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“Coffee” with a Clinician

Diagnosing ME/CFS

A brief case definition discussion
from the Clinical Care Guide

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Basic goals of my presentation today

- Explain the **2015 ME/CFS (IOM)NAM clinical diagnostic criteria** used in the BHC clinical care guide.
- Reference the **CCC (Canadian Consensus Criteria--2003)** and the **ICC (International Consensus Criteria—2011)**
- Learn why the **Fukuda Criteria 1994** (also called the CDC Case Definition) fell out of favor.
- Become familiar with the terms "**research criteria**" versus "**clinical criteria**"
- How do we **inform all clinical care providers** about diagnosing ME/CFS?

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ME/CFS historical background

- The term **Chronic Fatigue Syndrome (CFS)** was first published in 1988 (Holmes) to replace the misnomer *"Chronic EBV."* The paper described post-infection or post-viral syndromes and proposed a research case definition.

- The **Chronic Fatigue Syndrome (CFS)** research case definition was revised in 1994 (Fukuda) but proved too broad, encompassing many other causes of "chronic fatigue" (including fibromyalgia and many mental health conditions) because it didn't require PEM.

- Very descriptive clinical criteria for ME/CFS were published in 2003 based on expert clinical observations, eventually called the **"Canadian Consensus Criteria for ME/CFS,"** but the publication wasn't widely accessible to practicing clinicians, and the *Journal of CFS* went out of print in 2007. The clinical criteria were revised, updated and published in 2011 as the **"International Consensus Criteria for ME"** in *the Journal of Internal Medicine* (based in Sweden, but internationally distributed).

- Many other criteria have been published as well. See the **2015 NAM report** or go to **MEpedia**.

Holmes GP, et al. Chronic fatigue syndrome: a working case definition (**1988**). Ann Intern Med;108:387-9
Fukuda et al, Annals of Internal Medicine, Vol. 121, December 15, **1994**, pp. 953-959
Carruthers BM et al. (**2003**). Journal of Chronic Fatigue Syndrome 11 (1): 7–36. doi:10.1300/J092v11n01_02.
Carruthers, BM et al. **(2011**) Journal of Internal Medicine. https://doi.org/10.1111/j.1365-2796.2011.02428.x

In 2013 the **Institute of Medicine/IOM** accepted a contract offered by U.S. DHHS (NIH, CDC, FDA, SSD, AHRQ) to examine the ME/CFS evidence and propose clinical diagnostic criteria----**to facilitate more timely diagnosis and care, and enhance understanding among health care providers and the public**.

The 2014 year of work was presented in a report published Feb 10, 2015.

Documents produced:

- "Key Facts"
- "ME/CFS Clinicians Guide"
- The full 282 page 2015 IOM report and clinical diagnostic criteria: **Beyond Myalgic Encephalomyelitis/chronic fatigue syndrome: Redefining and Illness**. *https://pubmed.ncbi.nlm.nih.gov/25695122/*

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The purpose of the IOM/NAM* literature review was to **improve clinical diagnosis** of ME/CFS.
It was especially directed at primary care providers in the U.S. who were woefully unaware of ME/CFS.

- Publishing **ME/CFS clinical diagnostic criteria** that were **evidence-based**, developed through a **highly respected process** and **published in format accessible to clinicians** was critical to this plan.
- **Recommendations** in the NAM report are derived from published research from the 1980s through mid 2014. The core criteria were based on characteristics of well-defined ME/CFS patients seeing ME/CFS specialists.
- The existing ME/CFS case definitions currently in use at the time were carefully reviewed in the process.

