

Margaret Williams 9th May 2005

Given that the Medical Research Council intends to use the “London” criteria for what is described as ‘secondary analysis’ in the PACE trials that will use the Oxford 1991 criteria that deliberately include those with psychiatric disorders, it is imperative that the issue of the authenticity of the “London” criteria is publicly addressed.

Miss Ellen Goudsmit PhD has recently posted challenges to information supplied by others:

- (i) “As was noted last year, the London criteria have been used in various studies, some of which have been published. The London criteria are as defined and operationalised as the other research criteria from that time. The London criteria were devised for MEAction, now AFME, for use in all studies funded by them. All teams who received a grant, except one, kept to the contract. Amongst those who received a grant were Dr Durval Costa for his study on hypoperfusion (published in the QJM). I urge activists not to undermine (*the arguments of authors whom she continues to assert used the ‘London’ criteria in their research*) by giving inaccurate information” (“The London criteria: correction and clarification”: Co-Cure, 7th May 2005)
- (ii) “The LC (*‘London’ criteria*) were devised so researchers could identify the ‘real deal’ patients and they did! The abnormalities they found **using the LC**, e.g. hypoperfusion, reduced muscle power etc were found in ALL the patients who met the criteria. Costa et al was one of the most important studies to date. Too little blood to the brain. Paul et al was good and that too, was on people with ME. Those of us who fought for research on real deal patients back in the early 90s deserve credit. Not denial” (CFS Research, 8th May 2005).

FACT: The “London” criteria ***have never been published***. They were mentioned in the National Task Force Report as being one of nine different “PROPOSED” definitions and descriptions (see page 88, Appendix B, REPORT from THE NATIONAL TASK FORCE ON CFS/PVFS/ME: 13th September 1994: Westcare, Bristol --- note that Westcare no longer exists and is part of Action for ME). Merely being mentioned in a Report or published document is entirely different from and does not equate with the criteria having been published and used in research.

FACT: Before criteria can be USED to select patients for a study, they need to be PUBLISHED in an accessible form in a medical journal (the 1988 Holmes et al criteria were published in *Annals of Internal Medicine*:1988:108:387-389; the 1991 Oxford criteria were published in the *Journal of the Royal Society of Medicine*:1991:84:118-121 and the 1994 CDC criteria were published in *Annals of Internal Medicine*: 1994:121:953-959. The “London” criteria have never been so published or submitted for peer review.

FACT: The London criteria *have not been consistently defined* -- there are different VERSIONS of them and a definitive version has not been identified.

FACT: The *authors of the London criteria are unknown (various differing claims have been made by Ellen Goudsmit about the authorship.)*

FACT: The London criteria *have never been officially accepted into common usage, nor have they ever been validated or operationalised* (as conceded by Ellen Goudsmit herself on 4th September 2004 where she states “The LC have not been validated”).

Ellen Goudsmit makes specific claims about the London criteria:

(i) she claims that the London criteria (LC) have been USED to select patients and she provides various references that purport to support her claim and

(ii) she claims to have been a co-author of the LC but she also claims to have had nothing to do with the authorship of the LC.

These issues are addressed below.

(i) Consideration of the papers that Ellen Goudsmit claims used the “London” criteria in published research:

In an email dated 7th June 2004, Ellen Goudsmit PhD wrote to someone asking her (“for old times sake”) to confirm publicly the following about the “London” criteria:

“that they were first published in the National Task Force report and that they are very similar to Ramsay and Dowsett’s clinical definition **ie. they are operationalised criteria** for research on ME as defined by Ramsay and Dowsett. Those are the facts. They were, almost word for word, a copy of Dowsett’s work”.

(Criteria cannot be “operationalised” **before** they have been defined or published or if the authors have not been ascertained).

The same email also stated: *“They (ie. the “London” criteria) were used in all studies funded by AFME from 1993 to 1997, eg. Costa et al, who discovered hypoperfusion in the brainstem, and Scholey et al, who found cognitive impairment consistent with organic brain disease. Paul et al also used them and found support for Ramsay’s definition, especially the delayed recovery for muscle power”.*

From this, it seems that Miss Goudsmit believes that the “London” criteria were *used for patient selection* in the studies she mentioned, and that as a result of using the “London” criteria, significant abnormalities in patients with ME/CFS were elucidated.

