SAYING NO CAN BE POSITIVE Spring 2006 (updated 2017)

This document was originally written in response to the Chief Medical Officer's report in 2002 which triggered the current NHS Chronic Fatigue Syndrome/Myalgic Encephalomyelitis clinics, set up across the country. These clinics consist mainly of psychological therapies such as Cognitive Behavioural Therapy and Graded Exercise Therapy. This document may empower sufferers who choose to refuse attendance of the clinics; bedbound/housebound sufferers who are advised to have these therapies on domiciliary visits may also find this document helpful. It may also help those pressurised to undertake CBT and Graded Exercise Therapy by Private Health Insurers.

Those who wish to refuse psychological therapies for M.E. can be supported by the following facts:

1) The law protects patients from unwanted treatments if the patient is deemed to be mentally competent. Medical practitioners cannot give a treatment to a patient without the patient's consent. [1] Scientifically, M.E. is NOT in Mental Health, see below.

2) An M.E. patient doesn't have to comply with the NICE guidelines on CFS/M.E., supported by the above law, because M.E. is not scientifically in mental health.

3) The NICE guidelines, which support CBT and Graded Exercise Therapy for M.E., are not mandatory. In practice, GPs and all doctors do follow the NICE Guidelines: this is because all NHS organisations have a legal requirement to implement NICE guidance. **However, the treatment aspect is not enforceable.**

' I can clarify that NHS organisations are indeed expected (and in some cases, such as a type of guidance called Technology Appraisal guidance, legally obliged) to implement NICE's recommendations. This is not the same as saying that the NHS has the power to force a patient to undergo a treatment which they do not want.' [2]

Also,

' NICE clinical guidelines such as CG53 are not legally enforceable. [3]

4) M.E. patients have a right, under the NICE guidelines, to refuse the recommended treatments from NICE. The following could be used to help M.E. sufferers who wish to refuse NICE's recommendations of treatment:

'Healthcare professionals should be aware that – like all people receiving care in the NHS – people with CFS/ME have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their care, or future choices about care.' [4]

A patient's care plan can include state benefits and social services care, which are now also linked with the NICE guidelines.

The NICE guidelines do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient. Healthcare professionals should record their reasons for not following clinical guideline recommendations.

In other words, every patient case is individual and a doctor does have the right to express clinical freedom, along with consulting the patient, as to what is best. This may mean refusing Graded Exercise Therapy and CBT.

5) An M.E. patient who is in a comatose/semi comatose state cannot by law be forced into psychological treatment just because they have M.E. [5]

6) An M.E. patient has a medical legal right to oppose CBT and GET. In 2015 there was a landmark ruling which states that a doctor must inform a patient of ALL risks of treatment offered; ALL research known of the illness being treated and of alternative treatment. [6]

The General Medical Council, in its guidance on consent to medical treatment, advises that a patient must be told of other options to the treatment being offered, the risks and benefits of each option; **then it is for THE PATIENT NOT THE DOCTOR to advise which option they wish to choose.** [7]

7) Private Health Insurers cannot force an M.E. client to undergo unwanted treatment before making a payment, unless those treatments are specified in the contract. Unless the contract of a company states clearly that M.E. clients must undergo CBT and/or Graded Exercise Therapy before a payment is made, the company could well be in breach of contract. Also, every individual has freedom to express views as stated by The Human Rights Act 1998. If an insurance company ignores a client's reasons for refusing CBT and/or Graded Exercise Therapy, a client

could claim their 'freedom of expression' has been violated.[8] **The UK Law of Human Rights is still protected in spite of 'Brexit'.**

The following organisation may offer help, including a free telephone appointment for legal advice:

Disability Law Service
The Foundry
17 Oval Way
London SE11 5RR

Tel: 020 7791 9800

Email: advice@dls.org.uk Website: www.dls.org.uk

8) An M.E. patient cannot have their state benefits withdrawn for refusing CBT and Graded Exercise Therapy. Unfortunately, the NICE guidelines are now linked with the awarding of state benefits and Social Services care.

U.K. law says that if a patient refuses suitable treatment without good cause, benefits can be withdrawn.[9]

However, CBT and Graded Exercise Therapy could be argued as unsuitable treatments for M.E. sufferers (see facts below). Scientific opinion which is against CBT and GET for M.E. can be used to obtain state benefits for sufferers.

In addition, NICE has written the following in its CFS/ME Guidelines:

'Healthcare professionals should be aware that – like all people receiving care in the NHS – people with CFS/ME have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their care, or future choices about care.' (This is also quoted in section number 4 of this paper. See Footnote 4 for reference.)

