



## **MEMORANDUM to the HEALTH SELECT COMMITTEE**

### **SUBMISSION FOR YOUR INQUIRY in to National Institute for Health and Clinical Excellence (NICE)**

**20<sup>th</sup> March 2007**

#### **1 Introduction**

- (1) This memorandum has been prepared by "Invest in ME" and submitted to the Health Select Committee Inquiry into NICE. The subject material for this document is related to the NICE Guidelines (Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Diagnosis of Chronic Fatigue Syndrome/Myalgic Encephalomyelitis in Adults and Children) which was published in Draft format and which NICE has indicated will be formally published in August 2007.

#### **1.1 Invest in ME**

- (2) Invest in ME (IiME) is a UK charity registered in May 2006, that is run by people with Myalgic Encephalomyelitis (ME) or parents of children with ME on an un-paid, voluntary basis. The objectives of IiME are to educate about ME, to raise awareness of the illness and campaign for proper funding for biomedical research into ME. The contact e-mail: [info@investinme.org](mailto:info@investinme.org) web: [www.investinme.org](http://www.investinme.org) IiME are willing to give evidence to the Select Committee in person, if required.
- (3) Despite its short existence IiME has already organised two CPD accredited International ME/CFS conferences in London (the second to take place in May 2007), have produced an educational DVD on ME/CFS which has been distributed in twenty countries, and has organised several events and campaigns in the UK in order to educate and raise awareness of ME.
- (4) The areas of concern regarding NICE which IiME would like to highlight in relation to the NICE Draft Guidelines and NICE's performance on creating these guidelines are:
  - Lack of analysis of research material;
  - Lack of consistency or accuracy in terminology;
  - Lack of rigorous control of content;
  - Lack of regard for human rights of people with ME;
  - Lack of abundance of Standards for Clinical analysis; and,
  - Lack of declaration of vested interests apparent in the formation of these guidelines

#### **2 Executive Summary**

- (5) The NICE guidelines for ME are substantially lacking and a travesty of the real requirements for pwme and their carers. People with ME (pwme) expect their illness to be taken seriously by the medical profession, as the neurological illness that is ME (accepted by this government and by the WHO) and that research is publicly funded to provide early diagnosis, treatment, and eventually a cure
- (6) It is a flawed and unsatisfactory document, full of inconsistencies that will do nothing to improve the situation for pwme or their carers and families. It offers little new thinking and patently fails to deliver recommendations which will provide any hope for the future for pwme. This is, essentially, an opportunity missed by those entrusted with the responsibility for producing good quality guidelines backed-up by scientific evidence.

- (7) NICE repeat the same old myths about ME that have disenfranchised and discriminated against pwme for the last thirty years and provide a narrow and biased view of what ME is and how it should be treated.
- (8) NICE have not analysed or used the extensive biomedical research which proves that ME is of organic origin and separate from a broad range of fatiguing conditions. It is inappropriate and scientifically incorrect for the guidelines to use as broad a section of fatigue states as possible when describing ME.
- (9) NICE recommend psychological treatments such as Cognitive Behaviour Therapy (CBT) and Graded Exercise Therapy (GET) even though these treatments have been proven to be unhelpful or dangerous for pwme. NICE recommend GET as both a therapy and a treatment and in so doing potentially violate patients' human rights. NICE is entirely disingenuous by stating that these psychological therapies are used as first line treatment for other illnesses such as cancer. That is simply untrue. The possible consequences and risks of use of the Draft Guidelines have been ignored. For instance the recommendation to use Graded Exercise Therapy, ignores the fact that GET has been proven to be harmful to ME patients. Not only does this breach the AGREE standards but it also violates the human rights of patients.
- (10) IiME strongly disagree with the priority recommendation that the therapies of first choice should be CBT or GET. It is incredible that this should be a recommendation at all, since the Draft Guidelines document "a lack of evidence" and yet produce more **policy-based evidence making**. Even results from patient group surveys, which show rest made people feel better and GET made them worse, are given a spin which skews the result.
- (11) Psychiatric paradigms are referred to and recommended as therapies and then also as treatments for ME despite ME patients and groups stating they are ineffective or harmful. NICE compares the use of CBT with ME to its use with cancer and heart disease, etc. and then infers that CBT is a first line treatment for these illnesses. **This is patently not true**. CBT is not offered as a first line treatment for such illnesses. Where CBT is offered to cancer patients then it is not the same type of CBT as is being proposed here for ME/CFS, where patients are asked to change their illness beliefs!
- (12) Here NICE are shown to be totally disingenuous and undermine any possible confidence in the institute. IiME wonder why NICE sees fit to create this "spin", since it benefits nobody in the long run and pwme and the medical profession are at the receiving end of more erroneous information. The attempt to compare CBT usage with cancer and diabetes is an appalling obfuscation of the true facts and can only be seen as a shameful act by those responsible to misrepresent this information in such a skewed fashion.
- (13) In fact, GET has been shown to be useless or harmful yet it is wrapped-up into a psychiatric paradigm to allow vested interests to perpetuate the same old myths about ME. The Draft Guidelines explicitly state that:
 