This is not the case, as can be seen from the papers that Ellen Goudsmit claims USED the “London” criteria (ie. for selection of patients to be studied):

Costa, Tannock & Brostoff (1995)

(Brainstem perfusion is impaired in chronic fatigue syndrome. DC Costa, C Tannock and J Brostoff. Quarterly Journal of Medicine December 1995:88:767-773)

This paper makes no mention of the “London” criteria. It confirms about the population studied that “All ME/CFS patients were clinically assessed and diagnosed according to standard criteria (Oxford), CDC and ME Action”. The reference in the paper for the ME Action criteria is number 14. That reference states “**Criteria for a diagnosis of ME for use in the ME Action funded research. Based on the criteria suggested by WRC Weir in *Postviral Fatigue Syndrome* by Jenkins & Mowbray pp248-9**”. The Jenkins & Mowbray textbook at pp 248-249 sets out Dr Weir’s own modification of the Holmes et al 1988 criteria and is virtually identical to what was later published as the “London” proposed criteria in the Westcare Task Force Report in 1994. Thus the question arises as to how much of the modification to the Ramsay original case description of ME that Miss Goudsmit has variously claimed as being her own work and then as being taken almost word for word from Dr Betty Dowsett can be ascribed to Dr Dowsett and how much to Dr Weir.

Lorna Paul et al 1999

(Demonstration of delayed recovery from fatiguing exercise in chronic fatigue syndrome Lorna Paul et al. European Journal of Neurology 1999:6:63-69)

The case definition used in this study was the CDC Fukuda 1994: the authors state “**The patients were all ambulatory, and fulfilled established criteria for chronic fatigue syndrome (Fukuda et al, 1994)**”. There is no reference to the “London” criteria anywhere in the paper itself or in the references. The text does indeed mention the Oxford criteria, but the cited population studied under the “Methods” description refers only to the CDC 1994 Fukuda case definition, thus it cannot be claimed that the “London” criteria were used for patient selection.

Lorna Paul et al 2001

The effect of exercise on gait and balance in patients with chronic fatigue syndrome.

Lorna M Paul et al. Gait and Posture 2001:14: 19-27

Eleven subjects with CFS and eleven control subjects participated in this study. All patients fulfilled the CDC 1994 criteria for CFS. There is no reference to the “London” criteria anywhere in the paper.

Whiting et al --- the York Systematic Review (2001)

(Interventions for the Treatment and Management of Chronic Fatigue Syndrome. Penny Whiting et al JAMA 2001:Sept 19: 286:11:1360-1368)

Miss Goudsmit claims that her own work was based on the “London” criteria and was used in this Systematic Review. It is submitted that such a claim is misleading because once again, there is no mention of the “London” criteria, but the York Review does reference Ellen Goudsmit’s dissertation itself; it was called “Learning to Cope with Post-infectious Fatigue Syndrome: a Follow-up Study in the Psychological Aspects and Management of Chronic Fatigue Syndrome”: Uxbridge, England, Brunel University, 1996.

On 4th February 2005 Miss Goudsmit publicly posted the following in relation to her thesis: “(The York Review team) only assessed a pilot study which was included in my thesis. The title of my thesis is different”. Unless Miss Goudsmit provided misinformation to JAMA which published the York Review (JAMA 2001:286:11:1360-1368), the reference by Whiting et al of the York Review team to Miss Goudsmit’s work was indeed to her thesis. It is submitted that the correct reference and title for something that is within a thesis is the actual title of the thesis (and not the sub-context within the thesis, otherwise how could it be sourced?).

On the subject of Miss Goudsmit’s thesis, there would seem to be some discrepancy about the its title, given that on the official doctoral register it is listed as being “The Psychological Aspects and Management of Chronic Fatigue Syndrome”, whilst in the JAMA review Whiting et al refer to it as “Learning to Cope with Post-Infectious Fatigue Syndrome: a Follow-up Study in the Psychological Aspects and Management of Chronic Fatigue Syndrome”, but in her own CV posted on her website, Miss Goudsmit has changed it to “The psychological aspects and treatment of the chronic fatigue syndrome”. She also refers to it by this last title in her “Medical Updates” dated 1st September 1996.

The Scholey et al presentation (1999)

(A comparison of the cognitive deficits seen in myalgic encephalomyelitis to Alzheimer’s Disease. Pat McCue, Andrew Scholey and Keith Wesnes Proceedings of the British Psychological Society, 12th January 1999)

This was an abstract that was presented as a poster presentation at a BPS Conference in January 1999. Abstracts are recorded by the BPS but the study itself **has never been published.** This was confirmed by Professor Andrew Scholey himself and also by the British Psychological Society. The study looked at 20 patients (self reported from ME support groups in the North-East of England) and the abstract states that they satisfied the London criteria, although the criteria used were not defined in the abstract.

