ES	6.45	3.45	50.00

**Round 2: prefacing question self-efficacy**  
 'In the second round, before you evaluated each scale in terms of its usefulness for the IMI-PainCare PROMPT COS, we asked you if you give your recommendation for the PROMs related to self-efficacy...'

Response	Voted 'appropriate' (7-9)		
	All	HP	PWLE
...without restrictions	20.00	18.52	33.33
...only on the condition that the PROM will be replaced immediately when a more suitable one is available	63.33	66.67	33.33
I cannot decide/I have no opinion	16.67	14.81	33.33

**Round 2: self-efficacy domain**  
 For this domain, we noted overall high shares of participants that chose 'unable to rate', particularly in the group of PWLE (66.67%; 7.8-15.4% of health professionals). In addition, although the ASES IMI-PainCare PROMPT adaptation was rated much more 'appropriate' than other PROMs for all procedures, it is slightly under the 50% threshold for one of the assessed procedures (sternotomy). Hence, we decided to present the results of the votes analysed without all votes for 'unable to rate', too. These numbers are added in grey in the following table next to the numbers from the general analysis and in the detailed results below.

Instrument	Type of surgery	Voted 'appropriate' (7-9)		
		All	HP	PWLE
ASES IMI-PainCare PROMPT adaptation	TKA	55.17	54.00	57.69
ASES IMI-PainCare PROMPT adaptation	BS	55.17	54.00	57.69
ASES IMI-PainCare PROMPT adaptation	ES	55.17	54.00	57.69
ASES IMI-PainCare PROMPT adaptation	ST	48.28	56.00	50.00
ASES-8	TKA	20.69	25.00	19.23
K-SES	TKA	17.24	20.83	15.38
ASES	TKA	10.34	12.50	7.69
ASES-8	BS	10.34	12.50	7.69
K-SES	BS	10.34	12.50	7.69
ASES-8	ES	10.34	13.04	7.69
K-SES	ES	10.34	13.04	7.69
ASES-8	ST	10.34	12.50	7.69
K-SES	ST	10.34	12.50	7.69
RASE	ST	10.34	12.50	7.69
RASE	TKA	6.90	8.33	3.85
ASES	BS	6.90	8.33	3.85
RASE	BS	6.90	8.33	3.85
ASES	ES	6.90	8.70	3.85
RASE	ES	6.90	8.70	3.85
ASES	ST	6.90	8.33	3.85

**(d) Results for the adverse events domain**  
**Round 1: additional question adverse events**

'How appropriate do you consider PROMS as a part of COS assessment of adverse events related to effectiveness and efficacy of perioperative pain management after TKA, breast surgery, endometriosis, and sternotomy?  
 The IMI-PainCare PROMPT COS assessment tool should contain...'

Instrument	OP type	Voted 'appropriate' (7-9)		
		All	HP	PWLE
...always both PROMs and CROs	General question	64.52	62.07	100
...only PROMs	General question	19.35	17.24	50.00
...always either PROMs or CROs	General question	19.35	17.24	50.00
...only Clinician Reported Outcomes (CROs)	General question	6.45	3.45	50.00

**Round 1: adverse events domain**

PROM	Type of surgery	Voted 'appropriate' (7-9)		
		All	HP	PWLE
OR-SDS IMI-PainCare PROMPT adaptation	TKA	54.84	55.17	50.00
OR-SDS IMI-PainCare PROMPT adaptation	ES	54.84	55.17	50.00
OR-SDS IMI-PainCare PROMPT adaptation	BS	48.39	48.28	50.00
OR-SDS IMI-PainCare PROMPT adaptation	ST	48.39	48.28	50.00
Additional Scale for Moto-Function	TKA	25.81	27.59	0.00
Additional Scale for Moto-Function	ES	25.81	24.14	50.00
Additional Scale for Moto-Function	ST	25.81	24.14	50.00
Additional Scale for Moto-Function	BS	22.58	24.14	0.00
OR-SDS original scale	TKA	19.35	17.24	50.00
OR-SDS original scale	ES	19.35	17.24	50.00
OR-SDS original scale	BS	16.13	13.79	50.00
OR-SDS original scale	ST	16.13	13.79	50.00

