

NIH Research Task Force Recommended Minimum Dataset and BACPAC Minimum Dataset Crosswalk

V1-Aug 4, 2020

NIH Research Task Force Item	Minimum Data Set Working Group (MDSWG) Decision	Rationale
Duration: how long has low-back pain been an ongoing problem for you?	<ul style="list-style-type: none"> • Adopted RTF wording of question (Outcomes #1) • Will use alternate choices <ul style="list-style-type: none"> a. <3 months b. 3-6 months c. 6 months-1 year d. 1 to 5 years e. More than 5 years 	BACPAC will use the Research Task Force’s (RTF) definition of chronic low back pain: back pain lasting at least three months, and a response of “at least half the days in the past 6 months” to question 2 would define cLBP. MDWG felt that the choice of 1 month was unnecessary given that these patients would not qualify to participate in BACPAC studies
Frequency: How often has low-back pain been an ongoing problem for you?	Adopted RTF question and choice as written (Outcomes #2)	
In the past 7 days, how would you rate your low-back pain on average? (response options 1-10)	Adopted RTF wording of question (Outcomes #7). Will use a 0-10 scale with anchors of “no pain” (0) and “worst imaginable pain” (10)	The 0-10 scale is consistent with other common measures of pain intensity. Anchors were added to assist patient comprehension.
Has back pain spread down your legs in the past 2 weeks?	Minimum Data Set split radicular pain into two separate questions (Outcomes #3 and 4): <ul style="list-style-type: none"> • Has back pain spread to your buttock or thigh during the past 2 weeks? <ul style="list-style-type: none"> a. Yes b. No c. Not sure • Has back pain spread below your knee during the past 2 weeks? <ul style="list-style-type: none"> a. Yes b. No c. Not sure 	MDWG felt that differentiating loci of radicular pain was clinically relevant.
During the past 4 weeks how much have you been bothered by... <ul style="list-style-type: none"> • Stomach Pain 	Not adopted. Widespread pain assessed with the following question (Outcomes #5)	MDSWG members agreed that pain somatization and widespread pain were both important constructs and

<ul style="list-style-type: none"> • Pain in your arms, legs, or joints other than your spine or back • Headaches • Widespread pain or pain in most of your body 	<p>5. Do you have chronic pain in the following areas?</p> <ul style="list-style-type: none"> a. Head or face (yes/no) b. Right hand, arm, or shoulder (yes/no) c. Left hand, arm, or shoulder (yes/no) d. Right buttock, leg, or foot (yes/no) e. Left buttock, leg, or foot (yes/no) f. Chest, abdomen, or pelvis (yes/no) g. Neck or upper back (yes/no) <p>RTF Question adapted for following pain somatization question (Outcomes #6)</p> <p>6. During the past 4 weeks, how much have you been bothered by...</p> <ul style="list-style-type: none"> • Stomach pain <ul style="list-style-type: none"> ○ Not bothered at all ○ Bothered a little ○ Bothered a lot • Headaches <ul style="list-style-type: none"> ○ Not bothered at all ○ Bothered a little ○ Bothered a lot 	<p>that they should be assessed separately. Widespread pain was removed as an answer choice from the RTF and incorporated into a second question. This provides more detail than the task force recommendation.</p>
<p>Have you ever had a low-back operation?</p>	<p>Adopted RTF question and choices as written in baseline assessment (Baseline #13)</p>	
<p>If yes, when was your last back operation?</p> <ul style="list-style-type: none"> a. Less than 6 months b. More than 6 months but less than 1 year ago c. Between 1 and 2 years ago d. More than 2 years ago 	<p>Adopted RTF question and choices as written in baseline assessment (Baseline #14)</p>	
<p>Did any of your back operations involve a spinal fusion? (also called an arthrodesis?)</p>	<p>Adopted RTF question and choices as written in baseline assessment (Baseline #15)</p>	