Scholey et al also presented another abstract at a BPS conference in Belfast held on 8th-11th April 1999 (Cognitive deficits in Chronic Fatigue Syndrome are reversed by oxygen administration Andrew Scholey, Pat McCue, Ingrid Mackay, Mark Moss and Keith Wesnes). The abstract states that the participants were 16 patients satisfying both the Oxford and the London criteria. Again, this study has **not been published.**

With regard to Professor Scholey's work and the significance that can be drawn from it on the basis that the "London" criteria were used, patients were self-reported and it is **unpublished material**.

In her post of 8th May 2005 on CFS Research, Miss Goudsmit now concedes that the Scholey work has not been published: "Other researchers who used (the 'London' criteria) were McHale et al and McCue, Scholey et al. The former did not mention them in their paper and the other hope (*sic*) to submit a paper".

In the same post, Miss Goudsmit now states unambiguously: "Paul et al did not mention them (ie. the 'London' criteria) in their paper".

In that same post of 8th May 2005 on CFS Research, Miss Goudsmit states: "Here are the details of three of the published studies which made use of the London criteria. I hope this ends the misinformation once and for all. Here are the references again:

P McCue, CR Martin, T Buchanan, J Rodgers, AB Scholey

Psychology, Health & Medicine, 2003, 8, 4, 425-439. An investigation into the psychometric properties of the Hospital Anxiety and Depression Scale in individuals with chronic fatigue syndrome

Available online <http://www.tandf.co.uk/journals/online/1354-8506.asp>
Go to Browse the volumes, click on 2003, November. See p. 430.

Perrin, RN, Edwards, J and Hartely, P. An evaluation of the effectiveness of osteopathic treatment on symptoms associated with myalgic encephalomyelitis. A preliminary report. Journal of Medical Engineering & Technology, 1998, 22, 1, 1-13. See p.2.

Listed <http://www.tandf.co.uk/journals/archive/tmet-con.asp> but full text not available (so interested parties will have to order from a library).

Costa, DC., Tannock, C and Brostoff, J. Brainstem perfusion is impaired in chronic fatigue syndrome QJM, Vol 88, Issue 11 767-773.

(Miss Goudsmit did not provide the year of publication).

Summary online at <http://qjmed.oupjournals.org/cgi/content/abstract/88/11/767>

In the first of the three papers above (P McCue, A Scholey et al in Psychology, Health and Medicine, 2003), the paper itself states: "It is notable that some authors suggest that rates of current depression in CFS generally resemble those of patients with multiple sclerosis or cancer (Goudsmit 1996)" and it gives Miss Goudsmit's dissertation as the reference for this statement (Goudsmit E. (1996). Learning to Cope With Post-Infectious Fatigue Syndrome: A Follow-up Study. In: The

Psychological Aspects and Management of Chronic Fatigue Syndrome [dissertation]. Uxbridge, England: Brunel University). No mention is made of the “London” criteria in this reference.

Under “Procedure”, this paper states: “Participants were recruited in a number of different ways. Advertisements were placed in CFS/ME magazines and newsletters and flyers were posted to public libraries across the North East of England. All participants were requested to go to the study’s website, www.cfsresearch.net. At the site, participants proceeded to the next page on which the survey instrument was presented. This was comprised of the following questionnaires: a symptom questionnaire (derived from the CDC and London criteria for CFS/ME (*and other questionnaires about memory, diet and medication*)). Having completed the questionnaires, respondents clicked on a button labelled ‘Finished’ and the information they had submitted was added to our data file”.

No reference for or information about the “London” criteria is provided by the authors and it must be noted that patients may have been self-diagnosed and were self-referred, so it is unclear by what methods the authors decided that participants fulfilled the unpublished “London” criteria.

In the second of the three papers provided by Miss Goudsmit as having used the “London” criteria (Perrin et al, 1998), under “Procedure” the authors state: “All subjects in the patient group were selected from patients in the clinical practice of one of the authors. Each of them had to satisfy the definition for chronic fatigue syndrome of the Centre (*sic*) for Disease Control and Prevention (CDC). They also had to satisfy The London Criteria which were formulated by scientific advisers for the ME Association as well as Action for ME (1, 4) and validated by several groups including the National Task Force on CFS (24, 25)”.

The references refer to (1) “ ‘Epidemic Neuromyasthenia’ 1955-1978”. Ramsay AM: Postgraduate Medical Journal 1978;54:638: 718-721; (4) “Myalgic encephalomyelitis – a persistent viral infection?” Dowsett et al: Postgraduate Medical Journal 1990;66:526-530; (24) Report from The National Task Force on CFS/PVFS/ME; Westcare, Bristol, September 1994 and (25) “Brainstem perfusion is impaired in chronic fatigue syndrome”. Costa, DC, Tannock C and Brostoff J: Quarterly Journal of Medicine 1995;88:11:767-773

Whilst it is true that this paper does indeed state that participants had to satisfy the “London” criteria, the facts are as follows. The lead author has confirmed that he was misled at the time of the study into believing and accepting that the “London” criteria had indeed been published, operationalised and validated. He had no reason to doubt the information he sought and was given by the Medical Adviser to Action for ME, who in turn had been assured by Miss Goudsmit that this was the true situation. He was dismayed to learn that the “London” criteria had never been published and he cannot be held in any way responsible for having been misled.