"There was strong agreement that persistent, debilitating, post exertional fatigue characterised the condition".
- (14) Yet the Draft Guidelines still recommend GET as a therapy/treatment. In making this recommendation, NICE are ignoring credible evidence that such treatments are potentially dangerous for those who suffer from this illness, particularly in the case of GET. Of particular concern is a mounting body of evidence that shows that exercise or over-exertion can worsen the health of ME/CFS sufferers and that, as such, GET has the potential to induce relapse, rather than being an effective recuperative therapy.

- (15) GET cannot be recommended for severely, or even moderately affected ME patients. It is tantamount to inviting diabetics to take more sugar. This is where the NICE agenda for imposing psychological therapies onto ME patients shows the basic irresponsibility behind the policy and within NICE.
- (16) It is well known that those who perform GET studies "select or cherry-pick" their patients (i.e., choose only those patients that are sufficiently well to be able to exercise in the first place and thus contribute to the overall 'success' of the trials). **No severely affected ME patients have ever been shown to benefit from the use of GET.**
- (17) NICE recommend against resting during the illness or after a relapse. This shows little understanding of the illness. During the early onset of ME, rest is of paramount importance. The wording by NICE is easily able to be misconstrued, or misunderstood, by healthcare staff lacking in real knowledge of ME and will severely impact many ME patients if promoted via these Draft Guidelines. IiME consider the emphasis on exercise at the expense of proper rest is appalling. Surely, guidelines such as these ought to be for the benefit of the patient. These Draft Guidelines do not fulfil this objective.
- (18) The use of other treatments, such as supplements and alternative medicines are not recommended, even though patient experiences, as evidenced in the Draft Guidelines document and elsewhere, show them to be useful for some.
- (19) The current and previous biomedical research is ignored.
- (20) The suspicion that NICE are influenced by vested interests who advocate psychiatric paradigms as solutions to a neurological illness remain unanswered.
- (21) NICE have failed to comply with the Appraisal of Guidelines Research and Evaluation Instrument which it needs to abide by.
- (22) The NICE Draft Guidelines have been roundly condemned by the ME Community, by the Group for Scientific Research into ME (GSMRE) chaired by Dr. Ian Gibson MP and by the chair of the All Party Parliamentary Group (APPG) on ME – Dr. Des Turner MP.
- (23) IiME believe these guidelines will condemn pwme to a perilous future, which will again be dominated by psychiatrists and the institutionalised psychiatric dogma that currently pervades many organisations and healthcare departments.
- (24) These guidelines fail on a number of levels and give no real help to a GP or paediatrician to make an informed evaluation or provide any useful treatment. They are, in fact, an appalling shambles of perpetuated myths, psychiatric dogma, outdated practices and prejudice and inconsistencies.

### **3 First term of reference: Why NICE's decisions are increasingly being challenged**

#### **3.1 Lack of Comprehensive Analysis of Illness**

- (25) NICE have not performed any comprehensive research into this illness. There is a lack of analysis of the extensive biomedical research into the illness, which shows a lack of rigorous control exercised in the formulation of these guidelines. IiME ask, "**How can guidelines be produced when such compelling evidence has not been examined?**"
- (26) The draft guidelines are characterized by incorrect statements and inconsistencies. **The terminology is inconsistent and not correct.**

- (27) The membership of the Guidelines Development Group appears to have very little expertise in the clinical definition, analysis and research of neurological ME as defined by WHO ICD-10 G93.3. If there are specific levels of expertise, then these should be included but **none of the nationally or internationally recognised bio-medical experts in ME are included.**
- (28) The perception of these guidelines is that they are not attempting to provide good advice but instead are attempting to enforce psychological therapies, defined as treatments, on to a vulnerable section of ill people. They are thus violating the human rights of the people with ME.