<ul style="list-style-type: none"> a. Yes b. No c. Not sure 		
<p>Pain Interference: In the past 7 days, how much did pain interfere...</p>	<p>Adopted RTF question and choices as written (Outcome #10)</p>	
<p>Treatments: Have you used any of the following treatments for your back pain?</p> <ul style="list-style-type: none"> • Opioid Painkillers • Injections • Exercise therapy • Psychological counseling 	<p>Not assessed. Opioids assessed with a single question (Outcomes #8): Are you currently taking any opioid pain medication on a daily basis? (<i>Opioid or narcotic medications include prescription medications such as Vicodin, Lortab, Narco, Hydrocodone, codeine, Tylenol #3 or #4, Fentanyl, Duragesic, MS Contin, Percocet, OxyContin, oxycodone, Morphine, methadone, tramadol, Ultram, Diluadid</i>)</p>	<p>Additional treatment data (exercise, therapy, injections, and other interventions) will be collected separately by sites. Medications will be collected on a regular basis, in general will be more detail than task force. At the MRC cohorts, participants will receive additional prompts regarding new treatments</p>
<p>I have been off work or unemployed for 1 month or more due to low-back pain (Agree/Disagree/Does Not Apply)</p>	<p>Adapted wording of question in baseline assessment (Baseline #16): Have you been off work or unemployed for 1 month or more due to low-back pain?</p> <ul style="list-style-type: none"> a. Yes b. No c. Does not apply 	<p>MDSWG members preferred consistency in structuring questions (e.g. use of 2nd person vs. 1st person statements)</p>
<p>I receive or have applied for disability or workers compensation benefits because I am unable to work due to low-back pain (Agree/Disagree/Does Not Apply)</p>	<p>Adapted wording of question in baseline assessment (Baseline #17): Have you filed or been awarded a worker’s compensation claim related to your back problem?</p> <ul style="list-style-type: none"> a. Yes b. No c. Does not apply 	<p>MDSWG members preferred consistency in structuring questions (e.g. use of 2nd person vs. 1st person statements)</p>
<p>Physical Function: Are you able to do chores such as vacuuming or yard work... ...go up and down stairs at a normal pacego for a walk of at least 15 minutes ...run errands and shop</p>	<p>Included all 4 Physical Function items from RTF (Outcomes #11) and 2 additional physical function.</p>	<p>PROMIS Physical Function 6b was preferred by members of MDSWG and includes all items used in RTF</p>

Depression: In the past 7 days... I felt worthless ...helpless ...depressed ...hopeless	Included RTF question wording and choices (Outcome #16); also included PHQ-2	PHQ-2 is a HEAL-required CDE
Sleep disturbance: in the past 7 days my sleep quality was very poor/poor/fair/good/very good	RTF question wording and choices adopted as part of PROMIS Sleep Disturbance 6a (Outcomes #12). A single item Sleep Duration assessment (Outcomes #13) was also included.	Sleep was considered to be an important factor to measure and MDSWG members voiced a preference for longer PROMIS 6a measure
In the past 7 days... <ul style="list-style-type: none"> • My sleep was refreshing • I had a problem with my sleep • I had difficulty falling asleep 	RTF question wording and choices adopted as part of PROMIS Sleep Disturbance 6a (Outcomes #12)	Sleep was considered to be an important factor to measure and MDSWG members voiced a preference for longer PROMIS 6a measure
It's not really safe for a person with my back problem to be physically active (agree/disagree)	Not adopted. 6-item Pain Catastrophizing Scale will be used (Outcomes #14)	MDSWG members preferred 6-item pain catastrophizing scale and several sites already planned to use it in studies
I feel that my back pain is terrible and it's never going to get any better (agree/disagree)	Not adopted. 6-item Pain Catastrophizing Scale will be used (Outcomes #14)	Same domain at task force, but more precise measure
Are you involved in a lawsuit or legal claim related to your back problem (yes/no/not sure)	Included RTF question wording and choices (Baseline #18)	
Substance use: <ul style="list-style-type: none"> • In the past year, have you drunk or used drugs more than you meant to? • Have you felt you wanted or needed to cut down on your drinking or drug use? 	Not adopted in MDS. TAPS substance use screener was used instead.	TAPS substance use screened is a HEAL-required CDE
Age	Assessed in Baseline Assessment (Baseline #2)	
Gender Female/Male/Unknown/Unspecified	Sex and gender assessed with 2 separate items in Baseline assessment (Baseline #3 and #4) <ul style="list-style-type: none"> • Sex at birth: male/female/intersex/unknown • Gender Identity: male/female/unknown/other (specific) 	These measures were adopted to be more inclusive of sexual and gender minority populations

Ethnicity Hispanic or Latino/Not HoL/Unknown/Not Reported	Adopted RTF question wording and choices	
Race	Adopted RTF question wording and choices	
Employment status	<p>RTF question and wording not adopted. A HEAL-required CDE will be used in Baseline assessment (Baseline #8)</p> <p>What is your current employment status?</p> <ul style="list-style-type: none"> • Full-time employed • Not employed • Part-time employed 	The HEAL-required CDE for employment was used
Education Level	<p>RTF question and wording not adopted. A HEAL-required CDE will be used in Baseline assessment (Baseline #7)</p> <p>What is the highest level of education you have completed?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Did not complete Secondary School or Less than High School <input type="checkbox"/> Some Secondary School or High School Education <input type="checkbox"/> High School or Secondary School Degree Complete <input type="checkbox"/> Associate’s or Technical Degree Complete <input type="checkbox"/> College or Baccalaureate Degree Complete <input type="checkbox"/> Doctoral or Postgraduate Education 	The HEAL-required CDE for education level was used
How would you describe your cigarette smoking?	Not assessed in MDS	Tobacco use in past year assessed in TAPS substance use screener
Height and Weight	Assessed similarly in MDS	