

21ST ANNUAL PSC PARTNERS SEEKING A CURE CONFERENCE



***PSC Partners' Symptom Assessment Project (SAP):
Using PRO measures to communicate patient
experiences with fatigue, brain fog & liver pain***

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PSC Fatigue, Brain Fog, and Liver Pain

*Full body fatigue...
you are just
physically exhausted
head to toe.*

*Lying down most of
the day, trying to
take naps...making
it hard to even get
up the stairs.*

*it's a struggle to keep
my eyes
open...absolutely just
exhausting to sit up.*

*It's a 10. It's like a
knife. It's intense*

*It's like just an
internal aching pain*

**PSC
Fatigue
Brain Fog
Liver Pain**

*In conversations, I'll forget what
I'm saying, or if somebody will
ask me something, and I won't
be able to answer the question*

*It definitely just feels like the
mind should be working
faster than it is, and that
there's just like a fog that's,
sort of, blocking things that it
won't work through*

*I have to set a lot of
alarms...and a lot of
reminders on my calendar
so that I do not forget things*

*The dull pain around the whole liver area that's
more problematic honestly because it's a lot
more uncomfortable and lasts for a while*

Conflict of Interest

Dr. Evon has no conflicts of interest to disclose related to this project.

Discussion Points

- The value of patient-reported outcome (PRO) measures to patients
- Development of 3 symptom measures for PSC (PSC-SAP)
- Patients' descriptions of fatigue, brain fog and liver pain
- Evaluating 3 symptom measures in PSC-P Patient Registry
- Discordance between patient – doctor symptom reporting
- Using PRO measures to communicate symptoms to your doctors

Why have patient-reported outcome (PRO) measures become so important?



How you feel and function matter

Normal labs $\neq$ Better Quality of Life

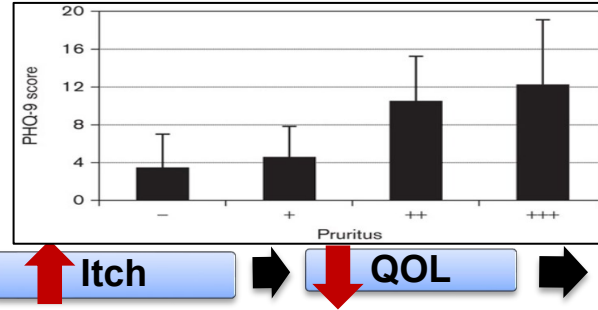
Symptoms are subjective experiences to be captured directly from the patient

Poor correlation between clinician-grading and patient-reported symptoms and side effects of treatment

Utilize PRO measures in the treatment and management of PSC

PRO
Symptom
Measure

Survey Research
studies

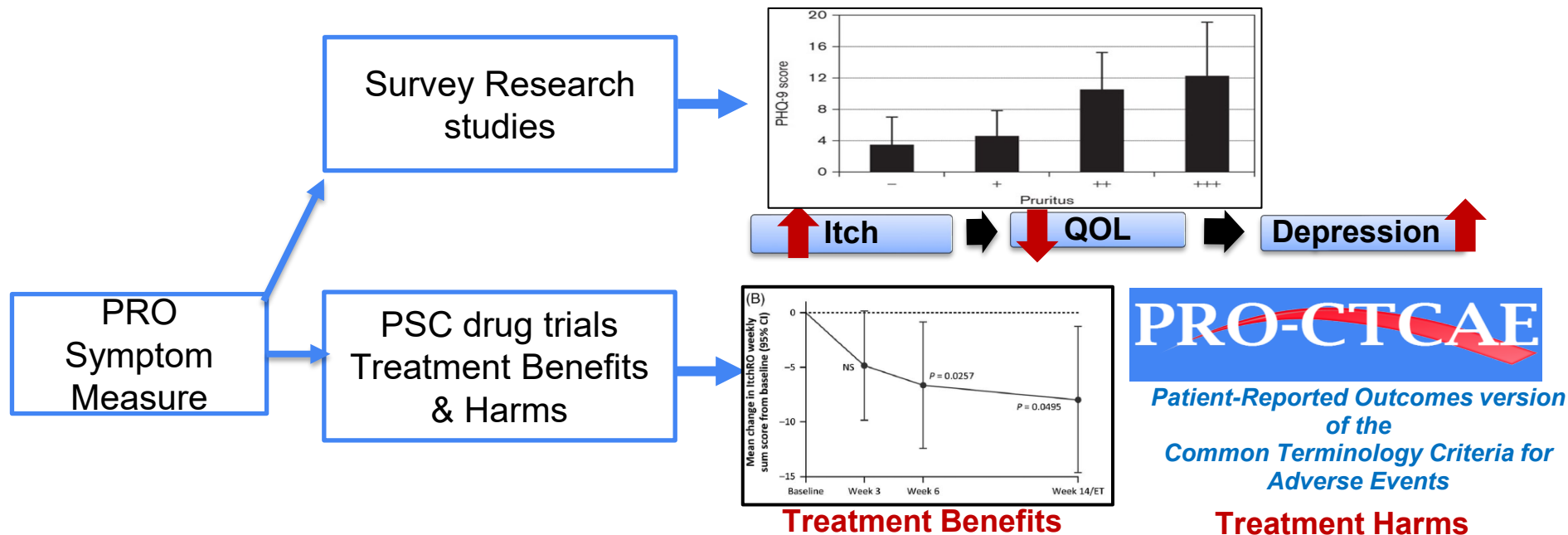


Itch

QOL

Depression

Utilize PRO measures in the treatment and management of PSC



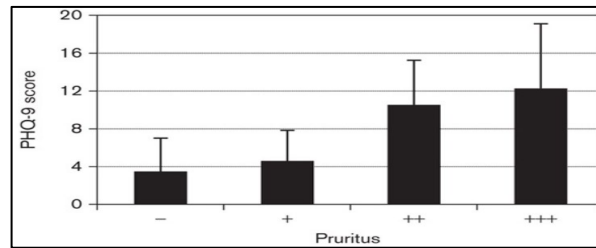
Utilize PRO measures in the treatment and management of PSC

PRO
Symptom
Measure

Survey Research
studies

PSC drug trials
Treatment Benefits
& Harms

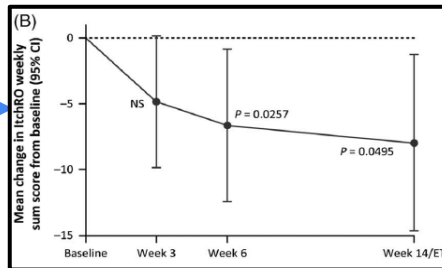
Healthcare



Itch

QOL

Depression

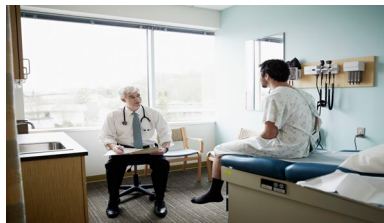


Treatment Benefits

PRO-CTCAE

*Patient-Reported Outcomes version
of the
Common Terminology Criteria for
Adverse Events*

Treatment Harms



Goal of the Symptom Assessment Project (PSC-SAP)

Design patient-reported outcome (PRO) measures that assess symptoms that are most important to adults with PSC that are appropriate for use in research and clinical trials to evaluate treatment benefits.