### 3.2 Lack of impartiality/Vested Interests

- (29) The recent GSRME led by Dr. Ian Gibson MP has openly stated that "There have been numerous cases where advisors to the DWP have also had consultancy roles in medical insurance companies. Given the vested interests medical insurance companies have in ensuring CFS/ME remains classified as a psychosocial illness, there is a blatant conflict of interest here. The Group finds this to be an area for serious concern and recommends a full investigation by the appropriate standards body."

### 3.3 The work performed by NICE is substandard and not fit for purpose.

- (30) The NICE Draft Guidelines draw on unrepresentative groups and individuals and so called experts who are biased, most of whom have never physically examined a patient with ME. The work of these "experts" is not only criticised by patient groups but also by other researchers and unbiased observers. By using such a broad base of patients for their research and using biased and flawed diagnostic criteria, the NICE guidelines are **unusable and scientifically incorrect.**

## 4 Second term of reference: Whether public confidence in NICE is waning, and if so why?

- (31) The confidence of pwme and their carers is near to zero. To spend so long on these guidelines and then produce an unusable and illegible collection of myths, and ignore essential biomedical research, is an appalling waste of resources and a missed opportunity.
- (32) The purpose of the Appraisal of Guidelines Research & Evaluation (AGREE) Instrument is to provide a framework for assessing the quality of clinical practice guidelines and is supposed to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'. The process involves taking into account the benefits, harms and costs of the recommendations, as well as the practical issues attached to them.
- (33) NICE are a party to the AGREE Instrument but have **failed to comply with it.** Their purpose is *"to make explicit recommendations with a definite intent to influence what clinicians do"* but with a view to influencing what clinicians do and how such action affects patients.
- (34) The NICE Guidelines Development Group did not include individuals from all the relevant professional groups – there was no endocrinologist, no virologist, no rheumatologist, no molecular biologist, no biochemist, no biostatistician, no vascular medical specialist, no nuclear medicine specialist as well as a number of other disciplines that were missing. Dr. Gibson's GSMRE Enquiry report has recommended the need for such multi-disciplinary approach for research into ME.

## 4.1 Management

- (35) The Draft Guidelines contain an inordinate number of pages on Management using psychological therapies. Much space has been devoted to cherry-picked research from psychiatrists, in stark contrast to the exclusion of biomedical research and analysis. Biomedical research is dealt with in a limited, dismissive and unscientific manner.
- (36) This disparity between the weight given to non-psychological treatments/therapies as compared to psychological treatments/therapies shows an obvious and unscientific bias in these Draft Guidelines. The information on CBT and GET in these guidelines often seems to read more like propaganda than a scientific, analytical review. The evident bias shown in favour of the psychological therapies undermines the value of the Draft Guidelines. In the Guidelines, 68 pages cover psychological therapies (treatments) and other self management techniques; 28 pages cover pharmacological interventions; 14 pages cover Dietary interventions and supplements; and, 4 pages cover Complementary therapies. From looking at the extent of the individual sections, one might ask whether the objectives and the result were predetermined before the publication.
- (37) The Draft Guidelines should clearly distinguish ME from other fatiguing syndromes and illnesses. It should be remembered that ME has been found to have inflammation of the brain and central nervous system and that pathology will provide increasing evidence. Some charities are proposing to support a protocol for pathologists, such that evidence can be collected. It is suggested that NICE should consider this further in the Draft Guidelines.
- (38) Every medication has to have a list of side-effects – surely, possible side-effects of the proposed therapeutic regimes also need to be stated within the Draft Guidelines. In light of the evidence presented, it is possible that use of GET for those with ME/CFS will ultimately be self-defeating. By increasing the risk of relapse and increasing overall health risks rather than reducing them, it is dangerous for patients and, therefore, risks worsening patient health and increasing the burden of the illness on society at large. NICE will be open to litigation that will undoubtedly follow if the Draft Guidelines are published as the standard method for treatment of ME patients.
- (39) The NICE Draft Guidelines provide an incredibly poor and limited summary on supplements and alternative medicines as aids in managing ME. These are not recommended even though patient experiences, as evidenced in a number of reports, show them to be useful to some. In some places within the Draft Guidelines, the use of supplements is rejected and is not considered worthy of more investigation, yet in other places in the Draft Guidelines it is stated that there may be a use for them. It becomes totally confusing which recommendations are meant to be used. This raises the question as to how GPs will react when reading the conflicting parts of the guidelines! IIME consider the inconsistencies within the document to be appalling.
- (40) Supplements are dismissed with little research or any attempt to analyse data. Yet they can be a useful part of the diet for pwme who are unable to cook or who cannot eat properly and could benefit from such supplements.

