

Prejudice-based Medicine?

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

Margaret Williams

27th October 2008

On 2nd November 1972 the London Medical Group held a closed meeting at which aversion “therapy” was promoted as a “cure” for homosexuality. The “therapy” was drug-induced nausea whilst the “patient” had to view homosexual acts (preferably live). The aim of this so-called “re-conditioning” was to “*change the emotions where the person cannot change them of his own free will*”. According to one of the speakers, psychologist Hans Eysenck, aversion “therapy” was “*only undertaken where it is of the patients’ own choice*”. Another speaker, Dr Isaac Marks, Senior Lecturer and Consultant Psychiatrist at the Maudsley Hospital, justified such abuse as being “*in society’s interest*”. The proponents of this “therapy” were praised by the chairman of the meeting for their “*outstanding contributions to psychology*” and were referred to as “*these great men*”. People who underwent this “therapy” ended up as chronically depressed asexual vegetables (<http://www.petertatchell.net/psychiatry/dentist.htm>).

On 28th April 2008, another closed medical meeting was held in London, this time at the Royal Society of Medicine; once again the intention was to promote another currently faddish “therapy” as a “cure” for another so-called “aberrant” disorder. This time it was not about homosexuality but about myalgic encephalomyelitis / chronic fatigue syndrome (ME/CFS), which the psychiatrists to whom the RSM offered a platform prefer to call “CFS/ME” and claim that it is a behavioural disorder. These psychiatrists (known as the Wessely School) lump ME/CFS together with on-going tiredness or chronic “fatigue” such as is seen in depression and anxiety states, even though ME/CFS has been formally classified as a neurological disorder by the World Health Organisation since 1969 and the WHO has confirmed in writing that what these psychiatrists are doing is not permitted under the WHO taxonomic principles.

People with ME/CFS have been referred to by a leading UK Wessely School psychiatrist as “*the undeserving sick of our society*”, so this time, the “therapy” is a mind-altering technique to disabuse patients of their belief that they are physically sick, combined with incremental aerobic exercise (because the psychiatrists believe that these patients are merely de-conditioned through self-indulgent lazing about for secondary gain in the form of state benefits).

Of course, as in 1972, the “therapy” is only to be offered to those who choose it, but those who refuse it (because they are simply too sick to participate or are sufficiently well-informed to be aware of the potential dangers) are deemed not to want to get better, so their state benefits are summarily stopped. The “Pathways to Work” programme will require Incapacity Benefit (now known as ESA, or Employment & Support Allowance)

claimants with ME/CFS to undergo CBT/GET before their benefits are reinstated. Not surprisingly, the suicide rate in ME/CFS has been documented at one per month, not because patients are mentally deranged, but because without help they have no means of surviving such a devastating disorder and can no longer cope with the extreme suffering.

It ought to be a matter of national concern that this current fad is now enshrined in a Guideline produced by the National Institute for Health and Clinical Excellence (NICE) and is to be implemented throughout the nation, even though the “therapy” in question may already have resulted in an untold number of non-suicide deaths (including a Member of Parliament who suffered from ME) and may have turned countless mildly affected sufferers into severely affected physical wrecks requiring 24 hour lifelong care. These very sick people are officially described on page 68 of the NICE Guideline as “*a substantial burden on society*”.

In supporting the psychiatric lobby’s attempt to make ME/CFS disappear within the maelstrom of undifferentiated fatigue states, NICE has contributed to the perpetuation of unacceptable practices by officially sanctioning – indeed promoting – this Government-funded current prejudice, the consequences of which will be catastrophic, not only for those afflicted by ME/CFS, but also for those committed researchers who are on the point of a breakthrough into the aetiology of what is by any standards a life-shattering multi-system disorder. Chronic “fatigue” has no more a relationship to ME/CFS than a pimple has to a malignant tumour.

In 2005, Professor Nancy Klimas, Professor of Medicine at Miami and President of the International ME/CFS Association was clear: “*Our patients are terribly ill, misunderstood, and suffer at the hands of a poorly informed medical establishment*”.

