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 Addiction 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

   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).

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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, Dilauidid)
   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)
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 be 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)?
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