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UPDATE 6 OCTOBER 2007

The One Click Group Stakeholder Response has finally been published by NICE on its website here <http://guidance.nice.org.uk/page.aspx?o=449835> in the difficult to view Proforma Comments format over which there has been much national dissent.

We now update The One Click document below so that readers can see what NICE has attempted to suppress. NICE expunged copy has been highlighted in **RED** and is located at page numbers 1, 3, 5, 6, 8, 9, 10, 11, 12, 13, 16, 17, 18, 35, 36, 37, 39, 54, 57, 58, 59, 60, 61, 62, 63 and 64. In all, NICE has attempted to censor the sum of approximately ten pages.

For Censorship Summary, view the [NICE Cuts One Click](#) document that houses the edits in one place.

UPDATED 6 October 2007
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THE ONE CLICK GROUP RESPONSE CFS/ME DRAFT NICE GUIDELINES

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16 November 2006

THE ONE CLICK GROUP RESPONSE CFS/ME DRAFT NICE GUIDELINES

As a Stakeholder on the CFS/ME National Institute for Health and Clinical Excellence (NICE) Guidelines, The One Click Group has consulted widely with its readers and participants (locally, regionally, nationally and internationally) over the development of these Guidelines. Our participants include patients (those who have the largest stake in this issue by far), their carers, the medical profession, health advocates, academics, politicians, the Department of Health, the media et al. We work out in the field and on the internet. The material published by the One Click pressure group is read by the residents of over seventy countries worldwide and at peak, our website receives over 4,000 hits per day, every day of the week.

The One Click Group has received an enormous amount of feedback in relation to the development of these CFS/ME NICE Guidelines that we have incorporated into this document. We thank our participants for this high level of interaction and hope that we have done their feedback justice.

1. SUMMARY

These CFS/ME Draft NICE Guidelines have been produced by a process of documented unethical political and medical manipulation of due process.

How has it come about that NICE has produced a 269 page document, with the concomitant expense involved in this exercise, that is based purely on psychiatric opinion and scant evidence? How is NICE proposing to justify the entirely unscientific approach it has adopted to the government, to the taxpayer and ultimately if this proves necessary, through the legal challenge of Judicial Review?

The NICE financial calculations are so misjudged in these Guidelines that it is proposing that in excess of £180million be spent on the psychosocial treatments of

Cognitive Behavioural Therapy/Graded Exercise Therapy/Graded Activity (CBT/GET/GA) for those mildly to moderately affected by ME/CFS in the full knowledge that these treatments, far from efficacious, have been shown to damage many. [Update. The final publication of the CFS/ME NICE Guidelines in August 2007 shows that the proposed outlay has now jumped to £300million].

For NICE to seriously suggest that millions upon millions of pounds of British taxpayer's money should be handed over to exclusively financially benefit a very small group of British psychiatrists and their colleagues whose studies are based purely on the psychosocial model of ME/CFS, are distinguished by the very small numbers of patients involved with very high drop out rates and subsequent relapse has left patients simply incredulous.

Critiquing the CFS/ME Draft NICE Guidelines line by line is a meaningless exercise since the entire premise on which they have been based is ethically and methodologically flawed.

In the production of these Guidelines, NICE has breached its own Code of Ethics by refusing to include the research and clinical literature, spanning over fifty years, documenting multi-system physiological abnormalities present in ME/ICD-10 CFS patients, at the level of laboratory, radiological and clinical investigation in the production of the York Systematic Review upon which the recommendations contained in these Guidelines are based. NICE has therefore been instrumental and party to research misconduct throughout.

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Fair and proper representation for ME/CFS labelled patients has not occurred throughout the development of these Guidelines. NICE and the Department of Health have together unethically politically and medically manipulated the composition of the Guidelines Development Group such that at least two-thirds of the selected members had exhibited overt psychiatric bias by word, deed and in print prior to joining.

Concerns in the ME/CFS community have abounded in the way in which ME/CFS labelled patients have been 'represented' during the production of the NICE Guidelines and this is nowhere more apparent than in the selection of the so called three 'Patient Representatives' on the Guidelines Development Group. These have failed to represent their constituents throughout and have not in any way correctly fulfilled their duties as set out in the [Guidelines Manual](#), April 2006.

NICE has also politically and medically manipulated the composition of the 'invited' Stakeholder Group such that membership in the Stakeholder Process was largely exclusionary during the development of these Guidelines. The NICE Guidelines Manual, April 2006 states: "The development processes are underpinned by NICE's key principles of basing recommendations on the best available evidence and involving all stakeholders in a transparent and collaborative manner." NICE has failed to adopt its own regulations in the production of the CFS/ME Draft NICE Guidelines, as we will show.

There are serious legal ramifications in the developmental process and content of the Draft ME/CFS NICE Guidelines that are in breach of ME/CFS labelled patients' Human Rights and that contravene the regulations as set out in the Guidelines Manual, April

2006. We refer you to R Mitchell, V Mitchell (2006) 'CBT, GET And Human Rights: A Response To The NICE Draft Clinical Guidelines On CFS/ME' that state: "By ignoring these serious issues with regard to CBT and GET, we believe that as currently drafted the NICE Guidelines violate the right of clinicians and patients to the highest, safest standards of medical practice and care, amounting to a violation of their Human Rights." This paper is available in the NICE Archives of The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/NICE/CBT%20GET%20and%20Human%20Rights.doc>

The Lord Campbell of Alloway QC in a legal opinion obtained pro bono by the Countess of Mar dated 6 April 2000, stated: "On the document you have sent me there is an overwhelming case for the setting up of an immediate independent investigation as to whether the nature, cause and treatment of ME as considered by The Wessely School [Simon Wessely, psychiatrist] is acceptable or consistent with good and safe medical practice." (Appendix 1)

The majority of the content of the CFS/ME Draft NICE Guidelines amounts to biased opinion based on the experimental Cognitive Behavioural Therapy/Graded Exercise Therapy (CBT/GET) psychosocial treatments, of which any studies that have been done are distinguished by their high drop out rate and subsequent patient relapse.

* We cannot endorse the NICE Draft Guideline issued on 29th September 2006 on Diagnosis and Management of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis in Adults and Children.

* The York Systematic Review must be completely rewritten to include the biomedical evidence on ME/CFS.

* The content of the CFS/ME Draft NICE Guidelines must be thoroughly overhauled, fundamentally altered and completely rewritten to include the biomedical evidence on ME/CFS. It must also include the views of patients and the biomedical evidence that The One Click Group and other organisations that work in this field have provided to NICE for the last eighteen months or more through due process.

Key Statements Summary

* The psychiatric paradigm on ME/CFS is the one that has been exclusively adopted by NICE for use in these Guidelines by a process of extremely serious unethical political and medical manipulation of due process.

* NICE and The Guidelines Development Group have failed to acknowledge and adopt the World Health Organisation classification of the ME/CFS as a neurological illness under ICD-10 G93.3., despite the United Kingdom being a signatory to the World Health Organisation rubric. As such, the United Kingdom must abide by this.

* The Guidelines Development Group has concentrated almost exclusively on providing the psychosocial treatments of CBT/GET to patients which have been demonstrated in many cases to do actual harm.

* All the biomedical submissions that The One Click Group as Stakeholder has submitted to NICE have been completely ignored. NICE has thus contravened the regulations set out by itself in the Guidelines Manual, April 2006.

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* Bagnall et al are now open to charges of research misconduct over the York Systematic Review since information has been skewed and deleted in order to cast the psychosocial treatments such as Cognitive Behavioural Therapy and Graded Exercise Therapy (CBT/GET) in a favourable light, as has been stated in the response by the 25% ME Group for the Severely Affected charity to the NICE Guidelines, with which we concur. This document is available on The One Click Group website at: <http://www.theoneclickgroup.co.uk/documents/NICE/Charities/NICE%20Concerns%20from%20Kate%20Stewart.pdf>

* At least two-thirds of the Guidelines Development Group members have exhibited overt psychiatric bias and their support of the psychiatric paradigm on ME/CFS. This is known as politically stacking the deck and it is utterly unethical political and medical manipulation of due process.

* The One Click Group formally requests that the three Patient Representatives stand down from the Guidelines Development Group whilst others more familiar with the biomedical evidence of ME/CFS stand in their place so that patients may be fairly represented prior to the publication of the final version of these Guidelines.

* Political and medical manipulation has also been exercised in the 'invited only' composition of the Stakeholder Group. Major decisions were made by the Guidelines Development Group without Stakeholder consultation. 80% of the material contained in the Guidelines has not been considered, rated or ratified by the Stakeholders. Stakeholder evidence submitted to NICE has gone unacknowledged, unrecorded, unpublished on the NICE website and has been completely ignored, thus contravening the regulations set out in the Guidelines Manual, April 2006.

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* In this Version September 2006 of these NICE Guidelines and through the Guidelines Development Group consensus refusal to allow bacterial and viral testing upon symptoms onset, NICE is deliberately placing the lives of patients at risk, with the full knowledge of the suffering and sometimes death that this will inevitably cause.

* The fact that NICE at the stroke of a misspelt pen has confined thousands upon thousands upon x thousands of Lyme Disease/Borreliosis sufferers to a life of misery, suffering and on occasion death, totally contrary to the medical evidence at hand, is quite simply extraordinary unethical malfeasance and provides excellent evidence for Judicial Review.

* It must be ensured that all patients about to be labelled with the wastepaper basket diagnosis of ME/CFS must be thoroughly tested for viral and bacterial infections first so that the cost effective treatment available in many cases can be applied. With Britain as part of the European Union and with German medical facilities currently offered to patients on the NHS on many occasions, this proven LTT-MELISA Test for Lyme Disease/Borreliosis accredited by the German Health Authorities at a cost of EU 160, must be offered to patients suspected of ME/CFS upon symptoms onset.

2. INTRODUCTION

Although The One Click Group is a Registered Stakeholder in the development of the ME/CFS Draft NICE Guidelines, all the evidence submitted to NICE by us has gone unacknowledged, unrecorded and unpublished. It is therefore necessary for legal purposes to place this evidence on the record in this submission to NICE that will assist with Judicial Review.

On 18 April 2006, The One Click Group presented evidence to the Parliamentary Inquiry on ME/CFS. We place this evidence on the NICE record in Appendix 1. The full text of this presentation is also available on The Parliamentary Inquiry website at: <http://www.erythos.com/gibsonenquiry/PresDocs.html>

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There are broadly two contesting paradigms of ME/CFS: The neurological (biomedical) paradigm, and the psychiatric paradigm. (Appendix 1). The psychiatric paradigm in Britain is supported by various psychiatric researchers such as Simon Wessely, Peter White, Michael Sharpe, Anthony Cleare and Elena Garralda, amongst others. It has been demonstrated to have serious theoretical, methodological and ethical flaws.

Proponents of this paradigm refuse to recognise the WHO ICD-10 neurological classification of ME/CFS. Indeed, they unilaterally misrepresented the term Chronic Fatigue Syndrome as being classified as a mental disorder in the ICD-10, wrongly advising the British government. This was corrected by the Countess of Mar during a House of Lords debate in 2004, with confirmation by the World Health Organisation. (Appendix 1).

Despite the overwhelming evidence to the contrary, proponents continue to assert the notion that the illness is caused and/or perpetuated by 'psychological' or 'behavioural' factors. They consistently portray sufferers as mentally and socially deviant. They illogically and incorrectly describe ME/CFS as 'Medically Unexplained'. Ironically, they then promote a state of 'cultivated ignorance' about the illness by discouraging all but the most limited of biomedical investigations/treatments for sufferers.

Instead of acknowledging the contested psychiatric paradigm on ME/CFS, NICE has elected to ignore it completely in these Guidelines.

Experimental psychiatric interventions over ME/CFS have been forced on patients for the last fifteen years or more and are still the only treatments consistently available. If these had been in any way efficacious, where are the lost legions of the recovered to show this?

No other organic disease has had so much attention on 'biopsychosocial factors' while biological factors are consistently ignored and trivialised in the UK and this special pleading about ME/CFS has thwarted the progress of biomedical research and clinical care.

British health, social and research policy on ME/CFS in recent years has been based on fundamentally flawed conjecture, and prejudiced opinion masquerading as 'science' causing endangerment and disenfranchisement to sufferers.

Key Statement: The psychiatric paradigm on ME/CFS has been exclusively adopted by NICE for use in these Guidelines by a process of unethical political and medical manipulation.

The Guidelines Development Group has failed to acknowledge and adopt the World Health Organisation classification of the ME/CFS as a neurological illness under ICD-10 G93.3., despite the United Kingdom being a signatory to the World Health Organisation rubric.

The Guidelines Development Group has concentrated almost exclusively on providing the psychosocial treatments of CBT/GET to patients that have been demonstrated in many cases to do actual harm.

3. STAKEHOLDER EVIDENCE SUBMISSIONS

All of the evidence that The One Click Group has submitted to NICE as a Stakeholder in the development of these Guidelines has gone unacknowledged, unrecorded and unpublished on the NICE website or anywhere else that we can detect for the last eighteen months or more. The work of many people, some of them experts in this field, would appear to have simply vanished.

In the NICE [Guidelines Manual](#), April 2006, **Section 7.2.2 Information from stakeholders**, it states: "If the GDG [Guidelines Development Group] decides not to use a piece of evidence, the reason should be made explicit."

The One Click Group has not been given any reason, explicit or otherwise, as to why our evidence has not been taken into account. NICE has contravened its very own regulations and has failed to act throughout in a collaborative and transparent manner as is laid out in the regulations.

For legal reasons and to inform the wider audience, we list below the following formal Submissions that we have made to NICE. Just as the biomedical evidence on ME/CFS has gone ignored and unrecorded in the [York Systematic Review](#), so have all of our of Stakeholder Submissions to NICE.

We have submitted the following documents through due process, from April 2005 to the present day.

3.1 One Click Submission to NICE - Stakeholder Comments 30 April 2005 (Appendix 1)

In this submission we highlighted that the 'invited' Stakeholder Process was largely exclusionary and concerns in the ME/CFS community abounded in the way in which ME/CFS sufferers have been 'represented'. We wrote: "There are serious legal ramifications with regard to the formulation of the NICE guidelines and the evidence we have provided in this submission. We must insist that this evidence is taken into full consideration and duly acted upon." We provided biomedical evidence in this submission and officially requested that this be considered in the Systematic Review/Literature Review on which these Guidelines were to be based.

3.2 One Click Submission to NICE - Systematic Literature Review. 28 February 2006 (Appendix 1)

We formally placed our objections on the record in this document. We noted that none of the biomedical evidence and research papers that we had highlighted in our formal submission to NICE dated 30 April 2005 had been taken into account in any way. We brought to NICE's attention the glaring discrepancies of this supposedly academic review.

We provided NICE with evidence from one of our Stakeholder nominees that critiqued fundamental parts of the Systematic Review such as the disease paradigm, information on GET/CBT, diagnostics and pharmacological interventions.

3.3 One Click Submissions to NICE - The Stakeholder Subset Questionnaire April and May 2006 (Appendix 1)

We placed our formal objections on the record in regard to this process in April and May 2006. We were unable to complete the Questionnaire for the reasons we delineate and in light of the prejudicial treatment favouring the psychiatric paradigm on ME/CFS that NICE has employed throughout this process by political and medical manipulation.

Key Statement: All the submissions that The One Click Group has submitted to NICE have been completely ignored. NICE has thus contravened the regulations set out by itself in the Guidelines Manual, April 2006.

4. YORK (2005) SYSTEMATIC REVIEW OF THE CFS/ME MEDICAL EVIDENCE BASE

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This document is the primary building block on which these Draft Guidelines have been based. **The process employed by Bagnall et al in the production of this Systematic Review amounts to research misconduct.**

We wish to state, for public record, that it is highly ironic, and indicative of the appalling state of affairs with regard to the ways in which ME/CFS patients and those with related illnesses are treated in this country, that it has fallen to patients and patient advocates to bring to NICE's attention the glaring discrepancies of an academic review as we did in our Submission to NICE dated February 2006.

We concurred with the detailed critique of the Bagnall et al paper, ['Inadequacy of the York \(2005\) Systematic Review of the CFS/ME Medical Evidence Base'](#) by Malcolm Hooper and Horace Reid, January 2006.

