Solve ME/CFS Initiative

Leveraging patient-centered research to cure ME/CFS

PHYSICIAN'S DIAGNOSIS FORM

PHYSICIANS: A licensed, practicing physician is required to complete as much of this form as possible. If you do not respond to a question, we will assume that you do not have an answer to that particular question.
Return to Solve ME/CFS Initiative by email to BioBank@SolveCFS.org or mail to
Solve ME/CFS Initiative C/O Biobank Coordinator, 5455 Wilshire Blvd. Suite 806, Los Angeles, CA 90036

Patient's Name _____ _____ _____ **Date of Birth** ___ / ___ /_____
Last **First** **M.I.**
Phone (_____) _____

DIAGNOSISTIC CRITERIA:
(Check all that apply)

- ☐ **ME/CFS according to IOM Criteria (See Page 2)**
- ☐ **ME/CFS according to Canadian Consensus Criteria (See Page 3)**
- ☐ **ME/CFS according to other criteria**
  please specify: _____

What was the date of this diagnosis? _____ /_____ /_____ (FIRST DIAGNOSIS)

Date of onset of symptoms: _____ /_____ /_____

Flu like onset? ☐ **Yes** ☐ **No**

Is your patient a homebound/ bedridden? ☐ **Yes** ☐ **No**

Can they work at least part time? ☐ **Yes** ☐ **No**

SYMPTOMS INCLUDE:

- ☐ **Post Exertional Malaise**
- ☐ **Cognitive Abnormalities**
- ☐ **Gastroparesis**
- ☐ **Exhaustion**
- ☐ **Unrefreshing sleep**
- ☐ **Autonomic dysfunction (positive tilt table test)**

TESTS CONDUCTED:

Liver function tests ____ /____ /_____
CBC with differential ___ /_____ /_____
TSH ____ /____ /_____

OTHER ILLNESSES: Are there any other illness we need to be aware of? ☐ **Yes** ☐ **No**
(If yes, please describe)

Physician's Name:_____ License Number: _____
Address: _____ City:_____ State:____ Zip:_____
Signature: _____ Date Completed: _____ /_____ /_____
Phone:(____) _____

Received ___/___/_____

IOM CRITERIA

Diagnosis requires that the patient have the following three symptoms:

☐ A substantial reduction or impairment in the ability to engage in pre-illness levels of occupational, educational, social, or personal activities, that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest, and

☐ Post-exertional malaise,* and

☐ Unrefreshing sleep*

At least <u>one</u> of the two following manifestations is also required:

☐ Cognitive impairment* or

☐ Orthostatic intolerance

* Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS (SEID) should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity

Definitions

Post-exertional malaise (PEM)
PEM is worsening of a patient's symptoms and function after exposure to physical or cognitive stressors that were normally tolerated before disease onset. Subjective reports of PEM and prolonged recovery are supported by objective evidence in the scientific literature, including failure to normally reproduce exercise test results (2-day cardiopulmonary exercise test) and impaired cognitive function after exertion. There is sufficient evidence that PEM is a primary feature that helps distinguish ME/CFS (SEID) from other conditions.

Unrefreshing sleep
Despite the absence of a specific objective alteration in sleep architecture, the data are strong that the complaint of unrefreshing sleep is universal among patients with ME/CFS (SEID) when questions about sleep specifically address this issue. While polysomnography is not required to diagnose ME/CFS (SEID), its use to screen for treatable sleep disorders when indicated is appropriate. Diagnosis of a primary sleep disorder does not rule out a diagnosis of ME/CFS (SEID).

Cognitive impairment
Cognitive impairment in ME/CFS (SEID) includes problems with thinking or executive function exacerbated by exertion, effort, or stress or time pressure. There is sufficient evidence that slowed information processing is common in patients with ME/CFS (SEID), and a growing body of evidence shows that it may play a central role in overall neurocognitive impairment associated with the disease (memory impairments, attention deficits, and impaired psychomotor function). Such a deficit may be responsible for disability that results in loss of employment and loss of functional capacity in social environments.

Orthostatic intolerance
Orthostatic intolerance is a general term that implies worsening of symptoms upon assuming and maintaining upright posture. Symptoms are improved, although not necessarily abolished, by lying back down or elevating the feet. Sufficient evidence indicates a high prevalence of orthostatic intolerance conditions in ME/CFS (SEID) as measured by objective heart rate and blood pressure abnormalities and physical findings during standing, bedside orthostatic vital signs, head-up tilt testing, or by patient-reported exacerbation of orthostatic symptoms with standing in day-to-day life. These findings indicate that orthostatic intolerance is a common and clinically important finding in ME/CFS (SEID).