Referring to the third of the three papers she provides, it is notable that Miss Goudsmit herself here states about the Costa et al paper that

“Costa did not refer to the London criteria but to the 'ME Action' Criteria. I can't be held responsible for the way he described them in his article. I did not see the proofs so could not correct.”

(ii) Ellen Goudsmit's disparate claims about authorship of the LC:

As mentioned above, the reason why the matter of the London criteria is important is because the Medical Research Council is about to undertake a major study on “CFS/ME” and intends to use the London criteria for secondary analysis, even though those criteria have never been defined, published, peer-reviewed, operationalised or validated and there is continuing debate involving Miss Goudsmit's role in the authorship.

It is submitted that the following illustrations provide unequivocal evidence concerning her misleading and inaccurate claims about her own involvement with the London criteria:

- ***“Old lie. [In that it has been stated by others that] I had nothing to do with the London criteria. I not only thought of the idea but was involved in writing and disseminating them” (21st October 2001)***
- ***“The London criteria are research criteria, for use in research, e.g. Costa et al, Scholey et al, Paul et al. I know this as I was one of the co-authors” (9th January 2002)***
- ***“Authors in alphabetical order were Dowsett, Goudsmit, Macintyre, Shepherd. Date was 1993 (I think)” (15th January 2002)***
- ***“Herewith... my own criteria for ME (son of ‘London’)” (9th February 2002)***
- ***“London criteria were not Ramsay's. He was deceased by the time they were formulated. By moi and others” (19th May 2002)***
- ***“There are a number of versions of the London criteria... Ellen (One of the co-authors)” (11th June 2004)***
- ***“Even on David's site (there are) just my own criteria...I accepted the text from others” (12th June 2004)***
- ***“The London criteria are used to diagnose ME. As I noted before, I did not write any of the text of the LC” (12th June 2004)***
- ***“Most of the text of the London criteria was Betty Dowsett's. I did not write a single word” (4th September 2004)***
- ***“They were initially used by Costa et al. I wasn't involved with later versions” (10th September 2004)***

The above quotations from Miss Goudsmit should be compared with what is on her website:

- *“THE DIAGNOSIS OF ME. The following are my criteria, which I based on the work of pioneers such as Gilliam, Ramsay, Parish, Acheson and Dowsett”* <http://freespace.virgin.net/david.axford/me-defin.htm> - 3k - 1999-08-15

On 14th September 2004 Miss Goudsmit wrote the following to a university lecturer about the alleged use of the London criteria:

- *“Given your status as a University lecturer, I felt it appropriate to offer you good evidence to show that Costa DID use the London criteria. I have his description of the study (and) the contract. It explains why he described them as something else”.*

(The Costa et al 1995 reference that Miss Goudsmit claims used the London criteria makes no mention of them).

On 3rd February 2005 Miss Goudsmit posted the following:

- *“I have NEVER made false claims about the London criteria. The BPS does not have information such as whether an (sic) study presented at a conference has been published. It means the person who passed this on was lying. They lied about the information obtained from Prof. Scholey, about what I claimed. I’ve got a problem and it relates to the rules of my professional organisation”.*

(Professor Scholey himself has confirmed that, contrary to Miss Goudmit’s claims, his material under discussion has not been published and a search of Medline confirms this).

Another example of Miss Goudsmit’s inconsistency in relation to the London criteria is to be found in her letter to the Chief Medical Officer:

- *“e.g. wrong reference to the London criteria, cited as 1990 but I didn’t think of them until 1993 let alone compile them with colleagues (in 1990)” .*

It is submitted that it is only too obvious that Miss Goudsmit has made numerous disparate claims about her involvement with the formulation of the London criteria.

In conclusion, it is submitted that currently, the “London” criteria have no justifiable or validated legitimacy that would in any way provide acceptable criteria for use by the MRC or by any other research bodies for use in identifying patients with ME/ICD-CFS. Not only are they now at least eleven years old, they have been superseded by the more robust and superior Canadian case definition (Myalgic Encephalomyelitis / Chronic Fatigue Syndrome: Working Case Definition, Diagnostic and Treatment Protocols. Bruce M Carruthers et al. JCFS 2003:11: (1): 7-115).

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