Patient-driven with extensive patient involvement

“Nothing about us, without us”

SAP Study Aims

Aim 1: Conduct in-depth interviews to characterize key symptoms and life impacts associated with PSC

Aim 2: Decide to select, modify, or develop self-report measures to assess three key symptoms associated with PSC

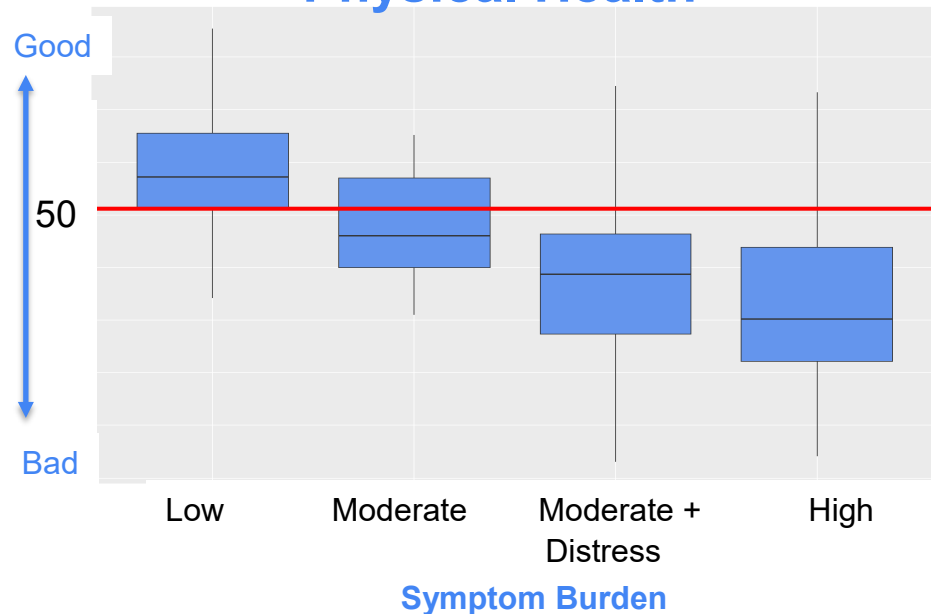
Aim 3: Conduct cognitive testing for three symptom measures to evaluate the relevance of content and clarity of the questions

Screening symptomatic patients helped identify key symptoms

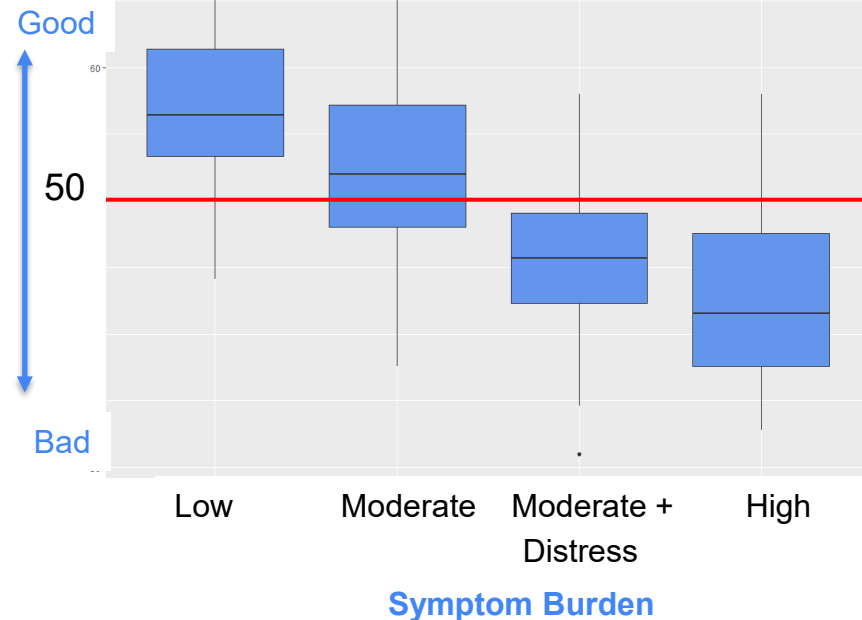
Symptoms N=126	Present in Last Month N (%)
Fatigue	105 (83%)
Daytime Drowsiness	92 (73%)
Anxiety	80 (63%)
Liver Pain	80 (63%)
Brain Fog	79 (63%)
Pruritus	78 (62%)
Difficulty Sleeping	77 (62%)
Sadness	59 (47%)
Nausea	57 (45%)
Night Sweats	42 (33%)
Other Belly Pain	38 (30%)
Vomiting	15 (12%)
Jaundice	12 (10%)

High Symptom Burden ➡ Worse Physical & Mental Health

Physical Health



Mental Health



Note: Score of 50 = US General Population Norms

Symptom Selection with PSC Partners & Community Advisors

(1) How important, (2) does a symptom tool exist, (3)
likelihood of being future study endpoint

Top Priorities

Fatigue

Brain Fog

Liver Pain

Qualitative Interviews- **FATIGUE**

Full body fatigue...
you are just
physically
exhausted head to
toe.

Your whole body is just so
tired. It's not "tired"...you feel
heavy and weak and just no
energy.

I'm fatigued all the time.
That's a 24-hour, 7-
days a week thing.

Frequent

Severe

PSC Fatigue

Interfering

Distressing

I could probably just
sleep through the day
and keep sleeping
through the night.

Lying down most
of the day, trying
to take
naps...making it
hard to even get
up the stairs.

When that's really
bad, there's no way I
can go out and
socialize.

