

This document contains highlighted live links. Sources for the contents of this document are listed at the end of this paper. We have attempted to gather a wide consensus of biomedical published opinion since the publication of these Guidelines in August 2007. The reaction and ME/CFS community response to these Guidelines has been definitive.

We outline legal propositions submitted by One Click to [Saunders Solicitors LLP](#).

10 October 2007

CFS/ME NICE GUIDELINES – JUDICIAL REVIEW ACTION

As a result of an unprecedented volume of critical responses from Stakeholders, NICE were forced to abandon their decision to publish the finalised [CFS/ME Guidelines](#) in April 2007. The Guidelines were eventually published on 22 August 2007 amidst the massive controversy that has surrounded their development for the last two years.

One of our greatest concerns over these Guidelines has been the complete lack of transparency employed in their production. Fair and proper representation for ME/CFS labelled patients has not occurred throughout the development of these Guidelines. We have failed to be treated in a transparent and collaborative manner contrary to the NICE Guidelines Manual, April 2006.

Declared by selected charities that operate in this field and patients as Unfit for Purpose, we call for these Guidelines to be withdrawn and rewritten by a group of health professionals who unambiguously accept that they are dealing with a physical rather than a psychosomatic illness, as the evidence shows.

1. BACKGROUND

There are broadly two contesting paradigms of ME/CFS: the neurological (biomedical) paradigm, and the psychiatric paradigm. A heated debate between academics and doctors has raged over this issue for many years.

NICE has exclusively adopted the psychiatric paradigm during the development of these Guidelines and comprehensively ignored the biomedical through a process of entirely unethical political and medical manipulation of due process.

According to Christopher Booker, The NICE 'consultation' processes are merely an empty exercise: the Government and its bodies pretend to "consult" those affected by their actions, then carry on doing exactly what they intended in the first place. The 'consultation' period is a farce, as the Government is not remotely interested in looking at the evidence (Sunday Telegraph, 20th June 2004).

For over two decades in their role as advisers to Government Departments, Wessely School psychiatrists have been tirelessly influencing Government Ministers and Departments of State on behalf of their paymasters, the pharmaceutical and the medical insurance industries, about what they term

'medically unexplained' disorders, notably ME/CFS and Gulf War Syndrome, both of which they assert do not exist.

NICE has failed to accept the conclusion of the World Health Organisation (WHO) that in our current state of knowledge, ME/CFS is best classified as a neurological disorder. NICE also failed to refer to any research evidence that supports neurological causation and they appear to deliberately omit any of the more serious neurological symptoms that were noted in the Chief Medical Officer's [Working Group Report](#). In fact, any reference to neurological cause, neurological symptomatology, or neurological symptom relief is a no go area for NICE when it comes to ME/CFS.

Over the development of these Guidelines, NICE has purposefully and unethically not taken into account the biomedical evidence in relation to ME/CFS.

NICE has refused "to take into account or neglected to take into account matters which it ought to take into account" as is so clearly dictated by the Wednesday unreasonable principles. As an official public body funded by the Department of Health, it has violated the criterion of necessary reasonableness in the development and publication of these Guidelines. The judicial control of governmental power is an essential element of democracy.

By failing to take into account the view of patients, NICE has breached their Human Rights.

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

This document (the Bagnall et al review) is the primary building block on which these Guidelines have been fraudulently constructed. NICE has been entirely unreasonable, even corrupt, in the way that it has conducted this Literature Review.

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.

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 sixty years, documenting multi-system physiological abnormalities present in ME/ICD-10 CFS patients, at the level of laboratory, radiological and clinical investigation.

The depiction of ME/CFS in the Bagnall et al review is highly biased in favour of unproven psychiatric theories and lacking in some of the most important biomedical research areas published to date. Methodological flaws with the Bagnall review include, as reported by Hooper and Reid, the restriction to Randomised Controlled Trials (RCT), which are considered by the reviewers to be the only studies of a sufficient quality to warrant inclusion. In doing so, the statistical approach adopted by the researchers of these studies included is strictly vetted which has resulted in a large body of evidence being excluded.

Conversely, other factors that might have been used to assess the quality of the research: authors' bias on the nature of ME/CFS (e.g. psychiatric vs. biomedical); the validity of the selection criteria i.e. whether the criteria are in line with the WHO ICD-10 neurological status of ME/CFS; the validity of the authors'

interpretation and conclusions of their data and any disagreement with other researchers were not taken into account.

At the launch by the US Centres for Disease Control in November 2006 of its "Toolkit" to promote better awareness of the reality of ME/CFS, Anthony Komaroff, Professor of Medicine at Harvard, said there are over 4,000 papers on the biomedical nature of ME/CFS. This extensive medical literature spans over 60 years. No one who is aware of this wealth of information can credibly doubt the reality, the validity and the devastation of this organic multi-system disease as NICE has just done.