We noted what evidence is, in actuality, conspicuous by its absence, in a review ostensibly about a serious medical impairment such as ME/CFS, such as:

4.1. The apparent ignorance, within the Bagnall et al review, of the vast amount of research and clinical literature, spanning over fifty years, documenting multi-system physiological abnormalities present in ME/ICD-10 CFS patients, at the level of laboratory, radiological and clinical investigation.

4.2 The lack of attention within the Bagnall et al review to issues of differential diagnosis, and emerging knowledge about possible causative factors such as, but not limited to, chronic infection with various types of bacteria such as borrelia, Chlamydia and mycoplasma strains.

4.3 The lack of attention to evidence demonstrating the harmful effects of Graded Exercise Therapy/Cognitive Behavioural Therapy in ME/CFS patients.

To summarise:

* NICE has ignored the large body of international biomedical evidence that ME/CFS is a neurological illness, in favour of a fundamentally flawed psychiatric paradigm of ME/CFS.

* NICE has employed arbitrary exclusionary strategies that it has purposefully put in place with regard to which evidence is to be considered.

* NICE has conducted inappropriate exclusion of essential evidence.

* The York Review team has almost exclusively reviewed research generated by the proponents of the psychiatric paradigm on ME/CFS.

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Key Statement: Bagnall et al are now open to charges of research misconduct over the Systematic Review since information has been skewed and deleted in order to cast the psychosocial treatments such as Cognitive Behavioural Therapy and Graded Exercise Therapy (CBT/GET) in a favourable light, as has been stated in the NICE Response to these Guidelines by the 25% ME Group for the Severely Affected charity, with which we concur. This document is available on The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/NICE/Charities/NICE%20Concerns%20from%20Kate%20Stewart.pdf>

5. PSYCHIATRIC BIAS – THE GUIDELINES DEVELOPMENT GROUP

Despite the United Kingdom government being a signatory to the World Health Organisation rubric, NICE has refused to recognise the World Health Organisation classification of ME/CFS as a neurological illness under ICD-10 G93.3.

We present evidence to show that constituency of the Guidelines Development Group and Stakeholder Group has been politically and medically manipulated by NICE and the Department of Health such that proper representation for ME/CFS patients has not occurred, in contravention of the regulations as set out in the Guidelines Manual, April 2006, by NICE itself.

5.1 The Guidelines Development Group

Instead of acknowledging the contested psychiatric paradigm on ME/CFS, at least two-thirds of the Guidelines Development Group members have exhibited overt

psychiatric bias and their support of the Wessely School psychiatrists, as we document below. The Guidelines Development Group has been constituted by a process of very serious, quite possibly criminal, unethical political and medical manipulation throughout.

We submit the evidence of psychiatric bias in the composition of the Guidelines Development Group below:

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Professor Richard Baker, (Chairman) Director, Clinical Governance R&D Unit, Leicester. When giving NICE evidence to the Gibson ME/CFS Parliamentary Inquiry on 10 May 2006 between 3.30pm - 5.30pm, the recorded Minutes of that meeting show this: "Richard Baker pointed to the PACE trial as a good example of work being undertaken within the UK at present. Ian Gibson (MP) pointed to the criticism that has been voiced about the trial and its underlying research, which some have accused of being biased toward a psychiatric model. Richard Baker responded by reaffirming that the cause of CFS/ME is still unknown and that he believed that after talking to PACE researchers, he did not believe this to be the case." From these Minutes it is shown that Professor Baker, the Chairman of the NICE Guidelines Development Group, does not subscribe to the World Health Organisation classification of ME/CFS as a neurological illness under ICD-10 G93.3 and is a supporter of the scientifically fraudulent PACE and FINE psychiatric clinical trials. Please see [The PACE Report](#) that includes the original copy of the PACE Trial Identifier, written by the Wessely School Psychiatrists upon application for the funding of these trials from the Medical Research Council.

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Dr William Hamilton has spent the last fifteen years employed by the Medical Insurance Industry and has a track record of overtly supporting the psychiatric paradigm on ME/CFS, maintaining that it is a behavioural disorder.

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Jessica Bavinton, Physiotherapy Clinical Specialist (CFS), London, is documented as an overt supporter of Graded Exercise Therapy and psychosocial interventions of a neurological illness. In an article penned by Bavinton in the Kent & Sussex ME/CFS Society Newsletter, Summer 2004 she promoted GET as "...one of the most effective therapy strategies currently known."

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Dr Esther Crawley, Consultant Paediatrician, Bath, is the Lead Clinician for the Bath/Bristol Paediatric ME/CFS service. **Dr Crawley** has been in receipt of Major Grants, Contracts and Consultancies in 2003 in the development of this 'CFS/ME' Centre such as:

* DOH grant for centre for CFS/ME, Co-author.

Competitive funding for administrative centre to co-ordinate care and data collection for adults and children with CFS/ME in the South West, Department of Health grant.

* DOH clinical service grant, Co-author.

Competitive funding for a new clinical service for children with CFS/ME in the South West, Department of Health grant.

These 'CFS/ME' Centres such as the one in which **Dr Crawley** is lead clinician have been roundly condemned by ME/CFS labelled patients around the United Kingdom in documentation provided by the RiME Group - Campaigning for Research into Myalgic Encephalomyelitis at www.erythos.com/RiME. These CFS/ME Centres exclusively employ the psychosocial regimes of Cognitive Behavioural Therapy/Graded Exercise Therapy (CBT/GET) that have been shown to do many patients serious harm.

Dr Crawley is also a Medical Adviser to the Association for Young People with Myalgic 'Encephalopathy' charity (AYME) that has assiduously promoted the psychosocial regimes of CBT/GET and that has in turn endorsed and promoted the Royal College of Paediatrics and Child Health Guidelines on CFS/ME. These have been roundly criticised and proscribed by child patients themselves, their families and health advocates.

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Details of **Dr Frederick Nye** and his involvement with ME/CFS are very well documented in the paper submitted by the 25% ME Group for the Severely Affected charity in its Response to NICE over these Draft Guidelines that states:

"**Dr Fred Nye** is a consultant physician and "Clinical Champion" of the Liverpool "CFS" Clinical Network Co-ordinating Centre, whose advertisement for therapists informed applicants that "CFS" patients have perpetuating illness behaviour; that they experience barriers to understanding; that there can be significant barriers to accepting the changes needed in behaviour, which have to be overcome in therapy in order to facilitate a successful outcome; that the Fatigue Therapist will be required to modify patients' predisposing personality style and provide motivation to patients with CFS; that some clients may be resistant to working in a psychological framework and that there may be verbal aggression (Chronic Fatigue Treatment Service: Ref: 2570. Closing date: 31st January 2005). Following the resultant distress and offence to patients, Nye apologised publicly and the advertisement was withdrawn but the question remains how, under Nye's leadership, such an advertisement came to be issued in the first place."

Dr Nye has been a supporter of the psychiatric paradigm on ME/CFS throughout all his dealings with ME/CFS labelled patients.

The only neurologist on the Guidelines Development Group, **Dr Richard Grünewald**, is a Consultant Neurologist at the Royal Hallamshire Hospital in Sheffield. A dedicated supporter of Somatoform Disorders, Dr Grünewald has produced work supporting and extensively referencing the work of Professor Simon Wessely, head of the Wessely School psychiatrists. (Functional symptoms in neurology: questions and answers, Journal of Neurology Neurosurgery and Psychiatry 2005;76:307-314 © 2005). Dr Grunewald has also written on 'fatigue states' and is Associate Editor of the Behavioural Neurology Journal that explores abnormal human cognition and behaviour, amongst his other activities.

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Miss Amanda O'Donovan, is a Senior Clinical Psychologist at St Bartholomew's Hospital. Barts Hospital contains the CFS/ME Centre that has recently been the

subject of an intense media campaign designed to hype and propagandize the services of psychiatrist Peter White, leader of the scientifically fraudulent PACE trial (See One Click Presentation to Gibson ME/CFS Parliamentary Inquiry, Appendix 1). Ms. O'Donovan stated in an interview carried out by the charity Action for ME (AfME) that sells these CBT/GET treatments direct to the public: "Graded activity can be a useful addition to CBT..." Other AfME interviewees on this occasion were Louise Ritson and CBT Psychotherapist and Clinical psychologist Dr Hazel O'Dowd. (See References).

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Dr Alastair Sainthouse works as a Consultant Psychiatrist at King's College, London in the Chronic Fatigue Research and Treatment Unit, London, with Professor Simon Wessely, the leader of the psychiatric lobby in the United Kingdom. The Head of Services is Professor Trudie Chalder.

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Dr Julia Smedley, Consultant Occupational Physician, Southampton University NHS Trust, has been closely involved in the production of the document entitled 'Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline' (DH Publication 2006/273539 http://www.nhsplus.nhs.uk/clinical-guidelines/Docs/273539_CFSyndrome.pdf) that has been simultaneously launched with these NICE Draft Guidelines. The content of this document is reflected by the fact that its own Guideline Development Group included Professor Trudie Chalder, with its External Assessors as psychiatrists Professors Michael Sharpe and Peter White, all of whom believe that ME/CFS is a Somatoform Disorder with the concomitant effect of labelling ME/CFS patients as mentally deviant. **Dr Julia Smedley** is thanked for her contribution to this document displaying overt psychiatric bias and it is announced: "We are grateful to the following colleagues who have commented on various sections and drafts of the manuscript:**Dr Julia Smedley**, Consultant Occupational Physician, Southampton University NHS Trust."

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Dr David Vickers is a Consultant Community Paediatrician in Cambridge who was involved as a Delphi Participant in the development of the RCPCH Guidelines in ME/CFS children that have been so roundly condemned due to the overt psychiatric bias of the treatments recommended for children that have never been scientifically tested on them. Dr Vickers works in Child Protection for the Cambridgeshire Local Safeguarding Children Board. **Dr Vickers** also works with Dr Peter Lachman, a designated Child Abuse specialist and an advocate of the methods of the disgraced Professor Sir Roy Meadow and Dr David Southfield in relation to Munchausen Syndrome by Proxy/FII, who have both now been disciplined by their professional body and the subject of much litigation. **Dr Vickers** and Lachman co-authored the paper entitled 'The national service framework for children' doi:10.1136/bmj.329.7468.693 BMJ 2004;329;693-694.

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Mrs. Gillian Walsh is the Network Co-ordinator Manchester Clinical Network, Manchester. This CFS/ME Centre is yet another on the list that has been condemned

by ME/CFS patients. A sufferer writes to RiME - Campaigning for Research into Myalgic Encephalomyelitis: "... everything about the Manchester CNCC suggests a stitch-up. The leading figure in the process is a psychiatrist Dr L. He appears to promote a psychosocial model of ME which fits in nicely with govt guidelines. Once again ME patients, those who suffer 24/7, are neglected and sidelined. Well done to the new Manchester Group for challenging what is happening here ..."

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Mrs. Carol Wilson is the Lead Occupational Therapist Cornwall CFS/ME Service, Falmouth. **Mrs. Wilson** is yet another individual involved in the production of the overtly psychiatrically biased RCPCH Guidelines on ME/CFS labelled children. Carol Wilson works closely with Professor Anthony Pinching, Chair of the CFS/ME Investment Steering Group and, as stated by the Royal Cornwall Hospitals NHS Trust, is the Lead "in Occupational therapy, focusing on activity management and adjustment linked to existing community rehabilitation teams."

5.2 Patient Representatives

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In addition, the three so-called Patient Representatives on the Guidelines Development Group (GDG), **Mr Richard Eddleston**, **Ms Ute Elliot** and **Ms Tanya Harrison** of the BRAME organisation, whose organisation is doubly represented on the Guidelines Development Group and Stakeholder Group, have failed to represent the concerns of ME/CFS patients either accurately or fairly. They have failed in their duty throughout.

We quote from the NICE [Guidelines Manual](#), April 2006, that states: "The patient/carer members have equal status on the GDG."

The Guidelines Manual lists the responsibilities of the Patient Representatives on the Guidelines Development Group and it states verbatim on page 25:

"4.3 Key roles of patient/carer members

The key contributions of patient/carer members are to:

- ensure that clinical questions embrace patient as well as professional issues
- identify grey literature (for example, patient surveys) highlighting patient issues that may inform the work of the GDG
- consider the extent to which published evidence has measured and taken into account outcome measures that patients consider important
- identify areas where patient preferences and patient choice may need to be acknowledged in the guideline
- ensure that recommendations address patient issues and concerns
- ensure that the guideline as a whole, and the recommendations specifically,

are sensitively worded (for example, treating patients as people not as objects of tests, investigations or treatments).”

It is perfectly clear that the Patient Representatives on the Guidelines Development Group have done none of these things correctly and with the best interests of ME/CFS labelled patients in mind.

These Patient Representatives have fully endorsed by consensus the contents of the CFS/ME Draft NICE Guidelines that have been extensively described by charities and health advocacy organisations as ‘unfit for purpose’. We refer you to the formal Responses submitted to NICE by the Myalgic ‘Encephalopathy’ Association and the 25% ME Group for the Severely Affected charities that also place this matter firmly in the public domain. These are available for view in The One Click Group [NICE Archives](#).

There have been serious concerns throughout this process as to how ME/CFS sufferers are to be represented and nowhere is this more apparent than in the arbitrary selection of these Patient Representatives to sit on the Guidelines Development Group who have consistently failed in their duty throughout.

Key Statement: At least two-thirds of the Guidelines Development Group members have exhibited overt psychiatric bias and their support of the psychiatric paradigm on ME/CFS. This is known as politically stacking the deck and it is utterly unethical political and medical manipulation of due process.

The One Click Group formally requests that the three Patient Representatives stand down from the Guidelines Development Group whilst others more familiar with the biomedical evidence of ME/CFS stand in their place so that patients may be fairly represented prior to the publication of the final version of these Guidelines.

6. THE STAKEHOLDER GROUP

As with the Guidelines Development Group, there has been political and medical manipulation of the composition of the ‘invited’ Stakeholder Group membership.

* The Stakeholder Process was largely exclusionary and was constructed by NICE by invitation only.

* NICE has ignored and refused to record Stakeholder Submissions that provide the evidence in relation to the neurological and biomedical basis of ME/CFS.

* The Assumptions that Stakeholders were asked to make in the Subset Questionnaire during the so-called ‘consultation’ period were unsafe due to the fact that NICE was withholding 80% of the information needed to inform response.

* Knowledge of 80% of the data on which these Guidelines are based was denied to Stakeholders, despite formal request for this information recorded by The One Click Group with the assistance of their solicitors.

* The Stakeholder Group was denied all knowledge of the ratified and graded Assumptions made by the Guideline Development Group that represents these Guidelines during the so-called ‘consultation’ process. Had we been given this completely germane and legitimate knowledge as requested, the answers that we

were asked to provide in the Subset Questionnaire would have been phrased very differently by us.

By the process that NICE has employed with the Stakeholder Group on the CFS/ME Draft NICE Guidelines, it has contravened the regulations set out in The Guidelines Manual, April 2006, that state: "The development processes are underpinned by NICE's key principles of basing recommendations on the best available evidence and involving all stakeholders in a transparent and collaborative manner."

We have failed to be treated in a transparent and collaborative manner throughout. Our evidence submitted has gone unacknowledged, unrecorded and unpublished. The full documentary evidence for this, including selected correspondence and papers, is publicly available in the NICE Archives of The One Click Group at:

<http://www.theoneclickgroup.co.uk/documents/NICE>

Key Statement: Political and medical manipulation has been exercised in the 'invited only' composition of the Stakeholder Group. Major decisions were made by the Guidelines Development Group without Stakeholder consultation. 80% of the material contained in the Guidelines has not been considered, rated or ratified by the Stakeholders. Stakeholder evidence submitted to NICE has gone unacknowledged, unrecorded, unpublished on the NICE website and has been completely ignored, thus contravening the regulations set out in the Guidelines Manual, April 2006.

7. VIRAL AND BACTERIAL TESTING

One of our greatest concerns over these Guidelines has been the complete lack of transparency employed in their production, together with the lack of adequate and proper Patient Representation. We predicted, as did others, that these NICE recommendations in these Guidelines would be presented as a *fait accompli* to patients without adequate consultation and representation. This is indeed what has come to pass.

