

CHRONIC OVERLAPPING PAIN CONDITIONS SCREENER

VERSION 11.0

Users Guide

**Andrew Schrepf, Ph.D.
David A. Williams, Ph.D.
William Maixner, DDS, Ph.D.**

The REDCap Version

Sponsored by:

NIH 3U01DK082345-08S1

NIH 3U01-DE017018-12S1

NIH 3U19AR076734-01W1

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The proper citation for this manual is as follows:

Schrepf A, Williams DA, Maixner W. Chronic Overlapping Pain Conditions Screener - The REDCap Version: Users Guide, Version 11.0. Ann Arbor, MI: University of Michigan; 2022.

Acknowledgements

We are indebted to our friend and colleague Bill Maixner who passed away unexpectedly during the development of the COPCS. He was a leader in the field of pain research and was passionate about understanding the mechanisms associated with COPCs.

We also wish to acknowledge the assistance of Brad Trumpower whose expertise was invaluable in converting the COPCS into REDCap.

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Chapter 1

Development of the Chronic Overlapping Pain Conditions Screener (COPCS)

The COPCS was designed to rapidly assess for the presence of one or more of the chronic overlapping pain conditions (COPCs) within a given individual. Until its development, there was no single self-reported measure that could capture all 10 of the COPCs within the same individual.

Background

In 2011 the Institute of Medicine released its report *Relieving Pain in America*¹ that highlighted the magnitude and significance of chronic pain to the American public. The report also noted that some common or highly prevalent chronic pain conditions appeared to coexist, and that these coexisting conditions were sensory neurological disorders that were generally more prevalent in females compared to males.³⁻⁵ The concept of coexisting pain conditions has also been recognized by the National Institutes of Health (NIH) as a set of disorders that co-aggregate and include, but should not be limited to, temporomandibular disorders (TMD), fibromyalgia (FM), irritable bowel syndrome (IBS), vulvodynia (VVD), myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), interstitial cystitis/bladder pain syndrome (IC/BPS) and chronic prostatitis, painful endometriosis (ENDO), chronic tension-type headache (cTTH), migraine headache (MI), and chronic lower back pain (cLBP). Collectively, these conditions are increasingly referred to as Chronic Overlapping Pain Conditions (COPCs).⁵ Together, they represent the most common and prevalent chronic pain conditions that impact millions of Americans, and consume billions of healthcare dollars annually^{3,5}. *Importantly, the lack of standardized classification tools for these conditions has impeded our ability to study the underlying etiology of these conditions and to develop optimal treatments.*

Given the tendency to treat pain complaints within medical specialties it has been difficult to study COPCs that occur in multiple body regions and therefore cross medical specialty boundaries. For example, a patient with both interstitial cystitis (IC) and temporomandibular disorder (TMD) would likely be seen by a urologist focused upon identifying pathology in the bladder as well as a dentist focused upon identifying pathology in the jaw. In practice, neither practitioner would be likely to suspect a common underlying mechanism such as aberrant central pain processing, and may not even be aware of the other pain complaint. Instead, treatment would likely focus on “correcting” the peripheral or anatomical source of each pain complaint - an approach which is not

likely to address the common underlying etiology of the conditions.^{3,4}

Historically, there has been no method for assessing each of the COPCs in a single individual and as such, there was no method for studying the mechanisms that might contribute to these COPCs in affected individuals. The existence of such an assessment tool would permit the stratification of pain patients into diagnostic groups and into clusters of overlapping conditions. Such a tool would also permit discovery of common risk factors and biological pathways that could pave the way to improved diagnostic procedures, and new personalized, non-opioid treatments for these conditions – a needed advance in reducing reliance on opioid therapies, reducing population level opioid exposure, and reducing negative life events including death.⁶

The NIH Pain Consortium lays the foundation for a COPC screener.

In 2015, the NIH Pain Consortium developed a task force charged with determining how best to study COPCs in existing and future NIH sponsored research. The Task Force determined that most existing pain studies and databases characterize only a single targeted (i.e., index condition) and fail to adequately account for other COPCs; thus, it was difficult to identify and study the mechanisms contributing to the co-occurrence of these conditions within a given individual. A necessary starting point for any meaningful investigation into the underlying mechanisms of COPCs would require a standardized classification tool.

