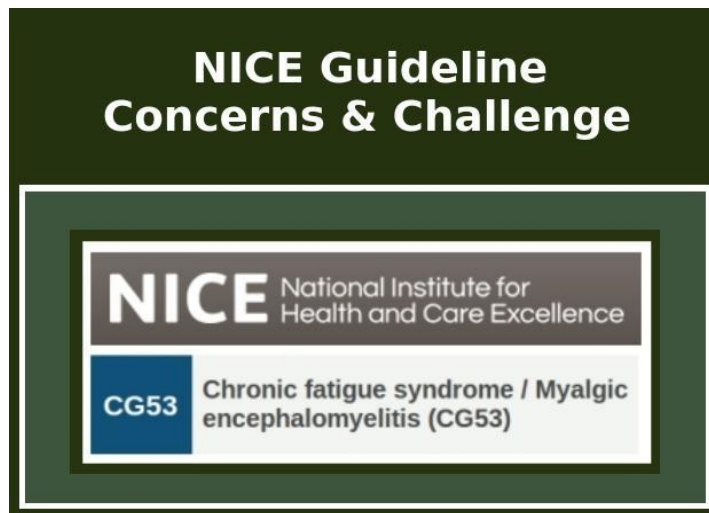


<http://angliameaction.org.uk/NICEJRdocs/NICE-JR-frontpage.pdf>

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NICE CG53 - 2009 Judicial Review Documents

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1. Introduction:

The NICE Guideline on CFS/ME (CG53)

In its First Report of Session 2007-2008, the House of Commons Health Select Committee was clear: “*NICE should not recommend interventions when the evidence is weak*” (Volume I:29) but that is exactly what NICE did in its Clinical Guideline on “CFS/ME” (CG53).

In alleged support of the PACE trial and prior to selective results being published in February 2011, the MRC conceded about CBT/GET that: “*there was a lack of high quality evidence to inform treatment of CFS/ME and in particular on the need to evaluate treatments that were already in use and for which there was insufficiently strong evidence from random controlled trials of their effectiveness*” (Dr Frances Rawle, Head of Corporate Governance and Policy, 6th January 2011).

That is a astonishing admission, since the NICE Clinical Guideline on “CFS/ME” of 22nd August 2007 relied upon the pre-PACE Wessely School “evidence-base” to recommend the use of CBT and GET nationally as the intervention of choice, yet the MRC confirmed – in writing -- that there was insufficient evidence for the implementation of this nationwide programme of CBT and GET recommended by NICE in its Clinical Guideline, so NICE jumped the gun by four years.

The draft NICE Guideline

The same scenario of “policy compliance” as existed in the RAG pertained throughout the public consultation process and production of the NICE Guideline on “CFS/ME” (CG53), but to a far greater and more sinister degree:

- A “policy decision” was taken by NICE not to consider any biomedical evidence that disproved the psychosocial model. The NICE Guideline Development Group (GDG) was specifically instructed not to consider the totality of the published evidence on ME.
- GDG members who would support “policy” were carefully chosen, and there was not a single medical expert on ME/CFS on the GDG (an unheard-of situation in the production of other NICE Guidelines, where GDGs are replete with experts in the disease in question). ME/CFS experts who requested to be on the GDG were dismissively brushed aside, and even the application of the

Medical Advisor to the ME Association to be a member of the GDG was refused.

- GDG members included doctors who work for the permanent health insurance industry (PHI) and who had a long track record of refusing legitimate claims by asserting that “CFS/ME” is a behavioural (mental) disorder and thus excluded from benefit; one such GDG member, Dr William Hamilton, had spent 15 years working for insurance companies and during production of the NICE Guideline on “CFS” was Chief Medical Officer for at least three such companies including Exeter Friendly Society, Friends Provident and Liverpool Victoria Friendly Society. Further, Hamilton had been funded by the Linbury Trust for his work on “CFS/ME” (£58,992 to collaborate with Peter White).