Round 2: prefacing question adverse events							
In the second round, before you evaluated each scale in terms of its usefulness for the IMI-PainCare PROMPT COS, we asked you if you give your recommendation for the PROMs related to adverse events...							
Response	Voted 'appropriate' (7–9)						
	All	HP		PWLE			
...without restrictions	20.69	19.23		33.33			
...only on the condition that the PROM will be replaced immediately when a more suitable one is available	58.62	61.54		33.33			
I cannot decide/I have no opinion	20.69	19.23		33.33			
Round 2: adverse events domain							
For this domain, we noted overall high shares of participants that chose 'unable to rate', particularly in the group of PWLE (66.67%; 15.4–30.8% of health professionals). In addition, although the OR-SDS IMI-PainCare PROMPT adaptation was rated much more 'appropriate' than other PROMs for all procedures, it is slightly under the 50% threshold for three of the assessed procedures. Hence, we decided to present the results of the votes analysed without all votes for 'unable to rate', too. These numbers are added in <a href="#">green</a> in the following table next to the numbers from the general analysis and in the detailed results below.							
PROM	Type of surgery	Voted 'appropriate' (7–9)					
		All	HP		PWLE		
OR-SDS IMI-PainCare PROMPT adaptation	ES	51.72	71.43	53.85	70.00	33.33	100
OR-SDS IMI-PainCare PROMPT adaptation	TKA	48.28	56.67	50.00	50.00	33.33	100
OR-SDS IMI-PainCare PROMPT adaptation	ST	48.28	56.67	50.00	50.00	33.33	100
OR-SDS IMI-PainCare PROMPT adaptation	BS	44.83	57.00	46.15	50.00	33.33	100
OR-SDS original scale	ES	17.24	17.74	15.38	18.18	33.33	100
Additional Scale for moto-function	ST	17.24	16.32	15.38	22.22	33.33	100
OR-SDS original scale	TKA	13.79	17.39	11.54	13.64	33.33	100
Additional Scale for moto-function	TKA	13.79	20.00	11.54	15.79	33.33	100
OR-SDS original scale	BS	13.79	17.39	11.54	13.64	33.33	100
Additional scale for moto-function	ES	13.79	20.00	11.54	15.79	33.33	100
OR-SDS original scale	ST	13.79	17.39	11.54	13.64	33.33	100
Additional scale for moto-function	BS	6.90	10.00	3.85	12.26	33.33	100

voted twice (November 2022 to January 2023) and submitted comments in all rounds. This feedback was incorporated by the steering committee into subsequent Delphi rounds and consensus meetings.<sup>14,21</sup> Results from professionals and PWLE were analysed and presented separately. For further details on the Delphi process, see [Supplementary material S1](#), Chapters S3.2. and S3.3.

### Final consensus meeting

PROMs endorsed by  $\geq 50\%$  of all panellists in the final Delphi round were included in a pre-final COS, which was presented, discussed, and finalised during the final online consensus meeting (March 7, 2023). A 50% threshold, adopted from our previous COS development and recommendations,<sup>14,19,21</sup> was chosen owing to the limited content validity of the found PROMs and the correspondingly expected lower acceptance.

## Results

### Systematic literature reviews

Results from all conducted SLRs are detailed in [Supplementary material S1](#), Chapter S1.1.3 for pain intensity, including findings of previous SLRs,<sup>25,26</sup> Chapter S1.2.5 for physical function, Chapter S1.3.3 for self-efficacy, and Chapter S1.4.3 for adverse events.

### Evaluation of identified patient-reported outcome measures

As recommended by COSMIN (<https://cosmin.nl/>),<sup>22,27</sup> results of the evaluation of the quality of the PROM developmental process, using the COSMIN Risk of Bias Checklist ([Supplementary Box S1](#)), are provided in [Supplementary material S1](#), Chapter S2.2, [Tables S8–S13](#). Further details on all PROMs, based on their developmental/inauguration articles, are provided in [Supplementary material S1](#), Chapter S2.3, [Tables S14–S19](#).

