

BACPAC Minimum Dataset: Required Baseline Demographic and Outcomes Measures

The Back Pain Consortium (BACPAC) Minimum Dataset defines a collection of core data elements to be collected in all longitudinal BACPAC studies involving chronic low back pain patients. The BACPAC Minimum Dataset is an expanded version of the HEAL Initiative Core Data Elements. These data elements are collected in addition to the NIH HEAL (Helping to End Addition Long-term Initiative) minimum dataset.

The minimum dataset includes a collection of demographic and baseline characteristic core data elements, which are administered to study participants at baseline only. Longitudinal assessments are performed at both baseline and 3-month follow-up visits (3-month +/- 2 weeks).

Demographic and Baseline Characteristic Core Data Elements

These questions are core data elements required for collection at baseline by BACPAC-funded projects. Those items in this form that are also marked with asterisks (*) are data elements required for collection by the NIH HEAL Initiative.

1. *Date of birth: (mm/dd/yyyy)

2. *Age: (xx)

3. *Sex at birth:

Male

Female

Unknown

Intersex

4. *Gender identity

Male

Female

Unknown

Other, Specify

5. *Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

6. *Race (Choose all that apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Pacific Islander

White

Unknown

Not Reported

7. *What is the highest level of education you have completed?

Did not complete Secondary School or Less than High School

Some Secondary School or High School Education

High School or Secondary School Degree Complete

Associate's or Technical Degree Complete

College or Baccalaureate Degree Complete

Doctoral or Postgraduate Education

8. *What is your current employment status?

Full-time employment

Not employed

Part-time Employment

9. *What category best describes your current relationship status?

Divorced

Married

Never married

Separated

Widowed

Domestic Partner

10. Including yourself, how many people live in your household? _____

11. *How long have you had the type of pain for which you are enrolled in this study?
(Please list the number of months) _____

12. Is your low back pain more severe than pain in other parts of your body?

Yes

No

Not sure

13. Have you ever had a low-back operation?

Yes, one operation

Yes, more than one operation

No

14. If yes, when was your last back operation?

Less than 6 months

More than 6 months but less than 1 year ago

Between 1 and 2 years ago

More than 2 years ago

15. Did any of your back operations involve a spinal fusion? (also called an arthrodesis?)

Yes

No

Not sure

16. Have you been off work or unemployed for 1 month or more due to low-back pain?

Yes

No

Does not apply

17. Have you filed or been awarded a worker's compensation claim related to your back problem?

Yes

No

Does not apply

18. Are you involved in a lawsuit or legal claim related to your back problem?

Yes

No

Not sure

19. *Have you ever applied for, or received, disability insurance for your pain condition?

Yes

No

20. *Height_____ [inches] [cm] [measured] [self-reported]

21. *Weight_____ [pounds] [kilograms] [measured] [self-reported]

22. *What is your annual household income from all sources?

Less than \$10,000

\$10,000--- \$24,999

\$25,000--- \$34,999

\$35,000--- \$49,999

\$50,000--- \$74,999

\$75,000---\$99,999

\$100,000--- \$149,999

\$150,000--- \$199,999

\$200,000 or more
 Prefer not to answer

Outcomes Measures

Domains and instruments for the longitudinal assessments in the BACPAC Minimum Dataset are below. They are collected at baseline and at ongoing intervals. Where applicable, core data elements of the BACPAC Minimum Dataset are taken from previously validated instruments (e.g., PROMIS measures).

Domain	HEAL Core Instruments	Additional BACPAC Instruments
Pain Intensity	PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)	Low-Back Pain Specific Pain Intensity
Pain Interference	PEG Scale Assessing Pain Intensity and Interference (Pain, Enjoyment, General Activity)	PROMIS-4 item Pain Interference
Physical Function/QOL	PROMIS Physical Functioning Short Form 6b	
Sleep	PROMIS Sleep Disturbance 6a + Sleep Duration	
Pain Catastrophizing	Pain Catastrophizing Scale - Short Form 6 (PCS-6)	
Depression	Patient Health Questionnaire (PHQ-2)	PROMIS-4 item Depression
Anxiety	Generalized Anxiety Disorder 2-item (GAD-2)	PROMIS-4 item Anxiety
Global Satisfaction with Treatment	Patients' Global Impression of Change (PGIC)	
Substance Use Screener	Tobacco, Alcohol, Prescription medications, and other Substance (TAPS1)	
Pain Location		Radicular Pain Questions Adapted from NIH Research Task Force Minimum Dataset