- One GDG member was paediatrician Dr Esther Crawley, a committed Wessely School supporter who was subsequently proven to exaggerate the success of the PACE trial, publishing a paper in which she claimed a success rate of up to 40% (when challenged, she was unable to provide any evidence for her claim).

- Another GDG member was an Occupational Health physician, Dr Julia Smedley, who confirmed in writing that: “*I do not treat patients with CFS/ME*”. Why was Dr Smedley even considered for the GDG? She clearly had no day-to-day experience of the disorder under discussion (a stated requirement for election to the GDG).

- Other GDG members included a dietician and a reflexologist/hypnotherapist, who were chosen in preference to dedicated medical practitioners who had devoted their whole career to the disorder.

- It was confirmed that advisors to the GDG included Simon Wessely, Peter White and Michael Sharpe.

- The Questionnaire sent out for public consultation contained a serious “misprint” relating to questions 29-61 (out of a total of 90 questions), making a nonsense of responses to those questions and meaning that over one third of answers would be likely to achieve results that respondents did not intend but which would support the pre-determined outcome.

- The GDG relied on the York Systematic Review of the CBT/GET literature, which was shown to be flawed (see: “Inadequacy of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base: Comments on

Section 3 of ‘The diagnosis and management of CFS/ME in adults and children: Work to support the NICE Guidelines’ ” by Professor Malcolm Hooper and Horace Reid, January 2006 – this academic review exposed the ineffectiveness of CBT and the potential dangers of GET as recorded by international researchers from the US, Canada, Australia and New Zealand).

- Patients’ own evidence was ignored, which perpetrated and even sanctioned the culture of contempt surrounding CFS/ME; this was embedded in the GDG’s decision not to accept CFS/ME as a physical disorder (which was in defiance of the WHO international classification of ME/CFS as a neurological disorder) and GDG members even went so far as to state that if a patient displayed abnormal neurological or cardiovascular features, they did not have “CFS/ME”.

- The draft Report stated categorically that “*some will recover fully*” and that “*there are no objective abnormalities*”.

- “CFS/ME” was portrayed as a somatisation disorder and the advice was that “*the concept of CFS (should be considered) through a biopsychosocial model*”, even though ME/CFS is a formally classified nosological entity that is organic, not psychosocial, in aetiology and nature.

- Of particular concern was that the draft NICE Guideline stated: “*Terminology used by doctors such as ‘functional syndrome’ and ‘medically unexplained symptoms’ are part of common usage in clinical practice today*”, thereby sending out the clear message that any doctor who did not subscribe to this would run the risk of being ridiculed by his/her peers and might even face sanctions.

- As anticipated, the draft Guideline effectively proscribed laboratory testing and focused only on CBT/GET as the interventions of choice.

- There were important technical anomalies in the draft Guideline, including the GDG’s failure to comply with the AGREE Instrument (Appraisal of Guideline Research and Evaluation Instrument), especially GDG members’ failure to declare any conflicts of interest; the GDG’s failure to describe precisely the patients to whom the Guideline was meant to apply, and the GDG’s absolute failure to include individuals from all relevant professional groups (the AGREE Instrument requires that NICE was obliged to give equal weight to three main sources of data: random controlled trials; the opinion and experience of physicians with expertise in the area, and the opinion and experience of the patient group for whom the Guideline is intended).

In its response to the draft Guideline, the ME Association said they were unwilling to endorse it; that it contained numerous recommendations which were based on opinion rather than on evidence-based medicine which normally dominates a NICE guideline, and that it was not fit for purpose: *“We find it hard to imagine another situation where a group of people, many of whom have little or no direct experience in the clinical care of an illness they are advising on, have produced such a poor quality guideline”*.

Also commenting on the NICE draft Guideline, in his Stakeholder Comments on 26th November 2006 Dr Neil Abbot, Director of Operations at the charity ME Research UK (MERUK) said: *“The draft produced by the GDG is unsafe and unsatisfactory because it does not engage with key issues involved in the diagnosis and management of ME/CFS....It would be preferable for NICE and the GDG to recognise that...evidence-based recommendations for treatment cannot be made at present than to incorporate an inadequate evidence base into...guidelines which feed into clinical care and government policy to the detriment of people with ME/CFS”*.