Despite the numerous viral and bacterial infections known in ME/CFS labelled patients and recognised by doctors around the world, the Guidelines Development Group decided by consensus that testing for viral and bacterial infections should not be carried out on patients at that most critical time – symptom onset.

Because there is no accepted laboratory test available for ME/CFS, it has become the wastepaper basket, catch-all diagnosis. ME/CFS misdiagnosis is being carried out on a massive scale in the UK and around the world because it is an easy box to tick and a simple label to append. As but a few examples, we list below the conditions that patients who have been labelled with ME/CFS have subsequently been shown to be suffering from: variant Creutzfeldt Jakob Disease (vCJD/Mad Cow), Multiple Sclerosis, Lupus, Parvovirus Infection, Guillain-Barre, Lyme Disease/Borreliosis, Stroke et al. The tests and treatment that these patients need are being denied to them on a massive scale because they have been erroneously labelled with the wastepaper basket ME/CFS diagnosis.

By the emerging evidence of chronic microbial infections being present in many people diagnosed with "CFS/ME" (sic) being ignored in the Bagnall et al review, patients diagnosed with ME/CFS and who have these infections are being placed at serious risk of being deprived treatment that might prevent the deterioration of their condition into serious illness and severe disability. Indeed this problem has occurred

and is occurring as we write, and this is a disgraceful situation facing such patients.

As but one example, we see Lyme Disease/Borreliosis featured in these Guidelines on page 103. This provides the evidence to show that the Guidelines Development Group unilaterally decided and without consultation that all Lyme Disease/Borreliosis tests and investigation for patients about to be labelled with the wastepaper basket ME/CFS diagnosis should be denied. The Draft Guidelines state: "Serology for chronic bacterial infections e.g. borelliosis (sic.) > Guideline Development Group disagrees > The GDG reached a consensus in the first round and the statement did not progress to Round 2."

This key question did not progress from the Guideline Development Group to the Stakeholder Group for their comments. This is an extremely irresponsible life-threatening edict in some cases.

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This issue of Lyme Disease/Borreliosis and ME/CFS and lack of adequate testing for patients is particularly pertinent in line with the recent [BADA-UK Statement](#) (Borreliosis & Associated Disease Awareness, Registered Charity No. 1113329) that included words from Dr Darrel Ho-Yen, the **self-styled Lyme Disease 'expert'**, head of Microbiology at the Raigmore Hospital, Inverness, Scotland who admitted possible figures of ME/CFS misdiagnosis that run into the thousands.

BADA-UK wrote: "Whilst Dr Ho-Yen is quite correct in his assertion that Lyme disease accounts for only a small percentage of those misdiagnosed as having ME/CFS, this in itself does not discount the possibility of one, or several, tick-borne diseases being the cause of a patient's ill health. For as indicated by Dr Ho-Yen, ME could be caused by quite literally hundreds of different viruses and bacteria, and it need not only be one infection to blame. Yet without more detailed and comprehensive medical studies, taking into account the exact nature of all bacterial/viral infections present in those diagnosed as having ME/CFS, the role of Lyme disease as a contributing factor cannot be excluded."

"With the highly advanced abilities of *Borrelia* to evade detection by the human immune system, along with the restrictive nature of the current two-tier blood testing procedure used as a diagnostic test in the UK and throughout Europe, it is not possible to conclusively exclude the role of *Borrelia* in a patient's ill-health."

"A great many patients have taken responsibility for their own health concerns, whilst the global medical establishment argues over whose guidelines and criteria are most appropriate. The various published ME/CFS diagnostic criteria currently require that any bacterial/viral infections are excluded as a possible cause of a patient's ill-health, before a diagnosis of ME/CFS can be given".

BADA-UK continued: "The recognition by Dr. Ho-Yen [Head of Microbiology at the Raigmore Hospital, Inverness, Scotland] of *Borrelia* to be misdiagnosed as ME/CFS in 5% of his patients should be heeded very carefully by the ME/CFS community as a whole, for 5% of the estimated 240,000 patients diagnosed as having ME/CFS equals 12,000 possibly

misdiagnosed Borreliosis patients. It also justifies the perceived link between those currently diagnosed as having ME/CFS, yet questioning Lyme disease, along with all other tick-borne infections, as an alternative diagnosis."

The full text of the [BADA-UK](#) (Borreliosis & Associated Diseases Awareness) [Statement](#) is to be found in Appendix 2.

In fact, this figure is far higher due to the flawed way in which the ELISA and Western Blot tests are carried out in the UK by the Health Protection Agency that so frequently result in false negatives.

Despite this confirmed medical knowledge readily available in the public domain, the CFS/ME Draft NICE Guidelines state that these patients must not be tested for Lyme Disease/Borreliosis upon symptoms onset. This will mean in practice that thousands upon countless thousands of patients in the throes of being labelled with the wastepaper basket diagnosis of ME/CFS will be denied testing and treatment upon onset of Lyme Disease/Borreliosis at – as all medical knowledge agrees, the most critical time – symptoms onset.

Moreover, NICE and its Guideline Development Group have elected to be so badly informed over this issue that they have misspelt the illness Borreliosis throughout the Guidelines on pages 98, 103, and 107 and label it as 'borelliosis' incorrectly. It is a pity that in a document circulated as widely as the CFS/ME Draft NICE Guidelines, the Guidelines Development Group cannot even get the name of the illness right in the published document, produced at considerable taxpayer expense, with the concomitant cost of the Advisers also no doubt.

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Key Statement: In this Version September 2006 of these NICE Guidelines and through the Guidelines Development Group consensus refusal to allow bacterial and viral testing upon symptoms onset, NICE is deliberately placing the lives of patients at risk, with the full knowledge of the suffering and sometimes death that this will inevitably cause.

The fact that NICE at the stroke of a misspelt pen has confined thousands upon thousands upon x thousands of Lyme Disease/Borreliosis sufferers to a life of misery, suffering and on occasion death, totally contrary to the medical evidence at hand, is quite simply extraordinary unethical malfeasance and provides excellent evidence for Judicial Review.

7.1 LTT-MELISA Test for Borreliosis

Accurate testing and diagnosis of Lyme Disease/Borreliosis has remained a problem for many years for several reasons. Currently, testing for Lyme Disease/Borreliosis is carried out in the UK by the Health Protection Agency Lyme Disease Specialist Reference Unit (HPA). It consists of a 'two-tier' blood-testing procedure, the highly unreliable ELISA (Enzyme Linked Immuno Sera Assays) used as a screening test and the second known as a Western Blot which was initially designed for the epidemiological study of Borrelia. It was never intended to be used as diagnostic of an individual patient's condition. Without a positive ELISA test, a Western blot test will generally not be performed. Neither test is 100% reliable, nor can conclusively

rule out the role of a current, and active, Borrelia infection. Because of this highly flawed testing procedure in the UK, countless numbers have been given false negative results, have slipped through the net and have gone undiagnosed and untreated, suffering horribly as a result.

A far more sensitive test for Lyme Disease/Borreliosis has come on to the market entitled the LTT-MELISA test. Available in Germany at the cost of EU 160, with the laboratory accredited by the German Health Authorities and the cost of the test reimbursed by private health insurance, the LTT-MELISA test picks up Lyme Disease/Borreliosis infection where the HPA tests have failed. See the paper entitled '**A novel lymphocyte transformation test (LTT-MELISA®) for Lyme borreliosis**', by Dr. Elizabeth Valentine-Thon, published in the Journal of Diagnostic Microbiology And Infectious Disease:

<http://www.theoneclickgroup.co.uk/documents/Borreliosis/The%20LTT-MELISA%20Test%20For%20Lyme%20Borreliosis.pdf>

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When the HPA that carries out the highly flawed **and disreputable** Lyme Disease/Borreliosis testing in the UK has been challenged as to its competency in the past in regard to testing outside the NHS two tier system and PCR (polymerase chain reaction), its response has been to cast doubt on other methodologies. In order to protect its reputation, it has even gone so far as **to employ execrable medical and political tactics** by maintaining that other laboratories concerned are disreputable and subject to closure shortly.

With Britain as part of the European Union and with German medical facilities currently offered to patients on the NHS on many occasions, this proven test accredited by the German Health Authorities at a cost of EU 160 is being denied to British patients. Moreover, even when the conclusive results of the LTT-MELISA Test have been obtained privately by patients, British doctors have often refused to accept the results of this test courtesy of the HPA and patients have been denied treatment.

It is essential that because of the numbers of ME/CFS labelled patients who are now testing positive for Lyme Disease/Borreliosis through the Igenex Laboratory (FDA approved), through Dark Field Microscopy (also used on Syphilis, another spirochaetal illness) and now the accredited LTT-MELISA test, that suspected ME/CFS patients are accurately and properly tested for Lyme Disease/Borreliosis upon symptoms onset.

See Appendix 3 for a small sample of patient Letters and Case Histories received.

Key Statement: It must be ensured that all patients about to be labelled with the wastepaper basket diagnosis of ME/CFS must be thoroughly tested for viral and bacterial infections first so that the cost effective treatment available in many cases can be applied. With Britain as part of the European Union and with German medical facilities currently offered to patients on the NHS on many occasions, this proven LTT-MELISA Test for Lyme Disease/Borreliosis accredited by the German Health Authorities at a cost of EU 160, must be offered to patients suspected of ME/CFS upon symptoms onset.

8. CFS/ME DRAFT NICE GUIDELINES - CONTENT

The entire content of the CFS/ME Draft NICE Guidelines focuses on the psychosocial treatments of CBT/GET. These are the treatments on which NICE is proposing to spend hundreds of millions of pounds that the National Health Service simply does not have at its disposal, that have not been properly researched and have been shown to do significant harm to a vast number of ME/CFS labelled patients.

In the Lord Campbell of Alloway QC [Legal Opinion](#) obtained pro bono for the Countess of Mar on 6 April 2000, it states: "On the document you have sent me there is an overwhelming case for the setting up of an immediate independent investigation as to whether the nature, cause and treatment of ME as considered by The Wessely School is acceptable or consistent with good and safe medical practice." (Appendix 1)

Despite the overwhelming evidence to the contrary, proponents continue to assert the notion that the illness is caused and/or perpetuated by 'psychological' or 'behavioural' factors. They consistently portray sufferers as mentally and socially deviant.

In [Myalgic Encephalomyelitis \(ME\): a review with emphasis on key findings in biomedical research](#) Malcolm Hooper, *J. Clin. Pathol.* published online 25 Aug 2006;doi:10.1136/jcp.2006.042408 it states:

"A common treatment programme advocated for CFS, whatever its origins, consists of Pacing, CBT (cognitive behavioural therapy) and GET (graded exercise therapy). The Government has spent huge sums of money (£8.2 million) on setting up clinics, manned by a psychiatrist(s) and located in psychiatric hospitals, to which CFS patients are commonly referred. Such an approach has been vehemently opposed by patients and carers. Studies among the 25% Group whose members suffer from severe disabling ME that leaves them housebound or bed-bound found that over 90% of its members were dissatisfied with CBT and GET 13-15 (Table 2). Other reports have found little or no effect with CBT, while GET is frequently positively harmful."

In L.D. Devanur, J.R. Kerr, [Chronic fatigue syndrome](#), *Journal of Clinical Virology* (2006), doi:10.1016/j.jcv.2006.08.013 it states:

"Numerous studies have been conducted to determine the effect of graded exercise therapy on patients with CFS despite the fact that it is known to have a detrimental effect on many patients. While some studies report benefit of CBT, this is admitted by its proponents to be a minor benefit and not a cure. In addition, a significant proportion of patients show no improvement following CBT (Akagi et al., 2001; Huibers et al., 2004). Neither GET nor CBT are specific treatments for CFS, as we do not yet understand the pathogenesis of CFS."

Before the consultation period for these NICE Guidelines has expired, we see that the NHS Plus has issued 'Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline', Department of Health: 6th October 2006: 273539 that concentrates exclusively on the psychosocial model of this illness. This provides a stronger indication than any other that the Consultation period for these Draft

NICE Guidelines is merely a cosmetic exercise designed to palliate patient opinion, rather than to seek the correct and meaningful public and expert patient consultation required.

Although the NICE Guidelines state that treatment by CBT/GET must not be forced on patients, the NHS Plus in its Guidelines to medical practitioners and employers state that "ill-health retirement is a possible outcome although it should only be considered if appropriate treatments (such as CBT or GET) have been explored" and that patients should "'negotiate' an aerobic exercise programme." NICE has failed to take into account that medical testimony from ME/CFS expert Dr Paul Cheney and others that state that aerobic exercise may actually kill ME/CFS patients.

The ME/CFS Canadian Guidelines, the only clinical criteria produced by international consensus available in the world today that have pulled together the research findings on ME/CFS for the last ten years or more, state that:

"Cautions: There are potential dangers if ME/CFS patients are pushed to increase their heart rate to age predicted target heart rates. As indicated in the chart on page 4, research studies suggest that their hearts may be functioning at a suboptimal level and many have autonomic disturbances; thus they may not be able to accommodate the normal target heart rate. Externally paced "Graded Exercise Programs" or programs based on the premise that patients are misperceiving their activity limits or illness **must be avoided.**"

The ME/CFS Canadian Guidelines state on CBT:

"A hypothesis underlying the use of Cognitive Behaviour Therapy (CBT) for ME/CFS is based on the premise that the patient's impairments are learned due to wrong thinking and "considers the pathophysiology of CFS to be entirely reversible and perpetuated only by the interaction of cognition, behaviour, and emotional processes. The patient merely has to change their thinking and their symptoms will be gone. According to this model, CBT should not only improve the quality of the patient's life, but could be potentially curative". Supporters suggest that "ideally general practitioners should diagnose CFS and refer patients to psychotherapists for CBT without detours to medical specialists as in other functional somatic syndromes". Proponents ignore the documented pathophysiology of ME/CFS, disregard the reality of the patients' symptoms, blame them for their illness, and withhold medical treatment."

Part of the NICE remit is to provide cost effective NHS solutions for ill-health. NICE is proposing in these Guidelines that the some 180,000 people affected with moderate to mild ME/CFS be referred by their GPs to a multidisciplinary hospital-based ME/CFS service comprising CBT/GET. Since the cost of this treatment is around £1,000 per patient, this will cost the NHS in the region of £180million. Precisely how is the NHS proposing to fund this? [Update. The final publication of the CFS/ME NICE Guidelines in August 2007 shows that the proposed outlay has now jumped to £300million].

In relation to the content of these CFS/ME Draft NICE Guidelines, The One Click Group concurs with the Formal Response to NICE for the 25% ME Group for the Severely Affected charity dated 19 October 2006 in its 'Comments on specific statements in the Draft Guideline' on page 44, available on One Click at:

<http://www.theoneclickgroup.co.uk/documents/NICE/Charities/NICE%20Concerns%20from%20Kate%20Stewart.pdf>

The One Click Group will not be able to endorse the CFS/ME NICE Guidelines unless the following is acknowledged, reviewed and included:

8.1 Full acknowledgement of ME/CFS as a neurological disease as classified by the World Health Organisation ICD 10 under G93.3.

ME/CFS has been classified as a neurological disease since 1969 in the ICD. ME/CFS is classified completely apart from the condition 'Idiopathic chronic Fatigue', which is classed as a mental disorder under F48 and ME/CFS is also classified apart from Fibromyalgia, which is classified as a soft tissue disorder.

This must therefore be acknowledged within the NICE Guidelines. This acknowledgement must include the proper name for this disease, Myalgic Encephalomyelitis (also known as Chronic Fatigue Syndrome). The term 'Encephalopathy' is NOT classified anywhere by the WHO ICD-10, and at present there is NO international consensus that the term 'Encephalopathy' is more accurate. In fact this is contested. Until such time that international consensus and the World Health Organisation officially sanctions a name change, the British Government must abide by the rubric of the WHO ICD-10 (namely, Myalgic Encephalomyelitis, not Encephalopathy). As a government agency, NICE also must abide by this rubric.