* The 2015 criteria were developed by a distinguished committee of the IOM, later called the NAM, then NASEM (National Academies of Science, Engineering and Medicine)

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The **2015* ME/CFS Clinical Diagnostic Criteria**

Beyond Myalgic Encephalomyelitis: Redefining an Illness. Institute of Medicine. Washington (DC): National Academies Press (US); 2015 Feb 10. ISBN-13: 978-0-309-31689-7ISBN-10: 0-309-31689-8

These CORE criteria are required for diagnosis and ***should be moderate-severe and present >50% of time**

1) **Impairment of normal function, accompanied by fatigue, persisting >6 months**
2) **PEM: post exertional malaise***
3) **Unrefreshing sleep***
4) Plus at least one of the following:
   - **Cognitive impairment***
   - **Orthostatic intolerance** (ANS dysregulation)

Additional common but not required features of illness in the ME/CFS population (next slide):

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Additional common but not required aspects of illness in the ME/CFS population:

- **Chronic pain** (headache, muscle and joint aches, hyperalgesia, central sensitivity)
- **Immune/inflammatory manifestations** (allergy, inflammation, chemical sensitivities)
- **Infection manifestations** (viral or atypical infections, sore throat, tender lymph nodes, low grade fevers)
- **Neuroendocrine manifestations**

*It is notable that research related to **neurologic** aspects of ME/CFS has advanced tremendously since mid-2014.*

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NAM REPORT: Clinicians should diagnose ME/CFS definitively after 6 months of supportive care and diagnostic investigations.

- But a ***working or provisional diagnosis*** of ME/CFS can be made anytime earlier than 6 months. **Supportive care and management should be provided from the beginning.**
- No "exclusionary criteria" are detailed but it is expected that a **differential diagnosis, appropriate workup of symptoms, and treatment**, including referral to specialists, will be ongoing by health care providers.
- **All other identifiable illnesses should be diagnosed and treated, including supportive care, observation, reduction of risk factors**

"**Clinical**" versus "**Research**" case definition

- **Clinical case definition**, or clinical diagnostic criteria:
  - Used to identify people with the diagnosis, even when objective markers are not available.
  - Inclusive not exclusive.
  - For example: can someone with ME/CFS still get diabetes, sleep apnea, obesity or a mental health problem? Of course they can! And they shouldn't be excluded from getting a diagnosis.

- **Research case definition:**
  - Used to identify subjects for research that clearly have the diagnosis but ideally uncomplicated by age, medical or mental health conditions that might confound the research outcomes.

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Canadian Consensus Criteria for ME/CFS (2003)

Most CCC criteria are included in 2015 NAM core clinical criteria…or common symptoms

1. **Substantial reduction in activity** level due to new onset, unexplained, persistent **fatigue** (at least 6 months in duration)
2. **Post exertional malaise** (payback), delayed recovery (>24 hrs)
3. **Sleep dysfunction** (wide range). Unrefreshing or altered rhythm.
4. **Pain –** muscles, joints, headaches,
5. **Neurologic/Cognitive manifestations** (concentration, short term memory, "sensory overload," disorientation/confusion, ataxia …)

6. *At least **one** symptom from **two** of the following:*

Autonomic manifestations e.g. orthostatic intolerance, POTS, IBS, vertigo, vasomotor instability, respiratory irregularities… [ANS]

Neuroendocrine manifestations e.g. temperature intolerance, weight or appetite changes, reactive hypoglycemia, low stress tolerance…

Immune manifestations e.g. tender lymph nodes, sore throat, flu-like symptoms, allergy symptoms, hypersensitivities…

Carruthers BM et al. (2003). "Myalgic encephalomyalitis/chronic fatigue syndrome: Clinical working definition, diagnostic and treatment protocols" (PDF). Journal of Chronic Fatigue Syndrome 11 (1): 7–36. doi:10.1300/J092v11n01_02.

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International Consensus Criteria (ICC) for ME (2011)

sought to clarify **PEM** by using the term **PENE (Post-Exertional Neuroimmune Exhaustion)** instead **:**

PENE: This cardinal feature is a pathological inability to produce sufficient energy on demand with prominent symptoms primarily in the neuroimmune regions. Characteristics are as follows:

1. **Marked, rapid physical and/or cognitive fatigability** in response to exertion, which may be minimal such as activities of daily living or simple mental tasks, can be debilitating and cause a relapse.
2. **Postexertional symptom exacerbation**: e.g. acute flu-like symptoms, pain and worsening of other symptoms.
3. **Postexertional exhaustion** may occur immediately after activity or be delayed by hours or days.
4. **Recovery period is prolonged**, usually taking 24h or longer. A relapse can last days, weeks or longer.
5. Low threshold of physical and mental fatigability (lack of stamina) results in a **substantial reduction in pre-illness activity level.**