Many other Stakeholders submitted cogent criticisms (for more details, see *“Corporate Collusion?”* by Malcolm Hooper, Eileen Marshall and Margaret Williams, September 2007).

The finalised NICE Guideline on “CFS/ME”

In contravention of usual practice, GDG members did not declare their competing interests until two months after the final Guideline was published.

The final Guideline was like the proverbial Curate’s egg: good in parts. It was clear that, to its credit, the Guideline Development Group took heed of many submitted representations but that the Wessely School retained control of the recommended management strategies, although to nothing like the extent they sought, and that even those management strategies (CBT and GET) were modified from those previously employed by the Wessely School (which sought to force patients to change their beliefs and accept that they were not suffering from a physical disorder, about which Dr Ellie Stein – herself a psychiatrist -- said at the ME Research UK International Conference in Edinburgh on 25th May 2007: *“I would never in my practice use the Wessely model of CBT – I find it disrespectful to try to convince somebody they don’t have an illness they clearly have”*).

However, reference was still made to “*unhelpful beliefs*”, to “*the relationship between thoughts, feelings, behaviours and symptoms and the distinction between causal and perpetuating factors*” and to the fact that CBT would include “*identifying perpetuating factors that may maintain CFS/ME symptoms*” and would address “*any over-vigilance to symptoms*”.

Research that indicates potential dangers of the recommended management regime was ignored and there was continued dismay that NICE again highlighted CBT and GET as the most effective forms of treatment.

Note: despite all the biomedical evidence contained in the above documents and the compelling scientific evidence that continues to mount since they were written, NICE has still got CFS/ME listed under mental health/behavioural conditions:

<http://www.nice.org.uk/guidance/CG53/chapter/1-Guidance>

The Judicial Review of the NICE Guideline on “CFS/ME”

The process of bringing a Judicial Review (JR) is costly and complex. Permission to bring a JR has to be sought and obtained from the High Court, which in itself is a significant hurdle. Obtaining bullet-proof evidence to withstand rigorous legal scrutiny is just the start. Finding suitably interested, competent and committed lawyers to act for Claimants who are effectively challenging a Department of State is a Herculean task. Ensuring that those lawyers are fully briefed and that they understand every aspect of the case is an almost insurmountable undertaking before the case even gets to Court. When the topic is ME/CFS, it is virtually impossible. However, after an inordinate amount of effort by many people, in 2008 Legal Aid was granted for this to proceed.

Reasons for a JR of the NICE Guideline included what has been addressed above in relation to the NICE Guideline on CFS/ME, especially:

- NICE’s failure to identify the disorder to which its Guideline purported to apply
- The GDG’s refusal to accept the WHO classification of ME/CFS as a neurological disorder, which under NICE’s own protocol is mandatory in the UK. NICE’s Progress Report No. 8 dated 18th September 2002 from NICE’s Communications Director Anne Toni Rodgers, which at the time was specifically drawn to the attention of NICE’s Board, is unequivocal:

“2.7.1 Institute Classification System

2.7.1.1. Following discussions with Department of Health and other national agencies the Institute has adopted a new classification system that will be applied Institute wide

2.7.1.3 The previous classification system was only used by the Institute

2.7.1.4 The ICD-10 classification has been used as the basis for the new Institute classification directed at the informed reader

2.7.1.5 The World Health Organisation (WHO) produces the classification and ICD-10 is the latest version. ICD-10 is used within the acute sector of the NHS and the classification codes are mandatory for use across England”.

