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Supplemental Table 1: Low or No Priority PROM Measures/Articles

PROM Name or Study	PROM or Study Purpose	Strengths	Weaknesses	Potential to be Adapted
PROMs Used in Dialysis				
<u>Low Prioritization</u>				
Numeric Rating Scale (NRS) for Pain (Multiple studies) ³²	Unidimensional measure of pain intensity in adults and is segmented numeric version of the visual analog scale	<ul style="list-style-type: none"> • Short • Interview or self-administration • Psychometrics evaluated • Evidence for use in dialysis³³ • Can be used for both severity ratings and average pain ratings • Cross-cultural adaptations available • Responsive to treatment 	<ul style="list-style-type: none"> • Unidimensional – only measures pain • Chronic back pain and symptomatic hip and knee osteoarthritis have found it to be inadequate to capture complexity and idiosyncratic nature of pain • No pediatric version 	No
PROMs Not Used in Dialysis				
<u>Low Prioritization</u>				
JOA Back Pain Evaluation Questionnaire (JOABPEQ) ³⁴		<ul style="list-style-type: none"> • Could be useful to get at impact Asks emotional questions • not just physical aspects • Translations available 	<ul style="list-style-type: none"> • Needs to be evaluated whether it could be translated into muscle cramping – written for low back pain • Similar to PROMIS Pain Behavior although seems to have more impact questions • Mostly yes/no response options 	
Abd-Elsalam, 2018 ³⁵ (modification of the questionnaire proposed by Chatrath et al., 2012 ²⁶)	The aim of this study was to assess the safety and efficacy of orphenadrine in the treatment of muscle cramps in cirrhotic patients	<ul style="list-style-type: none"> • Captured differences in baseline muscle cramps, frequency, severity, duration, timing, location, aggravating factors, relieving factors, or quality of life • Detailed description of muscle cramps (onset, precipitating events, frequency, duration, relief, and localization) and severity of pain 	<ul style="list-style-type: none"> • Telephone interview • Psychometrics unknown 	
Rajabally, 2018 (cited Johnson 2015 ³⁶ as the development article) ³⁷	To assess muscle cramp frequency, location, severity, duration and triggering factor	<ul style="list-style-type: none"> • Short, easy to answer • Determined specific anatomical location of cramp. • Asks about cramps interfering with sleep, daily activities, exercise and quality of life 	<ul style="list-style-type: none"> • Psychometric data not available 	Muscle cramp frequency, location, severity, duration and triggering factors
Study-specific PROM - Wake Forest Cramp/Fasciculation Survey: Caress, 2016 ³⁸	To assess the experiences patients with early stage ALS have with muscle cramps	<ul style="list-style-type: none"> • Cramp index score can be calculated • Measures difference over time. 	<ul style="list-style-type: none"> • Small sample size. • Psychometrics unknown 	