Pain Somatization		Abbreviated Pain Somatization Adapted from NIH Research Task Force Minimum Dataset
Widespread Pain		Widespread Pain Inventory
Chronic Lower Back Pain (cLBP) Definition: Pain Duration and Frequency		2 Items (low-back pain duration and frequency) from National Institutes of Health (NIH) Research Task Force Minimum Dataset
Opioid Use		Single-Item Current Opioid Use

Outcomes Assessment

Completed at baseline and 3 months. *=HEAL-required CDE

Pain Duration and Frequency

1. How long has low-back pain been an ongoing problem for you?
 - a. <3 months
 - b. 3-6 months
 - c. 6 months-1 year
 - d. 1 to 5 years
 - e. More than 5 years

2. How often has low-back pain been an ongoing problem for you over the past 6 months?
 - a. Every day or nearly every day in the past 6 months
 - b. At least half the days in the past 6 months
 - c. Less than half the days in the past 6 months

Pain Location

3. Has back pain spread to your buttock or thigh during the past 2 weeks?
 - a. Yes
 - b. No
 - c. Not sure

4. Has back pain spread below your knee during the past 2 weeks?
 - a. Yes
 - b. No
 - c. Not sure

Widespread Pain

5. Do you have chronic pain in the following areas?

- 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)

Pain Somatization

6. During the past 4 weeks, how much have you been bothered by...

- a. Stomach pain
 - Not bothered at all
 - Bothered a little
 - Bothered a lot

- b. Headaches
 - Not bothered at all
 - Bothered a little
 - Bothered a lot

Low-Back Pain Specific Pain Intensity

7. In the past 7 days... How would you rate your *low-back pain* on average?

 0 1 2 3 4 5 6 7 8 9 10

No Pain

Worst imaginable pain

Current Opioid Use

8. Are you currently taking any opioid pain medication on a daily basis?

(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)

- a. Yes
- b. No
- c. Not sure

PEG: Pain Intensity and Pain Interference*

9. Select the one number that describes your pain.

1) What number best describes your pain on average in the past week?

 0 1 2 3 4 5 6 7 8 9 10

No Pain

Pain as bad as you can imagine

2) What number best describes how, during the past week, pain has interfered with your enjoyment of life?

 0 1 2 3 4 5 6 7 8 9 10

Does not Interfere

Completely Interferes

3) What number best describes how, during the past week, pain has interfered with your general activity?

 0 1 2 3 4 5 6 7 8 9 10

Does not Interfere

Completely Interferes

Pain Interference

10. PROMIS Pain Interference 4a

In the past 7 days...

How much did pain interfere with your day-to-day activities?

Not at all

A little bit

Somewhat

Quite a bit

Very much

How much did pain interfere with work around the home?

Not at all

A little bit

Somewhat

Quite a bit

Very much

How much did pain interfere with your ability to participate in social activities?

Not at all

A little bit

Somewhat

Quite a bit

Very much

How much did pain interfere with your household chores?

Not at all

A little bit

Somewhat

Quite a bit

Very much

11. PROMIS Physical Function- 6b*

Please respond to each question or statement by marking one box per row.

Are you able to do chores such as vacuuming or yard work?

- Without any difficulty (5)
- With a little difficulty (4)
- With some difficulty (3)
- With much difficulty (2)
- Unable to do (1)

Are you able to go up and down stairs at a normal pace?

- Without any difficulty (5)
- With a little difficulty (4)
- With some difficulty (3)
- With much difficulty (2)
- Unable to do (1)

Are you able to go for a walk of at least 15 minutes?

- Without any difficulty (5)
- With a little difficulty (4)
- With some difficulty (3)
- With much difficulty (2)
- Unable to do (1)

Are you able to run errands and shop?

- Without any difficulty (5)
- With a little difficulty (4)
- With some difficulty (3)
- With much difficulty (2)
- Unable to do (1)

Does your health now limit you in doing two hours of physical labor?

- Not at all (5)
- Very little (4)
- Somewhat (3)
- Quite a lot (2)
- Cannot do (1)

Does your health now limit you in doing moderate work around the house like vacuuming, sweeping the floors or carrying in groceries?