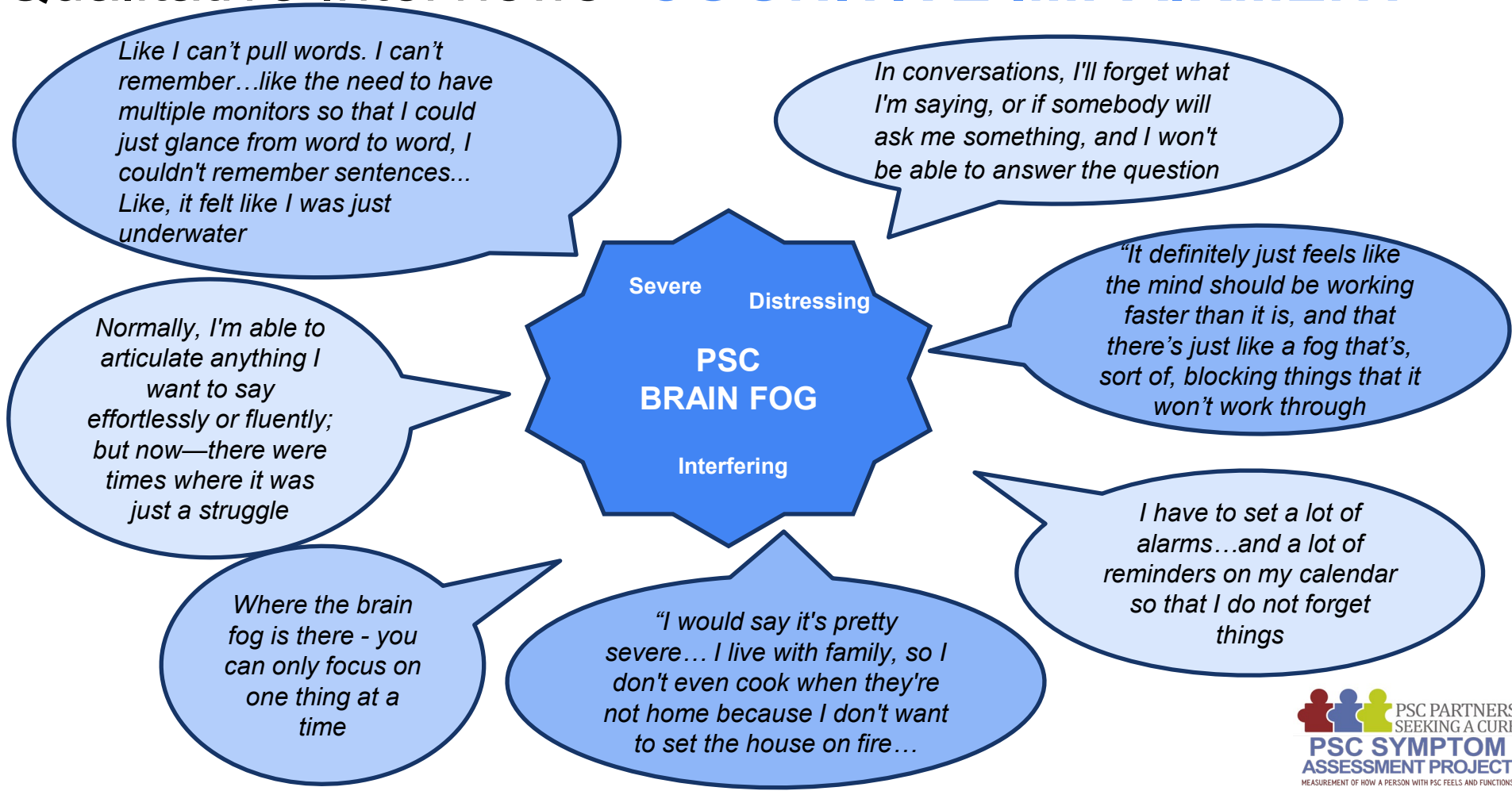
I'll go days without a
shower because it takes
so much out of me.

it's a struggle to
keep my eyes
open...absolutely
just exhausting to
sit up.

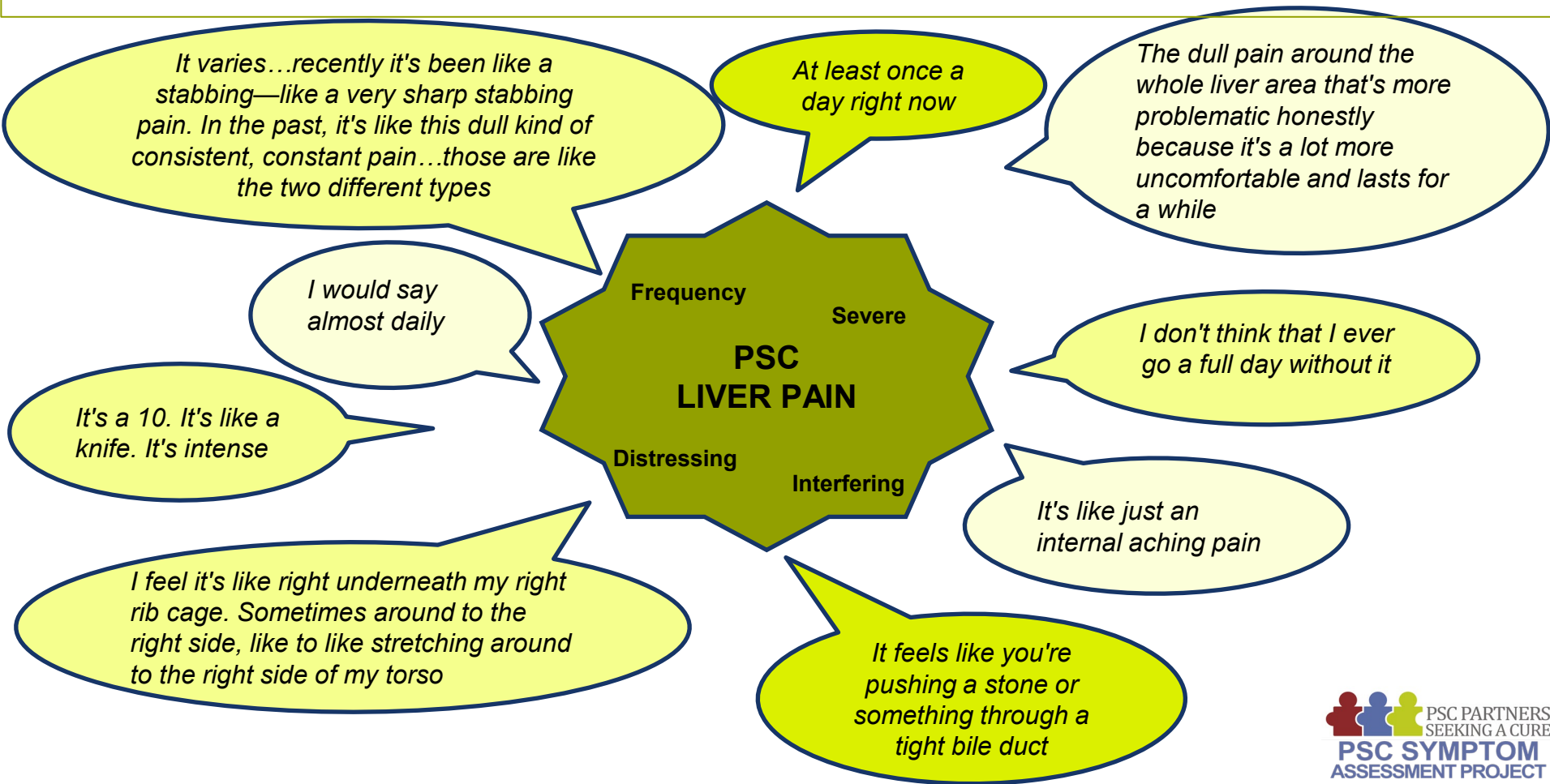
It's definitely
frustrating. I
worry about
it quite a bit.

There's times when I'm driving, I get
a little nervous because I'm like, "I
just need to get home" because I'm
nervous that I might fall asleep.