Study-specific, Nocturnal Cramps Sleep Diary ³⁹	Combined adaptation of the "assessment, Espie diary form," and the Two Week Sleep Diary	<ul style="list-style-type: none"> • Specific to cramps, but only nocturnal 	<ul style="list-style-type: none"> • Only asks questions about sleep • Focused on patients with multiple nocturnal cramps and may not be relevant to dialysis patients • Self-report diary 	Yes. Serial measures, day of week – could be adapted to dialysis and non-dialysis days
Study Specific, Weiker, 2017 ⁴⁰	Evaluate if correction of vitamin D insufficiency relieved muscle cramps in postmenopausal women	<ul style="list-style-type: none"> • Short • Asks questions about cramps affecting ability to fall asleep and about waking during night 	<ul style="list-style-type: none"> • Single center • Limited number of questions with yes/no response options 	Possibly
Visual Analogue Scale (VAS) of Pain	Unidimensional measure of pain intensity which is a continuous scale comprised of a horizontal or vertical line, usually 10 centimeters in length, anchored by 2 verbal descriptors, one for each symptom extreme.	<ul style="list-style-type: none"> • Used in dialysis^{41, 42} • Cross-cultural adaptations available • Pediatric version available 	<ul style="list-style-type: none"> • Unidimensional – only measures severity 	No
Fear of Pain Questionnaire (FPQ-III) ⁴³	Assesses fear associated with situation-specific medical, minor, or severe pain.	<ul style="list-style-type: none"> • Psychometrics evaluated 	<ul style="list-style-type: none"> • Only 1 question relevant to muscle cramping "I fear the pain associated with having a muscle cramp" 	Could inform new question development related to fear of activities around dialysis or activities of daily living
Guy's Neurological Disability Scale ⁴⁴	Clinical disability scale capable or embracing the whole range of disabilities which could be encountered in the course of multiple sclerosis.	<ul style="list-style-type: none"> • Subscales for fatigue and other disabilities. • Overall score can be calculated • Each domain graded according to severity and impact • Psychometrics evaluated 	<ul style="list-style-type: none"> • Focused on multiple sclerosis • One question addresses pain, spasms, or dizziness. • Long, administration by health care personnel • No translations • No pediatric version 	Potentially
<u>No Prioritization</u>				
Pain Catastrophizing Scale (PCS) ⁴⁵	To quantify pain catastrophizing characterized by magnification and rumination of pain beliefs.	<ul style="list-style-type: none"> • Short • Multiple languages available • Computerize Adaptive Testing available 	<ul style="list-style-type: none"> • Pain only 	
Disabilities of the Arm, Shoulder and Hand (DASH) ⁴⁶	The DASH is designed to evaluate disorders and measure disability of the upper extremities, and monitor change or function over time.	<ul style="list-style-type: none"> • Short • Self-administered • Other languages available 	<ul style="list-style-type: none"> • No pediatric version 	Yes (Conceptually to develop measure that relates cramping and activities of daily living)

PROM - Patient-reported Outcome Measure

Supplemental Table 2: Measure Mapping to Universally- and Variably-Experienced Components of Skeletal Muscle Cramping from Low or No

Prioritized Measures

PROM Name or Study	Universally-experienced Skeletal Muscle Cramping Attributes					Variably-experienced Skeletal Muscle Cramping Attributes							
	Frequency	Acute Pain Severity Or Intensity	Duration	Location	Timing	Residual Pain (Sore, Stiff, Achy Muscles)	Gross Motor Impact	Fine Motor Impact	Avoid Activity/ Movement	Impact on Sleep	Effects on Mood and/or Affect	Personal Interactions	Pain Avoidance Behaviors
PROMs Used In Dialysis													
Numeric Rating Scale (NRS) for Pain ³²	No	Yes	No	No	No	No	No	No	No	No	No	No	No
PROMs Not Used In Dialysis													
Study-specific PROM Weiker, 2017 ⁴⁰	Yes	Yes	No	No	No	No	No	No	No	Yes	No	No	No
Study-specific PROM Rajabally 2018 ³⁷ ; cited Johnson 2015 ³⁶ as development article	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No	No	No
Study-specific PROM Abd-Elsalam, 2018 ³⁵ ; modification of the questionnaire proposed by Chatrath et al., 2012 ²⁶	Yes	Yes - VAS	Yes	Yes	Yes	No	No	No	No	No	No	No	No
Wake Forest Cramp/Fasciculation Survey Caress, 2016 ³⁸	Yes	Yes	Yes	Yes	No	No	No	No	No	Yes	No	No	No
Nocturnal Cramps Sleep Diary ³⁹	Yes	Yes	Yes	No	No	Yes	No	No	No	Yes	No	No	No
Visual Analogue Scale (VAS) of Pain (Multiple studies)	No	Yes	No	No	No	No	No	No	No	No	No	No	No
Pain Catastrophizing Scale (PCS) ⁴⁵	No	No	No	No	No	No	No	No	No	No	Yes	No	No