8.2 Acknowledgement of the contesting paradigms of ME/CFS.

It must be acknowledged, within the NICE Guidelines, that there are broadly two contesting paradigms of ME/CFS (Chaudhuri, 2001): the neurological (biomedical) paradigm, and the psychiatric paradigm (Kennedy, 2005). The psychiatric paradigm has been demonstrated to have a number of serious theoretical, methodological and ethical flaws, not least of which is that the research claiming psychological or behavioural factors as causing or perpetuating ME/CFS, have used heterogeneous patient groups which have included patients OTHER than ME/CFS, and furthermore, have used criteria and methods which have had the potential effect of excluding ME/CFS sufferers, indicating that their claims cannot be generalised to sufferers of the neurological disease ME/CFS ICD-10 G93.3. (Hyde et al, 1992, Marshall et al, 2001, Carruthers et al, 2003, Kennedy and Bryant, 2004, Kennedy 2005.) What is more, there is ample, international evidence to support the continued ICD-10 classification of ME/CFS under G93.3, a large body of evidence too substantial to be included in this document, although an indication can be found in Hyde et al (1992), Marshall et al (2001), Carruthers et al (2003), Montague and Hooper (2001).

8.3 Full consideration and application of the Canadian ME/CFS Case Definition and Treatment Protocols.

The Canadian ME/CFS Case Definition and Treatment Protocols (Carruthers et al, 2003), CLINICAL CRITERIA, produced by international consensus, have now been available for THREE YEARS. They are the most up-to date clinical criteria in the world, and indeed appear to be the ONLY peer-reviewed criteria used in the world today.

Furthermore, the Jason et al study (2004) has demonstrated the ability of the Canadian ME/CFS Case Definition and Treatment Protocols in enabling a more accurate differential diagnosis of the neurological disease ME/CFS G93.3 from idiopathic chronic fatigue and other illnesses. As Jason (2005) reminds us in a recent

short article, until his team's latest study: "None of the current CFS case definitions have been empirically derived or prospectively contrasted with one another".

The Guidelines Development Group has totally rejected the ME/CFS Canadian Guidelines. Instead, based on no medical consensus whatsoever, it has elected to produce its very own set of clinical criteria for use in these Guidelines that have not been peer reviewed, published or operationalised anywhere in the world.

The NICE Guidelines MUST include the Canadian ME/CFS Case Definition and Treatment Protocols within its mandate, make them accessible to British clinicians, and act upon its recommendations. Failure to do this will be an abrogation of duty to patients.

8.4 Full consideration of the problems of validity and reliability in studies using the Oxford Criteria.

The Oxford case definition (Sharpe et al, 1991) excludes those with neurological disorders. Indeed, this was confirmed in 1991 by psychiatrist Anthony David who referred to the Oxford criteria shortly after they were published:

"British investigators have put forward an alternative, less strict, operational definition which is essentially chronic fatigue in the absence of neurological signs (but) with psychiatric symptoms as common associated features" (David, 1991)."

This confirmation by David that the Oxford Criteria exclude people with neurological signs, has major implications for sufferers of the neurological disease ME/CFS. The continued use of criteria such as the Oxford Criteria by some in particular, actually presents major methodological problems which proponents of the psychiatric paradigm continue to ignore.

The Oxford criteria exclusion definition technically prevents a patient with an organic brain disease from entering into the PACE trial. ME/CFS ICD-10 G93.3 is actually an organic brain disease as listed by the WHO and this classification is agreed by the UK Government. What is more, most ME/CFS labeled sufferers will exhibit signs and symptoms of organic brain disease, and especially those seriously affected. By the logic of the Oxford Criteria, they should be excluded. This anomaly is one of the major flaws of the Oxford Criteria, yet these criteria continue to be used by proponents of the psychiatric paradigm, for example, in the ongoing PACE Trial (Kennedy and Bryant, 2004, Bryant 2004).

Therefore, any research claiming success in diagnosing or treating sufferers of the neurological disease ME/CFS that has used the Oxford criteria in particular, will have problems of validity and reliability and therefore should be approached with extreme caution. This is particularly the case with claims about the efficacy of CBT/GET. In light of the Jason et al study, the same due caution should be applied to studies using the Fukuda et al criteria also.

8.5 Full literature review necessary, with avoidance of bias towards literature supporting the psychiatric paradigm.

There have been previous biases present in many of the reviews of ME/CFS, towards the psychiatric paradigm. The literature in which such bias has occurred includes but is not limited to:

The 1996 Report on CFS of the joint UK Royal Colleges
The Chief Medical Officer's Report

The RCPCH Guidelines

As a result of this bias, the large, international body of research evidence supporting the bio-medical (as opposed to the psychiatric) paradigm of ME/CFS has been largely ignored. This is precisely what has occurred in the production of the ME/CFS Draft NICE Guidelines by the adoption of unethical political/medical manipulation in what has been included in the York Systematic Review.

All evidence, including latest findings, must be considered. These latest findings include, for example those found in the recent conference on ME/CFS in Japan 2005, and the evidence around cardiac and other physiological abnormalities detailed in the references accompanying this representation. They should also include the results of the paper produced by L.D. Devanur, J.R. Kerr, [Chronic fatigue syndrome](#), Journal of Clinical Virology (2006), doi:10.1016/j.jcv.2006.08.013 that so clearly illustrate that the psychosocial treatments of CBT/GET are of minor benefit.

The references given within this document demonstrating physiological abnormalities in ME/CFS and those demonstrating the problems in the psychiatric paradigm do not represent an exhaustive list.

It is clear that the Guidelines Development Group has failed to give due equal consideration to all evidence on ME/CFS and this must be corrected.

Furthermore, there must be NO exclusionary strategies with regard to evidence. As the NICE Guidelines are Clinical Guidelines, Clinical Evidence must NOT be excluded in the literature review, and the literature must not be limited to peer review journals or Randomised Controlled Trial studies, particularly as these have been found to have fundamental flaws in validity and reliability, despite their RCT status. There also must NOT, therefore, be a bias towards including literature supporting the psychiatric paradigm, in the NICE Guidelines.

8.6 A removal of any 'limited investigations' recommendations for ME/CFS sufferers.

These Guidelines instruct that viral and bacterial testing upon symptoms onset is to be denied to patients in the throes of being labeled with ME/CFS. It is not the case with these Guidelines that all other conditions have been ruled out prior to diagnosis.

The recommendations made with regard to this issue in the psychiatric paradigm-biased 1996 Report on CFS of the joint UK Royal Colleges was and remains medically and scientifically untenable.

* It is unacceptable to be advising clinicians that investigations should be limited to a basic minimal screening, particularly as basic screening is known to be often 'normal' in ME/CFS.

* Best clinical practice in the area of ME/CFS is increasingly being understood to involve more complex tests to facilitate a better understanding of this complex disorder. This is particularly the case as we have highlighted with Lyme Disease/Borreliosis. Patients must be given the viral and bacterial tests that they require upon symptom onset.

* Some of the areas in which diagnostic investigations are yielding the most promising results, include imaging technologies such as (though not limited to) SPECT scans.

To insist that only limited investigations are needed in a disease in which so much is not yet understood is a ludicrous and untenable position, and an abrogation of duty to both patients and clinicians.

8.7 Consideration of the problem of contested claims of Cognitive Behavioural Therapy and other psychological therapies as 'Treatments'.

NICE is proposing that the NHS spends some £180million of British taxpayer's money on what it has classified as mild to moderate ME/CFS through new clinical criteria that it itself has invented. [Update. The final publication of the CFS/ME NICE Guidelines in August 2007 shows that the proposed outlay has now jumped to £300million]. This leads to the conclusion that either NICE could not find its way out of a budgetary paper bag or that the Department of Health has decided that the flawed and experimental treatments of the psychiatric lobby must take precedence over any other. The CFS/ME Draft NICE Guidelines are utterly impractical on every level and simply provide a blank cheque for the psychiatric lobby to further damage patients with the experimental CBT/GET treatments.

We are very concerned about the rationale, expressed by some key proponents of the psychiatric paradigm, that Cognitive Behavioural Therapy should be offered, NOT as a strategy of coping with one's illness, but as a 'cure' for ME/CFS, (which, it must be remembered, has been both classified and consistently demonstrated as a neurological illness). This fact is clearly demonstrated in the 'Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline' produced by NHS Plus.

This approach has been professed by proponents of the psychiatric paradigm, who, from the evidence, appear to believe that the multi-system physiological abnormalities (manifesting as symptoms) can be improved to the point of 'recovery', merely by challenging the illness beliefs and behaviour of the sufferer (see for example, Fulcher and White, 1997, Sharpe, 1996: 248, Stulemeijer et al, 2004). Their rationale for the use of CBT is as a 'cure' for a neurological illness that they do not even appear to recognise, an illogical position unheard of in regard to medical approaches to any other neurological or other organic illness.

This is a major theoretical problem inherent in the psychiatric paradigm of ME/CFS.

We note that the care plan advocated by Stein (2001) presents a more useful approach to psychological support and management strategies in ME/CFS:

"The treatment of psychological symptoms in CFS is fourfold:

1. Treat the physical illness,
2. Actively advocate for the patient's health, mental health and economic needs.
3. Offer or refer for psychotherapy to support the patient's grieving process and encourage the formation of sustainable values and expectations.
4. Use low dose psychotropics for those in whom anxiety or depression symptoms are disabling and/ or are interfering significantly with quality of life."

In light of these issues we submit that the contested approaches to Cognitive Behavioural Therapy or other psychological therapies in ME/CFS be fully delineated in the NICE Guidelines. There must be NO requirements for ME/CFS patients to undergo any such treatments, as is delineated in the 'Occupational Aspects of the Management of Chronic Fatigue Syndrome: a National Guideline' produced by NHS Plus.

8.8 Full acknowledgement of the potential risks of Graded Exercise/Activity Regimes to ME/CFS sufferers.

The claims that 'Graded Exercise/Activity Therapy' (GET or GAT) regimes are curative for ME/CFS patients have been criticised for the high drop out rate of patient samples in the research, and for the ways in which certain patients are excluded from such trials (Carruthers et al, 2003, Kennedy and Bryant, 2004).

Furthermore, proponents of GET or GAT continue to ignore the documented harmful effects and therefore potential dangers of 'Graded Exercise/Activity' for ME/CFS sufferers, for example as demonstrated in Van de Sande (2004) Carruthers et al (2003) 25% Group (2004) Shepherd (2001) Action for ME (2001).

There are also a number of studies demonstrating cardiac and other physiological abnormalities in ME/CFS patients - for a few (in no way exhaustive) examples, see Hyde et al (1992) Peckerman et al (2003) Montague and Hooper (2001) Marshall and Williams/Stewart (2001), Hooper (2006), Kerr (2006).

Lerner et al (1997, 2004) Behan et al (1991, 1999) and others in the reference list below - which supports concerns that GET/GAT must be applied with extreme caution, and NEVER forced upon patients (Carruthers et al, 2005). Therefore, medical recommendations to exercise must be used with as much caution as prescribing medication (Carruthers et al, 2003), for the doctor's protection as well as the patient. This should be made aware to clinicians within the NICE Guidelines.

The giving of full explanation to patients of the potential risks of Graded Exercise/Activity regimes MUST be recommended in the NICE Guidelines, to protect both patients and clinicians.

8.9 Full consideration of the special circumstances affecting severely affected sufferers.

Very little research has been undertaken on the severely affected. Therefore, extreme caution must be exercised when considering any studies that generalise their results to a severely affected population that have not been studied. To do otherwise is placing severely affected sufferers at serious risk of harm. (Kennedy 2005)

8.10 The problems of the PACE and FINE trials.

There must be no exclusionary strategies for considering evidence for the NICE clinical guidelines, or bias towards the psychiatric paradigm of ME/CFS. The inclusion of evidence must be seen not to be arbitrary.

There are a number of theoretical, methodological and ethical flaws inherent in both the PACE and FINE Trials (see for example, Bryant, 2004, Kennedy and Bryant, 2004). Therefore ongoing studies such as PACE and FINE in particular must NOT be included as evidence in the NICE literature review, without including the relevant critiques of these trials.

8.11 A full consideration of the contested constructions of 'fatigue' in ME/CFS.

We are concerned to ensure that 'fatigue' as applied to ME/CFS sufferers, is not incorrectly presented as merely 'tiredness', a common problem in the literature of the psychiatric paradigm in particular. The word 'fatigue' is inadequate to describe the physical abnormalities (both signs and symptoms) that occur in ME/CFS.

At the same time, it must be remembered that 'fatigue' (which might mean tiredness, drowsiness, exhaustion, disturbed level of consciousness, weakness, paralysis, or feelings of malaise, depending on how certain illnesses are experienced or linguistically constructed by individuals) is present in MOST organic illnesses, acute and chronic. Indeed: "Fatigue is both a normal and a pathological feature of everyday life' (Hyde 1992: 11).

Proponents of the psychiatric paradigm, in their literature, tend to associate 'fatigue' with a psychological state, ignoring the physiological reasons that may contribute to the bodily symptoms in ME/CFS, with the effect that these become generalised, and often trivialised, as 'fatigue'. As Hyde also points out, to place such an emphasis on such a generalised, unspecific, indefinable and immeasurable term as 'fatigue', present in both healthy patients and those with both organic and psychological illness, the elimination of hundreds of other diseases are necessitated. This logistical flaw results in only the most limited investigation being encouraged for ME/CFS patients, and NOT in areas that might yield definitive results, such as certain brain scans (as discussed and referenced in Hyde et al, 1992, Marshall et al, 2001, Carruthers et al, 2003).

Particularly relevant to ME/CFS sufferers also is the problem also identified by Hyde (1992: 11-12):

'...taking the fatigue as the flagship symptoms of a disease not only bestows the disease with a certain Rip Van Winkle humour, but removes the urgency of the fact that most ME/CFS symptoms are in effect CNS [Central Nervous System] symptoms.'

In this context the ramifications of such serious, disabling symptoms as found in ME/CFS are in danger of being both trivialised and ignored. The problem is compounded by the frequent tendency, by proponents of the psychiatric paradigm themselves and taken up uncritically by others, to use, incorrectly, the term 'chronic fatigue' instead of and interchangeably with 'chronic fatigue syndrome', even though both terms denote completely different diseases. Chronic Fatigue Syndrome is described in the WHO ICD-10 as synonymous with (therefore merely another name for) the neurological disease ME, while chronic fatigue is assigned a different category of illness in the ICD-10 (Psychiatric).

The NICE Guidelines therefore must specifically delineate the difference between ME/CFS and idiopathic chronic fatigue, and between ME/CFS and other illnesses, in which 'fatigue' may be common, but is a different phenomenon from that of the signs and symptoms in ME/CFS.

8.12 Full parity for children's rights in developing the NICE guidelines.

Within the NICE Guidelines, ME/CFS child sufferers must have full consideration of their diagnostic, treatment and support needs equally with adults. The points referred to in this document must be applied to children with parity.

Furthermore, we are also concerned that some of the recommendations of the RCPCH guidelines were highly unsound, for example the recommendation regarding the severely affected, as well as comments in the report discussing parent/child sexuality. This is not an exhaustive list of concerns.

We remind the NICE Guidelines Development Group that much of the RCPCH document was, by its own admission, opinion, not evidence based, and therefore if NICE act upon recommendations in the RCPCH report, there may well be adverse ramifications for child sufferers, which could lead to legal action being taken against NICE.

9. CONCLUSION

These CFS/ME Draft NICE Guidelines are a travesty of unscientific and medical mismanagement with the suggestion of inappropriately funded treatment and resources that the National Health Service has not got and cannot afford.

There are serious legal ramifications with regard to the formulation of the NICE Guidelines and the evidence we have provided in this submission and others.

NICE has been guilty of a severe abrogation of duty to ME/CFS sufferers.

The CFS/ME Draft NICE Guidelines are unfit for purpose.

If NICE fails to completely and fundamentally overhaul these Guidelines prior to publication in April 2007, it is intended to seek Judicial Review.

Please make this submission known to all relevant members of the NICE Working Groups, publish it and place it in the public domain on the NICE website.