Qualitative Interviews- COGNITIVE IMPAIRMENT



Qualitative Interviews- **LIVER PAIN**



Interview data led to measurement decisions

1. Customize a Fatigue measure for PSC using PROMIS® fatigue item bank
2. Customize a Cognitive Function measure for PSC using PROMIS® cognitive function item bank
3. Develop new Liver Pain measure for PSC

Rationale to modify PROMIS® measures for PSC

NIH- funded Patient-Reported Outcomes Measurement Information System

- Designed following best practices in survey development
- Robust reliability and validity data
- Trust and transparency in the process
- Allowed to customize symptom measures
- Free, accessible, translated >30 languages
- Used internationally



Example of Item Bank for Symptoms (PROMIS Fatigue Item Bank - 95 items)



Fatigue - Calibrated Item

Please respond to each item by marking how true you are.

In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often did you feel exhausted?	☐	☐	☐	☐	☐
How often did you experience extreme exhaustion?	☐	☐	☐	☐	☐
How often did you feel tired every when you had done something?	☐	☐	☐	☐	☐
How often did you feel your fatigue was beyond your control?	☐	☐	☐	☐	☐
How often were you sluggish?	☐	☐	☐	☐	☐
How often did you feel yourself getting tired easily?	☐	☐	☐	☐	☐
How often were you obviously tired?	☐	☐	☐	☐	☐
How often did you feel tired?	☐	☐	☐	☐	☐

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In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often were you bothered by your fatigue?	☐	☐	☐	☐	☐
How often did you have enough energy to move the things you do for fun?	☐	☐	☐	☐	☐
How often were you too tired to enjoy life?	☐	☐	☐	☐	☐
How often were you too tired to find fun?	☐	☐	☐	☐	☐
How often did you feel totally drained?	☐	☐	☐	☐	☐
How often were you energetic?	☐	☐	☐	☐	☐
How often did you find yourself getting tired easily?	☐	☐	☐	☐	☐
How often did you think about your fatigue?	☐	☐	☐	☐	☐
How often did you have physical fatigue?	☐	☐	☐	☐	☐

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In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often were you too tired to do your household things?	☐	☐	☐	☐	☐
How often did your fatigue make you feel like a slave?	☐	☐	☐	☐	☐
How often were you too tired to take a bath or shower?	☐	☐	☐	☐	☐
How often did your fatigue make it difficult to organize your thoughts when doing things at home?	☐	☐	☐	☐	☐
How often did you have trouble starting things because of your fatigue?	☐	☐	☐	☐	☐
How often was it an effort to carry on a conversation because of your fatigue?	☐	☐	☐	☐	☐
How often were you too tired to socialize with your friends?	☐	☐	☐	☐	☐
How often were you too tired to leave the house?	☐	☐	☐	☐	☐

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In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often were you too tired to think clearly?	☐	☐	☐	☐	☐
How often did your fatigue tend to cut work (include work at home)?	☐	☐	☐	☐	☐
How often did you have enough energy to exercise strenuously?	☐	☐	☐	☐	☐
How often were you too tired to take a short nap?	☐	☐	☐	☐	☐
How often did you have to force yourself to get up and do things because of your fatigue?	☐	☐	☐	☐	☐
How often were you too tired to socialize with your friends?	☐	☐	☐	☐	☐

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In the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
How fatigued were you on average?	☐	☐	☐	☐	☐
How much energy did you have on average?	☐	☐	☐	☐	☐
How much mental energy did you have on average?	☐	☐	☐	☐	☐
How physically drained were you on average?	☐	☐	☐	☐	☐
How energetic were you on average?	☐	☐	☐	☐	☐
How sluggish were you on average?	☐	☐	☐	☐	☐
How much did you feel yourself getting tired on average?	☐	☐	☐	☐	☐
How much did you feel yourself getting tired on average?	☐	☐	☐	☐	☐

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In the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
To what degree did you have to push yourself to get things done because of your fatigue?	☐	☐	☐	☐	☐
To what degree did your fatigue make you feel slowed down in your thinking?	☐	☐	☐	☐	☐
To what degree did you have trouble starting things because of your fatigue?	☐	☐	☐	☐	☐
How hard was it for you to carry on a conversation because of your fatigue?	☐	☐	☐	☐	☐
To what degree did you have to limit your social activities because of your fatigue?	☐	☐	☐	☐	☐
To what degree did your fatigue make it difficult to organize your thoughts when doing things at home?	☐	☐	☐	☐	☐
To what degree did your fatigue make it difficult to start something new?	☐	☐	☐	☐	☐

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PROMIS Item Bank v.1.0 - Fatigue

In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often did you have to push yourself to get things done because of your fatigue?	☐	☐	☐	☐	☐
How often did your fatigue interfere with your social activities?	☐	☐	☐	☐	☐
How often were you too effective at work due to your fatigue (include work at home)?	☐	☐	☐	☐	☐
How often did your fatigue make you feel slowed down in your thinking?	☐	☐	☐	☐	☐
How often were you too tired to watch television?	☐	☐	☐	☐	☐
How often did your fatigue make it difficult to take activities ahead of time?	☐	☐	☐	☐	☐
How often did your fatigue make it difficult to start something new?	☐	☐	☐	☐	☐
How often did your fatigue make you more energetic?	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

In the past 7 days...

	Never	Rarely	Sometimes	Often	Always
How often were you too tired to do anything?	☐	☐	☐	☐	☐
How often did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?	☐	☐	☐	☐	☐
How often did your fatigue interfere with your ability to respond to unexpected activities?	☐	☐	☐	☐	☐
How often did you have trouble finishing things because of your fatigue?	☐	☐	☐	☐	☐
How often did your fatigue make it difficult to make decisions about things?	☐	☐	☐	☐	☐
How often did you have to limit your social activities because of your fatigue?	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

During the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
I feel fatigued ("washed out").	☐	☐	☐	☐	☐
I feel tired.	☐	☐	☐	☐	☐
I have trouble <u>starting</u> things because I am tired.	☐	☐	☐	☐	☐
I have trouble <u>finishing</u> things because I am tired.	☐	☐	☐	☐	☐
I have energy.	☐	☐	☐	☐	☐
I am able to do my usual activities.	☐	☐	☐	☐	☐
I tend to sleep during the day.	☐	☐	☐	☐	☐
I am too tired to eat.	☐	☐	☐	☐	☐
I am bothered by being too tired to do things I want to do.	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

During the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
I have to limit my social activities because I am tired.	☐	☐	☐	☐	☐
To what degree did you feel tired every when you had to do activities?	☐	☐	☐	☐	☐
How tired were you on average?	☐	☐	☐	☐	☐
How fatigued were you when your fatigue was at its worst?	☐	☐	☐	☐	☐
How tired did you feel on average?	☐	☐	☐	☐	☐
How much were you bothered by your fatigue on average?	☐	☐	☐	☐	☐
How exhausted were you on average?	☐	☐	☐	☐	☐
How fatigued were you on the day you felt worst fatigue?	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

In the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
Due to your fatigue were you less effective at work (include work at home)?	☐	☐	☐	☐	☐
To what degree did your fatigue make it difficult to make decisions?	☐	☐	☐	☐	☐
To what degree did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?	☐	☐	☐	☐	☐
To what degree did your fatigue make you more forgetful?	☐	☐	☐	☐	☐
To what degree did your fatigue interfere with your ability to respond to unexpected activities?	☐	☐	☐	☐	☐
To what degree did you have to force yourself to get up and do things because of your fatigue?	☐	☐	☐	☐	☐
To what degree did your fatigue interfere with your social activities?	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

In the past 7 days...