JOA Back Pain Evaluation Questionnaire (JOABPEQ) ³⁴	No	No	No	No	No	No	Yes	No	Yes	Yes	No	Yes	No
Disabilities of the Arm, Shoulder and Hand (DASH) ⁴⁶	No	Yes	No	No	No	Yes	No	Yes	No	No	No	No	No
Fear of Pain Questionnaire (FPQ-III) ⁴³	No	No	No	No	No	No	No	No	No	No	Yes (fear)	No	No
Guy's Neurological Disability Scale ⁴⁴	No	No	No	No	No	No	Yes	Yes	No	No	No	No	No

NRS – Numeric Rating Scale; VAS – Visual Analog Scale

Supplemental Table 3: Examples of Potential PROM Question Adaptations to Capture Skeletal Muscle Cramping Attributes

SMC Attribute	Original PROM Source	Original PROM Question	Example of Potential Adaptations	Comments
Universally-experienced Skeletal Muscle Cramping Attributes				
Pain Severity	West Haven-Yale Pain Inventory ³¹	<p><u>Question 7. Section A.</u> “On the average, how severe has pain been during the last week?”</p> <p><u>Response Options</u> 0=Not at all severe to 6=Extremely</p>	<p>On the average, how severe has pain <i>from skeletal muscle cramping</i> been during the last week?</p> <p>Potentially keep response options</p> <p>Even simple quantification of “How long does each skeletal muscle cramping episode last on average? Longest?” with open ended answers in minutes or as categories may be tested.</p>	<p>Ideal recall period needs to be determined. Unclear if “last week” is the correct recall period for skeletal muscle cramping experienced by patients receiving dialysis.</p> <p>The workgroup recommends asking about both average or usual pain and most severe.</p> <p>There were no specific questions for duration of the cramping episode which may affect the perceived severity of the pain.</p>
Frequency	Study-specific PROM, Lynch ²³	<p><u>Question 3:</u> “How often do you get muscle cramps?”</p> <p><u>Response Options</u> Greater than 5 times a day Twice a day Daily Every other day Twice a week Once a week Twice a month Once a month Less than once a month</p>		<p>Used in dialysis patients and have face validity, but needs to be psychometrically evaluated.</p> <p>Original response option intervals need to be more inclusive and specific. For example, it is not clear how to answer Question 3 if patient has skeletal muscle cramping more than twice a day but less than 5 times a day</p> <p>Response options are more frequent as compared to other</p>

				PROMs which may be better for dialysis patients.
Location	Study-specific PROM, Lynch ²³	<p><u>Question 8:</u> “Where do you get muscle cramps?”</p> <p><u>Response Options</u> Leg Arm Chest Abdomen Neck Head Back Shoulder</p>	<p>Response Options should also include: Hands Fingers Forearms Feet</p>	<p>Used in dialysis patients and have face validity, but requires psychometric evaluation.</p> <p>A few focus group participants reported having cramps in multiple places. The response options should allow for respondents to indicate more than one area, potentially ranking from #1 as most common up to least common.</p> <p>Consider offering more specific locations such as thigh or calf.</p>
Timing	Study-specific PROM, Lynch ²³	<p><u>Question X:</u> “What time of day do you get muscle cramps?”</p> <p><u>Response Options</u> Morning Afternoon Evening Night</p> <p><u>Question X:</u> “Which days do you get muscle cramps?”</p> <p><u>Response Options</u> Dialysis days Non-Dialysis days Both</p> <p><u>Question X:</u></p>		<p>Used in dialysis patients and have face validity, but needs psychometric evaluation</p> <p>Compared to other PROMs these questions seem more specific.</p> <p>Need to allow for multiple choices of times; consider ranking with #1 as most likely, and so on as applicable.</p>