Although NICE Guidelines are now linked in with the awarding of Social Services care and State Benefits, the above quote can be used in favour of an M.E. sufferer's refusal to undergo CBT and Graded Exercise Therapy.

If sufferers find themselves in a legal battle with their benefits, those who qualify for legal aid may find the following organisation helpful:

Civil Legal Advice (formerly Community Legal Advice) Tel: 0845 3454345

Also, for general welfare benefit advice: www.turn2us.org.uk Tel: 0808 8022 000

The organisation Disability Rights UK can also help with benefit guidance and appealing against decisions:

Ground Floor
CAN Mezzanine
49-51 East Road
London N1 6AH
Email: enquiires@disabilityrightsuk.org

www.disabilityrightsuk.org

Tel: 020 7250 8181

9) M.E. is a neurological disorder. It has been classified as such by the World Health Organisation in the International Classification of Diseases since 1969.[10] Therefore psychological therapies could well be inappropriate.

10) M.E. has a strong medical history of being an organic disease. Dr. Gordon Parish is the curator of the Ramsey Archive, which is possibly the world's largest collection of medical papers on M.E.[11] It includes detailed world-wide epidemics of M.E. since 1934 and the viruses which triggered the disease.

12) There are over 9,000 international peer-reviewed papers showing that M.E. is an organic disorder. [12]
13) In November 2010, M.E. sufferers were permanently banned from giving blood; even if a sufferer says that they have recovered, they will still be permanently banned from giving blood. The Dept. of Health has said that the ban is a precaution to protect the donor's safety by ensuring the condition of M.E. is not made worse by

donating blood. They say that the move brings M.E. in line with other relapsing conditions such as Multiple Sclerosis and Parkinson's Disease, or neurological conditions of unknown origin. [13]

THIS DECISION BY GOVERNMENT IS PROOF THAT THEY KNOW M.E. IS A BIOMEDICAL DISEASE.

14) Many tests exist in aiding a diagnosis for M.E. Therefore, using psychological therapies for 'unexplained fatigue' is inappropriate. Although diagnostic tests for M.E. are still being worked upon with promise, nevertheless many tests and procedures can be administered in aiding a diagnosis of M.E. These include the use of SPECT, MRI and PET scans, test for NK cell activity and endocrine abnormalities, Tilt Table Test, viral tests and many more.[14] Although these tests are rarely offered by the NHS for M.E., they have nevertheless shown evidence of physical abnormalities.

15) "Patients who improve after physical exercise programmes do not have M.E./CFS.," says Dr. Byron Hyde, M.D. of the Nightingale Research Foundation for M.E. in Canada, who has studied M.E. since 1984.[15] Dr. Hyde stresses that M.E. is primarily a disease of the Central Nervous System.[16]

16) **Patients who respond well to CBT and Graded Exercise Therapy might not have M.E. due to the diverse criteria used. Some criteria focus on unexplained chronic fatigue only, omitting symptoms showing central nervous system involvement.** There are at least thirteen definitions of Chronic Fatigue Syndrome and/or M.E.*, all of them different.*[17] ***In the U.K., a frequently used case definition is the Oxford Criteria which includes patients with no physical signs and selects subgroups of patients with high levels of psychiatric diagnoses .***[18] ***The PACE and FINE trials (funded by the Medical Research Council) use the Oxford Criteria.***[19]

THE OXFORD CRITERIA HAS BEEN STRONGLY CRITICISED BY THE NIH (U.S. NATIONAL INSTITUTES OF HEALTH) WHO HAVE SUGGESTED THE OXFORD CRITERIA SHOULD BE 'RETIRED' AS IT MAY IMPAIR PROGRESS AND CAUSE HARM. [20]

17) **The assumption that an M.E. patient can always do more is an erroneous one.** There are overwhelming international research findings on M.E., which support multi-system involvement particularly of the immune, endocrine, cardiovascular and neurological systems.[21] Also, there is evidence indicating pathology of the central nervous system and immune system[22] and evidence of metabolic dysfunction in the exercising muscle.[23] Also, Dr. Jay Goldstein has demonstrated through SPECT scans the severely decreased brain perfusion of an M.E. patient 24 hours after physical exercise.[24] The Canadian Criteria (2003) states that ***the worsening of symptoms after exertion is a principal symptom of M.E.*** [25]

The International Criteria (2012) go further by stating that **PENE (Post-Exertional Neuroimmune Exhaustion)** is a compulsory symptom for an M.E. diagnosis**.**[26]

'PENE is characterised by a pathological low threshold of physical and mental fatigability, exhaustion, pain and ***an abnormal exacerbation of symptoms in response to exertion. It is followed by a prolonged recovery period.*** Fatigue and pain are part of the body's global protection response and are indispensable ***bioalarms*** that alert patients to modify their activities in order to prevent further damage.'

