

## ME/CFS: UK versus US

Margaret Williams

22<sup>nd</sup> December 2008

It is anticipated that the differences in the understanding of and the approach to ME/CFS in the UK as set out by NICE in its Clinical Guideline 53 on “CFS/ME” as compared with current biomedical research in the US will be brought to the attention of the Judge in the forthcoming Judicial Review on 11<sup>th</sup> and 12<sup>th</sup> February 2009 in the High Court in London.

Specifically, NICE failed to identify or define the disorder in question in that the Guideline Development Group (GDG) failed to differentiate ME from states of medically unexplained chronic fatigue and, importantly, advised against the very investigations that would do so. NICE also rejected the use of the Canadian case definition, these being the criteria that distinguish ME/CFS from other states of medically unexplained chronic fatigue.

For almost two decades, the Wessely School has called the shots about “CFS/ME” in the UK and, despite the denials, it is believed that it is their influence at the Medical Research Council (MRC) that has resulted in the MRC’s categorisation of “CFS/ME” as a mental disorder and in the MRC’s repeated refusal of funding for biomedical research. It is the case that, since 2002, approximately 91% of the MRC’s total grant spend on “CFS/ME” has gone on Wessely School trials of behavioural interventions and the MRC has refused no less than 33 biomedical grant applications for ME/CFS.

The approach in the US is radically different. Recruitment is currently taking place for participants in clinical trials that will look for specific sets of proteins in the cerebrospinal fluid (CSF) of ME/CFS patients. The study sponsors are Georgetown University / National Institute of Environmental Health Services (NIEHS) <http://tinyurl.com/8k4nfq>

The investigators have already shown (in a previous similar study) significant changes in proteins in the CSF which the investigators believe may be due to the fundamental pathology of ME/CFS.

The official title of the study is “Study Looking for Unique Set of Proteins in Cerebrospinal Fluid, which are believed to be found in Chronic Fatigue Syndrome Participants but not in Healthy Controls”. The investigators believe that these proteins (which are not seen in other disorders or in healthy controls) may identify the disease and define its mechanism.

The investigators note that increased cerebrospinal fluid pressure may be related to symptoms including headache, sleep problems, light-headedness, increased pain, excessive fatigue with even minimal work, and memory problems.

The detailed description states: **“Neurological dysfunction is a key component of the clinical expression and case designation of (ME)CFS. If the central nervous system is involved, then evidence will be present in the cerebrospinal fluid. Distinct patterns of proteins will be present in (ME)CFS compared to health control subjects. Other testing would include assessment of lung capacity and scoring of shortness of breathing testing (pulmonary function testing / PFT)”**.

Secondary outcome measures will look at differences in blood tests; at differences in blood pressure and heart rate in response to exercise, and at sensory nerve testing to determine the role(s) of altered nerve and brain function in ME/CFS. Skin tests for allergy will also be carried out.

The study is comprehensively placed in numerous topic categories which include gastrointestinal diseases, musculoskeletal diseases, neuromuscular diseases, multiple chemical sensitivity, central nervous system diseases, rheumatic diseases, myalgic encephalomyelitis, and virus diseases. Additional relevant MeSH terms are listed as pathological processes / immune system diseases and Environmental Illness.

In the UK, the NICE Guideline which forbids such investigations will become legally enforceable in 2009.