The One Click Group
16 November 2006

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APPENDIX 1 – ME/CFS INFORMATION AND EVIDENCE

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1. One Click Presentation, ME/CFS Parliamentary Inquiry.
2. A Short Summary Of The Psychiatric Paradigm, Angela Kennedy, 2005.
3. World Health Organisation Classification – ICD.10 G93.3.
4. One Click Submission to NICE – Stakeholder Comments Link.
5. One Click Submission to NICE – Systematic Literature Review Link.
6. One Click Submission to NICE – Subset Questionnaire Correspondence Link.
7. The Lord Campbell of Alloway QC - Legal Opinion for The Countess Of Mar, 6 April 2000

1. The One Click Group Presentation to the Gibson ME/CFS Parliamentary Inquiry, 27 April 2006. Available at the Parliamentary Inquiry website at: <http://www.erythos.com/gibsonenquiry/PresDocs.html>

Tuesday, 18th April 2006.

Oral Evidence Hearing
The Gibson Group on ME/CFS
House of Commons
Room E
7 Millbank
London SW1P 3JA
United Kingdom

Statement to Parliamentary 'Inquiry' into ME/CFS

By

The One Click Group

I am Angela Kennedy from the One Click Group, and this is my colleague Jane Bryant. One Click is a pressure group providing opposition to the psychiatric paradigm, for patients suffering from diseases such as Gulf War Syndrome, Lyme disease, Borrelia and the neurological disease ME/CFS.

Our children, previously diagnosed with ME/CFS, have both been subsequently diagnosed with Borrelia, a chronic spirochaete bacterial infection.

We carry breaking news, information and archive resources on our website, read by people in over 70 countries, often receiving in excess of 4,000 hits per day. We are read by Ministers, MPs, the Department of Health, the medical establishment, researchers, the media, patients and carers.

We bring to the attention of the Group that neither of our children can attend today because of the severity of their respective conditions, an all too common feature of this illness. We therefore are acting on their behalf and with their approval.

We give this presentation with the essential qualification that the enormous range and depth of problems related to British policies on ME/CFS is so great that it cannot possibly be done justice in 10 minutes.

Therefore what follows is a mere summary of some of the major problems facing sufferers both before and after the Chief Medical Officer's Report: During which, it must be noted, psychiatrists, led by Peter White of the PACE Trial, walked out because they objected to the biomedical facts of this disease.

A reasonable appraisal of the situation facing sufferers cannot take place in a historical vacuum, with an arbitrary 'cut-off' point at the year of the CMO's Report. The injustices facing sufferers began well before this time, and remain yet to be resolved.

We bring to the Group's attention the issue of Borreliosis. The links between ME/CFS and Borreliosis have been known for some time, both by the National Health Service and the ME/CFS charities. Research by Dr. John Gow shows that the gene expression in ME/CFS and Borreliosis is identical, as he has stated in public. Despite this, no research is being funded by the British government into this vital issue, and patients have had terrible difficulties in getting any treatment on the NHS. For some it has been impossible. One particular Borreliosis specialist in the UK has stated that some 95% of his ME/CFS patients have tested positive for Borreliosis.

We also bring to the Group's attention the large amount of international research evidence of organic, multi-system physiological abnormalities within this disease entity. This has been consistently ignored in various reviews, including the CMO's Working Group Report, and the recent Bagnall et al review for the NICE Guidelines. There also appears to have been a deliberate flooding of the literature with repetitive psychiatric papers consisting of conjecture and prejudiced opinion masquerading as 'science'.

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There are broadly two contesting paradigms of ME/CFS: the neurological (biomedical) paradigm, and the psychiatric paradigm. The psychiatric paradigm in Britain is supported by various researchers such as Simon Wessely, Peter White, Michael Sharpe, and Elena Garralda, among others. It has been demonstrated to have serious theoretical, methodological **and ethical** flaws.

Proponents of this paradigm refuse to recognise the WHO ICD-10 neurological classification of ME/CFS. **Indeed, they unilaterally misrepresented the term Chronic Fatigue Syndrome as being classified as a mental disorder in the ICD-10, wrongly advising the British government. This was corrected by the Countess of Mar during a House of Lords debate in 2004, with confirmation by the World Health Organisation.**

Despite the overwhelming evidence to the contrary, proponents continue to assert the notion that the illness is caused and/or perpetuated by 'psychological' or 'behavioural' factors. They consistently portray sufferers as mentally and socially deviant.

They illogically and incorrectly describe ME/CFS as 'Medically Unexplained'. Ironically, they then promote a state of 'cultivated ignorance' about the illness by discouraging all but the most limited of biomedical investigations/treatments for sufferers.

They promote the use of Cognitive Behavioural Therapy, NOT as a strategy of coping with illness, but as a 'cure' for a neurological disease they do not even recognise, an irrational position. They claim that multi-system physiological abnormalities can be improved to the point of 'recovery', merely by challenging the illness beliefs and behaviour of the sufferer.

They promote Graded Exercise, even though their own research in this area has been criticised for the high drop out rate of patient samples and the patients excluded from such research. They continue to ignore the documented harmful effects and therefore potential dangers of 'Graded Exercise' for ME/CFS sufferers.

Their research design is highly flawed, as will be demonstrated by my colleague.

JANE BRYANT:

Professor Simon Wessely stated in public at the Eliot Slater Memorial Lecture: "There is a phenomenon known as myalgic encephalomyelitis - or ME. I will argue that ME is simply a belief - a belief that one has ME," he said.

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From the scientifically unproven belief system of this psychiatrist and the group that surrounds him, over £11.1m of British taxpayers money has flowed to set up the methodologically **and ethically** flawed psychosocial PACE and FINE trials being conducted at these 'CFS/ME' Centres primarily run by the psychiatrists for psychiatric benefit. These are the 'CFS/ME' Centres that have been thoroughly condemned by ME/CFS patients' right around the United Kingdom as has been evidenced, as just one example, by the many letters from patients sent to RiME – the group for Research into Myalgic Encephalomyelitis.

What was the purpose of setting up the Chief Medical Officer's Working Group, preparing a complex report, taking into account at least some of the patients' views and then to all intents and purposes, ignoring them completely?

Psychiatric interventions over ME/CFS have been forced on patients for the last fifteen years or more and are STILL the only treatments consistently available. If these had been in any way efficacious, where are the lost legions of the recovered to show this? Just where are they?

The enormous irony **and scientific fraudulence** of the PACE trial is the way that it has been deliberately structured using the outdated and superseded Oxford criteria for patient inclusion into this trial purely to enhance the numbers recruited and to include patients suffering from Idiopathic Chronic Fatigue, a mental disorder classified as such under F48 that is entirely different from ME/CFS. The Oxford criteria specifically EXCLUDE patients suffering from a neurological disorder that ME/CFS IS as defined by many international experts and the World Health Organisation. How has it come about that millions of pounds of British taxpayers money, agreed by the Medical Research Council, are being spent on a trial that is actually excluding the very patient population that it is supposed to be studying by use of the Oxford criteria for entry to the PACE trial? ME/CFS must be the only illness in the world where the most severe sufferers are never properly studied.

There is also massive controversy surrounding the bolt on inclusion of the Fukuda and London criteria in the PACE trial. The so called London criteria have never been peer reviewed, published, operationalised or validated.

This makes these criteria unusable in any clinical trial and that, together with the use of the aforementioned Oxford criteria, makes the structure of the PACE trial a scientific nonsense from the outset.

Furthermore, the charity Action for ME, that has no mandate or remit to act for ME/CFS patients at government level or any other since it has not held an Annual

General Meeting that involved its members/subscribers for the last TEN YEARS is heavily involved in the PACE Trial protocol and has been given money by Section 64 government grant to promote this trial to their members. It clearly states in the PACE Trial Identifier produced by the psychiatrists for the Medical Research Council that: "Compliance with both the treatments and the study will be maximized by the COLLABORATION and SUPPORT of AfME."

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The PACE trial, as delineated in The PACE Report produced by One Click, is a deceit and scandal of massive proportions as has indeed been written up in the Independent national newspaper in 2004. The PACE and FINE trials are clearly little more than job providers for the psychiatrists that are running them who operate on the basis of a misguided but entrenched illness belief system for which there is absolutely no scientific basis, that ME/CFS is a mental disorder, not the neurological illness that it is, as defined by the World Health Organisation. Is it ethical for people with proven commercial interests in these studies to be designing and running these trials, give the proven evidence of their personal commercial interests in the desired outcome of these trials?

ANGELA KENNEDY:

Documented iatrogenic effects of the Psychiatric Paradigm of ME/CFS on patients include:

1. Lack of appropriate bio-medical investigation, treatment and support, contributing to deterioration in health.
2. Denial of benefits, insurance or pension payments to sufferers, even though the extent of their disabilities would, in other organic illnesses, entitle such sufferers to these.
3. Hostility, disbelief and lack of empathy from doctors, families, communities and society at large, who are frequently led to believe that the illness is a result of deviance.
4. Forced treatment of patients, including forced incarceration of children.

We bring to the Group's attention the TYMES Trust Dossier 'The Forgotten Children', the Panorama Survey, and the **Ean Proctor** Scandal, in which a semi-paralysed 11 year old ME/CFS diagnosed child was thrown into a swimming pool to see if his paralysis was genuine. The child sank. These are just a few examples of the mistreatment that sufferers, especially children, have had to endure as a result of the psychiatric paradigm.

5. There is adverse impact on quality of life to such a degree that some sufferers have committed suicide.
6. Progressive relapse into severe illness has resulted from Graded Exercise Regimes.

No other organic disease has had so much attention on 'psycho-social factors' while biological factors are consistently ignored and trivialised in the UK: and this special pleading about ME/CFS has thwarted the progress of biomedical research and clinical care.

In summary, we bring to the Group's attention that British health, social and research policy on ME/CFS in recent years has been based on fundamentally flawed conjecture, and prejudiced opinion masquerading as 'science', causing endangerment and disenfranchisement to sufferers. It is imperative that the British Government rectifies this wrong immediately.

This must include the urgent funding of biomedical research untainted by psychiatric vested interests, but also an overhaul of all social security and NHS practice, to reflect the already available evidence demonstrating serious disease processes, and it must move away from the erroneous and discredited claims that this illness is a result of deviance.

- ENDS -

18 April 2006

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2. A SHORT SUMMARY OF THE PSYCHIATRIC PARADIGM OF ME/CFS

By Angela Kennedy, 18 January 2005

Available on The One Click Group website:

http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/THE%20PSYCHIATRIC%20PARADIGM.pdf

This document provides a brief, critical overview of identified themes within the approaches to ME/CFS, that have been promoted extensively by a vociferous group of doctors and others known colloquially as the 'Wessely School', after Simon Wessely, a psychiatrist who has had a key role in facilitating the emergence of the notion that ME/CFS is a psychological disorder (Hansard, cited in Marshall et al, 2001).

Unfortunately for ME/CFS sufferers themselves, the ideas espoused by this group have been accepted uncritically by many others, even though there are fundamental theoretical, methodological and ethical problems with their approach, which have caused endangerment and disenfranchisement to ME/CFS sufferers worldwide, as well as further, unnecessary, suffering.

Their approach, theoretical assumptions and apparent beliefs, as delineated below, I have termed the 'psychiatric paradigm'. This is not meant to imply that all psychiatrists, psychologists and other mental health professionals subscribe to a 'psychiatric paradigm' of ME/CFS, as proposed by the 'Wessely School'. As will be demonstrated, some psychiatrists have critiqued the notions espoused by the 'Wessely School'. Dutton (1992), has used the word 'paradigm' in connection with depression/somatization explanations for 'CFS'. I am therefore using the term 'psychiatric paradigm' to describe the psychiatric causation explanations for the disease ME/CFS, espoused by those such as Simon Wessely, and various others.

The main problems of the Psychiatric paradigm can be summarised as follows:

1. Refusal to recognise ME/CFS as a neurological illness

Proponents of the psychiatric paradigm do not appear to subscribe to the WHO ICD-10 classification of Myalgic Encephalomyelitis/chronic Fatigue Syndrome as a neurological disease (for example, see David and Wessely, 1993). This is further

illustrated, for example by Wessely's own comment (1994), that: "I will argue that ME is simply a belief, the belief that one has an illness called ME".

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Another example of this position was illustrated, for example, when proponents of the psychiatric paradigm unilaterally (and incorrectly) represented the term Chronic Fatigue Syndrome as being classified as a mental disorder in the ICD-10, and advised the British government that this mis-classification was in order, until the British Government was corrected by the Countess of Mar during a House of Lords debate in 2004, with confirmation by the World Health Organisation. (Footnote 1)

The refusal to recognise that ME/CFS is a neurological illness is in direct contradiction to a very large body of international research/clinical literature illustrating the neurological and other physiological evidence as to the organic basis of this disease. (Footnote 2) Such literature, especially where it prevents a fundamental challenge to the psychiatric paradigm, has been consistently ignored in the Wessely's School's own literature, and frequent quoting of the work of the prime proponents of the psychiatric paradigm instead occurs regularly within this literature (for example, as discussed in Marshall et al, 2001. Also see discussion surrounding the continuing failure to engage with the Canadian Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Case Definition and Treatment Protocols (Carruthers 2003), for example, in Kennedy and Bryant, 2004).

2. Confused, Inconsistent Notions of 'Psychosomatic' Illness

Instead of accepting either the WHO's neurological classification, or the evidence of organic disease presented by the international research and clinical literature, proponents of the psychiatric paradigm continue to assert the notion that the 'illness' is caused and/or perpetuated by 'psychological' or 'behavioural' factors. This idea manifests itself in a number of ways, often used interchangeably and confusingly, where various discursive categories of 'psychosomatic' illness are assigned to ME/CFS sufferers within the literature supporting the psychiatric paradigm, implying that various mental, behavioural, or emotional processes, not organic processes of disease in the body, are the causes of their ill health. In this context, ME/CFS sufferers are often constructed as the authors of their own misfortune (McWhinnie et al, 1997), seen as either a conscious or unconscious process (Kennedy, 2004 (a)). Such categories identified in the literature of the psychiatric paradigm include:

Imaginary (the illness or symptoms are deemed not 'real', but imagined); Malingering (the 'sufferer' is implied as lying about the extent or even the existence of their illness, in order to receive financial or other benefits, including social or familial attention. Sometimes this can be implied to be occurring on an 'unconscious' level, i.e. 'lying to one's self'); Hypochondria (the 'sufferer' is deemed to have odd or 'aberrant' or 'irrational' illness beliefs, for example, believing they need to rest, when they 'should' be exercising, even though exertion has serious adverse implications for ME/CFS sufferers, and the idea that such concerns are 'irrational' are highly subjective and contested, as described in Kennedy 2004 (b); Personality disorders, often interspersed with notions of 'character flaw'.

- Functional (a disturbance of the function of an organ mediated by emotional tension);
- Structural (a physical structure disturbance mediated by emotional tension).

The last two Categories are used within the context of the psychiatric paradigm, usually to imply a unidirectional relationship between the mind and body (psychological problems are attributed by proponents as CAUSES of the illness, and not considered as EFFECTS of chronic, serious illness), privileging the mind's effect on the body without considering the body's effect on the mind, therefore frequently manifesting as an example of the cultural myth of 'mind over matter'. (Wendell, 1996)

A seventh Category, 'Holistic', an approach to any state of the body taking into consideration psychological factors in physical conditions and physical factors in psychological conditions as described by Bartol and Eakes, (1995) for example, an approach endorsed by the World Health Organisation, has been, so far, conspicuous by its absence in the deliberations on ME/CFS by proponents of the psychiatric paradigm. Often, within the literature of the psychiatric paradigm, the first six categories (but in particular the first FOUR categories) identified above are used concurrently, interchangeably, and confusingly. Frequent examples of this tendency in the literature are evident in the examples of text collated in Hooper (2004) and Marshall and Williams, (1996, 1999). (Footnote 3)

The various discursive categories of 'psychosomatic' illness, which have been broadly described above, can have many descriptive terms applied to them, which are also used interchangeably and confusingly within the literature of the psychiatric paradigm and applied to ME/CFS sufferers. Such descriptions include: 'psychosomatic' 'Functional Somatic Syndrome' 'somatization' 'hysteria' 'conversion disorder' and 'psychogenic'.