In 2016, two supplements were awarded: one to the NIDDK MAPP network (U01 DK092345-S1) and one to the NIDCR OPPERA project (U01 DE017018-S1). The aims of these supplements were to 1) gain consensus from expert knowledge leaders (i.e., KOLs) on self-reported diagnostic criteria for all 10 COPCs, 2) develop a diagnostic tool for all 10 COPCs (i.e., the Chronic Overlapping Pain Conditions Screener (COPCS), and 3) digitize the COPCS for future application in research and clinical practice. Aims 1 and 2 were led by the University of Michigan and Aim 3 occurred at Duke University.

Consensus around the diagnostic criteria.

While most of the COPCS have established diagnostic criteria, some do not, or in some cases multiple diagnostic approaches were in use. So, as to gain consensus on how best to operationalize the self-reported criteria for classifying individuals, a consensus panel of key opinion leaders for each of the COPCs was convened. Often this panel included individuals who were involved in publishing the formal diagnostic criteria. Three experts for each of the 10 COPCS were consulted and each group of 3 experts needed to reach consensus about how best to assess their respective conditions. *Table 1.1*

displays the list of experts, their affiliations, and the published criteria that was considered in developing the COPCS.

Table 1.1

COPC and Considered Criteria	Experts
<u>Fibromyalgia (FM)</u> ACR 1990 Research Classification ⁷ ACR 2010 Diagnostic Criteria ⁸ 2011 FM survey Criteria ⁹	Dan Clauw, M.D. - <i>University of Michigan</i> Lesley Arnold, M.D. - <i>University of Cincinnati</i> Don Goldenberg, M.D. - <i>Oregon Health Sciences University</i>
<u>Temporomandibular Disorder (TMD)</u> Research Diagnostic Criteria ¹⁰ TMD Screener ¹¹ DC/TMD ¹²	William Maixner, DDS, Ph.D. - <i>Duke University</i> Richard Ohrbach, DDS, Ph.D. <i>University at Buffalo</i> Roger Fillingim, Ph.D. - <i>University of Florida</i>
<u>Irritable Bowel Syndrome (IBS)</u> Rome III Criteria ¹³	Bruce Naliboff, Ph.D. - <i>University of California, Los Angeles</i> William Whitehead, Ph.D. - <i>University of North Carolina at Chapel Hill</i> Emeran Mayer, M.D. - <i>University of California, Los Angeles</i>
<u>Chronic Fatigue Syndrome (CFS/ME)</u> CDC Criteria ¹⁴ Revised Canadian 2010 Criteria ¹⁵ IOM 2015 (SEID) Criteria ¹⁶	Dane Cook, Ph.D. - <i>University of Wisconsin, Madison</i> Lucinda Bateman, M.D. - <i>Bateman Horne Center</i> Andrea Kogelnik, M.D., Ph.D. - <i>Open Medicine Institute</i>
<u>Migraine Headache (MI)</u> ID-CM ¹⁷ International Classification of Headache Disorders III ¹⁸	Richard Lipton, M.D. - <i>Albert Einstein College of Medicine</i> Tim Houle, Ph.D. - <i>Massachusetts General Hospital</i> Wade Cooper, M.D. - <i>University of Michigan</i>
<u>Chronic Tension-type Headache (cTTH)</u> Modified (for cTTH) ID-CM ¹⁹ International Classification of Headache Disorders III ¹⁸	Richard Lipton, M.D. - <i>Albert Einstein College of Medicine</i> Tim Houle, Ph.D. - <i>Massachusetts General Hospital</i> Wade Cooper, M.D. - <i>University of Michigan</i>
<u>Chronic Low Back Pain (cLBP)</u> NIH Task Force ²⁰	Michael vonKorff, ScD - <i>Kaiser Permanente Washington Health Research Institute</i> Bob Kerns, Ph.D. - <i>Yale University</i> Sean Mackey, M.D., Ph.D. - <i>Stanford University</i>