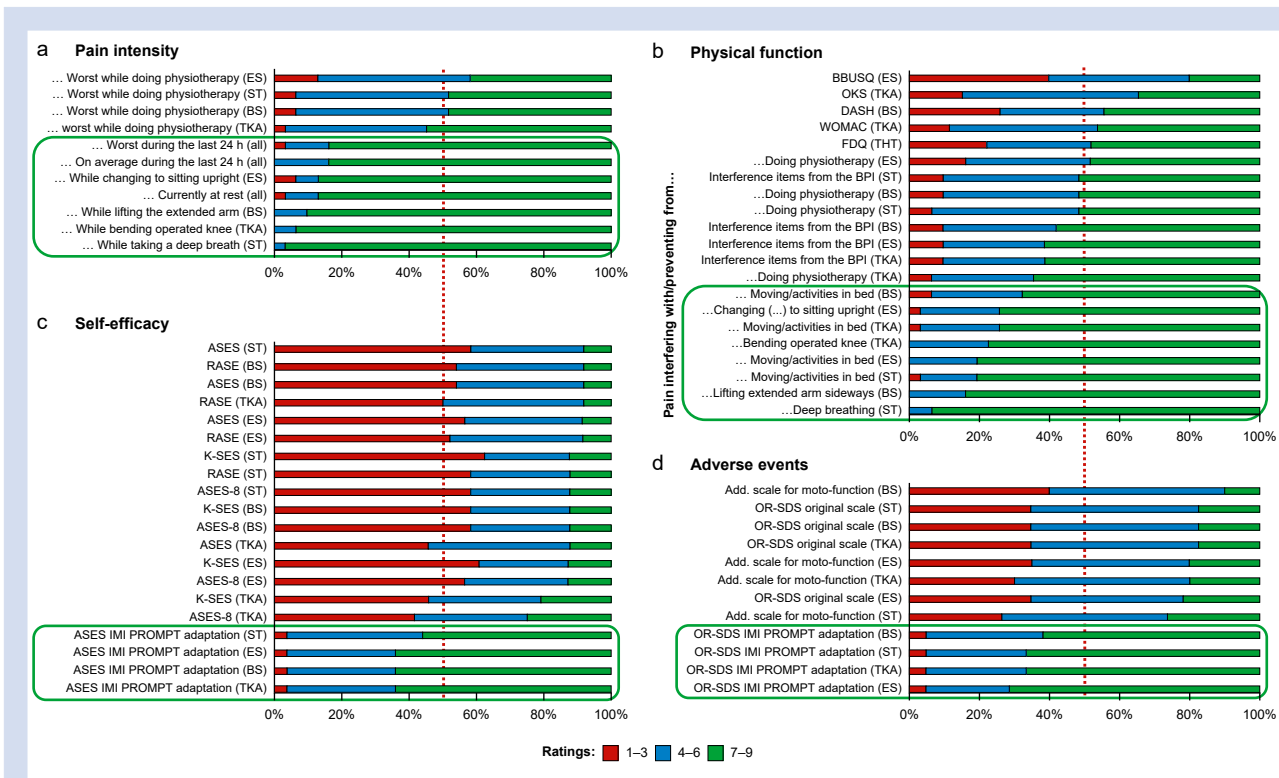
### Delphi process for the pain intensity domain

In round 1, eight PROMs were evaluated: three generic PROMs (applicable across various procedures), four procedure-specific

PROMs (designed for specific surgical contexts), and one generic PROM evaluated separately for each specific procedure. All PROMs were voted 'appropriate' (7–9 on a scale of 1–9) by  $>50\%$  of both groups, professionals and those with lived experience ([Table 2a](#)). The same PROMs were reassessed in round 2, with all eight again voted 'appropriate' by  $>50\%$  of both groups ([Table 2a](#) and [Fig. 2a](#)). For the subdomain pain intensity in general, the PROMs 'pain intensity on average' and 'worst pain intensity during the last 24 hours' were rated 'appropriate' by 83.9% of voters. For the subdomain pain intensity at rest, the generic PROM 'current pain intensity at rest' was voted 'appropriate' by 87.1%, and for the subdomain pain intensity during activity, the procedure-specific PROMs were voted 'appropriate' by 96.8%. Pain intensity during physiotherapy was excluded, receiving  $<50\%$  'appropriate' votes for three of the four surgical procedures, with many comments in both rounds stating that 'physiotherapy' was not specific enough. Thus, three generic PROMs aligned with the respective pain intensity subdomains, and one procedure-specific PROM for each procedure proceeded to the final COS of PROMs ([Fig. 2a](#), green-bordered box; [Fig. 3](#)).

### Delphi process for the physical function domain

In round 1, nine procedure-specific PROMs were evaluated: two for breast surgery (BS), sternotomy (ST), and endometriosis-related surgery (ES), and three for total knee arthroplasty (TKA). In addition, two generic PROMs were evaluated separately for each procedure. All but four PROMs (OKS, BBUSQ, DASH, and FDQ) were rated 'appropriate' by  $>50\%$  of both groups ([Table 2b](#)). Following comments and suggestions from round 1, an additional PROM (interference items from the BPI) was added in round 2 for each surgical procedure. In round 2, all PROMs except the BPI interference scale, the WOMAC and the same four voted out in the first round (OKS, BBUSQ, DASH, and FDQ) were again voted 'appropriate' by  $>50\%$  of both groups ([Table 2b](#)). Consequently, two PROMs, one generic and one procedure-specific PROM for each surgery, were included in the final COS of PROMs ([Fig. 2b](#), green-bordered box; [Fig. 3](#)).