The following year (2006) she repeated the message: “*There is evidence that the patients with this illness experience a level of disability that is equal to that of patients with late-stage AIDS, patients undergoing chemotherapy (and) patients with multiple sclerosis*”.

In 2007, evidence was presented at an international conference held in Florida that the cardiac index of these patients is so severe that it falls between the value of patients with myocardial infarction (heart attack) and those in shock.

Although this evidence and more was brought to its attention, NICE remained unmoved and recommended only behavioural interventions designed for mental disorders, talking about “*unhelpful beliefs*”; “*the relationship between thoughts, feelings, behaviours and symptoms*”, “*sleep hygiene*” and “*over-vigilance to symptoms*”.

It seems that so determined was the Wessely School that NICE should recommend this latest fad that the Guideline Development Group (GDG) was specifically instructed to ignore over 4,000 peer-reviewed papers which clearly demonstrate that ME/CFS affects all major bodily systems, especially the immune system, the neurological systems (central, autonomic and peripheral), the neuroendocrine system, the cardiovascular system, the respiratory system, the musculo-skeletal system, the gastrointestinal system, the reproductive system and the ocular system.

The Wessely School psychiatric lobby dismisses all this evidence as being “*not of clinical value*” and insists that patients “*are assumed to have ‘mental’ disease*” because there is “*no pathology*”. They refer to ME/CFS as a “*pseudo-disease*”. It seems that NICE agrees.

To be fair to NICE, it is not required to address causation in its Guidelines; however, its remit in this case was to produce a Guideline to aid diagnosis. To do so, it was necessary for NICE to identify and define the disorder in question by considering the existing knowledge-base. Indeed, NICE is required to do so under the terms of the AGREE instrument, to which it is a signatory. In its Guideline on “CFS/ME”, NICE signally failed to do so.

Virtually all the UK ME/CFS charities condemned the Guideline as unfit for purpose: such was the outrage and disgust throughout the ME/CFS community at the way that NICE had deliberately ignored so much evidence about ME/CFS that a Public Law firm (Leigh Day & Co, rated number one in Chambers’ legal directory) agreed to seek permission to challenge the Guideline in the High Court by way of Judicial Review.

The initial Hearing was on 17th June 2008 before Mr Justice Cranston (Sir Ross Frederick Cranston), who in his Judgment said: “*There is no doubt that ME is a debilitating condition and many of us will know of people who have the condition. Mr Hyam (for the Claimants) has pointed to the lack of balance in the composition of the group drawing up the Guidelines. Given the great public interest, it seems to me that this case ought to go forward for a full hearing*”.

NICE is therefore once again being dragged kicking and screaming into the High Court in an attempt to justify what cannot logically be justified.

For example, NICE decided to reject the WHO formal classification of ME/CFS as a neurological disorder. The ME/CFS community has obtained an abundance of evidence that this might be because the psychiatrists’ gravy train would hit the buffers if NICE acknowledged that ME/CFS is a discrete neurological disorder. NICE’s position on this is unsustainable because not only does the WHO classify ME/CFS as a neurological disorder, but since 2003 the UK Read Codes used by all GPs also classify it as a neurological disorder. Furthermore, ME/CFS is included in the National Service Framework for long-term neurological disorders, and the Department of Health (by whom NICE is funded and to whom it is answerable) also accepts that ME/CFS is a neurological disorder, as does the Chief Medical Officer himself. It will be interesting for the public to see what “evidence” NICE produces to convince the Court that its position in this regard is justified.

It will also be interesting for the public to hear NICE’s explanation about the composition of the Guideline Development Group that prepared the Guideline, in particular, how NICE justifies its decision to exclude clinicians with a professional lifetime’s expertise in ME/CFS who were willing to serve on the GDG, and instead head-hunted non-experts

with undeclared vested interests. For example, Dr William Hamilton was invited to be a member of the GDG specifically because of his published work which supports the notion that ME/CFS is a behavioural disorder that is best treated by CBT/GET (as recommended by the Guideline). Dr Hamilton just happens to be Chief Medical Officer of two medical insurance companies that rigorously resist claims made by ME/CFS patients, The Exeter Friendly Society and Liverpool Victoria (LV), which took over Permanent Health. The antics of LV in respect of ME/CFS claims have been brought to the attention of Members of Parliament at an All Party Parliamentary Group Meeting at the House of Commons.