Urologic Chronic Pelvic Pain (UCPPS) Interstitial Cystitis and Painful Bladder Syndrome (IC/PBS) GUPI ²¹ RICE criteria ²²	J. Quentin Clemens, M.D. - University of Michigan Michel Pontari, M.D. - Temple University Ursula Wesselmann, M.D., Ph.D. - University of Alabama, Birmingham
Painful Endometriosis (ENDO) Epidemiology Case definition ²³ Self-report of physician diagnosis	Susie As-Sanie, M.D. - University of Michigan Frank Tu, M.D., MPH - Northshore Research Institute Georgine Lamvu, M.D., MPH - Orland VA Medical Center
Vulvodynia (VVD) Consensus terminology ²⁴	Barbara Reed, M.D., MSPH - University of Michigan Ruby Nguyen, Ph.D. - University of Minnesota Christin Veasley - Chronic Pain Research Alliance

While some of the diagnostic categories required only 1 meeting and consensus was rapid (e.g., FM, IBS), other categories required multiple meetings of the experts in order to reach consensus. In the end however, consensus was reach for all COPCs.

Structuring the COPCS prototype.

One goal in the development of the COPCS was to produce a screener that would be more efficient than having a clinician administer the formal diagnostic criteria for all 10 COPCS to a given individual. With this goal in mind, the COPCS uses the combination of a body map and several questions to trigger the administration of each diagnostic module. For example, if the individual marks jaw pain on the body map, this would trigger the administration of the criteria for TMD. If no areas around the head are marked, the likelihood of this individual having TMD is low and therefore the TMD module is bypassed.

Once all of the items for the each of COPCs were finalized, the scoring algorithms were written, and the triggering logic was completed, the panel of experts was again convened to review and approve of the draft project. The project was approved, allowing the blueprints to be digitized into a working assessment tool.

Developing the digital version of the COPCS.

With the instructions now written, Duke University in combination with Research Triangle Institute (RTI) digitized the first working prototype of the COPCS.

Several versions of the COPCS were tested at Duke before ultimately deciding to incorporate the COPCS into their Pain Clinic's electronic data collection protocol. Early versions of the COPCS were also programmed into CHOIR at Stanford and into Qualtrics at Michigan. Versioning of the COPCS addressed updates to some of the diagnostic criteria as new criteria emerged or addressed patient feedback regarding ease of use.

The NIH HEAL Initiative requests broader access to the COPCS.

The Research Electronic Data Capture (REDCap) is a software system designed for use in clinical and translational research. It is available without charge to research institutions, which greatly expands access compared to fee-based platforms. The University of Michigan received supplemental funds from their NIAMS BACPAC parent grant to reprogram the COPCS into REDCap and conduct simple validation (NIH 3U19AR076734-01W1).

New to Version 11.0. With version 11.0, the reprogramming of the COPCS into REDCap reflects some major changes from prior versions. Since REDCap does not permit "clicking" within graphics, we created a simplified body map with accompanying check boxes. We consulted patient groups for guidance regarding the best layout, formatting, and colors, for this important aspect of the screener. In addition, logical changes to the scoring and/or skip logic were requested from the expert panelists associated with IC/CP, painful endometriosis, and VVD. The new version 11.0 was then reviewed by several patient panels for usability, comprehension, and administration time. A second cohort of patients participated in a validation study of the COPCS described later.

Ongoing and future studies with the COPCS will further support the validity of the COPCS and its use in clinical studies of individuals with COPCs.

Chapter 2 Items of the COPCS

WELCOME

COPCS

Chronic Overlapping Pain Conditions Screener

This survey is designed to identify pain conditions that often occur together in the same individual.

- The first part of the survey presents a body map and asks you to indicate the locations where you experience pain.
- Based upon where you indicate the presence of pain, additional questions about symptoms will be asked to help identify the type of pain condition(s) that you are experiencing in each location. You may be asked about more than one condition even if you have pain in only one area of the body.

