

“There are no tests and there are no treatments”:
What does that mean?
Testimony to the Chronic Fatigue Syndrome Advisory Committee
Of the U.S. Department of Health and Human Services
Washington, DC
Mary M. Schweitzer, Ph.D.
May 17, 2007

No matter how pretty the glossy handouts, no matter how lengthy the website, in the end we keep coming back to this single sentence, EVERYTHING that CDC sends out about CFS includes this sentence: "There are no tests and there are no treatments",

That single, bleak sentence is very costly - in terms of disability denied, healthcare reimbursement refused, and the sheer difficulty getting pharmaceuticals interested in finding drugs that will treat our disease. If there are no tests, how can a company judge whether or not they have been successful?

As I understand it, CDC does not consider anything useful as a test or treatment unless it works for every single person they have classified as having “chronic fatigue syndrome.” That has been difficult enough with the CFS (Fukuda, 1994) definition. As CDC shifts to a definition based primarily on the single symptom “chronic fatigue,” it will be impossible.

Consequences of CDC’s decision to insist “there are no tests and there are no treatments”:

There are perhaps unintended but nevertheless very real consequences to the CDC’s longstanding position that there are no tests or treatments for “CFS”.

- It makes it harder to get disability, and it makes it harder to get medical coverage from your insurance company.
- The default option in a “medically unexplained disease” is psychiatry. Stating that there are no tests or treatments that can demonstrate physical causation for the constellation of symptoms portrayed by patients provide such a loophole. All somatic syndromes require that there be no evidence of physical causation of the symptoms that are believed to be caused by a form of somaticizing. If “there are no tests and there are no treatments,” it’s open season for psychiatry – whether the diagnosis is neurasthenia (as in England), or simply problems handling stress (as in the U.S.).
- Patients are denied treatment that could help them; researchers are denied information that would help push knowledge about this secretive disease further.

Let's look at a case where both CDC and NIH agreed there was a test that, in general, was abnormal in patients with CFS (Fukuda, 1994). A sample of CFS patients have lower than average levels of the hormone cortisol, compared with a sample of controls.

There was, presumably, variance in that sample. So there were some CFS patients in that study who personally had abnormally low levels of cortisol.

Normally, when a patient presents to a doctor with abnormally low levels of cortisol, there will be a discussion of the condition called Addison's Disease. According to Medline Plus, Addison's Disease is a hormone deficiency (not enough hormone) caused by damage to the outer layer of the adrenal gland (the part known as the adrenal cortex). In one form, Addison's Disease may be an autoimmune condition. That's interesting, because usually patients with CFS (Fukuda, 1994) have an unusual number of comorbid autoimmune conditions.

The discussion might not center on Addison's Disease per se, but perhaps a version of it unique to patients with CFS (Fukuda, 1994). But it seems that would be the most obvious place to start.

Certainly when I tested positive for hypothyroidism and Hashimoto's thyroiditis, we discussed the known treatments for the disorders. As it turned out, I have an unusual form of hypothyroidism in which my body fails to convert T4 (the hormone made by the thyroid and stored in the thyroid gland) to T3 (the hormone that is actually used by the body, most of the time). So I have to take Cytomel, which is T3 – the usual remedies for hypothyroidism, levithroid and synthroid, do not work.

However, in the world of CFS at CDC and NIH, the discovery of abnormal levels of cortisol did not lead to existing information about Addison's Disease – or even use of the terminology. Instead, the information became incorporated into a rather advanced model involving the entire HPA axis (hypothalamic, pituitary, and adrenal) axis. Instead of discussing known treatments for hypocortisolism, articles appeared positing that an abnormal HPA response was central to understanding CFS. Either patients could not "handle" stress, which led to the abnormal HPA response, or CFS itself left patients unable to "handle" stress – but either way, instead of the evidence of hypocortisolism leading to the known medical literature on the hormonal abnormality called Addison's Disease, we find ourselves in the fuzzy world of neo-psychiatry (or the biopsychosocial school of psychiatry). Somehow a physical disorder is transformed into a character flaw with a behavioral solution.

When asked why no one from CDC ever spoke to the media about the severity of CFS (at one time termed one of the top five new and emerging diseases by CDC), I remember receiving the response that until we could find a way to change behaviors such that CFS could be avoided, there's no real reason to proceed with the information – indeed, it could just cause panic.

So now we had the prize: evidence that CFS was a character flaw (physical in nature) that could be corrected by behavior modification (don't get so stressed).

I consider that to be a most bizarre approach to the scientific study of a disease about which little is known, except that it impacts roughly one million Americans and the majority of them are undiagnosed; of those who are diagnosed, a majority cannot work full time. This is not a minor illness. Yet we could not discuss it in public without being able to offer some type of personal behavior modification.

Known treatments for CFS (Fukuda, 1994) and M.E.:

I found it odd that CDC was so convinced there were no tests or treatments, because I have been taking tests and receiving treatments for some time. Most of you may not remember when I would come here in a wheelchair – sometimes pushed by my aging mother – barely able to do anything except present my short little paper that had taken weeks to write.

