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1994 CDC CASE DEFINITION AND DIAGNOSTIC CRITERIA

The Centers for Disease Control and Prevention's (CDC) website presents a summarized version of the 1994 definition of Chronic Fatigue Syndrome (CFS) which was first published (the full version) in the 1994 *Annals of Internal Medicine.*

The summarized version may be found at: http://www.cdc.gov/cfs/case-definition/1994.html . As a reference guide, it is useful to print out this summarized version. You may also want to give a copy to your physician.

Many clinicians will rely on the abridged version at the CDC site for making diagnoses, rather than obtaining a copy of the full case definition—which is substantially longer and more detailed. A number of the terms and definitions in the summarized version are not adequately explained. For instance, in the summary, the term "mental status examination" is stated as a part of the evaluation of CFS/ME (myalgic encephalomyelitis) along with a medical history, physical examination, and laboratory tests. Without reference to the full Criteria, the mental status examination, as well as many other important diagnostic requirements, cannot be properly understood or interpreted.

Therefore, in this article, we will explain many of elements of the full,unsummarized 1994 Diagnostic Criteria, so that patients and physicians will be able to understand both the entire Criteria, as well as its limitations and perceived errors. It will be practical in learning about the criteria to print out the summarized version and refer to it when reading an explanation of the full Criteria given below.

SUMMARY OF THE 1994 DIAGNOSTIC CRITERIA

Major steps in applying the Criteria:

- 1. The major diagnostic focus is prolonged, persistent and unexplained chronic fatigue. The diagnostic process proceeds in a step-by-step fashion:
- 2. Exclusion from a diagnosis of CFS other illnesses and conditions which explain or may explain the fatigue condition.

- 3. Recognition of other illnesses or conditions that are current or under successful treatment that do not exclude a diagnosis of CFS.
- 4. After other illnesses or conditions have been excluded or included, CFS is directly diagnosed through meeting a stipulated number of symptom criteria.

Patients who do not meet the specific diagnostic standards for CFS, are then diagnosed with "idiopathic chronic fatigue", which essentially means that the fatigue remains unexplained.

CDC 1994 Diagnostic Criteria (summarized)

"Definition and Clinical Evaluation...of Chronic Fatigue

Chronic Fatigue is defined as self-reported or relapsing fatigue of 6 or more consecutive months". [Despite this six month formal requirement of the Criteria, a clinician experienced with CFS can make a preliminary diagnosis without having to wait a full six months.]

"The presence of prolonged or chronic fatigue requires clinical evaluation to identify underlying or contributing conditions that require treatment. Further diagnosis or classification of chronic fatigue cases cannot be made without such an evaluation. The following areas should be included in the clinical evaluation.

- 1. A thorough history that covers medical and psychosocial circumstances at the onset of fatigue; depression or other psychiatric disorders; episodes of medically unexplained symptoms; alcohol or other substance abuse; and current use of prescription and over-the-counter medications and food supplements.
- 2. A mental status examination to identify abnormalities in mood, intellectual function, memory and personality. Particular attention should be directed toward current symptoms of depression or anxiety, self-destructive thoughts, and observable signs such as psychomotor retardation. Evidence of a psychiatric or neurological disorder requires that an appropriate psychiatric, psychological or neurologic evaluation be done."

Comment: In these two initial steps, emphasis is placed on evaluating possible psychiatric conditions.

Item 1, just quoted, requests an evaluation of any depression, both preceding and following onset of the illness. It is critical that both the patient and the physician distinguish between a primary and secondary depression. A primary depression, either currently or in the past, could exclude or make more difficult a diagnosis of CFS; while a finding of secondary depression can be very consistent with a CFS diagnosis. Secondary depression often occurs as a reaction to a chronic physical illness as an individual's response to a lack of physical improvement and limitations imposed by the illness. Also, any evaluation of a history of depression prior to the illness's onset should distinguish between major severe chronic depression, and infrequent episodes of minor depression.

Item 2, quoted above, requires a "mental status examination" for all patients to be given by the diagnosing physician. The term "mental status examination" does not refer to any standardized or formal test or procedure of evaluation; rather the term refers to a fairly informal and basic assessment of the presence of any disorders or symptoms listed in item 2. Item 2 indicates that if evidence of a psychiatric or neurological disorder is found, then a further examination should be made by a psychiatrist or neurologist.