	Not at all	A little bit	Sometimes	Often a lot	Very much
To what degree did your fatigue interfere with your social activities?	☐	☐	☐	☐	☐
Did fatigue make you less effective at home?	☐	☐	☐	☐	☐
To what degree did you have trouble finishing things because of your fatigue?	☐	☐	☐	☐	☐
To what degree did your fatigue make you feel less sharp?	☐	☐	☐	☐	☐
During the past 7 days...					
I feel fatigued.	☐	☐	☐	☐	☐
I feel tired all over.	☐	☐	☐	☐	☐
In the past 7 days...					
On how many days were your fatigue worse in the morning?	☐	☐	☐	☐	☐
What was the level of your fatigue on your worst day?	☐	☐	☐	☐	☐

PROMIS Item Bank v.1.0 - Fatigue

Customizing a PROMIS® Fatigue Measure for PSC

		In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
General fatigue →	1	I feel fatigued.					
Weakness →	2	I feel weak all over.					
Sleep →	3	I need to sleep during the day.					
Frustration, emotional impact →	4	I am frustrated by being too tired to do the things I want to do.					
Interference with social activity →	5	I have to limit my social activity because I am tired					
Exhaustion →	6	How exhausted were you on average?					
Interference with work →	7	Due to your fatigue were you less effective at work (include work at home)?					
Impact on cognitive function →	8	To what degree did your fatigue make you feel slowed down in your thinking?					
Overall interference →	9	To what degree, did you feel tired even when you hadn't done anything?					
Impact on initiation / motivation →	10	To what degree, did you have to force yourself to get up and do things because of your fatigue?					
Impact on finishing tasks →	11	To what degree did you have trouble finishing things because of your fatigue?					
Feelings of heaviness →	12	My body and limbs feel heavy.					
Full body experience →	13	My fatigue is a full body experience.					

		In the past 7 days...	Not at all	A little bit	Somewhat	Quite a bit	Very much
Energy →	14	I have energy.					

Customizing a PROMIS® Cognitive Function Measure for PSC

		In the past 7 days...	Never	Rarely (once)	Sometimes (two or three times)	Often (about once a day)	Very Often (several times a day)
Attention & Concentration →	1	I have had trouble concentrating.					
Attention: Sustained Vigilance →	2	I have had to work <u>really hard</u> to pay attention or I would make a mistake.					
Attn&Con, Exec Function, Working Memory →	3	I have had trouble shifting back and forth between different activities that require thinking.					
Processing Speed →	4	My thinking has been foggy.					
Lang/Verbal skills: Naming and Fluency →	5	I have had to work harder than usual to express myself clearly.					
Lang/Verbal skills: Naming →	6	I have had trouble recalling the name of an object while talking to someone.					
Processing Speed →	7	My thinking has been slow.					
Working Memory →	8	I have walked into a room and forgotten what I meant to get or do there.					
Working Memory / Numeracy →	9	I have had trouble adding and subtracting numbers in my head.					
Work Interference →	10	My problems with memory, concentration, or making mental mistakes have interfered with my ability to work.					
Quality of Life Interference →	11	My problems with memory, concentration, or making mental mistakes have interfered with the quality of my life.					

Developing a new Liver Pain Measure for PSC

If you selected dull or achy pain, please answer questions #2 to question #8.

2. In the past 7 days, how often did you have dull or achy pain in the area around your liver?
 - Never
 - 1 to 2 days
 - 3 to 4 days
 - 5 to 6 days
 - All 7 days
3. In the past 7 days, how many times per day did you usually have dull or achy pain in the area around your liver?
 - None
 - Once a day
 - 2-3 times a day
 - 4-5 times a day
 - 6 or more times, or constant pain during the day
4. In the past 7 days, how would you rate the dull or achy pain in the area around your liver at its worst?
 - No pain
 - Mild
 - Moderate
 - Severe
 - Very severe
5. In the past 7 days, how much did the dull or achy pain in the area around your liver interfere with your daily activities?
 - Not at all
 - A little bit
 - Somewhat
 - Quite a bit
 - Very much

- Ask about dull vs sharp pain separately
- Use skip logic to reduce # of items

6. In the past 7 days, how much did the dull or achy pain in the area around your liver interfere with your sleep?
 - Not at all
 - A little bit
 - Somewhat
 - Quite a bit
 - Very much
7. In the past 7 days, how much did the dull or achy pain in the area around your liver cause you distress?
 - Not at all
 - A little bit
 - Somewhat
 - Quite a bit
 - Very much
8. In the past 7 days, how much did the dull or achy pain in the area around your liver interfere with your quality of life?
 - Not at all
 - A little bit
 - Somewhat
 - Quite a bit
 - Very much

Cognitive Testing Ensured Relevance and Clarity

Fatigue

In the past 7 days...	Not at all	A little	Somewhat	Quite a bit	Very much
1 I feel fatigued.					
2 I feel weak all the time.					
3 I am too tired to get things done.					
4 I am exhausted by having too much to do.					
5 I have to limit my social activity because I am tired.					
6 I have exhausted more energy than I want to.					
7 Due to your fatigue were you less effective at work (include work at home)?					
8 To what degree did your fatigue make you feel slowed down at work (include home)?					
9 To what degree, did you feel tired even when you hadn't done anything?					
10 To what degree, did you have to force yourself to get up and do things because of your fatigue?					
11 To what degree did you have trouble finishing things because of your fatigue?					
12 My body and limbs feel heavy.					
13 My fatigue is a full body experience.					

Round 1



Interviews
8 patients

Revised

Round 2



Interviews
6 patients

Finalized

Brain Fog

In the past 7 days...	None	Rarely (once)	Sometimes (three or four times)	Often (almost every day)	Very often (every day)
1 I have had trouble concentrating.					
2 I have had to work really hard to pay attention or I would make a mistake.					
3 I have had trouble shifting back and forth between different activities that require thinking.					
4 My thinking has been foggy.					
5 I have had to work harder than usual to express myself verbally.					
6 I have had trouble recalling the name of an object while talking to someone.					
7 My thinking has been slow.					
8 I have walked into a room and forgotten what I meant to say or do.					
9 I have had trouble adding and subtracting numbers in my head.					
10 My problems with memory, concentration, or making mental calculations have interfered with my ability to work.					
11 My problems with memory, concentration, or making mental calculations have interfered with the quality of my life.					