CANADIAN CONCENSUS CRITERIA

Although it is unlikely that a single disease model will account for every case of ME/CFS, there are common clusters of symptoms that allows a clinical diagnosis.

Clinical Working Case Definition of ME/CFS

A patient with ME/CFS will meet the criteria for fatigue, post-exertional malaise and/or fatigue, sleep dysfunction, and pain; have two or more neurological/cognitive manifestations and one or more symptoms from two of the categories of autonomic, neuroendocrine and immune manifestations; and adhere to item 7.
1. *Fatigue:* The patient must have a significant degree of new onset, unexplained, persistent, or recurrent physical and mental fatigue that substantially reduces activity level.
2. *Post-Exertional Malaise and/or Fatigue:* There is an inappropriate loss of physical and mental stamina, rapid muscular and cognitive fatigability, post exertional malaise and/or fatigue and/or pain and a tendency for other associated symptoms within the patient's cluster of symptoms to worsen. There is a pathologically slow recovery period–usually 24 hours or longer.
3. *Sleep Dysfunction:** There is unrefreshed sleep or sleep quantity or rhythm disturbances such as reversed or chaotic diurnal sleep rhythms.
4. *Pain:** There is a significant degree of myalgia. Pain can be experienced in the muscles and/or joints, and is often widespread and migratory in nature. Often there are significant *headaches* of new type, pattern or severity.
5. *Neurological/Cognitive Manifestations: Two or more* of the following difficulties should be present: confusion, impairment of concentration and short-term memory consolidation, disorientation, difficulty with information processing, categorizing and word retrieval, and perceptual and sensory disturbances–e.g., spatial instability and disorientation and inability to focus vision. Ataxia, muscle weakness and fasciculations are common. There may be overload[1] phenomena: cognitive, sensory–e.g., photophobia and hypersensitivity to noise–and/or emotional overload, which may lead to "crash"[2] periods and/or anxiety.

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6. *At Least <u>One</u> Symptom from <u>Two</u> of the Following Categories:*

   a. *Autonomic Manifestations:* orthostatic intolerance–neurally mediated hypotenstion (NMH), postural orthostatic tachycardia syndrome (POTS), delayed postural hypotension; light-headedness; extreme pallor; nausea and irritable bowel syndrome; urinary frequency and bladder dysfunction; palpitations with or without cardiac arrhythmias; exertional dyspnea.
   b. *Neuroendocrine Manifestations:* loss of thermostatic stability–subnormal body temperature and marked diurnal fluctuation, sweating episodes, recurrent feelings of feverishness and cold extremities; intolerance of extremes of heat and cold; marked weight change–anorexia or abnormal appetite; loss of adaptability and worsening of symptoms with stress.
   c. *Immune Manifestations:* tender lymph nodes, recurrent sore throat, recurrent flu-like symptoms, general malaise, new sensitivities to food, medications and/or chemicals.

7. *The illness persists for at least six months. It usually has a distinct onset,** although it may be gradual*. Preliminary diagnosis may be possible earlier. Three months is appropriate for children.

*To be included, the symptoms must have begun or have been significantly altered after the onset of this illness. It is unlikely that a patient will suffer from all symptoms in criteria 5 and 6. The disturbances tend to form symptom clusters that may fluctuate and change over time. Children often have numerous prominent symptoms but their order of severity tends to vary from day to day. *There is a small number of patients who have no pain or sleep dysfunction, but no other diagnosis fits except ME/CFS. A diagnosis of ME/CFS can be entertained when this group has an infectious illness type onset. **Some patients have been unhealthy for other reasons prior to the onset of ME/CFS and lack detectable triggers at onset and/or have more gradual or insidious onset.*

Exclusions: Exclude *active* disease processes that explain most of the major symptoms of fatigue, sleep disturbance, pain, and cognitive dysfunction. It is essential to exclude certain diseases, which would be tragic to miss: Addison's disease, Cushing's Syndrome, hypothyroidism, hyperthyroidism, iron deficiency, other treatable forms of anemia, iron overload syndrome, diabetes mellitus, and cancer. It is also essential to exclude treatable sleep disorders such as upper airway resistance syndrome and obstructive or central sleep apnea; rheumatological disorders such as rheumatoid arthritis, lupus, polymyositis

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