Please complete this survey on your own in a quiet location. Depending on your answers the survey should take 10-30 minutes to complete. Thank you.

Demographics

Note: "name" can be replaced with study ID

Note: biological sex is needed for branching logic

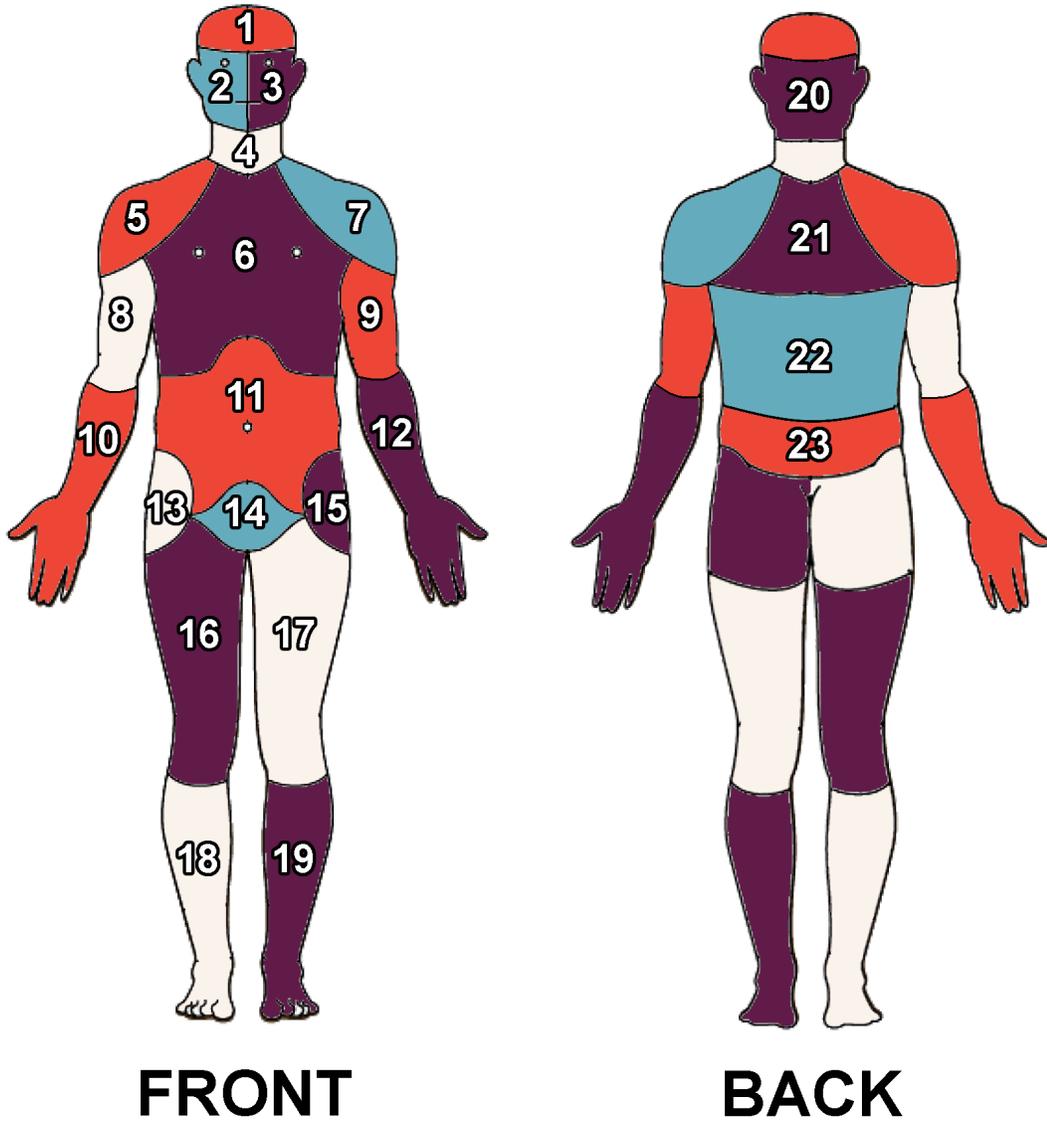
First name: _____

Last name: _____

What is your biological sex? [Male](#) | [Female](#)

The next section displays the body map and supplemental questions that trigger the modules

Body Map



Instructions: Select each area of the body map where you have had pain or tenderness over the **past 30 days**. If you have had no pain in the **past 30 days**, then leave the body map blank.