Carruthers BM, van de Sande MI, De Meirleir KL, et a. **Myalgic encephalomyelitis: International Consensus Criteria**. J Intern Med. 2011 Oct;270(4):327-38. doi:10.1111/j.13652796.2011.02428.x. PMID: 21777306

2.4 Common Comorbid Conditions of ME/CFS[12]

AUTONOMIC DYSFUNCTION Postural Orthostatic Tachycardia Syndrome (POTS), Neurally Mediated Hypotension (NMH), Orthostatic Hypotension	**RHEUMATOLOGICAL DISORDERS** Fibromyalgia, Ehlers-Danlos Syndrome, Temporomandibular Joint Dysfunction, Sicca Syndrome (dry eyes/mouth)	**NEUROLOGICAL DISORDERS** Sensory Hypersensitivities (light, sound, touch, odors or chemicals), Poor Balance, Migraine Headaches, Peripheral Neuropathy, Small Fiber Neuropathy
IMMUNOLOGICAL DISORDERS New or worsened allergies, Mast Cell Activation Syndrome, Multiple Chemical Sensitivites, Chronic infections & immunodeficiencies	**GASTROINTESTINAL DISORDERS** Food Allergy and Intolerances, including to milk protein, Gut motility issues, Celiac Disease, Irritable Bowel Syndrome, Small Intestinal Bacterial Overgrowth	**ENDOCRINE/METABOLOIC DISORDERS** Hypothyroidism, Hypothalamus-Pituitary-Adrenal Axis dysregulation (low normal or flattened cortisol curve), Metabolic Syndrome
SLEEP DISORDERS Sleep Apnea, Restless Leg Syndrome, Periodic Limb Movement Disorder	**PSYCHIATRIC DISORDERS** Secondary Anxiety, Secondary Depression	**GYNECOLOGICAL DISORDERS** Endometriosis, Premenstrual Syndrome, Vulvodynia
MISCELLANEOUS: Interstitial Cystitis, Overactive Bladder, Nutritional deficiencies. Vitamin B12 and D deficiencies, Obesity		

Bateman L, et al. **US ME/CFS Clinician Coalition. ME/CFS Essentials of Diagnosis and Management.** Mayo Clin Proc 2021. PMID 34454716

CHAPTER 2: BASICS OF LONG COVID, ME/CFS, AND COMORBIDITIES

2.3 Additional Symptoms Supporting Diagnosis[72,95]

Systems Affected	Symptoms
Immune System	Acute infection-like onset, flu-like symptoms, sore throat, tender lymph nodes, increased infections, new or worsened sensitivities (foods, medications, chemicals). Poor NK cell cytotoxicity correlates with severity
Neurological System	Impaired psychomotor function, muscle weakness, twitching, instability, ataxia, sensory sensitivities (light, noise, touch)
Autonomic & Endocrine Systems	Cold extremities, temperature dysregulation, excessive sweating, loss of appetite, alcohol intolerance, weight changes
Pain Manifestations	Headaches, myalgia, arthralgia, neuropathic pain
Gastrointestinal & Genitourinary Systems	IBS-like symptoms, gastroparesis, interstitial cystitis, chronic nausea

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Important reference links

- BHC Clinical Care Guide
- The full 2015 NAM report and clinical diagnostic criteria
  - https://pubmed.ncbi.nlm.nih.gov/25695122/
- The US Clinician Coalition expert consensus paper. 2021.
  - https://pubmed.ncbi.nlm.nih.gov/34454716/

Bateman L, Bested AC, Bonilla HF, Chheda BV, Chu L, Curtin JM, Dempsey TT, Dimmock ME, Dowell TG, Felsenstein D, Kaufman DL, Klimas NG, Komaroff AL, Lapp CW, Levine SM, Montoya JG, Natelson BH, Peterson DL, Podell RN, Rey IR, Ruhoy IS, Vera-Nunez MA, Yellman BP. **Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Essentials of Diagnosis and Management.** Mayo Clin Proc. 2021 Nov;96(11):2861-2878. doi: 10.1016/j.mayocp.2021.07.004.