Most importantly, NICE failed to conform to the AGREE Instrument (The Appraisal of Guidelines for Research and Evaluation) which requires that NICE is obliged to give equal weight to three main sources of data: "evidence-based" medicine, usually deemed to be random controlled trials (RCTs); 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.

The reviewers have failed to realise the limitations of the RCT (randomised controlled trials) evidence base, failed to integrate the great body of literature on individual clinical expertise and failed to fully reflect the rights, preferences and choices of the patient community.

- 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.

It has to all intents and purposes ignored [The Canadian ME/CFS Case Definition and Treatment Protocols](#) (Carruthers et al, 2003), CLINICAL CRITERIA produced by international consensus, that have now been available for FOUR 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 that have pulled together the research findings on ME/CFS for the last ten years or more. This NICE has largely ignored. 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.

NICE is quite literally washing its hands of having any need to consider underlying disease process in formulating the Literature Review. How can NICE possibly avoid this as a centre of 'Clinical Excellence'? How can clinicians rely upon a set of guidelines formulated by those who shrug at the idea of a clinical understanding of the disease?

Bagnall et al are 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.

It is insufficient for the Guidelines Development Group to claim that consideration of the biomedical evidence did not come within its remit – it was charged with

providing guidance on the diagnosis of 'CFS/ME', so the literature which demonstrates the clear biomedical aetiology should have formed part of the literature review. It did not.

The decision to exclude all the biomedical evidence on ME/CFS in the production of this Literature Review is Wednesbury unreasonable and will have a devastating effect on the health prospects of all patients.

3. GUIDELINES DEVELOPMENT GROUP

Instead of acknowledging the contested psychiatric paradigm on ME/CFS, NICE elected to bury any legitimate and evidenced biomedical opposition by structuring the membership of the Guidelines Development Group (GDG) to favour the psychiatric lobby's vested interests exclusively.

At least two-thirds of the Guidelines Development Group members had 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.

NICE and The Guidelines Development Group have failed to adopt the World Health Organisation classification of the ME/CFS as a neurological illness under ICD-10 G93.3 – ironically, a classification that is accepted by the Department of Health. The United Kingdom being a signatory to the World Health Organisation rubric, NICE must be forced to abide by this whether it suits the psychiatrists or not.

The Association of British Neurologists said the following: "The GDG should also be criticised for its total lack of reference to the neurological aspect of fatigue and its overemphasis and over-reliance on the psychiatric literature from a group of psychiatrists".

The results of this stacking of the deck are self-evident with £300m proposed to be spent exclusively upon psychiatric treatments that do not work for the physically, neurologically impaired. How and from where will the Department of Health fund this initiative precisely?

To purposefully and with design politically and medically manipulate the constitution of the Guidelines Development Group in this way to benefit the Psychiatric Lobby so extensively and lucratively is Wednesbury unreasonable.

3.1 Patient Representatives

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 arbitrary selection of the so called three 'Patient Representatives' on the Guidelines Development Group.

The Guidelines Manual, April 2006 outlines the duties of the Patient Representatives thus:

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.

The One Click Group formally requested that the three Patient Representatives stand down from the Guidelines Development Group in November 2006, subsequent to the publication of the Draft Guidelines on 29 September 2006 produced and signed off by all the members of the GDG by consensus, 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. This was ignored

One Patient Representative who subsequently resigned from the GDG just prior to publication of the Guidelines in August 2007 is on record as stating: "I do believe that the guideline has not fully taken into account the patient and biomedical evidence, because if it had, then it would not be recommending the widespread use of CBT and GET [the psychosocial treatments of Cognitive Behavioural Therapy/Graded Exercise]. It is said that patient evidence is not given high weighting due to it being biased". This is another illustration of a clear breach of the AGREE Instrument to which NICE is obliged to conform.

4. STAKEHOLDERS PROCESS

NICE has politically and medically manipulated the composition of the 'invited' Stakeholder Group such that membership of the group was largely exclusionary during the development of these Guidelines. Admission to the Stakeholder Group was by invitation only. In order to force NICE to provide One Click with a place at the Stakeholder table for example, we had to threaten the intervention of solicitors before this invitation was so reluctantly granted.

* 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 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. 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.

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

By the process that NICE has employed with the Stakeholder Group on the CFS/ME 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."

The way that Stakeholders have been manipulated and excluded by NICE during the development of these Guidelines is Wednesbury unreasonable.