**Fig 2.** Final voting results of the second round for each domain: (a) pain intensity, (b) physical function, (c) self-efficacy, and (d) adverse events. Inclusion criteria for a PROM to be included in the final COS were that  $\geq 50\%$  of the panel rated the PROM between 7 and 9 ('appropriate', green). The vertical red dotted line indicates the 50% cut-off threshold for inclusion, and the PROMs ultimately included (after final discussion in the second meeting) are highlighted in the green-bordered box. Rating scale consists of 1–3, not appropriate (red); 4–7, potentially appropriate (blue); and 7–9, appropriate (green). all, all types of surgery; ASES-8, Arthritis Self-Efficacy Scale Short Form; ASES, Arthritis Self-Efficacy Scale; BBUSQ-22, Birmingham Bowel and Urinary Symptoms Questionnaire; BS, breast surgery; DASH, Disabilities of the Arm, Shoulder and Hand; ES, endometriosis related surgery; FDQ, Functional Difficulties Questionnaire; K-SES, Knee Self-Efficacy Scale; OKS, Oxford Knee Score; OR-SDS, Opioid-Related Symptom Distress Scale; PROM, patient-reported outcome measure; PROMPT, Providing Standardized Consented PROMs for Improving Pain Treatment; RASE, Rheumatoid Arthritis Self-Efficacy Scale; ST, sternotomy; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

### Delphi process for the self-efficacy domain

In round 1, all proposed PROMs were rated 'appropriate' by  $< 50\%$  of both groups for all four surgeries and by 50% from those with lived experience (Table 2c). Many participants commented that the existing PROMs assessing self-efficacy in people with acute postoperative pain were inadequate. Therefore, in round 2, participants were asked to recommend the PROM for self-efficacy 'without restrictions' or 'on the condition that the PROM will be replaced immediately when a more suitable one is available' (with restrictions) or to express their inability to decide. Sixty-six percent of all participants agreed to recommend the PROM with restrictions (Table 2c). The ASES IMI-PainCare PROMPT adaptation received the most 'appropriate' votes for all surgeries in round 2 (55.2% for TKA, BS, and ES and 48.3% for ST). Although it did not meet the 50% threshold for ST, the lower proportion of votes from those with lived experience was attributed to 'unable to rate' responses rather than outright rejection. Compared with all other items in this domain, which scored  $< 20.7\%$  'appropriate' (Table 2c), the

ASES IMI-PainCare PROMPT adaptation demonstrated relatively strong agreement and was therefore included in the COS for all types of surgery (Fig. 2c, green-bordered box; Fig. 3), contingent upon immediate replacement when a more suitable PROM becomes available ('with restrictions'; Fig. 3).

### Delphi process for the adverse events domain

In round 1, only the OR-SDS IMI-PainCare PROMPT adaptation for TKA and the OR-SDS original scale for ES were voted 'appropriate' by  $> 50\%$  of both groups (Table 2d). In addition, for the adverse events domain, participants were asked about appropriateness of including PROMs in this COS; 64.5% (62.1% HP, 100% PWLE) chose 'The IMI-PainCare PROMPT COS assessment tool should contain always both PROMs and Clinician-Reported Outcomes' (Table 2d).

In round 2, as with the domain self-efficacy, participants were asked whether they would recommend the PROMs without restrictions or only on the condition of replacement whenever possible or whether they were undecided before