## 4.2 Terminology

- (41) Terminology is crucial in dealing with ME, especially as GPs, paediatricians, other healthcare personnel and the media use different terms. This is of paramount importance but NICE appear to have made a mess of this by using incorrect terms and being inconsistent in use of such terms. The Draft Guidelines state *"Appropriate and agreeable terminology and understanding is important when making a diagnosis and establishing a therapeutic relationship."* IiME totally agree with this statement. So it is even more surprising that NICE remains committed to perpetuating the terminological mess around ME, as evidenced by the document title.
- (42) A major problem is that ME/CFS does not have a "clean" diagnosis. Indeed, the terms Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS) mean different things to different people. None of the professionals in medical schools use the term "ME", they use CFS from the 1994 definition of CFS - flawed though it is - which has come to be the dominant catch-all definition. These Draft Guidelines should have taken advantage of the opportunity to make progress by using and recommending the term recognised and used by the WHO - under ICD 10 G93.3 - ME/CFS. However, NICE has chosen to ignore this international definition.
- (43) The Draft Guidelines often refer to research into chronic fatigue. Let us be unequivocal - Chronic Fatigue is a symptom, not a disease or illness. This means that the Draft Guidelines and evidence are flawed, as we are dealing with ME/CFS. Indeed the lack of precision in the document has CFS being used interchangeably with CFS/ME. Again this is an indication of a lack of scientific rigour in not employing robust, unambiguous terms.
- (44) The term "encephalopathy" is also used which maintains vagueness. IiME strongly believe that neurological ME is not Myalgic Encephalopathy - but Myalgic Encephalomyelitis, as defined by WHO ICD 10 G93.3.
- (45) IiME believe that NICE should demand that the correct terminology is used by all healthcare staff. ME/CFS is the name that should be used. Instead, NICE proves itself to be hypocritical in stating the need for consistent terminology yet using a variety of contradictory terms. This alone undermines the Draft Guidelines and the integrity of NICE.
- (46) Views by ME support groups show that ME/CFS must be seen as a distinct and separate illness from CFS so IiME fail to understand why NICE often use the term CFS alone in these Draft Guidelines. This, we feel, is part of the problem with healthcare staff and others - by broadening the view of what ME is it will inevitably dilute the requirements for diagnosing and treating ME patients.

## 4.3 Epidemiological Data

- (47) The NICE Draft Guidelines admit that there is a lack of epidemiological data for the UK. NICE do not question why the UK Department of Health (DoH) is not collecting epidemiological data, does not question how old the data is that states "prevalence of at least 0.2-0.4%" and does not ask "What is the latest estimate for the UK"?
- (48) It has been reported that ME is now the leading cause of long-term absence from school for children. NICE is derelict in its duty by not proposing to make ME a "Notifiable Illness" in schools, and/or supporting the collection of data to allow epidemiological studies to be augmented. The lack of comment on epidemics and vaccinations shows how lacking in vision, scope and thoroughness has been the analytical work performed by the NICE Draft Guidelines preparation team. The NICE Draft Guidelines do not carry a single reference to vaccinations, despite research and evidence being present from over ten years ago.

- (49) The recent investigations in Norway (published prior to NICE's August review of new research information) reveal the extent of ME cases caused by vaccinations. None of this has been mentioned within the NICE Draft Guidelines.
- (50) The NICE guidelines do not carry one reference to ME epidemics despite strong evidence to support this from numerous references in the USA, Iceland and the UK.
- (51) The NICE Draft Guidelines do not include any reference to ME and organo-phosphate (OP) poisoning despite the mounting evidence indicating that exposure to OP chemicals can cause ME. IiME ask why this has not been had at least a passing reference?
- (52) We consider that the foregoing are all points of major oversight by NICE in the preparation of the Draft Guidelines. IiME considers that such possible links to other causality factors and aggravating conditions are important and should at least be included in any serious review of the bio-medical situation for patients who present with conditions similar to ME.
- (53) IiME proposes that research should be performed on historical records and evidence from epidemics and vaccinations that have resulted in similar conditions to ME and that the NICE Draft Guidelines authors should have analysed these topics sufficiently to include comment, since such information could directly affect diagnosis and management. Yet again, NICE could have been shown to have taken the initiative here, but another opportunity to provide such leadership has been lost.