3. Failure to differentiate psychological problems found in chronic illnesses from psychiatric illness per se.

Proponents of the Psychiatric Paradigm consistently fail to clearly demarcate the differences in any 'anxiety' or 'depression' or other emotional/psychological problems that might be diagnosed in some (by no means all) ME/CFS sufferers (Dutton, 1992). This has the effect of incorrectly attributing such problems as the causes or perpetuating factors of 'CFS'. So, for example, they frequently fail to demarcate the possible types of anxiety or depression that might be found in ME/CFS (certainly not always), e.g. as delineated by Stein (2001):

- "1. grief due to loss of health, social connections, family support, financial capability, career and uncertainty re (sic) all of these;
2. change in mood/cognition as part of the physical disorder of CFS (similar to mood change in MS or Parkinson's disease);
3. comorbid depressive disorder and
4. mood change due to medication or food or withdrawal from either of these."

It is significant that, while psychiatrists such as Stein are concerned with the impact on quality of life of serious illness such as ME/CFS (as exemplified in this comment):

"Grief is not a disorder. It is a normal developmental process which enables people to deal with overwhelming loss. It is an understandable reaction to a serious, uncertain, stigmatizing and chronic disorder. Grief is therefore common during the initial post diagnostic period and may recur each time there are new changes in health or life situation."

Such considerations are not deliberated or considered within the vast majority of the literature advocating the psychiatric paradigm. This indicates that the high figures of

'co-morbid anxiety and depression' in 'CFS' claimed frequently by proponents of the psychiatric paradigm are untenable: firstly because of the heterogeneity of patient samples in research conducted under the auspices of the psychiatric paradigm (discussed later in this paper), but also, in regard to the issue of psychological problems, because proponents of the psychiatric paradigm fail to differentiate normal grief or fear reactions to chronic illness, neurologically mediated mental disturbances, and other environmentally-mediated mental disturbances such as, for example, reactions to medication or hypoglycaemia due to lack of food (all of which may be transitory), from anxiety and depressive disorders that might be present independent of the illness of ME/CFS (the 'co-morbid' or even 'pre-morbid' (Dutton, 1992) disorders), and place them under a catch-all category of 'co-morbid' psychological disorder.

4. Flawed research design

Within their research projects, proponents of the psychiatric paradigm consistently fail to demarcate ME/CFS from other disorders involving 'fatigue', some of which may have a psychological component (Jason et al, 1997), such as idiopathic chronic fatigue (classified by the WHO as ICD-10 F48, a psychiatric disorder), depression, Fibromyalgia (Classified by the WHO as a Soft Tissue Disorder), 'burnout' and indeed ANY 'fatigue state', none of which are ME/CFS. They then generalise any results from a highly heterogeneous sample which may NOT apply to those who are ME/CFS sufferers (Caruthers et al, 2003, Jason et al, 1997). In light of their theoretical assumptions regarding CBT/GET, and the dangers associated with those treatments to ME/CFS G93.3 sufferers, they are therefore placing such sufferers at risk (see Kennedy & Bryant, 2004, and point 7 below).

Significantly, their research has failed to include Seriously Affected Sufferers to date, and yet their generalisations are applied to this group also. They also sometimes exclude patients with cardinal symptoms of ME/CFS in their samples, for example, sleep disorder in Fulcher and White, (1997) yet continue to generalise, within their literature, any 'successes' of their proposed 'treatments' (especially Cognitive Behavioural Therapy and 'Graded Exercise/Activity' regimes, discussed below) to all patients (for example, even those with sleep disorders).

The continued use of criteria such as the Oxford Criteria by some in particular, actually presents a major methodological problems which proponents of the psychiatric paradigm continue to ignore. The Oxford criteria exclusion definition technically prevents a patient with an organic brain disease from entering into this trial. ME/CFS ICD-10 G93.3 is actually an organic brain disease as listed by the WHO and this classification is agreed by the UK Government. What is more, most ME/CFS sufferers will exhibit signs and symptoms of organic brain disease, and especially those seriously affected. By the logic of the Oxford Criteria, they should be excluded. This anomaly is one of the major flaws of the Oxford Criteria, yet these criteria continue to be used by proponents of the psychiatric paradigm, for example, in the ongoing PACE Trial (Kennedy and Bryant, 2004, Bryant 2004).

5. Fatigue as a trivialising term

Proponents of the psychiatric paradigm consistently fail to discuss the problem of the issue of 'fatigue' as applies to ME/CFS sufferers, thereby incorrectly presenting 'fatigue' as merely 'tiredness', despite the evidence that the word 'fatigue' is inadequate to describe the physical abnormalities (both signs and symptoms) that occur in ME/CFS. In the same context, they fail to acknowledge that 'fatigue' (which might mean tiredness, drowsiness, exhaustion, disturbed level of consciousness, weakness, paralysis, or feelings of malaise, depending on how certain illnesses are

experienced or linguistically constructed by individuals) is present in MOST organic illnesses, acute and chronic. Indeed: "Fatigue is both a normal and a pathological feature of everyday life" (Hyde 1992: 11).

Proponents of the psychiatric paradigm, in their literature, tend to associate 'fatigue' with a psychological state, ignoring the physiological reasons that may contribute to the bodily symptoms in ME/CFS, with the effect that these become generalised, and often trivialised, as 'fatigue'. As Hyde also points out, to place such an emphasis on such a generalised, unspecific, indefinable and immeasurable term as 'fatigue', present in both healthy patients and those with both organic and psychological illness, the elimination of hundreds of other diseases are necessitated. This logistical flaw results in only the most limited investigation being encouraged for ME/CFS patients, and NOT in areas that might yield definitive results, such as certain brain scans (as discussed and referenced in Hyde et al, 1992, Marshall et al, 2001, Carruthers et al, 2003).

Particularly relevant to ME/CFS sufferers also is the problem also identified by Hyde (1992: 11-12): '...taking the fatigue as the flagship symptoms of a disease not only bestows the disease with a certain Rip Van Winkle humour, but removes the urgency of the fact that most ME/CFS symptoms are in effect CNS symptoms.'

In this context the ramifications of such serious, disabling symptoms as found in ME/CFS are both trivialised and ignored. The problem is compounded by the frequent tendency, by proponents of the psychiatric paradigm themselves and taken up uncritically by others, to use, incorrectly, the term 'chronic fatigue' instead of and interchangeably with 'chronic fatigue syndrome', even though both terms denote completely different diseases. Chronic Fatigue Syndrome is described in the WHO ICD-10 as synonymous with (therefore merely another name for) the neurological disease ME, while chronic fatigue is assigned a different category of illness in the ICD-10 (Psychiatric). This incorrect practice of using the terms 'chronic fatigue' and 'chronic fatigues syndrome' interchangeably and confusingly has a direct relationship to the research design flaws delineated in point 4 of this document, and the actions described in point 1.

6. Promotion of Cognitive Behavioural Therapy as 'cure' for a neurological illness

They promote the use of Cognitive Behavioural Therapy, NOT as a strategy of coping with one's illness, but as a 'cure' for ME/CFS, (which, it must be remembered, has been both classified and consistently demonstrated as a neurological illness) believing that the multi-system physiological abnormalities (manifesting as symptoms) can be improved to the point of 'recovery', merely by challenging the illness beliefs and behaviour of the sufferer (see for example, Sharpe, 1996: 248, Stulemeijer et al, 2004). Their rationale for the use of CBT is as a 'cure' for a neurological illness that they do not even recognise, an illogical position unheard of in regard to medical approaches to any other neurological or other organic illness.

7. Promotion of Graded Exercise despite the evidence of risk

They promote 'Graded Exercise/Activity Therapy' (GET or GAT) regimes, even though their own research in this area has been criticised for the high drop out rate of patient samples, and the patients excluded from such trials (Carruthers et al, 2003, Kennedy and Bryant, 2004). In promoting GET or GAT, they continue to ignore the documented harmful effects and therefore potential dangers of 'Graded Exercise/'Activity' for ME/CFS sufferers, for example as demonstrated in Van de

Sande (2004) Carruthers et al (2003) 25% Group (2004) Shepherd (2001) Action for ME (2001)

8. Cultivation of a 'Culture of Ignorance'

Proponents of the Psychiatric Paradigm frequently and illogically describe ME/CFS as 'Medically Unexplained' (see for example, Rief and Sharpe, 2004). Ironically, they then promote a state of 'cultivated ignorance' about patient signs and symptoms, by discouraging all but the most limited of biomedical investigations/treatments for ME/CFS sufferers (as demonstrated in Montague and Hooper, 2001).

9. Prejudicial Descriptions of Patients

Within their literature, proponents of the Psychiatric Paradigm consistently discursively construct ME/CFS sufferers as mentally, socially, and emotionally deviant (Footnote 4) in various ways, applying their own subjective moral judgements and thymic categories of dysphoria (Footnote 5), which frequently appear prejudicial, on to sufferers. Examples of these are comprehensively documented in, for example, Hooper (2004) and Marshall and Williams, (1996, 1999), and discussed in Kennedy, 2004 (a).

10. Lack of reflexivity or epistemological and methodological insight

There is a marked lack of the reflexivity or critical self reflection by proponents of the psychiatric paradigm that would be normally be expected in such literature, in order to identify potential theoretical problems in research, (Harding, 1987) and therefore this epistemological problem, identified as a problem to be addressed in the social sciences, (Brunskell, 1998) and therefore much more frequently considered within those disciplines, remains un-addressed by proponents of the psychiatric paradigm within their literature.

The above problem is confirmed when considering another methodological criticism to be made of research conducted by proponents of psychiatric paradigm. Much of their studies involves quantitative method. The potential problem with any quantitative approach is that qualitative factors, those which are subjective, for example, bodily experiences such as pain, exhaustion, emotions, are measured quantitatively, but the parameters for measurement are constructed within the context of the researcher's own assumptions. So, when research subjects (or patients) are questioned, they have to comply with answering a set of closed questions, which are constructed according to the researcher's agenda (and possibly ideological assumptions), leaving no room for qualitative clarification by the patient/research subject.

An example of this phenomenon within the psychiatric paradigm include the use of the 'SPHERE' checklist (Hickie et al, 1996). In this method, a number of closed questions (requiring a YES or NO answer) are put to the patient. Answers in the positive to any of these questions can lead to a diagnosis (from either researcher or clinician) of psychiatric disorder. Ironically, the majority of the questions relate to bodily symptoms that will be experienced in MANY organic illnesses, and will be specifically experienced by ME/CFS sufferers, and which can be explained as resulting from Central Nervous System dysfunction, (Hyde and Jain, 1992) for example. The symptoms include: head pain, irritability, poor memory, pains in limbs, muscle pain after activity, fatigue, emotional lability, fainting, nausea, arms and legs feeling heavy, flatulence and abdominal distension, pyrexia, back pain, hypersonic, post-exertional malaise, sore throats, numbness or tingling sensations, muscle weakness, Diarrhoea or constipation, sleeping difficulties, dizziness, fatigue even at rest, difficulties with concentration, and aphasia.

If a researcher (or doctor) assumes that ME/CFS is a psychological or behavioural disorder, they will diagnose a sufferer of the above symptoms as mentally ill, even though such symptoms indicate a high level of physical dysfunction and suffering, and are entirely consistent with Central Nervous System Dysfunction as discussed, for example, in Hyde et al, 1992. The WHO ICD-10 neurological classification of ME/CFS is based on the large amount of research indicating neurological dysfunction.

This specific way that the personal subjective bias of a researcher or doctor will influence the diagnosing of somatization disorder in this way is discussed in Jason et al (1997), and demonstrated in Johnson et al (1996). As Stein (2001) also states:

"It is a mistake to use screening instruments such as the Beck Depression Inventory, the General Health Questionnaire or the SPHERE to diagnose mental illness in persons with undiagnosed somatic complaints including those with CFS because of the unstated, unproven and incorrect assumption that the somatic complaints are of psychological origin."

The construction of YES/NO-type or other closed-answer questions, and the expression of apparently ideological assumptions as mathematical data, can be very simplistic ways of attempting to measure human experience, and, as has been demonstrated above, subject to skewed results, based on the biases of the researcher. In the case of the psychiatric paradigm, the often demonstrably prejudicial value judgements as illustrated by, for example, key members of the Wessely School, immediately raises doubts about any claims to objectivity inherent in their research literature, and this problem is compounded by their lack of critical self-reflection, even though faced with critique of the value judgments expressed within their literature (for examples of these see Hooper, 2004, and Marshall and Williams, 1996, 1999), and the continuing protests by ME/CFS sufferers about the damage to health and welfare caused by such assumptions.

Does the Psychiatric Paradigm result in failure of care?

The approaches towards 'treatment' of sufferers of ME/CFS, by proponents of the psychiatric paradigm are in stark contrast to the care plan advocated by psychiatrists such as Stein (2001) :

"The treatment of psychological symptoms in CFS is fourfold:

1. treat the physical illness
2. actively advocate for the patient's health, mental health and economic needs,
3. offer or refer for psychotherapy to support the patient's grieving process and encourage the formation of sustainable values and expectations and
4. use low dose psychotropics for those in whom anxiety or depression symptoms are disabling and/or are interfering significantly with quality of life."

The psychiatric paradigm as proposed by Wessely et al fails to achieve the above exemplar because:

(a). They do not accept the demonstrated organic, neurological nature of ME/CFS, despite the large body of evidence that demonstrates this, preferring to maintain that it is caused or perpetuated by psychological, social, emotional and behavioural factors. In line with this position, they discourage all but the most limited of biomedical investigations/treatments for ME/CFS sufferers, and, ironically, discouraging those investigations in which strongest evidence of organic pathology are being delivered (Hooper et al, 2001, Marshall et al, 2001).

(b) They are involved in discursive constructions of ME/CFS sufferers as social and mental deviants, therefore contributing to a stigmatization of sufferers, leading to social exclusion, and material and social inequalities (as described, for example, in Michell, 2004, Hyde et al, 1992, p 25-37, TYMES Trust, 2003, Jason, 2000).

There is also evidence to show that key members of the 'Wessely School' are involved in denying benefits and pensions to ME/CFS sufferers. (e.g. Walker, 2003)

Uncritical acceptance of the psychiatric paradigm has led to the forced incarceration of ME/CFS children, against their own and their parents' wishes, and enforced exercise regimes and psychiatric treatment (Mar, 2001, TYMES Trust, 2003, Michell, 2004) There is also evidence of personal involvement of key proponents of the psychiatric paradigm in such treatment of ME/CFS child sufferers (Walker, 2003).

(c) They promote Cognitive Behavioural Therapy (CBT) in their literature, but frequently ignore the other available forms of psychological support strategies for ME/CFS sufferers (if needed). Indeed, they do not promote CBT as a support strategy, but as a 'cure' for ME/CFS, (a neurological illness) believing that the multi-system physiological abnormalities (manifesting as symptoms) can be improved to the point of 'recovery', merely by challenging the illness beliefs and behaviour of the sufferer. Their rationale for the use of CBT is as a 'cure' for a neurological illness that they do not even recognise, a position unheard of in regard to any other neurological or other organic illness.

(d) They fail to differentiate between the different forms of psychological problems that might (though not always) be faced by ME/CFS sufferers, implying ANY psychological problem is a CAUSE rather than EFFECT of the illness. This leads to a conspicuous lack of commitment to promoting ways of offering psychological and social support for the impact on quality of life caused by this chronic illness.

The contrasts between Stein's model of care, and the positions adopted and the actions taken by proponents of the psychiatric paradigm, demonstrates a failure of care of ME/CFS sufferers on the part of the latter, and this failure has specific adverse affects upon the health and welfare of such patients.

Effects of the Psychiatric Paradigm on ME/CFS sufferers

Documented iatrogenic effects, on patients, resulting from the Psychiatric Paradigm of ME/CFS, include:

1. Lack of medical investigation of physical abnormalities.
2. Lack of appropriate bio-medical treatment and support (Footnote 6)
3. Denial of benefits, insurance or pension payments to sufferers, even though the extent of their disabilities would, with regard to other organic illnesses, entitle such sufferers to these.
4. Hostility and/or lack of empathy from many in the medical profession, families, communities and society at large, who frequently believe that the illness is a result of social, mental and behavioural deviance.
5. Social Exclusion, and other material and social inequalities resulting from the above and from lack of social, welfare and financial support associated with the belief that this illness is a result of deviance.
6. Forced treatment of patients, including forced incarceration of both children and adults.