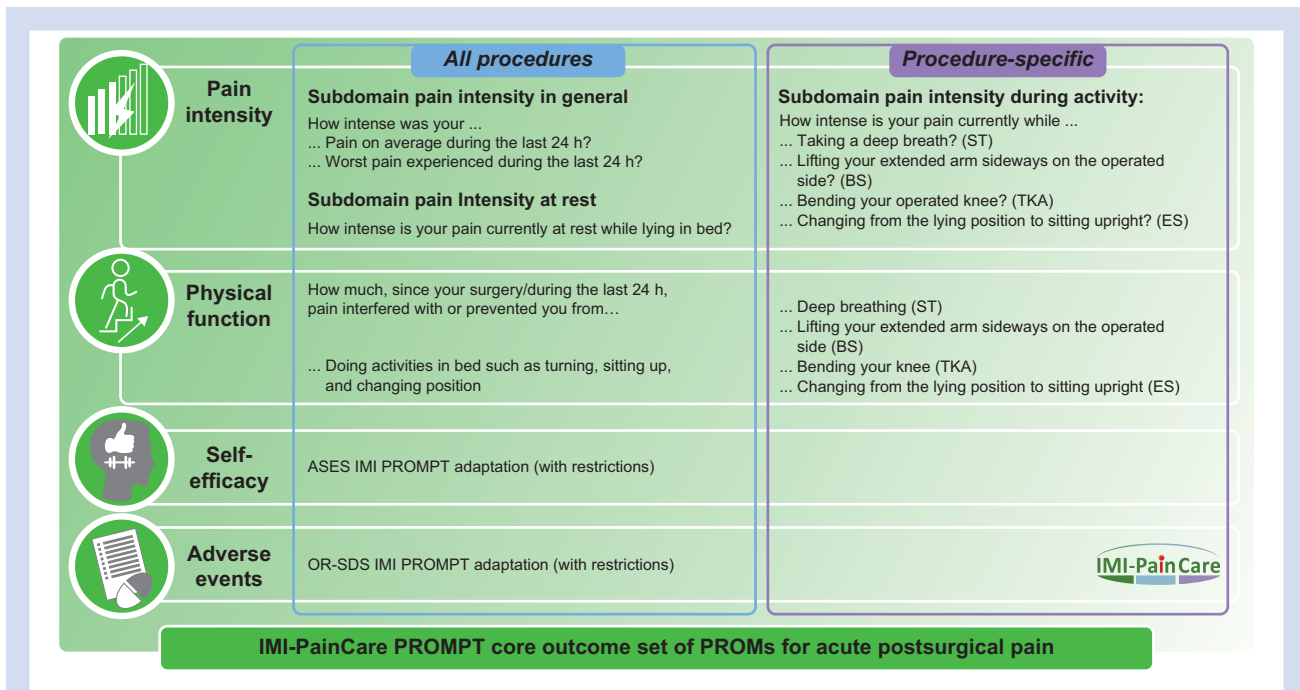


Fig 3. Final COS of PROMs enabling assessment of efficacy and effectiveness of pain management in the acute phase after surgery. BS, breast surgery; COS, core outcome set; ES, endometriosis-related surgery; PROM, patient-reported outcome measure; ST, sternotomy; TKA, total knee arthroplasty.

evaluating them. Fifty-eight percent of all participants agreed to recommend the PROMs only on the condition of replacement whenever possible (Table 2d). Again, there was a notably high share of participants selecting ‘unable to rate’ in round 2, particularly among those with lived experience (66.67%; 15.4–30.8% of HP; Table 2d). In round 2, only the OR-SDS IMI-PainCare PROMPT adaptation was voted ‘appropriate’ by >50% of the entire group for ES (51.7%). For all other types of surgery, this PROM narrowly missed the threshold (48.3% for TKA and ST and 44.8% for BS), but it was rated ‘appropriate’ by 50% of professionals for TKA and ST. As with self-efficacy, the lower ratings from those with lived experience were attributed to ‘unable to rate’ responses rather than rejection. Thus, the OR-SDS IMI-PainCare PROMPT adaptation for all types of surgery was included in the COS (Fig 2d, green-bordered box; Fig 3), also contingent upon immediate replacement when a more suitable PROM becomes available (‘with restrictions’; Fig 3).

### Final consensus process

Figure 3 presents the final COS of PROMs for postoperative assessment through the four outcome domains, including subdomains related to pain intensity, as discussed and consented during the final consensus meeting. Table 3 provides the precise phrasing of the PROMs, including the descriptors, ranges, and anchors. The complete questionnaires with all PROMs of the COS are available in Supplementary material S2.





### Discussion

An international, multiprofessional stakeholder panel, including individuals with lived experience, developed consensus on a COS of PROMs for assessing the effectiveness

and efficacy of perioperative pain management in adults. For each of the four predefined key domains, reflecting the biopsychosocial complexity of pain management,<sup>21</sup> at least one PROM was identified for use across all surgical procedures (Fig 3, left side; Table 3). In addition, procedure-specific PROMs were recommended for two domains: pain intensity during activity and physical function (Fig 3, right side; Table 3). For pain intensity during activity, one PROM was selected for each exemplar surgical procedure, aligning with recent requests to assess pain intensity not only at rest but also during activity using ‘common, procedure-specific pain-evoking manoeuvres’.<sup>8</sup> Similarly, for physical function, the COS of PROMs includes easy-to-use single-item tools, with one PROM for all surgical procedures and one specific to each surgical procedure. For procedures not covered, the general PROMs can be used, although further procedure-specific PROMs require development in the future.