Please read the following list of symptoms.

During the **past 30 days** have you had any:

a. persistent fatigue?

No | Yes

b. sensitivity to or difficulty tolerating sounds?

No | Yes

c. sensitivity to or difficulty tolerating odors?

No | Yes

d. sensitivity to or difficulty tolerating bright lights?

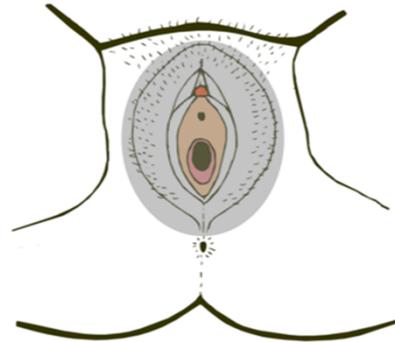
No | Yes

e. sensitivity to or difficulty tolerating certain chemicals, such as perfumes, laundry detergents, gasoline and others?

No | Yes

If female, the following questions will be asked if the pelvic region was marked on the body map

The next question will ask about symptoms in your genital and rectal area.



During the **past 30 days** have you had any genital pain or discomfort in the shaded area?

No | Yes

g. Have you **ever** been diagnosed with endometriosis?

No | Yes

Based upon your responses to the previous screening questions (i.e., body map and questions) you will now be presented with some diagnostic questions associated with chronic pain conditions.

Fibromyalgia (FM)

Instructions: You have reached this module because you indicated having pain in multiple areas of your body. Please answer the following questions.

Note: The previous body map is used to calculate the widespread pain index for FM

1. Using the scale below, indicate for each item how problematic each symptom was over the **past week** by checking the appropriate box.

- No problem
- Slight or mild problems (e.g., generally mild or intermittent)
- Moderate (e.g., considerable problems; often present and/or at a moderate level)
- Severe (e.g., pervasive, continuous, life-disturbing problems)

a. Fatigue

No problem | Slight or mild problems | Moderate | Severe

b. Cognitive symptoms (e.g., trouble thinking or remembering)

No problem | Slight or mild problems | Moderate | Severe

c. Waking up tired (unrefreshed)

No problem | Slight or mild problems | Moderate | Severe

2. During the **past 6 months** have you had any of the following symptoms?

a. Pain or cramps in lower abdomen

No | Yes

b. Depression

No | Yes

c. Headache

No | Yes

3. If you indicated having any of the symptoms on the previous 2 pages (e.g., fatigue, cognitive, waking up tired, pain in the abdomen, depression or headache), have they been generally present for **at least 3 months**?

No | Yes

Temporomandibular Disorder (TMD)

Instructions: You have reached this module because you indicated having pain in areas associated with your jaw and/or temple. Please answer the following questions.

1. In the **last 30 days**, on average, how long did any pain last in your jaw or temple area on either side?

No Pain | From very brief to more than a week, but it does stop | Continuous

2. In the last 30 days, have you had pain or stiffness in your jaw upon awakening?

No | Yes

3. In the last 30 days, did the following activities change any pain (that is, make it better or make it worse) in your jaw or temple area on either side?

a. Chewing hard or tough food

No | Yes

b. Opening your mouth or moving your jaw forward or to the side

No | Yes

c. Jaw habits such as holding teeth together, clenching/grinding, or chewing gum

No | Yes

d. Other jaw activities such as talking, kissing, or yawning

No | Yes

Chronic Low Back Pain (cLBP)

Instructions: You have reached this module because you indicated having pain in areas associated with your lower back. Please answer the following questions.