		<p>“When you get cramps on your dialysis day, when do they occur?”</p> <p><u>Response Options</u> Before dialysis During dialysis After dialysis Not applicable</p>		
Variably-experienced Skeletal Muscle Cramping Attributes				
Sleep	Joint and Muscle Measure ²⁴	<p>Question X: “Do cramps or spasms wake you when you are sleeping or make it difficult to get to sleep?”</p> <p><u>Response Options</u> Rarely or not at all Less than once a week One to 2 times a week 3 to 5 times a week, or more</p> <p>Question X: “Do muscle aches or pains, stiffness or other problems wake you when you are sleeping or make it difficult to get to sleep?”</p> <p><u>Response Options</u> Rarely or not at all Less than once a week One to 2 times a week 3 to 5 times a week, or more</p>	<p>Do skeletal muscle cramps wake you when you are sleeping or make it difficult to get to sleep?</p> <p><u>Response Options</u> Rarely or not at all Less than once a week One to 2 times a week 3 to 5 times a week, or more</p> <p>Do muscle aches or pain, stiffness from skeletal muscle cramping wake you when you are sleeping or make it difficult to get to sleep?</p> <p><u>Response Options</u> Rarely or not at all Less than once a week One to 2 times a week 3 to 5 times a week, or more</p>	Ideal recall period needs to be determined for skeletal muscle cramping impacts on sleep in dialysis patients and also if the frequency pattern in the response options is relevant to this patient population

Avoidance Physical Activity/Movement	Multiple Sclerosis Spasticity Scale ²⁸	<p><u>Question, Sections 7 & 8:</u> “As a result of your muscle spasticity, how much in the past 2 weeks have you been bothered by: Feeling reluctant to go out?”</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p>	<p>As a result of your <i>skeletal muscle cramping</i>, how much in the past 2 weeks have you been bothered by: Feeling reluctant to go out?</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p>	<p>Ideal recall period needs to be determined for skeletal muscle cramping. Two 2 weeks may or may not be appropriate.</p> <p>4-item bother response options may be limited in detecting a difference when evaluating treatment.</p> <p>This type of question could enhanced understanding of reluctance to go out may be connected with avoiding physical activity or movement.</p>
Residual Pain (achy, sore, stiff muscles)	Multiple Sclerosis Spasticity Scale ²⁸	<p><u>Question, Section 1:</u> “As a result of your muscle spasticity, how much in the past 2 weeks have you been bothered by: 02. Stiffness anywhere in your lower limbs? 07. Stiffness when standing up? 08. Tightness in your muscles?”</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p>	<p>As a result of your <i>skeletal muscle cramping</i>, how much in the past 2 weeks have you been bothered by: 02. Stiffness anywhere in your lower limbs? 07. Stiffness when standing up? 08. Tightness in your muscles?</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p>	<p>Ideal recall period needs to be determined Two weeks may or may not be appropriate.</p> <p>4-item response options may be limited in detecting a difference with treatment.</p> <p>This type of question could provide further understanding on whether reluctance to go out is connected with avoiding physical activity or movement.</p>
Gross Motor. Potentially avoidance of movement	JOA Back Pain Inventory ³⁴	<p><u>Q2-1</u> “Because of the low back pain, you sometimes ask someone to help you when you do something.”</p>	<p>Because of pain <i>from skeletal muscle cramping</i>, you sometimes ask someone to help you when you do something.</p>	<p>Needs psychometric evaluation for use in patients on dialysis.</p> <p>Yes/No response options provide limited information.</p>