The PROMs presented to the panel during the consensus process underwent systematic identification and rigorous evaluation, including content validity and examination of their development process.<sup>18–20</sup> Several PROMs included in the voting process demonstrated a significant lack of content validity, raising concerns about whether they accurately measure the intended constructs.<sup>28</sup> This challenge is common in COS development, including those addressing pain.<sup>29</sup> To ensure responsiveness of the PROMs, we evaluated adaptations and face-valid scales for sensitivity to change.<sup>3</sup> Nevertheless, the included PROMs require further evaluation or replacement with higher-quality PROMs when available, as recommended by this Delphi panel for the PROMs selected for the domains adverse events and self-efficacy (‘with restrictions’; Fig 3). COS updates are a common part of the development process, enabling re-evaluation and refinement

**Table 3** IMI-PainCare PROMPT Final Core Outcome Set of PROMs (exact wording of questions, range of scales, anchors, and descriptors). BS, breast surgery; ES, endometriosis-related surgery; PROM, patient-reported outcome measure; ST, sternotomy; TKA, total knee arthroplasty.

	PROMS FOR ALL PROCEDURES	PROCEDURE-SPECIFIC PROMS																																			
<b>Pain intensity</b> 	In the following questions, please specify the intensity of your pain on a scale from 0 (no pain) to 10 (worst pain imaginable):																																				
	<p><b>Pain intensity (general)</b>                      How intense was your...                      ... pain on average during the last 24 h?                      ... worst pain experienced during the last 24 h?</p> <p><b>Pain intensity at rest</b>                      How intense is your pain currently at rest while lying in bed?</p> <p><b>Pain intensity during activity</b>                      How intense is your pain currently while...                      ... lifting your extended arm sideways on the operated side? (BS)                      ... taking a deep breath? (ST)                      ... bending your operated knee? (TKA)                      ... changing from the lying position to sitting upright? (ES)</p>																																				
<b>Physical function</b> 	In the following questions, please specify how much your pain interfered with specific activities on a scale from 0 (did not interfere) to 10 (completely interfered):																																				
	<p>Circle the one number below that best describes how much, since your surgery/during the last 24 h, pain interfered with or prevented you from doing activities in bed such as turning, sitting up, and changing position.</p> <p>Circle the one number below that best describes how much, since your surgery/during the last 24 h, pain interfered with or prevented you from ...                      ... lifting your extended arm sideways on the operated side. (BS)                      ... deep breathing. (ST)                      ... bending your operated knee. (TKA)                      ... changing from the lying position to sitting upright. (ES)</p>																																				
<b>Self - efficacy</b> 	<p><b>PROMs for all procedures</b></p> In the following questions, we would like to know how your pain caused by surgery affects you and what you think about your abilities to control your pain. In each of the following questions, please mark the one number that corresponds best to your level of certainty that you can now perform the following activities (0 = very uncertain to 10 = very certain).																																				
	<p>How certain are you that you can decrease your pain caused by surgery quite a bit?</p> <p>How certain are you that you can keep your pain caused by surgery from interfering with your sleep?</p> <p>How confident are you that you can keep the physical discomfort of your pain caused by surgery from interfering with the things you want to do?</p> <p>How certain are you that you can regulate your activity so as to be active without aggravating your pain caused by surgery?</p> <p>How confident are you that you can keep the fatigue caused by surgery from interfering with the things you want to do?</p> <p>How certain are you that you can do something to help yourself feel better if you are feeling blue?</p> <p>Compared with other people in your situation, how certain are you that you can manage pain caused by surgery during your daily activities?</p> <p>How certain are you that you can deal with the frustration of pain caused by surgery?</p>																																				
<b>Adverse events</b> 	<p><b>PROMs for all procedures</b></p> During the last 24 h, did you have any of the following symptoms?																																				
		<table border="1"> <thead> <tr> <th></th> <th>Did not have</th> <th>Did have</th> </tr> </thead> <tbody> <tr> <td><i>Fatigue</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Drowsiness</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Inability to concentrate</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Nausea</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Dizziness</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Constipation</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Itching</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Difficulty with urination</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Confusion</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Retching/vomiting</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><i>Reduction of muscular strength in one or more limbs</i></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>		Did not have	Did have	<i>Fatigue</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Drowsiness</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Inability to concentrate</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Nausea</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Dizziness</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Constipation</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Itching</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Difficulty with urination</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Confusion</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Retching/vomiting</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Reduction of muscular strength in one or more limbs</i>	<input type="checkbox"/>
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over time.<sup>19</sup> The four exemplar surgical procedures reflect a broad spectrum of surgical trauma and conditions, patient demographics, pain mechanisms, and treatment approaches.<sup>3,21</sup> We recommend adopting this COS in research and clinical settings while acknowledging flexibility to include additional outcomes as required for specific surgeries or health conditions.