4.1 One Click Document

In response to the Draft Guidelines published by NICE in September 2006, Stakeholder One Click produced the document that has caused so much controversy, [The One Click Group Response – NICE Guidelines](#) in November of that year. Firstly NICE attempted to refuse acceptance of this document unless it was produced on its unwieldy and purposefully difficult to use Comments Proforma. This precisely serves to confuse and makes the perusal of any Stakeholder work published by NICE problematic to find and difficult to read. NICE and the Department of Health rely on this difficulty with forms especially designed for poor ease of use for controversial procedures.

On 22 August 2007, simultaneous to publication of the Guidelines themselves, NICE refused to publish this Expert Patient Stakeholder document on its website claiming that the contents contained defamatory and unsubstantiated material.

After 43 tick tock legal days with many international incentives to act and much Stakeholder pressure, NICE finally bit the bullet and gave a bloody, high forceps delivery birth to a bastardised and censored version of the One Click Stakeholder document with which NICE has had such evidenced difficulty for the last eleven months.

The evidence shows that NICE has elected to expunge the sum of some ten typewritten pages - thousands and thousands of words - from the One Click Stakeholder document, produced by formal due process and crafted with care involving the endeavours of so many. Despite being in receipt of formal copy approval permission from patients, NICE has also elected to suppress the Patient Case Histories entirely without approval or permission. NICE has no right – legally, morally and ethically – to stifle the Expert Patient voice in this way.

We question precisely how much British taxpayer's money has been spent on legal bills to suppress the voice of the Registered Stakeholder Expert Patient.

The suppression, censorship, and bastardisation of this Expert Patient document by NICE is Wednesbury unreasonable.

5. VIRAL AND BACTERIAL TESTING

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 proper testing for viral and bacterial infections should not be carried out on patients at that most critical time – symptom onset.

ME/CFS 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.

By the emerging evidence of chronic microbial infections being present in many people diagnosed with 'CFS/ME' (sic) being ignored in the York Systematic 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, severe disability and sometimes death. The Guidelines restrict investigations that may be performed on those with ME/CFS.

To restrict biomedical testing on so many patients who are now known to be suffering from chronic microbial infections is Wednesbury unreasonable.

6. CONCLUSION

What has been provided in this short paper is a brief summary of some of the many grounds on which NICE can be charged as Wednesbury unreasonable. We have merely highlighted a selection of the few.

A Judicial Review is the way in which the courts supervise government ministers and departments, industry regulators, local authorities and other public bodies to ensure that they act lawfully and fairly. The principles of judicial review are based on case law which is continually being developed by the courts. It is, therefore, a very flexible area of the law that tends to reflect changes in society.

To be unreasonable, the decision would have to be one where an authority had "taken into account matters which it ought not to take into account, or, conversely, has refused to take into account or neglected to take into account matters which it ought to take into account".

The principles have since become the touchstone of the courts when deciding judicial review cases and the legal phrase "Wednesbury unreasonable" is shorthand for a decision of a public body or official that violates the criterion of necessary reasonableness established in this case. The judicial control of governmental power is an essential element of democracy.

What has transpired over the development of the CFS/ME NICE Guidelines meets every one of these criteria.

We call for these Guidelines to be withdrawn and rewritten by a group of health professionals who unambiguously accept that they are dealing with a physical rather than a psychosomatic illness, as the evidence shows.

The One Click Group
10 October 2007

SOURCES

Information in this document has been obtained from various sources, some verbatim. These include, but are by no means confined to:

The One Click Group Response – NICE Guidelines

<http://www.theoneclickgroup.co.uk/documents/NICE/ONE%20CLICK%20RESPONSE%20-%20NICE%20GUIDELINES.pdf>

Inadequacy of the York (2005) Systematic Review of the CFS/ME Medical Evidence Base.

<http://www.theoneclickgroup.co.uk/documents/NICE/Inadequacy%20of%20the%20York%202005%20Systematic%20Review%20of%20the%20CFS-M..pdf>

Nice Literature Review Critique

<http://www.theoneclickgroup.co.uk/documents/NICE/NICE%20Literature%20Review%200Critique.pdf>

Corporate Collusion, Hooper et al, September 2007.

<http://www.theoneclickgroup.co.uk/documents/NICE/Corporate%20Collusion,%20Hooper%20&%20Williams.htm>

NICE guideline on ME/CFS – ME Association statement

<http://www.meassociation.org.uk/content/view/335/>

Dr Charles Shepherd, ME Association, British Medical Journal, 1 Sept 2007

<http://www.meassociation.org.uk/content/view/339/>

25% ME Group Statement ON NICE ME/CFS Guidance Document, August 2007

<http://www.theoneclickgroup.co.uk/documents/NICE/Charities/Final%2025pc%20NICE%20STATEMENT%20August%202007.doc>

Mental Health Movement – Persecution of Patients

http://www.theoneclickgroup.co.uk/documents/ME-CFS_docs/The%20Mental%20Health%20Movement%20-%20Persecution%20of%20Patients.pdf