Interviews
8 patients

Revised



Interviews
6 patients

Finalized

Liver Pain

6. In the past 7 days, how much did the dull or aching pain in the area around your liver interfere with your sleep?	Not at all	A little bit	Somewhat	Quite a bit	Very much
7. In the past 7 days, how much did the dull or aching pain in the area around your liver cause you distress?	Not at all	A little bit	Somewhat	Quite a bit	Very much
8. In the past 7 days, how much did the dull or aching pain in the area around your liver interfere with your quality of life?	Not at all	A little bit	Somewhat	Quite a bit	Very much

Round 1



Interviews
8 patients

Revised

Round 2



Interviews
8 patients

Finalized

Cognitive Testing Ensured Relevance and Clarity

Fatigue

In the past 7 days...	Not at all	A little	Somewhat	Quite a bit	Very much
1. I feel fatigued.					
2. I feel weak all the time.					
3. I am too tired to do things during the day.					
4. I am exhausted by having too much to do the things I want to do.					
5. I have to limit my social activity because I am tired.					
6. I have exhausted more energy than I want to.					
7. Due to your fatigue, you are less effective at work (include work at home).					
8. To what degree did your fatigue make you feel slowed down at work?					
9. To what degree, did you feel tired even when you hadn't done anything?					
10. To what degree, did you have to force yourself to get up and do things because of your fatigue?					
11. To what degree did you have trouble thinking things because of your fatigue?					
12. My body and limbs feel heavy.					
13. My fatigue is a full body experience.					

Round 1



Interviews
8 patients

Revised

Round 2



Interviews
6 patients

Finalized

Brain Fog

In the past 7 days...	None	Slightly	Somewhat	Quite a bit	Very much
1. I have trouble concentrating.					
2. I have had to work really hard to pay attention or I would make a mistake.					
3. I have trouble thinking back and forth between different activities that require thinking.					
4. My thinking has been foggy.					
5. I have had to work harder than usual to express myself verbally.					
6. I have had trouble recalling the name of an object while talking to someone.					
7. My thinking has been slow.					
8. I have walked into a room and forgotten what I meant to get or do there.					
9. I have had trouble adding and subtracting numbers in my head.					
10. My problems with memory, concentration, or making mental calculations have interfered with my ability to work.					
11. My problems with memory, concentration, or making mental calculations have interfered with the quality of my life.					



Interviews
8 patients

Revised



Interviews
6 patients

Finalized

Liver Pain

6. In the past 7 days, how much did the dull or aching pain in the area around your liver interfere with your ability to?	
• Not at all	
• A little bit	
• Somewhat	
• Quite a bit	
• Very much	
7. In the past 7 days, how much did the dull or aching pain in the area around your liver cause you distress?	
• Not at all	
• A little bit	
• Somewhat	
• Quite a bit	
• Very much	
8. In the past 7 days, how much did the dull or aching pain in the area around your liver interfere with your quality of life?	
• Not at all	
• A little bit	
• Somewhat	
• Quite a bit	
• Very much	

Round 1



Interviews
8 patients

Revised

Round 2



Interviews
8 patients

Finalized

Next Steps

- Evaluate how the measures perform
- Patient Registry
 - WIND
 - Industry

Evaluate measures performance via PSC Partners Patient Registry

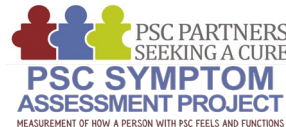


Online global registry of PSC patients: 2700 participants from 54 countries

Building real world evidence at large scale:

1. What is the distribution of responses?
2. Is increased symptom burden associated with disease history?
3. How do responses compare when retaken 7 days later?

Launched 8/19: Currently available for Registry participants experiencing symptoms

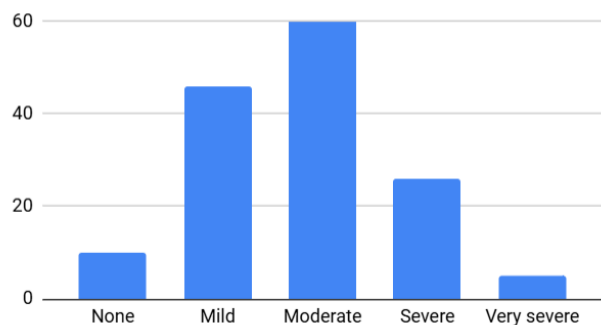


Evaluate measures performance via PSC Partners Patient Registry

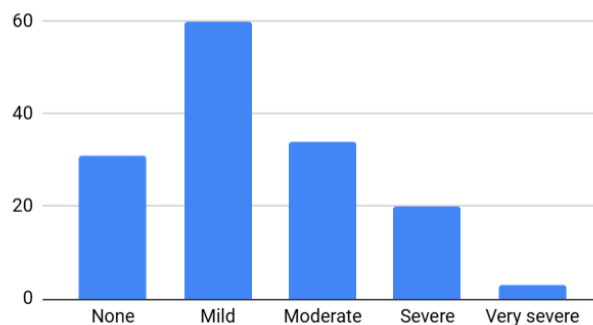


Patients' overall ratings of symptoms

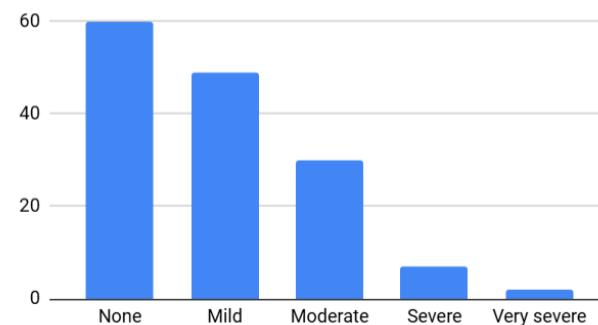
Fatigue



Brain Fog



Liver Pain



Preliminary data as of 9/2

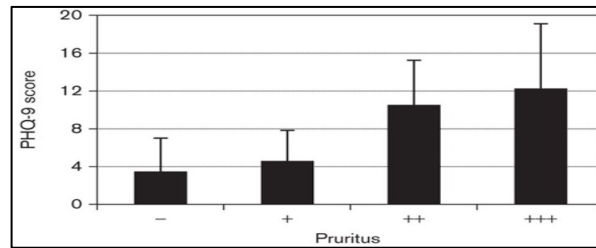
Utilize PRO measures in the treatment and management of PSC

PRO
Symptom
Measure

Survey Research
studies

PSC drug trials
Treatment Benefits
& Harms

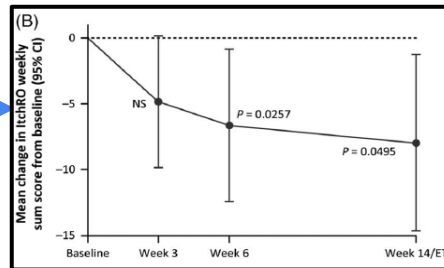
Healthcare



Itch

QOL

Depression

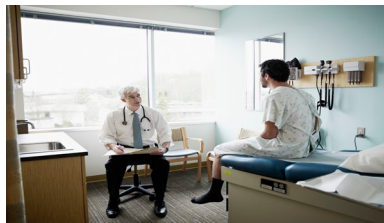


Treatment Benefits

PRO-CTCAE

*Patient-Reported Outcomes version
of the
Common Terminology Criteria for
Adverse Events*