1. How long has low-back pain been an ongoing problem for you?

Less than 1 month | 1-2 months | 3-5 months | 6 months-11 months | 1-5 years | 6, More than 5 years

2. How often has low-back pain been an ongoing problem for you over the **past 6 months**?

Less than half the days in the past 6 months | At least half the days in the past 6 months | Every day or nearly every day in the past 6 months

Interstitial Cystitis/Bladder Pain Syndrome and Chronic Prostatitis (IC/BPS) (CP)

Instructions: You have reached this module because you indicated having pain in areas associated with your pelvic region. Please answer the following questions.

1. In the **past 3 months**, have you ever had a feeling of pain, pressure, or discomfort in your lower abdomen or pelvic area -- that is, the part of your body that is above your legs and below your belly button?

Yes|No

2. In the **past 3 months**, have you had a feeling of a strong urge or feeling that you had to urinate or "pee" that made it difficult for you to wait to go to the bathroom?

Yes|No

3. Would you say this urge to urinate is mainly because of pain, pressure or discomfort or mainly because you are afraid you will not make it to the toilet in time to avoid wetting?

PAIN, PRESSURE, DISCOMFORT | FEAR of WETTING

4. In the **past 3 months** (when you were having symptoms), how many times on average have you had to go to the bathroom to urinate during the day when you are awake?

Free numeric entry

MALES ONLY-Chronic Prostatist:

1. In the **last three months**, have you experienced any pain or discomfort in the following areas?

- a. Area between rectum and testicles (perineum)

Yes|No

- b. In the **last week**, have you experienced: Pain or discomfort during or after sexual climax (ejaculation)?

Yes|No

- c. Which number best describes your AVERAGE pain or discomfort on the days that you had it, over the **last three months**?

0 - No Pain | | 10 - Worst Imaginable Pain

Migraine/Chronic Tension-Type Headache (MI/TTH)

Instructions: You have reached this module because you indicated having pain in areas associated with your head and face. Please answer the following questions.

1. In the past three months, have you experienced headaches on at least half of the days?"
Yes|No

What were your SYMPTOMS when you had headaches in the **last month (past 30 days)**? Describe the pain and other symptoms you have with your headaches. If you have more than 1 type of headache, please answer for your most severe type.

2. How often in the **last month (past 30 days)** were you unusually sensitive to light (e.g., you felt more comfortable in a dark place)?

Never| Rarely| Less than half the time| Half the time or more

3. How often in the **last month (past 30 days)** were you unusually sensitive to sound (e.g., you felt more comfortable in a quiet place)?

Never| Rarely| Less than half the time| Half the time or more

4. How often in the **last month (past 30 days)** was the pain moderate or severe?

Never| Rarely| Less than half the time| Half the time or more

5. How often in the **last month (past 30 days)** did you feel nauseated or sick to your stomach?

Never| Rarely| Less than half the time| Half the time or more

What was your MEDICATION USE for headache in the **last month (past 30 days)**? When answering the next 2 questions, only count medications you take as needed to relieve headache.

6. How many days in the last month (past 30 days) did you use over-the-counter medications to treat your headache

7. How many days in the **last month (past 30 days)** did you use prescription medications to treat your headache attacks?

Irritable Bowel Syndrome (IBS)

Instructions: You have reached this module because you indicated having pain in areas associated with your abdomen and/or rectal areas. Please answer the following questions.

1. In the **last 3 months (90 days)**, how often did you have pain anywhere in your abdomen?
Never | Less than one day a month | One day a month | Two to three days a month | Once a week | Two to three days a week | Most days | Every day | Multiple times per day or all the time
2. How often did this pain in your abdomen happen close in time to a bowel movement -- just before, during, or soon after? (Percent of times with pain)
0% Never | 50% | 100% Always
3. How often did your stools become either softer than usual or harder than usual when you had this pain? (Percent of times with pain)
0% Never | 50% | 100% Always
4. How often did your stools become either more frequent than usual or less frequent than usual when you had this pain? (Percent of times with pain)
0% Never | 50% | 100% Always

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

Instructions: You have reached this module because you indicated having persistent fatigue. Below are some definitions of fatigue and some questions about your fatigue. The following questions are related to periods of fatigue lasting **at least 6 months**. An episode of fatigue or exhaustion is defined as "beginning" when you no longer felt that you had your normal amount of energy. An episode of fatigue or exhaustion is defined as "ending" when you felt basically back to normal.