Here are tests which my own doctors used that were positive in my case:

- Simple office tests: Romberg test, subtracting from 100 by 7's, remembering 3 items with a distractor;
- NMH/POTS
- Hashimoto's thyroiditis/hypothyroidism
- Oxygen reuptake during a treadmill test
- Low natural killer cell function
- 37kDa Rnase-L; abnormally high levels of Rnase-L
- Chronically reactivated Epstein-Barr Virus
- Active HHV-6A

Cheney uses a different test – bicycle ergometry with gas analysis – but the purpose is the same as the one Peterson uses (oxygen reuptake during a treadmill test). Cheney found that most of his patients shifted to anaerobic metabolism within minutes of beginning the test. When I did the test for Peterson, my oxygen reuptake was 19, below the legal disability limit of 20 (that is, on the basis of that test alone I was disabled). It is better than that now, with the treatment I have had.

But don't you think we should be telling physicians about exercise testing before we suggest exercise therapy? Shouldn't the physician have some idea about the ability of the patient to conduct normal aerobic exercise?

Other patients have suggested tests that led to successful treatment (that alleviated symptoms and/or suggested a direction to head).

I'm certain Nancy Klimas can provide a list of other immunological tests and how physicians can use that information - certainly apoptosis, nK count as well as function, T-

cell ratio, α/β ratio – I probably do not have this precisely correct, but Dr. Klimas can correct me.

Returning to my own case, surely if a patient has a low natural killer cell function the physician should know it. Surely your physician should know if your oxygen reuptake during a treadmill test is so low that by that single criteria you are legally disabled.

Why are we withholding this information, simply on the basis that it cannot be proven (and never will be) that every patient who has one or another of these abnormalities fits the ever-broadening description of CFS by Dr. Reeves?

Finally, although I tested negative for these conditions, it was important to have them anyway: tests for HHV-7 and 8, mycoplasma, Chlamydia pneumoniae, cytomegalovirus, coxsackie viruses, adenoviruses.)

Because I have private insurance and because my extended family was willing to help pay for whatever testing was available, I was able to find out that I had some things and not others, and I have received treatment for what I have. If I need more treatment, my physician looks for what is available and we do the best we can getting it and paying for it.

Should patients be denied testing because insurance companies and Medicare don't want to have to pay for the testing? Should patients be denied treatment because insurance companies and Medicare don't want to have to pay for the treatment?

Should that be the business of CDC?

Questionnaires as "tests"

CDC might respond that their questionnaires are a kind of "test". Frankly, I've had to answer most of them every other month since 1999, and I don't think they get at the symptoms I had the months where the disease was at its worst (before I began Ampligen treatment. So I would like to suggest some more questions for these questionnaires, showing abnormalities that are actually quite common in the "CFS" community. Going solely for the fatigue questionnaires, I would at least ask:

- Do you have trouble with balance?
- Can you cross the street unassisted,
- Can you cross the room unassisted?
- Do you used a wheelchair and/or a cane?
- Can you stand up from a straight-backed chair unassisted?
- How many steps can you take up a stepladder without something to hold on to?
- Can you read the newspaper or understand the evening news? Can you follow a simple sitcom plot?
- How often have you mixed up where to put items away (e.g., milk in the cabinet, sugar bowl in the refrigerator)?

- Can you drive a car?
- Do you experience blackouts?
- Do you pause in the middle of a sentence, unable to remember how to complete it?
- Do you use the wrong word for things or have so much trouble with word retrieval that you are blocked from being able to finish the sentence?
- Do you speak in a halting, slow manner?
- Do you walk in a halting, slow manner?

Those are questions I would ask, if I was writing the questionnaire.

A questionnaire for M.E.

Previously I have given testimony about Myalgic Encephalomyelitis (M.E.), the disease that was also called atypical polio and, in the United States, Epidemic Neuromyesthesia. When the Holmes committee came together, they rejected the notion that there was any relationship between M.E. and any of the cluster outbreaks that had occurred in the U.S. in the mid-1980s. However, by 1991 NIH had published a booklet stating that M.E. was an outdated term for CFS.

More recently, CDC has added a sentence to the website that states M.E., like fibromyalgia, overlaps somewhat with CFS, but is not the same disease.

Perhaps what we need is not yet another series of tests on “fatiguing diseases that are medically unexplainable,” but a questionnaire for M.E. Then again, that might be too simplistic. The Canadian consensus criteria for ME/CFS, adopted in 2003, offer an excellent set of criteria for clinicians – and researchers – to diagnose this illness in all its complexity. They should be adopted here. Oh – and they include tests and treatments.

Conclusion

Twenty years after the Holmes meeting in 1997 chose the name CFS and the Holmes definition, that's *all* CDC and NIH have been able to come up with? “There are no tests and there are no treatments.”

Roughly one million people in the United States have “CFS”. The vast majority has no idea what is wrong with them, and of those who do have the diagnosis, their doctors have no idea how to help them.

After twenty years, that's a pretty sad state of affairs.