- the GDG's failure of procedure: because the intention of a NICE Guideline is to influence clinicians (which immediately impacts on patients), there are rigorous criteria that must be observed in the production of a Guideline, but in the case of CG53 these were ignored

- NICE's fabricated statements about cost effectiveness of CBT/GET and there were also mathematical errors in NICE's figures and statistics; (NICE's statisticians transferred data from one study to another to achieve the figures it wanted: since even NICE could not procure non-existent evidence to support its recommendations for behavioural therapy, it decided to create its own evidence by transferring data from one study and inserting that data into a totally different study to produce what might have been the desired results if the study in question had run for five years instead of only fourteen months. The fact that the transplanted data came from a study that had used different entry criteria and whose own data had been corrupted (admitted by the authors themselves) seems not to have troubled the Institute for Clinical Excellence. Most straight-thinking people might regard such doctoring of the evidence as fraudulent

- the proscribing of testing and treatments that have been shown to help PWME

- the GDG's failure to consider the totality of the evidence, in particular, the biomedical evidence: it was charged with providing guidance on the diagnosis as well as the management of CFS/ME, so the literature which demonstrates clear biomedical pathology ought to have formed part of the GDG's literature review and not been specifically excluded from the GDG's remit (but of course

that evidence would have invalidated the behavioural research on which the use of CBT/GET was based so they had to ignore it)

- the potential dangers of the recommended interventions
- the rejection of patients' views and preferences
- the deliberate refusal to have a medical expert experienced in ME/CFS on the GDG as required
- the bias of certain GDG members
- the covert conflicts of interest of some GDG members
- the fact that some GDG members were voting on studies that they themselves had authored in support of the psychosocial model
- the GDG's ignoring of the documented signs and symptoms in ME/CFS and the demonstrated pathology of major body systems
- the GDG's ignoring of the existing evidence that CBT/GET are both ineffective and harmful (especially if inflammation is present)
- the fact that even before the GDG started work, a policy decision had been taken about the outcome
- the fact that NICE is funded by and accountable to the Department of Health, which formally accepts ME/CFS as a neurological disorder yet NICE's GDG refused to accept it as such, which is inconsistent.

The Application Hearing was heard on 17th June 2008 before The Honourable Mr Justice Cranston and was successful: the Approved Judgment stated:

"There is no doubt that ME is a debilitating condition and many of us will know of people who either have the condition, or who know of other people who have the condition.....Given that there is this obvious divide between the biomedical and psychosomatic approaches to ME, given the great public interest....it seems to me that this case ought to go forward for a full hearing".

The Full Hearing was held on 11th and 12th February 2009 before The Honourable Mr Justice Simon and it failed on all counts. Before he became a Judge, Peregrine Simon QC worked out of Brick Court, a leading set of chambers that acts for the insurance industry against claimants.

The Judgment was handed down on 13th March 2009. The Judge said that the Claimants' evidence was unconvincing, unreliable, unfounded and untrue, and

entirely without merit; the Claimants' contentions could not be sustained; their allegation that there was insufficient representation of the biomedical approach was misconceived; there was no conflict of interest among members of the GDG; no GDG member had a closed mind about ME/CFS and GDG members' financial conflicts of interest (eg. working as Chief Medical Officer for three insurance companies with a financial interest in keeping CFS/ME excluded from benefits) were not sufficient to preclude membership of the GDG and the claim was seen to be baseless.

The Judge said the claim contained the "vice" which was repeated against a number of members of the GDG and that there was no bias among members of the GDG (even though the known bias of the professional members of the GDG was substantial and indisputable).

The Judge found that it was not accepted by NICE that Professor Peter White was a leading proponent of any particular view, and certainly not the psychosocial model of "CFS/ME".

The Claimants' written evidence that some GDG members had misled the High Court in their Witness Statements was not heard (yet there are criminal sanctions if there is evidence that someone has made a false statement to the Court).

Furthermore, the Claimants' evidence that NICE's lawyer (Charles Bear QC) had misled the High Court was not heard (even though it was substantiated in written evidence).

The Judge accepted all NICE's evidence and their experts' Witness Statements without equivocation (not every member of the GDG provided a Witness Statement and some members provided more than one; in total, there were 24 Witness Statements on behalf of NICE).

Permission to appeal was refused.

The outcome was a grave miscarriage of justice and a legal travesty; it was also a tragedy for patients with ME/CFS.