Beyond acute postoperative pain, COS have been developed for other painful conditions, such as complex regional pain syndrome,<sup>28</sup> low back pain,<sup>29,30</sup> and perioperative pain in trials on regional anaesthesia.<sup>31</sup> Overarching pain-related COS of domains, such as developed recently by the INTEGRATE group for acute, acute-to-chronic, chronic, and recurrent pain,<sup>32</sup> or by IMMPACT for chronic pain in general,<sup>33</sup> facilitate data harmonisation and comparability across different pain conditions. These COS reflect several aspects of the biopsychosocial complexity of both acute and chronic pain by additionally integrating psychological domains, such as self-efficacy, alongside physical function or quality of life. This better reflects patient experiences of pain, as raised by those with lived experiences during our initial domain process.<sup>21</sup> Recent studies have shown that relying solely on pain intensity as an outcome measure can lead to unidimensional pain management, including overprescription of opioids.<sup>5–7,31</sup> Integrating multiple domains beyond pain intensity will guide future pain management towards comprehensive, targeted and multimodal approaches rather than reliance on opioid use. Harmonising PROMs across domains simplifies their assessment by guiding the selection of measurement tools. However, guidance for treatment through implementation of the COS of PROMs in clinical practice is complex and will require defining treatment thresholds and minimal clinically important differences for each PROM.

Certain limitations apply to our COS development process. Although the distribution of panel members was uneven across locations and countries of origin, the professional and personal diversity of all members, and inclusion of those with lived experiences, ensured a broad range of perspectives, reflected in lively and comprehensive discussions and leading to a balanced consensus despite the relatively small panel size. Following available recommendations,<sup>18,19</sup> we carefully ensured panel diversity by including representatives from various stakeholder groups (researchers, clinicians, HTA experts, and persons with lived experience) while limiting the total to 40 participants to balance broad perspectives with practical feasibility for consensus meetings. Consistency in panel composition throughout the COS development process<sup>2,21</sup> allowed for knowledge transfer, and the strong engagement of those with lived experience, whose input was prioritised in cases of divergent voting, helped to address the limitation of their smaller numbers. The flexible and multi-round nature of the Delphi process poses risks of participant dropout and bias towards majority views, particularly in smaller panels.<sup>34</sup> To mitigate this, we provided extensive background information on all PROMs and the process and gave feedback to panellists after each round to enable informed decision-making. Furthermore, we considered and discussed participants' reluctance to rate certain PROMs and near-threshold voting results when finalising the COS. In addition, votes from professionals and those with lived experience were presented separately to the panel. Cross-cultural

translation ensures items perform well after translation or cultural adaptation, which is relevant for global usability of the COS.<sup>27</sup> Although our COS and the development process of the included PROMs do not fully address patient diversity, such as the full range of socioeconomic status, education, race, or ethnicity, we tested all PROMs for sensitivity to change in a prospective study<sup>3</sup> and translated them into French, German, Italian, Serbian, Finnish, Spanish, and Portuguese<sup>35</sup> to facilitate cross-cultural adaptation studies.

## Conclusions

The IMI-PainCare PROMPT core outcome sets of patient-reported outcome measures for assessing the effectiveness and efficacy of perioperative pain management was completed. Despite some restrictions, it provides a set of outcome measures enabling a comprehensive and harmonised assessment of postoperative pain, extending beyond common pain intensity scales. Simple, easily applicable tools such as single-item scales for postoperative pain intensity and pain-related physical function were considered most appropriate. Adopting this COS will align outcome assessment in acute perioperative pain, thus enhancing comparability and generalisability of clinical trial results, advancing translation of results from clinical practice to research and back, reducing reporting bias, and ensuring relevance of outcome assessment to all stakeholders, including patients.