Treatment Harms



Discordance between patient – doctor symptom reporting

Doctor symptom monitoring does not adequately capture patient symptoms

Generally, clinicians report:

- Fewer symptoms
- Lower severity
- Across different diseases
- In clinical trials
- In clinical care

Agreement is modest:

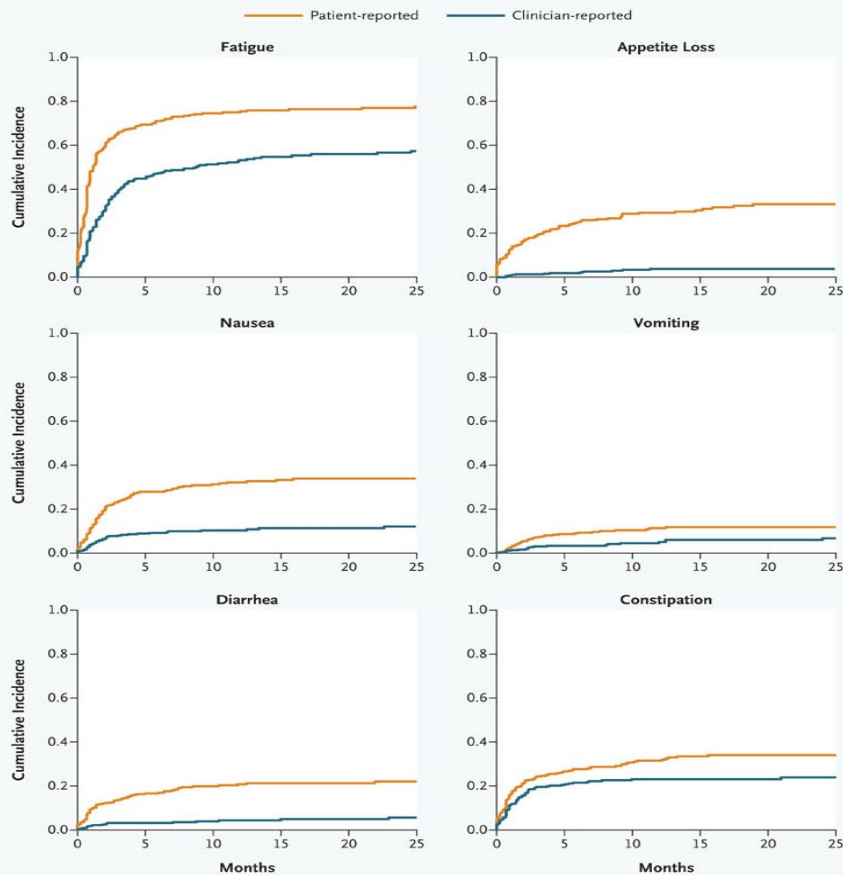
Correlations: 0.30 to 0.50

(0=no overlap to 1.0 = perfect overlap)

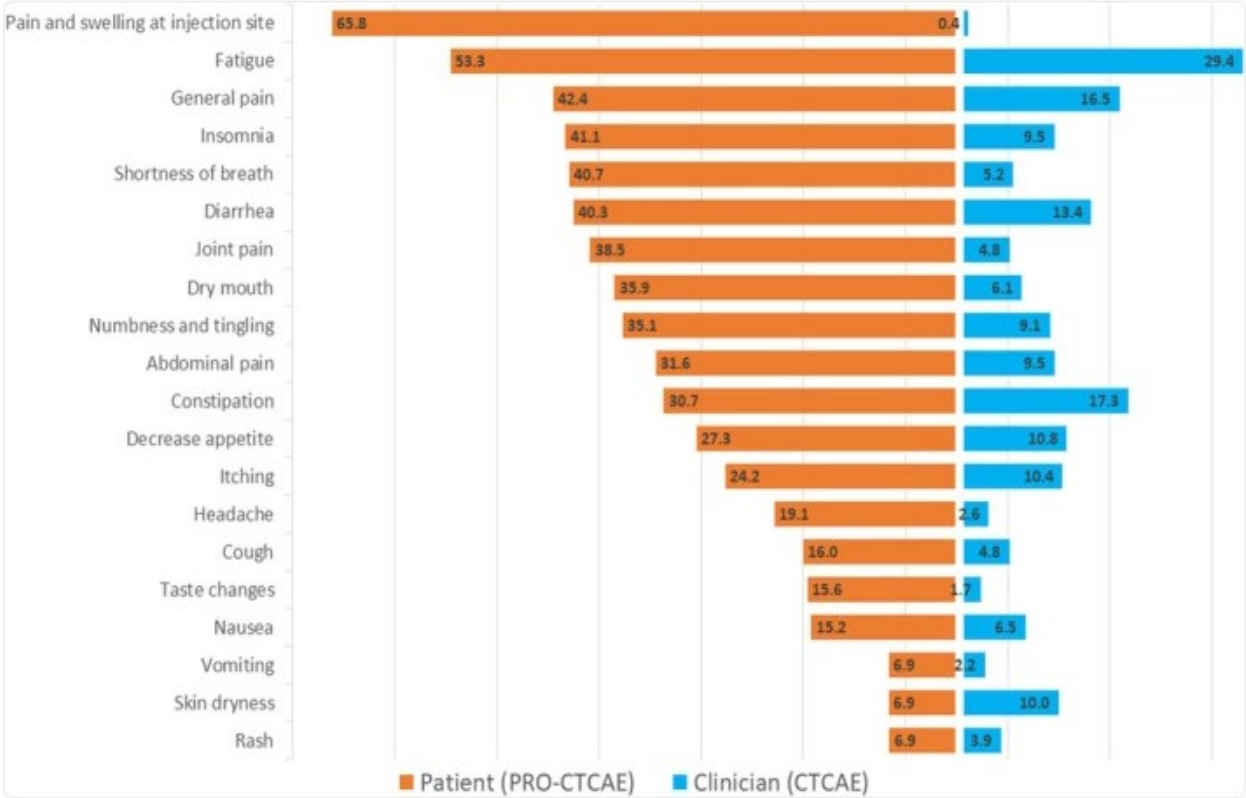
Discordance between patient – doctor symptom reporting