1. a. Have you ever had a period of unexplained ongoing fatigue or exhaustion lasting **at least 6 months**?
No | Yes
- b. Are you currently experiencing such a period of ongoing fatigue or exhaustion lasting **at least 6 months**?
No | Yes
2. a. Compared to before the fatigue began, how often has the fatigue resulted in a substantial reduction in your capacity to function normally in work, educational, personal or social activities?
Less than half the days in the past 6 months | At least half the days in the past 6 months | Every day or nearly every day in the past 6 months

- b. Compared to before the fatigue began, how often has the fatigue been at least moderate to severe?

Less than half the days in the past 6 months | At least half the days in the past 6 months | Every day or nearly every day in the past 6 months

Vulvodynia (VVD)

Instructions: You have reached this module because you indicated having pain in areas associated with your genitalia. Below you will find a diagram of the genitalia for females along with labeling and definitions. The next few questions ask about pain or discomfort in the "vulva". The "vulva" refers to the external genital area from the opening of the vagina to the external vulvar lips. It also includes the clitoris, the opening to the urethra, and the area behind the vagina (toward the anus). This is the shaded area shown on the figure above.

1. Have you ever had pain/discomfort in the vulva, either with touch/pressure (such as during intercourse or tampon insertion) or spontaneously (without touch, pressure or vaginal insertion)?
No | Yes
2. Did you ever have pain/discomfort in the vulva that continued to be a problem (either continuously, or off and on) for **at least 3 months**?
No | Yes

Painful Endometriosis (ENDO)

Instructions: You have reached this module because you indicated being diagnosed with endometriosis. Please answer the following questions.

1. Was your diagnosis of endometriosis diagnosed by a physician?
No | Yes
2. Was your diagnosis confirmed by laparoscopy or laparotomy (a surgical diagnostic procedure)?
No | Yes
3. In the **last 6 months**, have you had pain or discomfort associated with any of the following:
 - a. pelvic region No | Yes
 - b. lower abdomen No | Yes
 - c. menstrual period No | Yes
 - d. bladder No | Yes
 - e. deep vaginal penetration (vaginal intercourse or insertion) No | Yes

	<p>f. bowel movements No Yes</p> <p>4. How long has the feeling of pain or discomfort in your lower abdomen or pelvic area been an ongoing problem for you?</p> <p style="color: green;">Less than 30 days 1-2 months 3-5 months 6-11 months 5, 1-5 years 6, More than 5 years</p>

Chapter 3

Scoring and Output from the COPCS Version 11.0

Scoring. In most cases, scoring adheres to the published scoring criteria for each condition (See Table 3.1). In addition to identifying the presence of the condition, some scoring criteria further allows for the identification of sub-types of the condition. For purposes of the COPCS, we followed the scoring algorithm only as far as was needed to identify the presence of the condition. The COPCS does not identify sub-types of the COPCs.

Table 3.1

Condition	Criteria
FM	ACR2016: ²⁵ WPI and SSS are calculated internally according to ACR2016 scoring
IBS	Rome IV Criteria ²⁶
TMJ	DC-TMD Pain Screener ¹²
ME/CFS	Modified Fukuda Criteria ¹⁴
cLBP	NIH Task Force on chronic low back pain ²⁰
IC/BPS & CP	Combined case definitions for IC/PBS and chronic prostatitis. ^{27,28}
ENDO (with pain)	Epidemiology case definition ²³
Migraine	International Classification of Headache Disorders III ¹⁸
Tension-type Headache	International Classification of Headache Disorders III ¹⁸
Vulvodinia	Self-reported symptom survey ²⁹

Note: While consistent with the published scoring criteria for each condition, the digital logic used to derive COPCS classifications aggregates data from multiple modules over the course of the administration so as to improve administration efficiency. Hand scoring of the COPCS is not possible.