The authors of the International Criteria panel consist of twelve countries.

In addition, raised levels of noxious by-products of abnormal cell membrane metabolism, associated with exercise and correlating with patients' symptoms have been demonstrated.[27]

18) CBT and Graded Exercise Therapy can worsen M.E. symptoms. In a survey of 3074 M.E./CFS patients conducted between 1998 – 2001, ***55% of patients said that CBT had made no difference to their illness, whilst 22% said CBT had made their illness worse. 16% of patients said that graded exercise had made no difference to their illness whilst 48% said it had made their illness worse***.[28] A survey by the 25% ME Group (for severe sufferers) of 437 patients, demonstrated that of the 39% of group members who had used graded exercise, 95% had found this therapy unhelpful, whilst ***82% reported their condition had been made worse by graded exercise. Some patients were not severely ill with M.E. until after graded exercise.*** In the same survey ***93% of those who had undergone Cognitive Behavioural Therapy had found it unhelpful***.[29]

In 2011, a paper by Tom Kindlon was published in a peer reviewed journal, demonstrating deterioration of M.E. sufferers from GET/CBT. Kindlon's pooled data from several patient surveys, showed that 51.24% of ME/CFS sufferers had been harmed from GET and 19.91% from CBT.[30]

19) The 2002 CMO's Report recommended CBT and Graded Exercise Therapy despite the objection of two patient support groups. The patient support groups of BRAME (Blue Ribbon for the Awareness of ME) and the 25% ME Group refused to endorse the CMO's Report of 2002 based on its recommended treatments of CBT and graded exercise. These support groups mainly represent the needs of severe M.E. sufferers and were part of the CMO's Working Group.

20) Medical Concerns were raised about the CMO's Report. The Journal of Chronic Fatigue Syndrome , mentions criticism by health professionals and the public of both the British and the Australian M.E./CFS guidelines. "***These criticisms included claims of bias in the recommendations toward a psychiatric outcome and failure to understand the limitations of patients to perform exercise programs as well as many others."***[31]

Also, the Canadian Guidelines specifically warn against graded exercise programmes.
'Externally based "Graded Exercise Programs" or programs based on the premise that patients are misperceiving their activity limits or illness ***must be avoided.***[32]

21) The NICE guidelines for CFS/ME have received widespread condemnation. The NICE guidelines were NOT supported by the following registered U.K. M.E. charities: The M.E. Association, the 25%M.E. Group, Invest in M.E., and the Grace Charity for M.E. Also, the organisation BRAME did not support the guidelines outcome, despite the latter serving on the panel. There are many other M.E. groups who also condemn these guidelines. The NICE guidelines received so much criticism that NICE were taken to court by two M.E. sufferers in February 2009. Views from international researchers (e.g. Carruthers, Peterson, Lerner, Hooper and Drs involved with M.E. Research UK) regarding the potential negative effects of Graded Exercise Therapy and CBT, were not acknowledged in the Judge's decision.

Also, the NICE guidelines group had no-one offering a biomedical aetiology (cause) of M.E: therefore, the disease M.E. was never properly addressed by NICE because researchers offering a biomedical cause were not allowed to serve on the guideline group.

''Most Independent M.E. charities and patient organisations have rejected the NICE guidelines..."[33]

22) After the CFS/ME clinics were set up by the 2002 CMO's report, the controversial PACE trial results were published in February 2011, promoting CBT, Graded Exercise Therapy and APT (Adaptive Pacing Therapy, a form of Graded Exercise) . The acronym PACE stands for Pacing, graded Activity and Cognitive behaviour therapy; a randomised Evaluation. The trial was funded by the Medical Research Counsel, Dept. of Health and the Dept. for Work and Pensions and uses the Oxford Criteria (psychiatrically prejudiced criteria, see bullet point no.16 of this document). The PACE results are viewed (wrongly) as evidence based and safe treatments; the therapies from PACE are currently the NHS standard treatment, dominating clinical policy in both the UK and other countries, in government funded health care and private medical insurance.