Following the Judgment, Professor Peter Littlejohns, Clinical and Public Health Director of NICE, announced in a Press Release:

"The Judge recognised the key role that professionals have in contributing to the development of NICE guidelines and therefore understood the vigorous approach NICE took in defending these health experts".

What he actually meant by the term “vigorous” was that less than 48 hours before the case was to be heard, having seen the Claimants’ evidence in full, NICE’s lawyers (Messrs Beachcroft LLP, who act for NHS providers and commissioners) ambushed the Claimants’ solicitor and barrister with the threat of a career-damaging “wasted costs” order, at which the Claimants’ lawyers capitulated and – without consulting the Claimants (a gross breach which itself initiated a professional negligence claim that was upheld) they withdrew about 60% of the Claimants’ evidence and apologised to the Court and to NICE. Without the Claimants’ knowledge or permission, their lawyers themselves submitted attenuated “evidence” (which meant that the case could never have succeeded because so much of the Claimants’ evidence about the failings of the Guideline was not considered by the Court).

Notwithstanding, in July 2009 Mr Justice Simon ordered the Claimants’ solicitors to pay NICE £50,000 damages in wasted costs as compensation for what he ruled to be improper conduct of the case.

The JR challenge to NICE’s Guideline on CFS/ME was pervaded by what has been described as dishonesty, but it preserved State-sanctioned “policy” at the expense of justice.

The Claimants stood no chance against such powerful opponents who appear dedicated to silencing the evidence which does not support “policy”.

On 28th October 2006 the BMJ had carried an article and responses that pertain to ME/CFS (“Vested interests will always trump evidence”: BMJ 2006:333:912-915). One response from an NHS Consultant was especially relevant:

“Over the past few decades the practice of Medicine has moved from a basis of personal experience and understanding of the disease process and its treatment towards the application of authorised protocols and guidelines. (The article) raises concerns about the situation in which an inadequate evidence-base has become canonised into established guidelines, Government policy and incentivised practice”.

Nowhere has this been more clearly demonstrated than in the NICE Guideline on “CFS/ME”.

Some key documents pertaining to the JR

There was massive support for the JR, not only from most of the ME charities (excluding AfME and AYME) but also from individuals and local support groups as

well as medical scientists and clinicians. The Claimant's solicitor said : *“Since permission was granted in this case in June 2008...I have been approached by a significant number of medical practitioners and academics who are supportive of the legal challenge and critical of both the Guideline and the process which went into producing it”*. From the many received, the following professional Witness Statements were submitted but were not permitted to be considered by the Court [Note, some of these statements are available via the links following this introductory text]:

- Professor Malcolm Hooper (Emeritus Professor of Medicinal Chemistry, University of Sunderland)
- Dr William Weir (Consultant Physician)
- Professor Nancy Klimas (USA – Professor of Medicine & Immunology, Miami)
- Professor Mary Ann Fletcher (USA -- Professor of Medicine & Microbiology, Miami)
- Professor Bruce Carruthers (Canada – lead author of the Canadian Clinical Working Case Definition of ME)
- Professor Julia Newton (Professor of Cellular Medicine, University of Newcastle, UK)
- Dr Terry Mitchell (consultant clinical lead of Norfolk, Suffolk and Cambridgeshire NHS ME/CFS service)
- Dr Ian Gibson MP (Biologist; former chair of the House of Common Science & Technology Select Committee)
- Dr Jonathan Kerr (Department of Cellular & Molecular Medicine, St George's, University of London)
- Dr Irving Spurr (Researcher & Lecturer in ME/CFS)
- Dr Byron Hyde (Canada – Physician specialising in ME/CFS)
- Dr Derek Enlander (New York CFS/ME Centre)
- Dr Terry Daymond (Consultant Rheumatologist; former Clinical Champion for ME in North East England)
- Dr Charles Shepherd (Hon Medical Advisor, the UK ME Association).