— Patient-reported

— Clinician-reported

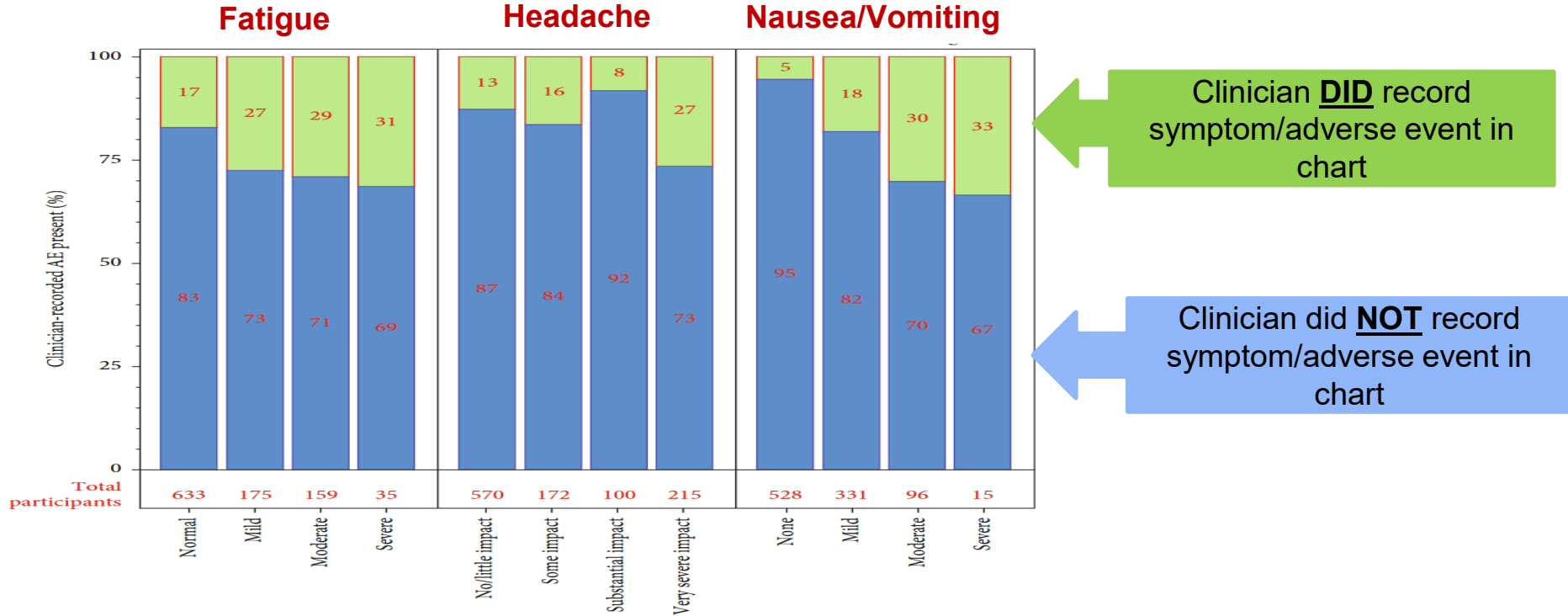


Discordance between patient – doctor symptom reporting



Annakib et al. Patient Vs Clinician Reported Symptoms Agreement in Advanced Metastatic Bladder Cancer Patients. Cancer Med. 2025 PMC12010202.

Discordance between patient – doctor symptom reporting



Why does discordance happen?

- Symptoms are subjective and non-observable
- Symptoms do not correlate with disease activity
- Overlap with other issues (e.g., depression) or other condition
- Clinicians are busy/overworked
- Inadequate time to communicate

What can be done?

- Use PRO surveys to communicate
- Electronic PROs in medical record
- Shared patient-clinician symptom review helps
- Real time ePRO measures helps

Use PRO measures to communicate your symptoms to your doctors

PSC Fatigue measure

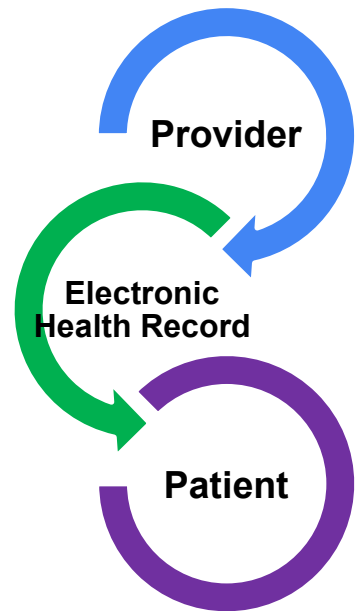
PSC Cognitive Function measure

- Complete before clinic visits
- Upload attachment to EHR
- Communicate attributes:
 - Frequency
 - Duration
 - Severity
 - Distress
 - Interference with life

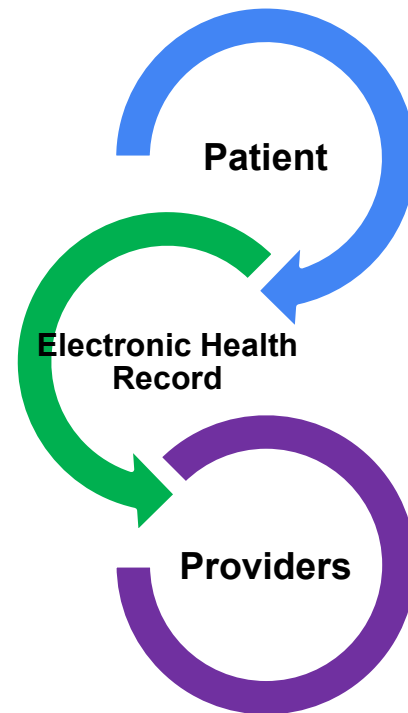
Instructions: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom during this past week, let us know how OFTEN you had it, how SEVERE it was usually and how much it DISTRESSED or BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE."

DURING THE PAST WEEK Did you have any of the following symptoms?	DID NOT HAVE	IF YES How OFTEN did you have it?				IF YES How SEVERE was it usually				IF YES How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost Constantly	Slight	Moderate	Severe	Very Severe	Not at all	A Little Bit	Somewhat	Quite a Bit	Very Much
Difficulty concentrating		1	2	3	4	1	2	3	4	0	1	2	3	4
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Cough		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Dry mouth		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Numbness/tingling in hands/feet		1	2	3	4	1	2	3	4	0	1	2	3	4
Difficulty sleeping		1	2	3	4	1	2	3	4	0	1	2	3	4

PROs Improve Patient Care and Patient-Provider Communication



- Complete ePROs in Patient Portal
- Checklists identifies patient issues:
 - Medical
 - Psychosocial
 - Informational
 - Nutritional
- Results populate in EHR
- Message is sent to right provider
- SUPPORT is on the way



Take home points

- Patient reported outcome (PRO) measures are tools to communicate subjective experiences
- PSC-SAP has developed symptom measures for PSC fatigue, brain fog and liver pain
- PROs – research, clinical trials, healthcare
- Use PRO measures to communicate your symptoms





With Gratitude



- Ricky Safer & PSC-Partners for funding the PSC-SAP
- 126 people living with PSC who contacted us to participate in PSC-SAP
- 13-member Community Advisory Board
- Duke: Bryce Reeve, Nicole Lucas, Laura Mkumba, Lauren Wright
- UNC: Kaya Merkler