In recent years, however, the PACE trial has been seen as ethically flawed and recorded as such by both science journalists and medical researchers. [34]

There are several reasons why the PACE trial is seen to be flawed but the most obvious one is when its authors *changed the assessment outcome* during the middle of their trial![35]

Another crucial point against the PACE trial is that its lead author, Prof. Peter White, is on record as saying that PACE was never meant to be for M.E. sufferers! He also says that the World Health Organisation's neurological classification of M.E. was not used.

' We did not use the ICD-10 classification of myalgic encephalomyelitis (ME) because it does not describe how to diagnose the condition using standardisation criteria, so cannot be used as reliable eligibility criteria. The PACE trial paper refers to chronic fatigue syndrome (CFS) which is operationally defined; it does not purport to be studying CFS/ME but CFS defined simply as a principal complaint of fatigue that is disabling, having lasted six months, with no alternative medical explanation (Oxford Criteria). '[36]

References

[1] See the case of St.George's Healthcare NHS Trust v S (1998) 3 All ER 673 (Court of Appeal), p.758 of Hepple, Howarth and Matthews Tort, Cases and Materials, 5th Edition by DR Howarth and JA O'Sullivan, ISBN 0 406 063265 (Butterworths, 2000)

[2] Quote from Kathleen Jackson-Heppell, Communications Co-ordinator (Enquiry Handling and Internal Communications for NICE), in an email to the Grace Charity for M.E. dated 15/02/2011

[3] Quote from Natalie Whelan, Communications Executive (Enquiry Handling) for NICE, in a letter to the Grace Charity for M.E. dated 23rd September 2009.

[4] NICE guidance document on CFS/ME, Clinical Guideline 53, 22 August 2007, page 8. http://guidance.nice.org.uk/CG53

[5] See above publication in endnote 1 (Hepple, Howarth and Matthews Tort) regarding section attributed to Lord Brandon of Oakbrook, pp.744, 745

[6] Full UK Supreme Court Judgement, UK Supreme Court documentation on Montgomery (Appellant) v Lanarkshire Health Board (Respondent) Case ID UKSC 2013/0136, 11th March 2015 https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf

[7] Clinical Negligence: A Change to the Law of Informed Consent, Robbie Wilson, May 05, 2015 http://www.drummondmiller.co.uk/new...ence-a-change-to-the-law-of-informed-consent/

Above information taken from Phoenix Rising www.pheonixrising.me *The Significance to ME/CFS of the Landmark Change to the UK Law on Consent*

[8] The Human Rights Act 1998, European Convention for the Protection of Human Rights and Fundamental Freedoms, Section 1, Article 10, no.1

[9] U.K. law on state benefits, Regulation 18 Social Security (Incapacity For Work) Regulations. A similar law applies to other state benefits for sickness and disability. (This was information given to the Grace Charity for M.E. in 2006.)

[10] World Health Organisation - International Classification of Diseases 10-G93.3

[11] What is ME? What is CFS? Information For Clinicians and Lawyers, Dec. 2001, Marshall, Williams, Hooper, page 11. Available from Prof. Malcolm Hooper, Dept.of Life Sciences, University of Sunderland SR2 7EE. Also, see www.meactionuk.org.uk

[12] Taken from Phoenix Rising website http://forums.phoenixrising.me/index.php?threads/the-significance-to-me-cfs-of-the-landmark-change-to-the-uk-law-on-consent.41989/ 9000 peer-reviewed papers on ME/CFS were used to uphold decisions by the Institute of Medicine and the National Institute of Health Pathways to Prevention, USA 2015

[13] See report from BBC NEWS HEALTH, October 8 2010, ME patients face UK ban on donating blood by Michelle Roberts. www.bbc.co.uk/news/health-11465723
Also, letter from Department of Health to the M.E. Association, 27th August 2010
http://www.meassociation.org.uk/2010/08/people-with-mecfs-to-be-permanently-excluded-from-giving-blood-in-the-uk-from-1-november-this-year-department-of-health-announcement/

[14] Leaflet A Physician's Guide to Myalgic Encephalomyelitis Chronic Fatigue Syndrome, The Nightingale Research Foundation, Vol.1, Issue 7, revised, 1992, page 17. Also, Journal of Chronic Fatigue Syndrome Vol . II, No.1, 2003, Canadian Criteria, page 25, The Haworth Press Inc. www.nightingale.ca

[15] Ibid., A Physician's Guide to Myalgic Encephalomyelitis Chronic Fatigue Syndrome, page 25

[16] Clinical Observations of Central Nervous System Dysfunction in Post-Infectious, Acute Onset M.E/CFS, page 38, The Clinical and Scientific Basis of Myalgic Encephalomyelitis Chronic Fatigue Syndrome 1992, Byron Marshall Hyde, M.D., The Nightingale Research Foundation www.nightingale.ca

[17] Report from the National Task Force on Chronic Fatigue Syndrome, Westcare, Bristol 1994. This states nine definitions: the Canadian definition in 2003 makes ten; the Reeves definition (2005) makes eleven; the International Consensus Primer (2012) makes twelve and the U.S. Institute of Medicine definition (2015) makes thirteen. There are more which are used for CFS including the Chalder fatigue scale but the latter merely judges fatigue rather than neurological M.E.