		<p><u>Q2-2</u> “Because of the low back pain, you refrain from bending forward or kneeling down.”</p> <p><u>Q2-3</u> “ Because of the low back pain, you have difficulty in standing up from a chair.</p> <p><u>Q2-4</u> “Because of the low back pain, turning over in bed is difficult.</p> <p><u>Response Options</u> 1) Yes 2) No</p>	<p>Because of pain <i>from skeletal muscle cramping</i>, you refrain from bending forward or kneeling down. Q2-3 Because of pain <i>from skeletal muscle cramping</i>, you have difficulty in standing up from a chair.</p> <p>Because of pain <i>from skeletal muscle cramping</i>, turning over in bed is difficult.</p>	
Fine Motor	Disorders of Arm, Shoulder and Hand ⁴⁶	<p><u>Question:</u> 1. Open a tight or new jar. 2. Write. 3. Turn a key. 4. Prepare a meal. 10. Carry a shopping bag or briefcase. 17. Recreational activities which require little effort (e.g., card playing, knitting, etc.)</p> <p><u>Response Options</u> 1=No difficulty 2=Mild difficulty 3=Moderate difficulty 4=Severe difficulty 5=Unable</p>		<p>Could potentially select certain items of relevance.</p> <p>Also has questions on other activities including sports, work etc that could be potentially modified to address computer use, gaming, fishing, etc Needs to be psychometrically evaluated in dialysis patients</p> <p>Question lead in would need to specifically refer to muscle cramping in fingers or hands.</p>
Mood	Multiple Sclerosis Spasticity Scale ²⁸	<p><u>Question, Section 7:</u> “As a result of your muscle spasticity, how much in the past 2</p>	As a result of your <i>skeletal muscle cramping</i> , how much in the past 2 weeks have you been bothered by:	Ideal recall period needs to be determined.

		<p>weeks have you been bothered by: 77. Feeling frightened, 79. Feeling panicky, 80. Feeling nervous.”</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p> <p><u>Question, Sections 7 & 8:</u> “As a result of your muscle spasticity, how much in the past 2 weeks have you been bothered by: 68. Feeling frustrated, Feeling reluctant to go out?”</p> <p><u>Response Options</u> 1=Not at all bothered 2=A little bothered 3=Moderately bothered 4=Extremely bothered</p>	<p>77. Feeling frightened, 79. Feeling panicky, 80. Feeling nervous.</p> <p>As a result of your <i>skeletal muscle cramping</i>, how much in the past 2 weeks have you been bothered by: 68. Feeling frustrated, Feeling reluctant to go out?</p>	<p>May be important to not only ask about amount of bother but also impact.</p>
Personal Interactions	West Haven-Yale Multidimensional Pain Inventory ³¹	<p><u>Question:</u> “indicate <u>how often</u> your significant other generally responds to you in that particular way <u>when you are in pain.</u>”</p> <ol style="list-style-type: none"> 1. Ignores me. 2. Asks me what he/she can do to help. 4. Expresses irritation at me. 6. Talks to me about something else to take my mind off the pain. 7. Expresses frustration at me. 8. Tries to get me to rest. 	<p>indicate <u>how often</u> your significant other/<i>care giver/dialysis staff</i> generally responds to you in that particular way <u>when you are in pain due to skeletal muscle cramping.</u></p> <ol style="list-style-type: none"> 1. Ignores me. 2. Asks me what he/she can do to help. 4. Expresses irritation at me. 6. Talks to me about something else to take my mind off the pain. 7. Expresses frustration at me. 	<p>Needs formal psychometric evaluation for use in dialysis patients.</p> <p>Potentially more useful in clinical practice than for research purposes evaluating new devices or therapies for skeletal muscle cramping.</p> <p>Need to determine specifically who want to assess (care giver, spouse, significant other, dialysis</p>

		<p>9. Tries to involve me in some activity 10. Expresses anger at me. 11. Gets me some pain medications.</p> <p>Response Options 0=Never to 6= Very often</p>	<p>8. Tries to get me to rest. 9. Tries to involve me in some activity 10. Expresses anger at me. 11. Gets me some pain medications.</p>	<p>staff) and not clump all three together in one question.</p> <p>Consider revising question #11 to dialysis staff intervenes with pain medication, adjusting dialysis machine, etc.</p> <p>Need to assess if never to very often constitute the appropriate response options.</p>
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