But caution and common sense should be exercised in this regard. Many CFS patients do not suffer from significant depression or other emotional disorder-however they do suffer the expected emotional trouble and frustrations due to chronic physical illness. Since these individuals do not suffer from a "psychiatric disorder" they should discuss with their physicians whether psychiatric evaluation is necessary. Such evaluations occasionally result in a psychiatric misdiagnosis.

If a referral for depression is made as part of the diagnostic process, the patient should explain to the specialist that the depression is a result of their physical illness (if the patient is reasonably certain this is the case).

Also, during the mental status exam, it is important for the patient and the physician to distinguish cognitive dysfunction (memory and thinking problems) and neurological problems caused by the CFS, from psychologically-caused problems. Referral to specialists who understand CFS for the assessment of cognitive dysfunction and neurological disorder can certainly be helpful in the diagnostic process.]

The next two items in the clinical evaluation list are	Τ	he	next	two	items	in	the o	clinical	l eva	luation	list	are:
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- 3. A thorough physical examination.
- 4. A minimum battery of laboratory screening tests, including complete blood count with leukocyte differential; erythrocyte sedimentation rate; serum levels of alanine aminotransferase, total protein, albumin, globulin, alkaline phosphatase, calcium, phosphorus, glucose, blood urea nitrogen, electrolytes and creatinine; determination of thyroid-stimulating hormone; and urinalysis."

"Routinely doing other screening tests for all patients has no known value...However, further tests may be indicated on an individual basis to confirm or exclude another diagnosis, such as multiple sclerosis. In these cases, additional tests or procedures should be done according to accepted clinical standards."

[Comment: See our main article for other laboratory tests for ruling out other illnesses as well as tests that can provide suggestive confirmation of ME/CFS (these are cited by a number of international CFIDS researchers, including Dr. Komaroff.) The next two paragraphs of the CDC definition go on to state that except for cases of specialized research there are no further recommended tests for the diagnosis of chronic fatigue syndrome. A list of unnecessary tests is given. However, given subsequent research and clinical experience, as well as the Social Security Administration Ruling on CFS, 1999, other tests may be indicative of CFS

Conditions that Exclude a Diagnosis of CFS

- 1. Any active medical condition that may explain the presence of chronic fatigue...such as untreated hypothyroidism, sleep apnea, and narcolepsy, and iatrogenic conditions such as side effects of medication.
- 2. Any previously diagnosed medical condition whose resolution has not been documented beyond reasonable clinical doubt and whose continued activity may explain the chronic fatiguing illness. Such conditions may include previously treated malignancies and unresolved cases of hepatitis B and C infection.

3. Any past or current diagnosis of a major depressive disorder with psychotic or melancholic features; bipolar affective disorders; schizophrenia of any subtype; delusional disorders of any subtype; dementia of any subtype; anorexia nervosa; or bulimia nervosa.

[Comment, item 3.1] Here the guidelines state that any current or previous major mental illness or bulimia or anorexia nervosa disqualifies an individual from receiving a diagnosis of CFS. Again, despite the guidelines, an individual with one of these conditions, either in the past or present, could clinically suffer from CFS. For instance, an individual could develop CFS even though he or she had recovered from a major depression ten years previously. Again, individuals who have recovered from anorexia nervosa or bulimia nervosa could develop CFS years later. The guidelines later clearly recognize these possibilities:

"We distinguish between psychiatric conditions for pragmatic reasons. It is difficult to interpret symptoms typical of the Chronic Fatigue Syndrome in the setting of illnesses such as major psychotic depression or schizophrenia." Also, the case definition makes clear that it is a research definition with the goal of separating out possible confounding diagnoses. Individuals who actually have these excluding conditions should seek expert treatment for them - however, it is possible that a person could have one of these conditions and CFS. If this is a possibility, the patient should seek expert diagnosis for each illness."]

4. Alcohol or other substance abuse within 2 years before the onset of the chronic fatigue or any time afterwards.

[Comment: Again it is possible for a person who two years previously suffered from substance abuse to develop CFS and to be diagnosed accordingly .]

5. Severe obesity...as defined by a body mass index [body mass index = weight in kilograms/(height in meters) squared] equal to or greater than 45.

"Any unexplained physical examination finding or laboratory or imaging test abnormality that strongly suggests the presence of an exclusionary condition must be resolved before further classification."