## Authors' contributions

Led and conceptualised the project: EMP-Z

Contributed to the conceptualisation of the project: HL, WM, UK

Developed the protocols for the consensus process: EMP-Z

Developed the protocols for the systematic reviews: UK, EMP-Z

Performed the assessments of psychometric properties of the PROMs: EMP-Z, SDL, DR, PZ, UK, HH

Planned and coordinated the consensus process, including the consensus meetings and Delphi process: EMP-Z

Contributed to development of the consensus meeting: SDL, LH, KV, JV, PZ, UK, WM, HL, DR, CW

Contributed to the organisation of the consensus meetings and the Delphi process: CW, HL, DR, UK

Analysed the results of the Delphi process: EMP-Z, DR

Analysed the PROMs related to the sensitivity-to-change properties: JV

Drafted the first version of the manuscript: EMP-Z, DR, SDL

Coordinated all follow-up versions, including the final version: EMP-Z

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Revised the manuscript: LH, HL, WM, KV, JV, PZ, UK, CW

Read and commented on the final version of the manuscript: all authors

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## Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used the local large language model of the University of Muenster Llama 3–70B to check orthography, punctuation, and grammar. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

## Appendix A. Supplementary data

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## Appendix 1. Collaborators

The authors thank all members of the IMI-PainCare PROMPT consensus panel, including (in alphabetical order) Alexander Avian (Institute for Medical Informatics, Statistics and Documentation, Medical University of Graz, Graz, Austria), Ralf Baron (Section Neurological Pain Research and Therapy, University Hospital Schleswig Holstein, Kiel), Irmgard Boesl (Grünenthal GmbH, Aachen, Germany), Didier Bouhassira (UVSQ-Paris-Saclay University, CHU Ambroise Paré, Boulogne-Billancourt, France), Karoline Buhre (Bundesinstitut für Arzneimittel und Medizinprodukte, Bonn, Germany), Rebecca Chandler (Paramedic Science and Operating Department Practice Cluster, School of Allied Health and Social Care, Cambridge, UK), Hans-Peter Dauben (EuroScan international network e.V., Köln, Germany), Dominique Fletcher (Service d'Anesthésie, CHU Ambroise Paré, Boulogne-Billancourt, France), Patrice Forget (Dept. of Anesthesia, University of Aberdeen, UK), Stephan Freys (Chirurgische Klinik, DIAKO Ev. Dianonie-Krankenhaus gGmbH, Bremen, Germany), Magdalena Kocot-Kępska (Dept. for Pain Research and Treatment, Medical College, Jagiellonian University, Krakow, Poland), Albere Koke (School for Public Health and Primary Care, Dept. of Rehabilitation Medicine, Maastricht University, Maastricht, NL), Britta Lambers (Hochschulen Fresenius gemeinnützige Trägergesellschaft mbH, Köln, Germany), Patricia Lavand'homme (Dept. of Anesthesiology and Postoperative Pain Service, Cliniques Universitaires St Luc, University Catholic of Leuven, Brussels, Belgium), Dileep Lobo (Nottingham Diseases Centre, Division of Translational Medical Sciences, School of Medicine, University of Nottingham, Queen's Medical Centre, Nottingham, UK; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA), Alexandros Makris (Dept. of Anesthesiology, Asklepion Hospital of Voula, Athens, Greece), Niamh Moloney (Curtin School of Allied Health, Curtin University, Bentley, Western Australia), David Mott (Office of Health Economics, London, UK), Nadja Nestler (Institut für Pflegewissenschaft und –praxis, Paracelsus Medizinische Privatuniversität, Salzburg, Austria), Paul Nilges (Institut für klinische Psychologie, Johannes Gutenberg Universität Mainz, Germany), Heike Norda (Unabhängige Vereinigung aktiver Schmerzpatienten in Deutschland e.V., Neumuenster, Germany), Madelon Peters (Dept. of Clinical Psychological Science, Faculty of Psychology and Neuroscience, Maastricht University, Netherlands), Daniel Pöpping (Dept. of Anesthesiology, Intensive Care and Pain Medicine, University Hospital Muenster, Germany), Alexander Schnabel (Dept. of Anesthesiology, Intensive Care and Pain Medicine, University Hospital Muenster, Germany), Audun Stubhaug (Dept. of Pain Management and Research, University of Oslo, Oslo, Norway), Rolf-Detlef Treede (Institute of Neurophysiology, Medical Faculty Mannheim, University of Heidelberg, Germany), Rianne van Boekel (Expertise Center for Pain and Palliative Medicine, Radboud University Medical Center, Nijmegen, NL), Dimitri Van Ryckeghem (Faculty of Psychology and Neuroscience, Maastricht University, Maastricht, NL), Harriet Wittink (Utrecht University of Applied Sciences, Utrecht, NL), and Sigridur Zoëga (Landspítali University Hospital and University of Iceland, Reykjavik, Iceland).

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