- Not at all (5)
- Very little (4)
- Somewhat (3)
- Quite a lot (2)
- Cannot do (1)

12. PROMIS Sleep Disturbance 6a*

Please respond to each question or statement by marking one box per row.

In the past 7 days...

My sleep quality was...

- Very poor (5)
- Poor (4)
- Fair (3)
- Good (2)
- Very good (1)

In the past 7 days...

My sleep was refreshing...

- Not at all (5)
- A little bit (4)
- Somewhat (3)
- Quite a bit (2)
- Very much (1)

I had a problem with my sleep...

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- Quite a bit (4)
- Very much (5)

I had difficulty falling asleep...

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- Quite a bit (4)
- Very much (5)

My sleep was restless...

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- Quite a bit (4)
- Very much (5)

I tried hard to get sleep...

- Not at all (1)
- A little bit (2)
- Somewhat (3)
- Quite a bit (4)
- Very much (5)

13. Sleep Duration*

During the past month, how many hours and minutes of actual sleep did you get at night? (This may be different than the number of hours and minutes you spent in bed).

___ hours and ___ minutes of sleep per night

14. 6-item Pain Catastrophizing Scale*

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are six statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

When I'm in pain...

1. It's awful and I feel that it overwhelms me

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

2. I feel I can't stand it anymore

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

3. I become afraid that the pain will get worse

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

4. I keep thinking about how much it hurts

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

5. I keep thinking about how badly I want the pain to stop

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

6. I wonder whether something serious may happen

___0___ ___1___ ___2___ ___3___ ___4___
Not at all To a slight degree To a moderate degree To a great degree All the time

Depression

15. PHQ-2*

a. Over the past 2 weeks, how often have you been bothered by the following problems?

i. Little interest or pleasure in doing things

Not at all	Several days	More than half the days	Nearly every day
0	1	2	3

b. Feeling down, depressed, or hopeless

Not at all	Several days	More than half the days	Nearly every day
0	1	2	3

16. PROMIS 4-item Depression

In the past 7 days...

I felt worthless

Never Rarely Sometimes Often Always

I felt helpless

Never Rarely Sometimes Often Always

I felt depressed

Never Rarely Sometimes Often Always

I felt hopeless

Never Rarely Sometimes Often Always

Anxiety

17. GAD-2*

a. Over the past 2 weeks, how often have you been bothered by the following problems?

i. Feeling nervous, anxious or on edge

Not at all	Several days	More than half the days	Nearly every day
0	1	2	3

b. Not being able to stop or control worrying

Not at all	Several days	More than half the days	Nearly every day
0	1	2	3

18. PROMIS 4-item anxiety

Emotional Distress – Anxiety – Short Form 4a

Please respond to each question or statement by marking one box per row.

In the past 7 days...

I felt fearful

Never (1)

- Rarely (2)
- Sometimes (3)
- Often (4)
- Always (5)

I found it hard to focus on anything other than my anxiety

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Always (5)

My worries overwhelmed me

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Always (5)

I felt uneasy

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Always (5)

19. Patient Global Impression of Change*

Since the start of (INTERVENTION), my overall pain is...

- 1 – Very much improved
- 2 – Much improved
- 3 – Minimally improved
- 4 – No Change
- 5 – Minimally worse
- 6 – Much worse
- 7 – Very much worse

20. TAPS* Substance Use Screener

General Instructions:

The TAPS Tool Part 1 is a 4-item screening for tobacco use, alcohol use, prescription medication misuse, and illicit substance use in the past year. Question 2 should be answered only by males and Question 3 only by females. Each of the four multiple-choice items has five possible responses to choose from. Check the box to select your answer.

1. In the PAST 12 MONTHS, how often have you used any tobacco product (for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco)?

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never

2. In the PAST 12 MONTHS, how often have you had 5 or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. (Note: This question should only be answered by males).

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never

3. In the PAST 12 MONTHS, how often have you had 4 or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. (Note: This question should only be answered by females).

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never

4. In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never

5. In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? Prescription medications that may be used this way include: Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone) Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin)

Medications for ADHD (for example, Adderall or Ritalin)

- 0 - Daily or Almost Daily
- 1 - Weekly
- 2 - Monthly
- 3 - Less Than Monthly
- 4 - Never