[18] Katon & Russo, 1992; Freiberg, 1999, Unhelpful Counsel? MERGE's response to the CMO report on CFS/ME, 2002, p15.

[19] See the website of the Medical Research Council at www.mrc.ac.uk

[20] http://www.bmj.com/content/350/bmj.h2087/rr-6 letter to the BMJ (British Medical Journal) by Margaret Williams 11th May 2015

[21] ME and/or CFS paper, September 2001, page 1, V.A. Spence PhD, Chairman of MERGE (ME Research Group for Education and Support). MERGE has become MERUK since this publication (ME Research UK.) This paper quotes from several published findings. Available from MERUK, The Gateway, North Methven Street, Perth PH1 5PP. Also, see www.meresearch.org.uk

[22] The Biology of the Chronic Fatigue Syndrome, Prof. Anthony Komaroff, The American Journal of Medicine 2000: 108: 99-105.

[23] Mitochrondrial abnormalities in the postviral fatigue syndrome, Behan, W.M.H. et al., Acta Neuropathologica 83, 1991, pages 61-65.

[24] The Negative Effects of Exercise on an M.E./CFS Dysfunctional Brain, page vii, The Clinical and Scientific Basis of Myalgic Encephalomyelitis Chronic Fatigue Syndrome 1992, Byron Marshall Hyde, M.D., The Nightingale Research Foundation.

[25] Journal of Chronic Fatigue Syndrome Vol. 11, No.1, 2003, Canadian Criteria, page 22, The Haworth Press Inc.

[26] Myalgic Encephalomyelitis Adult and Paediatric: International Consensus Primer for Medical Practitioners. Publishers: Carruthers and van de Sande, 2012. ISBN: 978-0-9739335-3-6 pages 2, 7

[27] Oxidative stress levels are raised in Chronic Fatigue Syndrome and are associated with clinical symptoms, Kennedy, Spence, Belch, Free Radical Biology & Medicine 2005:39:584-589

[28] Directly from the Horses' Mouths, Doris M. Jones MSc, Reference Group Member, CMO's Working Group. This survey was part of the Working Group on ME/CFS set up by the Chief Medical Officer Sir Kenneth Calman in 1998.

[29] Analysis Report by 25% ME Group March 2004 www.25megroup.org

[30] Reporting of Harms Associated with Graded Exercise Therapy and Cognitive Behavioural Therapy in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Tom Kindlon, Journal of the International Association for CFS/ME Fall Bulletin 2011, Issue 19(2): pages 59-111

[31] See Footnote 25, page 2 of the editorial

[32] Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Clinical Case Definition and Guidelines for Medical Practitioners. An Overview of the Canadian Consensus Document copyright 2005 by Carruthers B.M. and van de Sande M.I. ISBN: 0-9739335-0-X page 5 Self-powered exercise, under Cautions.

[33] Letter from IiME (Invest in M.E.) to Mr. Des Turner, former Chairperson of the APPG (All Party Parliamentary Group) on M.E./CFS, November 2008. Also, see www.investinme.org

[34] See Professor Malcolm Hooper's response, 17th February 2011, Professor Hooper's Initial Response to the MRC PACE Trial Press Release hosted by The Lancet www.meactionuk.org.uk

Also, Professor Ron Davis et al. see page 8 Diagnosis and Treatment of CFS and ME Second Edition 2017, Hammersmith Health Books, Dr. Sarah Myhill

Academic journalist Rebecca Goldin writes in Sense about Statistics PACE: The research that sparked a patient rebellion and challenged medicine March 21 2016
http://www.stats.org/pace-research-sparked-patient-rebellion-challenged-medicine

[35] Diagnosis and Treatment of CFS and ME Second Edition 2017, Hammersmith Health Books, Dr. Sarah Myhill page 9, The PACE study, Chapter One

[36]See letter PD White et al., to *The Lancet* 2011, Response to the complaint to the Lancet of March 2011 www.meactionuk.org.uk/1fwhitereply.htm