There were Witness Statement of GDG members (on behalf of NICE); of the 15 professional members of the GDG, no less than 7 were involved with Professor

Anthony Pinching's Service Investment Programme for the implementation of the Clinical Network Coordinating Centres (CNCCs or CFS Clinics) whose remit was to deliver CBT and GET for "CFS/ME". It is therefore ludicrous to suppose that any of those 7 members of the GDG would have voted against the recommendation of CBT/GET.

Witness Statements for NICE were provided by the following: Professor Richard Baker, Dr Fred Nye; Ms Nancy Turnbull; Dr Esther Crawley; Dr Richard Grunewald; Dr Alastair Santhouse; Dr William Hamilton; Second Witness Statement of Professor Richard Baker; Ms Mary-Jane Willows, Ms Amanda O'Donovan; Mrs Jill Moss; Dr Anthony Downes; Dr Philip Wood; Dr David Vickers; Dr Julia Smedley; Ms Carol Wilson; Second Witness Statement of Ms Mary-Jane Willows; Miss Jessica Bavinton; Ms Gillian Walsh; Ms Judith Harding and by Stephen Hocking of Beachcrofts.

There was also a Witness Statement by Professor Anthony Pinching, who was responsible for selecting the GDG members. Pinching was also involved with the design the MRC PACE trial; the documentation states: "*The authors thank Professors Tom Meade, Anthony Pinching and Simon Wessely for advice about design and execution*". Thus there is evidence that Pinching advised on a psycho-social trial which had "*predictors*" that included "*mood disorder, membership of a self-help group (such as the ME Association), being in receipt of a disability pension, focusing on physical symptoms, and pervasive inactivity. CBT will be based on the illness model of fear avoidance. GET will be based on the illness model of deconditioning*".

It is notable that although permission had been sought and granted by the Royal Courts of Justice for the transcript of the JR hearing to be placed in the public domain free of charge, the Judge himself, Mr Justice Simon, specifically overturned that permission and ruled that the hearing transcript should not freely enter the public domain.

Extracts from *The UK Government's three-pronged strategy for "CFS/ME"*

by Margaret Williams, 15th July 2014, AMEA-Amended.

Full text available at:

www.angliameaction.org.uk/docs/Williams-UK-Government-Strategy-for-CFS-ME.pdf

2. Summary of Reasons JR Needed (2009):

Margaret Williams & Horace Reid (<http://angliameaction.org.uk/docs/Preview-of-the-NICE-Judicial-Review-Feb09.pdf>)

3. The 2008 JR Permission Judgement:

Justice Cranston (<http://angliameaction.org.uk/docs/JusticeCranston17June2008.pdf>)

4. Key Witness Statements:

Dr Neil Abbott (http://angliameaction.org.uk/NICEJRdocs/Neil_Abbot_MERUK_WS.pdf)

Dr Bruce Carruthers (http://angliameaction.org.uk/NICEJRdocs/Bruce_Carruthers_WS.pdf)

Dr Ian Gibson (http://angliameaction.org.uk/NICEJRdocs/Ian_Gibson_WS.pdf)

Professor Malcolm Hooper

(http://angliameaction.org.uk/NICEJRdocs/Malcolm_Hooper_WS.pdf)

Dr Terry Mitchell (http://angliameaction.org.uk/NICEJRdocs/Terry_Mitchell_WS.pdf)

5. The 2009 Judgement:

R(Fraser & Short) v NICE (<http://angliameaction.org.uk/NICEJRdocs/JUDGEMENT.pdf>)

6. Essential Overview Pre- and Post- JR (2014):

Margaret Williams (<http://angliameaction.org.uk/docs/Williams-UK-Government-Strategy-for-CFS-ME.pdf>)

7. Context – Concerns about NICE from Inception:

Professor Bruce Charlton (<http://www.angliameaction.org.uk/docs/Professor-Bruce-Charlton-NICE-Infostat.pdf>)

Margaret Williams (<http://www.angliameaction.org.uk/docs/nice-giga-2007.pdf>)

<http://angliameaction.org.uk/>

<http://angliameaction.org.uk/NICEJRdocs/NICE-JR-frontpage.pdf>