Note: Migraine and Tension-Type Headache diagnoses are mutually exclusive.

Output. The output from the COPCS is the presence or absence of each of the 10 COPCs. Below we identify the elements of the output report.

- Chronic Low Back Pain
- Painful Endometriosis
- Fibromyalgia
- Irritable Bowel Syndrome
- Migraine-type Headache
- Myalgic Encephalomyelitis / Chronic Fatigue Syndrome
- Temporomandibular Disorder
- Tension-type Headache
- Interstitial Cystitis/Bladder Pain Syndrome or Chronic Prostatitis
- Vulvodynia

In addition, the report identifies how many of the 10 conditions co-occur within a given individual (e.g., x/10).

PLEASE NOTE: While these screening categories are based upon the actual diagnostic criteria, the COPCS is a screener and not a diagnostic tool. Thus the output of the COPCS is not a diagnosis; rather it identifies possible co-aggregation of COPCs within individuals.

Chapter 4

Validation Properties of the COPCS

Expert Panel.

As described in Chapter 1, an expert panel of 30 scholars familiar with the diagnostic criteria for each of the 10 COPC conditions participated in a consensus building project so as to identify relevant classification criteria for each condition. Three experts per condition participated in this project. In most cases, the published Research Diagnostic Criteria, Clinical Diagnostic Criteria or the Epidemiological Classification Criteria were able to be adopted. Slight modifications were needed in some conditions (e.g., VVD, CFS, UCPPS) where there were competing diagnostic criteria and no established gold standard. Use of the existing diagnostic criteria that defines each condition, along with expert consensus supports the construct validity of this instrument.

Patient focus groups.

Two sets of patient focus groups were conducted. In each, patients were asked to comment on comprehension, usability, formatting and navigation. The first set of patients offered suggestions pertaining to the body map needing fewer regions, needing to be color coded (front and back), and needing colors that could be comprehended by individuals who were color-blind. Usability and comprehension by this group was excellent. After making the recommended modifications, a second patient focus reviewed the changes and again commented on comprehension, usability and navigation. This second group found the body map acceptable and had no difficulties with comprehension or navigation. These patient panels support the content validity of the COPCS, its usability, and comprehension.

Construct Validity Study.

Ideally, the COPCS would return the same diagnostic classifications and number of COPCS as would a clinician administering all 10 diagnostic criteria to the same individual. A study comparing clinician administered diagnostic criteria to the administration of the COPCS was conducted.

Methods. N=30 individuals (i.e., 3 with each of the 10 COPCS as an index condition) were recruited. Order of administration was counter-balanced. Physicians administered scripted versions of all 10 published diagnostic criteria from Table 3.1 to each participant. Patients also completed the COPCS in a separate session.

By this methodology, each participant had the possibility of receiving 10 diagnoses from the COPCS and 10 diagnoses from the physician. Thus, with a sample of n=30, the concordance of 300 diagnoses could be evaluated. The percentage of matches out of 300 possible will be reported along with Cohen's Kappa statistics for agreement between methods.

Results. The diagnostic agreement between the physician administered criteria and the COPCS was 88%. This is considered "excellent" and acceptable for research and clinical application. Errors in matching were random and did not suggest a problem with any given diagnostic category or scoring algorithm. Deeper analysis of the discrepancies found that in each case, the participant was inconsistent in how they responded to an identical item (e.g., reporting positive criteria to one method and negative criteria to the other).

Kappa Statistics:

cLBP	0.78
ENDO	0.889
FM	0.866
IBS	0.722
IC/BPS	0.619
CPPS	1
ME/CFS	0.659
Migraine/ cTTH	0.664
TMD	0.798
VVD	1
Global Kappa	0.813

Conclusion. The consistency between the COPCS and the more labor intensive physician-administered method was sufficiently high to support the construct validity of the screener.

Future studies will explore the long-term test-re-test reliability of the COPCS acknowledging that some of the COPC's are themselves highly variable over time.

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