7. Continued distress at not having one's physical suffering and limitations believed.
8. Adverse impact on quality of life to such a degree that some ME/CFS sufferers have committed suicide. (Footnote 7)
9. Increased Post exertional malaise following Graded Exercise/Activity

Regimes, which have been reported as reducing functional ability levels and increasing symptom severity (see point 7 for references).

Conclusion

This document has provided only a brief summary of the psychiatric paradigm and the fundamental flaws to be found within. The range and depth of problems with this paradigm raises serious issues of validity and reliability.

A full discussion of the philosophical problem of how the mind and body is to be considered in medicine is outside the scope of this document. However, it is important to remember that assumptions around 'psychosomatic illness' promoted within the psychiatric paradigm have been heavily critiqued (for example, Webster, 1995), are unverifiable at present (Stein, 2004, Dalen, 2003), and may remain so indefinitely.

Crucially, the lack of clarity of concepts demonstrated within the psychiatric paradigm, the refusal to accept the problems with and lack of proof of their own speculative hypotheses, evidence that regularly disproves the psychiatric paradigm and, most importantly, their refusal to acknowledge the prejudicial judgements made about ME/CFS sufferers within the psychiatric paradigm and the iatrogenic suffering this has caused (and continues to), has rendered the theoretical position of this paradigm untenable.

As the proponents of this paradigm continue to promote such flawed concepts, within their own literature, and in advice to government and other parties, even though they have been made aware of these flaws and the critically adverse impact they have on ME/CFS sufferers, on many occasions, it is impossible to reach any conclusion other than that such continued actions represent a clear breach of medical ethics: primarily, a fundamental abrogation of duty to patients suffering from this disease.

In light of the considerable theoretical, methodological and ethical problems identified within the psychiatric paradigm, and the endangerment and disenfranchisement to ME/CFS sufferers these continue to cause, a review of all 'bio-psychosocial' approaches to ME/CFS adopted in health and social policies, globally, is necessary as a matter of urgency.

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18 January 2005

FOOTNOTES

1. See Marshall et al, 2001, for an account of this. Also see:

See Hansard:

<http://www.publications.parliament.uk/pa/ld199697/ldhansrd/pdvn/lds04/text/40311w05.htm>

Also see 'WHO Geneva Headquarters, classification information ME/CFS' Available on the One Click Website:

http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/

2. An indication of the extensive body of evidence supporting the recognition of ME/CFS as a neurological disease, in line with its classification as such by the WHO ICD-10, and the multi-systemic physiological abnormalities presenting as part of the disease can be found in documents and publications such as Montague and Hooper (2001) Marshall, Williams and Hooper (2001), Hyde et al (1992) Carruthers et al (2003) and the Journal of Chronic Fatigue Syndrome. It must be noted, however, that such references, and evidence, contained in these documents, are by no means exhaustive.

3. These themes, and others, have been identified as part of a research project into the writings of the psychiatric paradigm that I am currently undertaking (summarised in Kennedy, 2004), using social science research techniques of narrative, linguistic, textual and discourse analysis. I am currently writing up the results of this research, which will be available later this year.

4. Deviance is defined as being or doing outside cultural norms (Macionis and Plummer, 1997, p.208). Labels of deviance are not 'natural'; they are socially constructed, i.e. by the culture we live in. Crime is an example of 'deviance', though not all criminals are considered deviant (for example, those committing petty crimes such as using the telephone at work for personal calls). 'Deviance' usually involves moral value judgements of 'badness' (see footnote below) being applied to an act, or, more worryingly, a person. The extensive quotes collated in Hooper's and Williams' documents demonstrate a frequent categorisation of ME/CFS sufferers as being outside social norms in terms, not of having a disability, but of the frequent implication that their illness is the result of character flaws or morally inappropriate ('deviant') behaviour such as malingering or hypochondria (Kennedy 2004 (a)).

5. The term THYMIC CATEGORIES (Martin and Ringham, 2000) refers to the linguistic categorisation of subjects or objects as 'good' or 'bad', that can be identified when conducting discourse analysis on produced texts. Thymic categories are constructed by two poles of euphoria (good or pleasant feelings) and dysphoria (bad or unpleasant feelings), corresponding to evaluations of goodness or badness. Such characteristics are a feature of all discourses, including academic and medical. My concern in this respect regards the way in which observable dysphoric categories are frequently applied to the behaviour, thoughts, actions and characters of ME/CFS patients within the literature of proponents of the psychiatric paradigm, with a corresponding absence of euphoric categories. The observable, overall effect of such linguistic constructions is that of an author's consistent evaluation of ME/CFS patients and their feelings, beliefs, actions and characters as 'bad'.

6. For example, the proposed 'CFS/ME' centres in Britain will only provide CBT/GET 'treatments' as a matter of course, and there has been no evidence of provision of, for example, SPECT or other brains scans which have been shown to provide clear evidence of brain dysfunction in a high majority of ME/CFS patients (Hyde et al, 1992, Carruthers et al, 2003, Marshall et al, 2001). Nor is there any apparent system for referral to neurological, immunological or endocrinological specialists for either diagnosis or treatment of this neurological disease. See for example the 'Harrow and Hillingdon Bid', available on the One click Website: http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/

7. The Suicide Register was organised by Sheila Barry after her 27 year old daughter, an ME/CFS sufferer, committed suicide (See Walker, 2003: vii).

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2. Information Provided From The World Health Organisation Headquarters, Geneva. Classification Principles provided by the World Health Organisation re ME/CFS

Available on The One Click Group website at:

http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/WHO%20Geneva%20Headquarters,%20Classification%20Information,%20%20ME%20-CFS.doc

On 28th June 2001 Andre L'Hours, the Technical Officer at the WHO headquarters in Geneva who is responsible for the ICD, confirmed that it was "unacceptable" if the same disorder had been included in two places in the ICD-10 and that the same disorder could not be differently categorised under the one WHO banner. When he was informed of what was happening in the UK, he promised to look into the matter.

Andre l'Hours confirmed that the ICD classifications are approved by the World Health Assembly and therefore take legal precedence over unapproved modifications made by a WHO Collaborating Centre.

On 16th October 2001, Dr B Saraceno from the WHO provided the following clarification in writing:

"I wish to clarify the situation regarding the classification of neurasthenia, fatigue syndrome, post-viral fatigue syndrome and benign myalgic encephalomyelitis. Let me state clearly that the World Health Organisation (WHO) has not changed its position on these disorders since the publication of the International Classification of Diseases, 10th Edition in 1992 and versions of it during later years.

"Post-viral fatigue syndrome remains under the diseases of nervous system as G93.3. Benign myalgic encephalomyelitis is included within this category.

"Neurasthenia remains under mental and behavioural disorders as F48.0 and fatigue syndrome (note: not THE CHRONIC FATIGUE SYNDROME) is included within this category. However, post-viral fatigue syndrome is explicitly excluded from F48.0.

"The WHO ICD-10 Diagnostic and Management Guidelines for Mental Disorders in Primary Care, 1996, includes fatigue syndrome under neurasthenia (F48.0) but does not state or imply that conditions belonging to G93.3 should be included here.

"I would also like to state that the WHO's position concerning this is reflected in its publications and electronic material, including websites.

"It is possible that one of the several WHO Collaborating Centres in the United Kingdom presented a view that is at variance with WHO's position.

"Collaborating Centres are not obliged to seek approval from WHO for the material they publish. I understand that the Collaborating Centre concerned has now made changes to the information on their website after speaking with WHO".

In the debate on ME/CFS in the House of Lords on 22nd January 2004, the Health Minister (Lord Warner) stated:

"The current version, ICD-10, classifies CFS in two places: as neurasthenia in the mental health chapter, F48.0; and also as myalgic encephalomyelitis in the neurology chapter, G93.3. The diagnostic criteria used in the ICD shows that the WHO has essentially put the same condition in both places. That is the WHO's formal position".

Following his speech (recorded in Hansard at column 1195), a copy of this letter was given to the Health Minister by the Countess of Mar; Lord Warner said that he would take it to the Chief Medical Officer to be discussed.

On 23rd January 2004, Andre l'Hours from the WHO headquarters provided the following clarification (in writing):

"This is to confirm that according to the taxonomic principles governing the Tenth Revision of the World Health Organization's International Statistical Classification of Diseases and Related Health Problems (ICD-10), it is not permitted for the same condition to be classified to more than one rubric as this would mean that the individual categories and subcategories were no longer mutually exclusive".

Andre l'Hours also stated that if a country accepts the WHO Regulations concerning nomenclature (which the UK does), then that country is obliged to accept the ICD classification. For the avoidance of doubt, the UK has registered no reservations about the ICD-10 and therefore formally accepts it.

4. One Click Submission to NICE – Stakeholder Comments.

Available on The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/NICE/One%20Click%20Stakeholder%20Comments.doc>

5. One Click Submission to NICE - Systematic Literature Review.

Available on The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/NICE/One%20Click%20Literature%20Review%20Response%20to%20NICE.doc>

6. One Click Submission to NICE – Subset Questionnaire Correspondence.

<http://www.theoneclickgroup.co.uk/documents/NICE/NICE%20Questionnaire%20Correspondence.doc>

7. The Lord Campbell of Alloway QC - Legal Opinion for The Countess Of Mar – 6th April 2000. Available on The One Click Group website at:

http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/Lord%20Campbell%20of%20Alloway%20Legal%20Opinion.%20ME%20CFS.doc

TRANSCRIPT OF LORD CAMPBELL OF ALLOWAY’S LEGAL OPINION FOR THE COUNTESS OF MAR – 6th April 2000

1. On the document you have sent me there is an overwhelming case for the setting up of an immediate independent investigation as to whether the nature, cause and treatment of ME as considered by The Wessely School is acceptable or consistent with good and safe medical practice.
2. There is substantial doubt as to whether such could be the case in view of the clear division of medical opinion.
3. A formal request should be made to the GMC to set up such an enquiry, at which evidence should be adduced and interested parties (if so advised) could be represented by Counsel. It is all but essential that a reputable firm of solicitors should be instructed to make such request and as suggested an approach to Lord Mishcon would be well advised.
4. (No paragraph 4 – enumeration goes straight on to point 5)
5. The document and a copy of this opinion should be sent to the NHS by the good offices of Lord Hunt of Kingsheath with whom informal contact should be made and it could well be that the Department would wish to send an observer to the enquiry and (if so advised) participate.
6. Before tendering definitive advice a copy of all rules and regulations of the GMC governing the maintenance of standards of medical practice and the setting up of such an enquiry would be required. The solicitor would no doubt attend to this before any formal request were to be made as advised.
7. On the basis of such information, if the formal request were to be refused it could be possible to seek (? defamatory) relief against the GMC but on this at this stage no advice can be tendered.
8. It is of course open to patients, their parents, their guardians, their next of kin to seek Judicial Review of any proposed treatment on the facts and circumstances of a particular case. On this I am not asked to advise.

9. This opinion is written 'pro bono' for the Countess of Mar at her request and not on the instructions of a solicitor.

**Campbell of Alloway
(The Lord Campbell of Alloway QC)
2, Kings Bench Walk, Temple, London EC4Y 7DE
6th April 2000**

APPENDIX 2 – ME/CFS, Lyme Disease/Borreliosis

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~~2. Letters/Case Histories From Patients~~

~~—2.1 Katrina Anderson~~

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3. The LTT-MELISA Test

A novel lymphocyte transformation test (LTT-MELISA®) for Lyme borreliosis, E. Valentine-Thon et al, Diagnostic Microbiology and Infectious Disease doi:10.1016/j.diagmicrobio.2006.06.008.

The One Click Group has received so many communications and we thank our participants for this. We regretfully cannot publish them all due to number, so have attempted to incorporate the contents in the body of this document.

We have countless numbers of Case Histories on file that can be obtained by request.

1. BADA-UK STATEMENT, Lyme Disease/Borreliosis and ME/CFS.

Available on The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/Borreliosis/BADA%20Ho-Yen%20Statement.pdf>

10 October 2006

BADA-UK

Borreliosis & Associated Diseases Awareness

Registered Charity 1113329

www.bada-uk.org

10 October 2006

STATEMENT FROM BADA-UK

Providing the facts in relation to the Dr Darrel Ho-Yen article entitled [Lyme Disease - let's dispel the myths](#), published by the UK ME/CFS Myalgic 'Encephalopathy' Association charity magazine, ME Essential.

Whilst Dr Ho-Yen is quite correct in his assertion that Lyme disease accounts for only a small percentage of those misdiagnosed as having ME/CFS, this in itself does not discount the possibility of one, or several, tick-borne diseases being the cause of a patient's ill health. For as indicated by Dr Ho-Yen, ME could be caused by quite literally hundreds of different viruses and bacteria, and it need not only be one infection to blame. Yet without more detailed and comprehensive medical studies, taking into account the exact nature of all bacterial/viral infections present in those diagnosed as having ME/CFS, the role of Lyme disease as a contributing factor cannot be excluded.

Lyme disease, in the strict sense, is predominantly an American infection, brought

about by a spirochaetal infection known as *Borrelia Burgdorferi sensu stricto* (Bb.ss). In the UK, and throughout Europe, *Borrelia Burgdorferi sensu lato* (Bb.sl) is more prevalent such as *Borrelia garinii*, *Borrelia afzelii* and *Borrelia valaisiana* to name but a few.

To complicate diagnosis further, it is also accepted that for each recognised strain of *Borrelia*, there are quite literally hundreds of sub-species of strain still to be investigated to any degree by modern science.

What is also recognised by the scientific establishment is the many ways in which *Borrelia* is able to evade or suppress the human immune system. One method for example is *Borrelia*'s ability to change its physical form from the worm like spirochaete, to small cyst like structures able to situate themselves within selected and sequestered sites throughout the human anatomy. *Borrelia* is also known to hide within the immune system cells themselves using the cell membrane as a cloaking device, thus enabling it to evade the production of antibodies. However, the standard form of testing carried out in the UK involves the need for antibodies to be present in blood samples drawn, yet as indicated above, *Borrelia* need not necessarily be found in the blood of a patient, but can still be present within their system.

Furthermore, in the published paper 'Audit of the laboratory diagnosis of Lyme disease in Scotland' by Dr. Ho-Yen et al, it was noted 'When the revised scoring system was applied retrospectively (April 2003 to March 2004), 39 (33 %) of the 116 serum samples previously negative or equivocal became weak positive or stronger.' Therefore, surely it would be incumbent upon Dr. Ho-Yen to review all 500 patients over the past 10 years using this revised scoring system, to more accurately reflect those for whom Lyme disease could be a contributing factor?

The current 'two-tier' blood testing procedure, as designed and patented by the American Centres for Disease Control and Prevention (CDC), was never intended for use as a diagnostic technique in individuals. Its intended purpose was for the epidemiological study of the infection amongst the American population. As such, the qualifying biomedical requirements were set artificially high, to exclude other medical conditions. With the highly advanced abilities of *Borrelia* to evade detection by the human immune system, along with the restrictive nature of the current two-tier blood testing procedure used as a diagnostic test in the UK and throughout Europe, it is not possible to conclusively exclude the role of *Borrelia* in a patient's ill-health. And indeed, in America, Public Law 107-116 was signed by President Bush in 2002, in an attempt to cease the misuse of what was intended as surveillance case definition being used as a diagnostic tool.

(See <http://www.lyme.org/legislative/publaw107116.html> for full details of Public Law 107-116)

Currently in the UK and Europe positive serological evidence of infection is still required to confirm the 'clinical' diagnosis of Lyme disease. Yet according to EUCALB (European Union Concerted Action on Lyme Borreliosis) 'A minimum standard of at least 90% specificity for the screening tests and 95% specificity for the immunoblot should be established in the population where the assay is to be used.' Without positive serology following an initial screening test, no further immunoblot testing will be undertaken, yet neither provide 100% reliable results.

The recognition by Dr. Ho-Yen of *Borrelia* to be misdiagnosed as ME/CFS in 5% of his patients should be heeded very carefully by the ME/CFS community as a whole, for 5% of the estimated 240,000 patients diagnosed as having ME/CFS equals 12,000 possibly misdiagnosed Borreliosis patients. It also justifies the perceived link between those currently diagnosed as having ME/CFS, yet questioning Lyme disease, along with all other tick-borne infections, as an alternative diagnosis.