[Comment:: Again despite the guidelines, the possibility exists, as discussed above, that an individual with severe obesity could also suffer from CFS. However, the two conditions would each have to be diagnosed separately .]

Conditions That Do Not Exclude a Diagnosis of CFS

1. Any condition defined primarily by symptoms that cannot be confirmed by diagnostic laboratory tests, including fibromyalgia, anxiety disorders, somatoform disorders, nonpsychotic or nonmelancholic despression, neurasthenia, and multiple chemical sensitivity disorder.

[Comment: This step obviously allows for the multiple diagnoses of fibromyalgia and CFS, and multiple chemical sensitivities and CFS. The step also allows for a CFS diagnosis in the presence of non-psychotic depression and anxiety disorders. However, the item itself along with other language in the definition and statements by its authors, create a serious misunderstanding of CFS by confusing CFS with the psychiatric diagnoses of somatoform disorders and neurasthenia. Throughout the 1990s many presumed "experts" on the illness believed that CFS itself was one or both of these psychiatric illnesses. For more informed information on this issue, please see the section on differential diagnosis of CFS and psychiatric disorders in our Diagnosis documents.

- 2. Any condition under specific treatment sufficient to alleviate all symptoms related to that condition and for which the adequacy of treatment has been documented. Such conditions include hypothyroidism for which the adequacy of replacement hormone therapy has been verified by normal thyroid-stimulating hormone levels, or asthma in which the adequacy of treatment has been documented by pulmonary function and other testing.
- 3. Any condition, such as Lyme Disease or syphilis, that was treated with definitive therapy before the development of chronic symptomatic sequelae.

[Comment: Since the publication of this diagnostic criteria, many experts on Lyme Disease believe that the illness can exist in chronic form, even after short term treatment. Today numbers of patients believed to have had CFS are being diagnosed with Chronic Lyme disease. Some older diagnostic procedures for Lyme are no longer considered reliable by experts. Therefore, if Lyme disease is suspected, a patient should see an expert in current approaches to Lyme disease diagnosis. Please see more in the section on the differential diagnosis of Lyme

disease under Diagnosis and also other articles in Resources... 4. Any isolated and unexplained physical examination finding or laboratory or imaging test abnormality that is insufficient to strongly suggest the existence of an exclusionary condition. Such conditions include an elevated antinuclear antibody titer that is inadequate to strongly support a diagnosis of a discrete connective tissue disorder without other laboratory or clinical evidence. **Final Diagnostic Requirements for CFS** Following these initial steps, an individual will be diagnosed according to the following diagnostic criteria: "A case of the chronic fatigue syndrome is defined by the presence of the following: (1) clinically evaluated, unexplained, persistent or relapsing chronic fatigue that is of new or definite onset (has not been lifelong); is not the result of ongoing exertion; is not substantially alleviated by rest; and results in substantial reduction in previous levels of occupational, educational, social, or personal activities; and (2) the concurrent occurrence of four or more of the following symptoms, all of which must have persisted or recurred during six or more consecutive months of illness and must not have predated the fatigue: 1.self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, educational, social or personal activities; 2. sore throat; 3. tender cervical or axillary lymph nodes;

4. muscle pain
5. multi-joint pain without swelling or redness;
6. headaches of a new type, pattern, or severity;
7. unrefreshing sleep; and
8. post-exertional malaise lasting more than 24 hours.
These guidelines complete the diagnosis of Chronic Fatigue Syndrome.

Idiopathic chronic fatigue: If an individual fails to meet all the criteria, above, for Chronic Fatigue Syndrome diagnosis, s/he will be classified as having *idiopathic chronic fatigue*.

A final note on diagnosis under the 1994 CDC definition:

A person who actually has CFS may be excluded by the formal definition. For example, a person who had primary depression in the past would be excluded. However, this person may have CFS. Once all the other diagnostic steps had been taken, the individual could be diagnosed on the basis of the symptom profile by a doctor experienced in the diagnosis of CFS. Especially important in this type of diagnosis would be the documentation of history, treatments, and the extent of resolution of any previous or current illness or condition that qualifies as exclusionary. Documentation of lab and other testing showing consistency with CFS and inconsistency with the exclusionary illness would be especially important. Please see "Some Tests to be conducted to help patients determine objectivity of CFS/CFIDS and/or other disabling symptoms", from Dr. Charles Lapp [pg. 62, Disability booklet] and the list of CFIDS symptoms in the Diagnosis article on this website.