NICE may be required to clarify why it preferred the expertise of a dietician, a reflexologist who also works as a hypnotherapist, an occupational therapist and a physiotherapist to experienced ME/CFS clinicians such as Dr William Weir, Dr Jonathan Kerr, Professor Julia Newton, Dr Terry Mitchell, Dr Nigel Speight and Dr Charles Shepherd. Again, it will be interesting to hear NICE's explanation, especially as the physiotherapist just happened to have worked with psychiatrist Professor Peter White and it was she who wrote the handbook on graded exercise for the Medical Research Council's "CFS" trial, of which Peter White is a Principal Investigator. This physiotherapist also works for the same medical insurance company as Peter White, which pays her to recommend (and carry out) GET for claimants (so could it be said that her vote in favour of GET was a forgone conclusion?). Furthermore, she works as a "healing" therapist using Human Givens "therapy" (which claims to "empower" patients but is described by one clinician as "dodgy psychobabble"). Many people have difficulty in understanding how this physiotherapist had more to offer the patients for whom the Guideline is supposed to be intended than the Medical Adviser to the ME Association.

None of the many competing interests of GDG members was declared in the Guideline: it was not until two months after the Guideline had been published that NICE released what purported to be the List of Competing Interests of the GDG; it barely scratched the surface of GDG members' vested interests.

Then there is the interesting matter of how this Institute for Clinical Excellence produced its "evidence" out of thin air: 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.

Another interesting area is the "Consensus" methodology that was used in the production of the Guideline on "CFS/ME". It does seem to be the case that formal consensus methodology was conspicuous by its absence: indeed, on 10th May 2006 NICE made it known that the consensus technique was to be "modified" by NICE for the development

of this particular Guideline. Scrutiny of this “modification” as it appears in the Guideline makes very interesting reading. It will not escape attention that the person described in the Guideline as the “Consensus Development Expert” was Professor Rosalind Raine, whose published track record happens to be that “CFS/ME” is a behavioural disorder that should be managed by CBT/GET. Raine specifically singled out “CFS” for study (funded by the MRC) and she is clear: CBT should aim to “*modify thoughts and beliefs with the expectation that emotional and behavioural changes will follow*”; behavioural therapies focus on “*the modification of behaviour to positively reinforce healthy behaviours*” and they “*emphasise the role that social factors can play in the development and maintenance of functional somatic complaints. The goal is to identify and reinforce ‘well’ behaviours while reducing reinforcement for somatic behaviours*” (Lancet 2004:364:429-437). The ME/CFS community may well be justified in maintaining that NICE’s “consensus” exercise was cosmetic.

There is in addition the matter of NICE informing the Court on 17th June 2008 at the initial Hearing before Mr Justice Cranston that it had no knowledge of certain documents before that Hearing, even though receipt of some of those documents had previously been acknowledged in writing on 23rd January 2006.

There is also the serious issue of Social Services continuing to seek to remove children with ME/CFS from their parents and placing them in “care”, citing the NICE Guideline as the reason.

NICE appears to be in breach of the AGREE instrument (to which it is obliged to conform in the production of its Guidelines) on no less than seven separate counts. It will be interesting to hear why this should be so in the production of the Guideline on “CFS/ME” and the Court may be keen to hear why NICE appears to have broken its own guidelines (that it is obliged to observe) in so many respects in the production of this particular Guideline.

This is undoubtedly a high profile case. At the preliminary Hearing in June, there was standing room only.

The Hearing is listed for 11th-12th February 2009. High Court officials are now busy rearranging the Court venue in order to ensure not only disabled access and facilities, but also to accommodate the coach-loads of people from the UK ME/CFS community who are expected to turn up to witness what will undoubtedly be a landmark legal action that will have global ramifications.

Literature References: http://www.meactionuk.org.uk/Quotable_Quotes_Updated.pdf