Further justification is also demonstrated by those who have gone on to improve and

recover their health following a misdiagnosis of ME/CFS, having experienced no benefits from the psychological intervention offered by means of Graded Exercise Therapy and Cognitive Behavioural Therapy (GET/CBT), which have in themselves proven to be harmful to some diagnosed as having ME/CFS. It has also been demonstrated that the more prolonged intervening period between infection to commencement of treatment, correlates directly to the duration of treatment required to eradicate a chronic, late stage infection. To discount the effectiveness of any antibiotic treatment regime, purely on the basis that an extended course of treatment is required, is contrary to all that is known about the treatment of Tuberculosis, for example, or a chronic infection of Syphilis, which is another spirochaetal infection.

Whilst it is true that the Highlands is by far more heavily populated by ticks, in comparison to those living in more urban areas, infected ticks have been found in areas such as Richmond and Bushy Park in London. Additionally, infected ticks have been found in other areas throughout the UK such as Exmoor, the New Forest, the South Downs, parts of Wiltshire and Berkshire, Thetford Forest, the Lake District and the Yorkshire moors. How many patients, that have been diagnosed with ME/CFS, have visited the countryside, or even a city centre park for a picnic, have been involved in outdoor sports or had close contact with animals and wildlife in general, and been bitten unknowingly by an infected tick? Contrary to the majority of published medical guidance on the diagnosis of Lyme disease, which state that a patient will experience a 'characteristic rash', it is well documented that as few as 40% of people, positively diagnosed, recall any visible rash. It is also known that there are specific strains of Borrelia infection which are less likely to produce any Erythema migrans (EM) rash.

Ticks within the UK are also known to be capable of passing on more than one bacterial infection following a single bite. Bartonella, Babesiosis and Ehrlichiosis are co-infections found within UK ticks. Yet testing for co-infections is not undertaken as a matter of course for any patient attending their GP's surgery following a known tick bite, and not discussed in the original article written by Dr. Ho-Yen.

A great many patients have taken responsibility for their own health concerns, whilst the global medical establishment argues over whose guidelines and criteria are most appropriate. The various published ME/CFS diagnostic criteria currently require that any bacterial/viral infections are excluded as a possible cause of a patient's ill-health, before a diagnosis of ME/CFS can be given. Sadly, to date, there is no conclusive testing procedure available to doctors that can conclusively rule out the role of Borrelia, or co-infections, in a patient experiencing symptoms of ME/CFS. As such, many patients have been required to take it upon themselves to fund private treatment in order to exclude the possible role of a bacterial/viral infection being to blame for their chronic ill-health, and as a result, many have regained their health following treatment for infection. If only this same approach were to be taken by those charged with improving patient's health. Yet it is the case that once diagnosed as having ME/CFS any further physical examinations are deemed as unwarranted, according to the guidelines Dr. Ho-Yen believes should be adhered to by those diagnosed as having ME/CFS.

- ends -

**To learn more about Lyme Disease/Borreliosis, please visit [BADA-UK](#)
Registered Charity No. 1113329**

**For further information on the links between Lyme Disease/Borreliosis
and ME/CFS, click [here](#)**

EXPUNGED BY NICE > >>

2. Letters from Patients/Case Histories

We have many Case Histories available from patients. Further Case Histories and letters are available upon request. In this Appendix we provide but a few verbatim examples.

2.1 From Katrina Anderson

26 October 2006

EXPUNGED BY NICE IN ITS ENTIRETY > >>

To Whom It May Concern

I was bitten by a tick in 1991 and shortly thereafter my health began to deteriorate. I attended my GP's surgery, described my symptoms of pain and fatigue, whilst at the same time pointing out a small hole in at the top of my left leg which I now know to be the tick bite.

The GP knew nothing of tick-borne infections, and as a result, for the next two years I underwent a barrage of tests by the NHS to rule out other known medical conditions. Throughout this two-year period I was given a variety of diagnoses such as palindromic rheumatism and Myalgic Encephalomyelitis (ME), all of which I knew did not fully explain my symptoms. After two years of inconclusive testing I eventually began to doubt my own sanity and asked to be referred to a psychiatrist.

This shocked my GP into renewed efforts to try and understand the cause of my illness, and out of desperation, as apposed to inspiration, he referred me to the Regional Infectious Disease (ID) Unit at my local hospital.

I was very quickly, and luckily, diagnosed with a positive Lyme disease blood test. I say luckily as the form of testing offered within this country is woefully inadequate, and the majority of the medical professions understanding of such infections is even less well founded. The feeling of relief that I felt at that time was incredible, I finally had a reason for my ill health, I wasn't just imagining it.

Had only my GP been better informed of the effects of tick-borne diseases the NHS would not have been required to finance such a prolonged, and expensive, process of elimination.

Today, it would seem that a great majority of the medical profession still remain ignorant to the effects of all tick-borne infections, and the testing for such infections is still woefully inadequate. Yet it would seem that this is of no consequence to NICE, who without a shred of scientific evidence or reasoning, have deemed it appropriate, and cost efficient, to deny such testing to all ME/CFS patients.

Had this illogical and unfounded edict been in place when I first fell ill I dread to think what cost this would have had on my personal health? I would still be suffering under the management of my physical symptoms with treatment regimes such as GET & CBT, and getting nowhere fast, instead of returning to work and being a contributory member of society, as all those with ME/CFS wish to be.

The World Health Organisation recognise ME/CFS to be an illness of bacterial/viral origin. Dr. Ho-Yen recognises that even with such unreliable blood tests as those that are available today, 5% of patients referred to him as having ME/CFS test positive for Lyme disease/Borreliosis.

The majority of patients diagnosed as having ME/CFS have most likely never been offered testing for tick-borne infections, either in the six month period leading up to their diagnosis of ME/CFS, or at any time thereafter.

These new NICE guidelines will ensure that they never do, and are more representative of clinical exclusion, rather than clinical excellence.

Katrina Anderson

2.2 From Nigel Hall, Sheffield

30 October 2006

EXPUNGED BY NICE IN ITS ENTIRETY > >>

After struggling with extreme exhaustion, chronic back pain and frequent migraines for about three years, I was diagnosed with CFS in 1998. My GP was unable to recommend any treatment except anti-depressants which I have now been taking for several years. I did have an (inadequate) NHS test for Lyme Disease, but the result was negative.

However following a private test for Lyme Disease two years ago I was diagnosed with Chronic Borreliosis. Although at the time my GP seemed willing to go along with this diagnosis, he has since withdrawn his co-operation by refusing to prescribe the drugs recommended by my private specialist.

I cannot afford to fund private prescriptions, and therefore I have become resigned to leading a life severely restricted by my constant battle with pain and fatigue. I am now 56 and, unless the NHS is prepared to abide by its duty of care to me, I do not expect to be able to work again.

Despite my problems I always try to stay positive, too much so as I often suffer the delayed consequences of failing to strictly pace myself. CBT would therefore be of no benefit to me, and GET could make my condition considerably worse by forcing me to function outside my tried and tested limits.

ME/CFS is a neurological condition which urgently needs bio-medical research and treatment, and most definitely *not* psychological intervention. Therefore this appalling decision by NICE amounts to a life sentence of suffering for the 260,000 or so people who have ME or CFS. It is a disgrace.

**Nigel Hall
Sheffield**

2.3 From Peter Kemp 9 October 2006

EXPUNGED BY NICE IN ITS ENTIRETY > >>

COMMENT

In their Draught Guidelines for ME/CFS the National Institute for Health and Clinical Excellence (NICE) have stated: [\[0\]](#)

1.2.2.3 The following tests should not be done routinely.
• Serology testing for chronic bacterial infections (for example, borreliosis)[\[sic\]](#) in the absence of any indicative history.

What is meant by 'indicative history'? If they mean patients with a history of the symptoms of borreliosis then it would seem that many people who are, or could be diagnosed with ME/CFS have a long and convincing 'indicative history'. They would therefore require testing for the bacteria.

Borreliosis is difficult to diagnose[\[23\]\[24\]\[27a\]](#) and can be mistaken for other conditions.[\[3a\]\[25\]](#) The symptoms of ME/CFS, and borreliosis appear the same in many respects.[\[15\]\[16\]\[17\]\[18\]](#) I imagine it is for this reason that the famous microbiologist, Dr. Ho-Yen[\[14\]](#) routinely tests all his patients with ME/CFS for Lyme disease (borreliosis caused by certain strains of the bacteria).[\[20\]](#)

Perhaps 'indicative history' means an erythema migrans rash? The rash is thought by some to occur in only around 50% to 80% of people with Lyme disease[\[1\]\[2\]\[3\]\[29\]](#) and is often so indistinct that it is easily overlooked or mistaken for something else.[\[4\]\[19\]](#) The Health Protection Agency (HPA) state that 42% reported an erythema migrans rash.[\[10a\]](#) The National Guidelines Clearinghouse observe; 'The EM rash may be absent in over 50% of Lyme disease cases.'[\[29\]](#)

Could NICE mean that people who were bitten by a tick have an 'indicative history'? Many people with Lyme disease do not recall being bitten by a tick.[\[5\]\[6\]\[7\]\[8\]\[9\]](#) The HPA figures show that only 55% reported a tick bite.[\[10a\]](#)

Maybe 'indicative history' means people who have been somewhere where Lyme disease is known to be endemic? In England and Wales Lyme disease is not a notifiable illness,[\[10\]](#) so nobody actually knows where it is endemic. The Health Protection Agency receive voluntary reports of borreliosis cases, which their estimates suggest might be around 22% to 36% of the total number of annual cases.[\[10\]](#) The HPA state, 'Cases have been reported from most counties in England and Wales'.[\[10\]](#)

Maybe 'indicative history' means people who have been somewhere where the tick *Ixodes Ricinus* (a common vector for borreliosis in the UK) are known to occur. An HPA map of "'Known" Distribution of *Ixodes ricinus* ticks', shows the tick to occur in most counties in England and Wales.[\[10b\]](#) Neither are the ticks confined to the countryside, NHS Direct note; 'they can also be found in some parks'.[\[27\]](#)

How many doctors in England and Wales will know what an 'indicative history' of borreliosis is? My GP was quite frank about never having heard of borrelia or

Lyme disease. The Benefits Agency doctor I saw a few weeks ago was equally innocent of any knowledge of the disease. The consultant microbiologist my GP referred me to some months ago had heard of Lyme disease but admitted that he knew nothing about it. Perhaps the 'absence of any indicative history' refers to doctors, not their patients.

NHS Direct remark on Lyme disease; (after erythema migrans rash) 'Other common symptoms with early Lyme disease include tiredness, headache, joint pains, and flu-like symptoms'.[\[27\]](#) All of these symptoms are also very common in ME/CFS. The symptoms of the two illnesses are so similar that I find it easy to conceive that in the 'absence of any indicative history', persons with borreliosis could be misdiagnosed with ME/CFS.

My impression is that 'Indicative history' in relation to borreliosis is a misleading phrase that should not be used in the NICE guideline without qualification and a full explanation taking into account the authoritative references provided

17 years ago I was diagnosed with M.E. This year I had the 2 stage, ELISA / Western Blot blood test for borreliosis. It was negative. This was no great surprise as the unreliability of these tests have been noted.[\[3a\]](#) The National Guidelines Clearinghouse observe; [\[29\]](#)

The two-tier diagnostic criteria, requiring both a positive enzyme-linked immunosorbent assay (ELISA) and western blot, lacks sensitivity and leaves a significant number of individuals with Lyme disease undiagnosed and untreated.

In a study of 90 patients, Tylewska-Wierzbanowska and Chmielewski concluded that: [\[28\]](#)

There is no correlation between the level of antibodies (ELISA), the number of protein bands (Western blot) and the presence of spirochetes in body fluids (culture and PCR), indicating that in addition to serological testing the use of PCR and cultivation in the diagnosis of Lyme borreliosis should be recommended.

Using my own microscope I have been able to see and film borrelia bacteria in a tiny periferal blood drop (see [\[26\]](#)). I find it very painful to think that a few weeks of antibiotics at the beginning of the illness might have saved me from 17 years of hell. I do not blame anyone for failing to diagnose me. I do not doubt the dedication and skill of the doctors that investigated me when I was first ill. Borreliosis was simply not thought of back then.

Things are somewhat different now. A great deal of research has provided a broad knowledge base for borreliosis and other tick-borne infections. It is perhaps, understandable that some doctors are still unfamiliar with borreliosis as this disease has not yet been brought to their attention. A major institution such as NICE should not require such latitude and might be expected to avail themselves of the latest information before referring to borreliosis in their draught guideline for ME/CFS. NICE might also consider it part of their duty to make doctors aware of this disease that can so easily be mistaken for ME/CFS.

NICE guidelines carry weight. If the current draught comes into force without modification the consequences could be terrible for many unfortunate people. NICE state that; 'Once NICE publishes clinical guidance, health professionals and the organization that employ them are expected to take it fully into account when deciding what treatments to give people.'[\[13\]](#) and; 'In general, doctors, nurses

and other healthcare professionals in the NHS are expected to follow NICE's clinical guidelines.'[\[12\]](#)

How many people diagnosed with ME/CFS actually have borreliosis? How many people face years, decades or perhaps the whole remainder of their life doomed to suffering and loss because they have a bacterial infection? An infection that NICE propose discouraging doctors from testing for, even when their patients have clearly indicative symptoms.

Bacteria have been visible to microscopy since the 1680's.[\[11\]](#) With a little practice, the right equipment and a suitable technique; seeing borrelia with a microscope is not difficult or time consuming. It is a method that might usefully supplement serological testing and other diagnostic means to identify borreliosis.

Two major research projects conducted for the U.S. Centers for Disease Control by Fukuda *et al*[\[21\]](#) and Reeves *et al*,[\[22\]](#) make it clear that a significant challenge to the progress of research, diagnosis and treatment of ME/CFS is identifying exclusionary illnesses and defining subgroups. NICE have the opportunity to make a valuable contribution to this field by recommending a broad approach (symptoms, serology, microscopy) for identifying borreliosis in people who could be misdiagnosed with ME/CFS.

Peter Kemp MA
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3. The LTT-MELISA® Test

A novel lymphocyte transformation test (LTT-MELISA®) for Lyme borreliosis, E. Valentine-Thon et al, Diagnostic Microbiology and Infectious Disease doi:10.1016/j.diagmicrobio.2006.06.008.

Abstract

Diagnosis of active Lyme borreliosis (LB) remains a challenge in clinically ambiguous, serologically indeterminate, and polymerase chain reaction-negative patients. Lymphocyte transformation tests (LTTs) have been applied to detect specific cellular immune reactivity, but their clinical application has been severely hampered by the poorly defined *Borrelia* antigens and nonstandardized LTT formats used. In this study, we describe the development and clinical relevance of a novel LTT using a validated format (MELISA®) together with well-defined recombinant *Borrelia*-specific antigens. From an initial screening of 244 patients with suspected *Borrelia* infection or disease, 4 informative recombinant antigens were selected: OspC (*Borrelia afzelii*), p41-1 (*Borrelia garinii*), p41-2 (*B. afzelii*), and p100 (*B. afzelii*). Thereafter, 30 seronegative healthy controls were tested in LTT-MELISA® to determine specificity, 68 patients were tested in parallel to determine reproducibility, and 54 lymphocyte-reactive symptomatic patients were tested before and after antibiotic therapy to assess clinical relevance. Most (86.2%) of the 36.9% (90/244) LTT-MELISA®-positive patients were seropositive and showed symptoms of active LB. Specificity was 96.7% and reproducibility 92.6%. After therapy, most patients (90.7%) showed negative or markedly reduced lymphocyte reactivity correlating with clinical improvement. This novel LTT-MELISA® assay appears to correlate with active LB and may have diagnostic relevance in confirming LB in clinically and serologically ambiguous cases.

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The full text of this paper is available on The One Click Group website at:

<http://www.theoneclickgroup.co.uk/documents/Borreliosis/The%20LTT-MELISA%20Test%20For%20Lyme%20Borreliosis.pdf>