#### **4.4 Sub-Grouping**

- (54) The Draft Guidelines make no mention of the need for sub-grouping of the current CFS and ME patients. To quote Dr. Vance Spence of ME Research UK *"This illness is very big, very complicated and we are not going to solve anything by pushing everyone in to one large group called CFS. At present, what patients are left with is a "devalued" diagnosis consisting of (in one researcher's words) a "...ragbag of common non-specific symptoms with many causes, mistakenly labelled as a syndrome"."*

## 5 Third term of reference: NICE's evaluation process and whether any particular groups are disadvantaged by the process

- (55) The Draft Guidelines continue to allow pwme and their carers to be disadvantaged, as described in the following text.

### 5.1 Diagnosis

- (56) The recommendations regarding diagnosis of ME in the Draft Guidelines are conspicuous by their absence. (An example - to disqualify a check for Lyme Disease is incomprehensible, especially with evidence of misdiagnosis in many ME patients).
- (57) There are at least ten definitions of CFS. In the Draft Guidelines a frequently used case definition is the Oxford Criteria, which includes patients with no physical signs and selects subgroups of patients with high levels of psychiatric diagnoses. IiME suggests that the use of the Oxford Criteria for any discussion/diagnosis or treatment for ME should be terminated forthwith. Most researchers now ignore the Oxford Criteria as they believe them to be worthless. The NICE Draft Guidelines should not be using research based on these criteria as they are flawed and biased –which will cause all research results based on these criteria to be worthless. The continued usage of these criteria disadvantage genuine ME sufferers.
- (58) IiME believe that NICE has lost an opportunity to bring discipline and consistency to this area by not adopting the latest and most **stringent** guidelines available (as described by NICE themselves in their Draft Guidelines) – the Canadian Diagnostic Criteria (or Guidelines). The 2003 Canadian definition states that cardinal symptoms are no longer optional and that patients must have neurological, immune and/or neuroendocrine manifestations. Adoption of the Canadian Guidelines would have led to a substantial improvement in the diagnosis and treatment of ME in the UK. NICE have again failed in this respect.
- (59) There is little in the Draft Guidelines that would persuade a GP to conduct a proper and full medical examination before diagnosis. Imaging is mentioned only once as regards recommendations. It is never mentioned anywhere else, although many doctors now believe that proper medical examination to exclude other illnesses should include SPECT scans.
- (60) NICE state that “*several factors have been suggested (as to the cause), including: immunological, genetic, viral, psychological and neuroendocrine.*” If this is accepted as a biological illness then, why is the report slanted at psychological paradigms to manage the illness? Essential research showing the multi-system nature of ME has been ignored and is not considered or discussed, e.g. enteroviruses, orthostatic intolerance and oxidative stress.
- (61) Current and previous biomedical research is ignored. IiME dispute the frequent statements within the Draft Guidelines characterised by this text “*There is little understanding of the nature of the disease*”. **There are over 4000 biomedical research papers on the illness**, which the NICE searches should have discovered and analysed.



- (62) IiME cannot accept that these Draft Guidelines use as broad a section of fatigue states as possible in describing ME. The Draft Guidelines present a quite biased and narrow-looking report which mixes up far too many illnesses and research information simply to prove the original intention of the document – to force pwme to be given psychological therapies and repeat the myths of the past. The document also attempts to subjugate ME into a bag of common illnesses all falling under the term CFS. In this, NICE has done a major disservice to pwme who are needlessly suffering from the perceptions of biased healthcare professionals who maintain their pejorative views with little good scientific evidence. This questions the impartiality of NICE and the Draft Guidelines.

## **5.2 Human Rights**

- (63) It has been stated that by ignoring the serious issues with regard to CBT and GET, the NICE Draft Guidelines, as currently drafted, may 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 by subjecting patients to these therapies via a set of guidelines from a government sponsored organisation, such as NICE.
- (64) IiME considers that NICE are opening themselves up for possible litigation in the future due to their recommendations for GET for pwme. IiME could foresee where NICE could be liable for damages if the recommended psychological therapies were forced on pwme and then cause a degradation in health.
- (65) There seems to be no regulatory framework governing the development and use of CBT and GET, thus leaving pwme vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice. IiME contest that this is already the case. The NICE Draft Guidelines could exacerbate such exploitation.

## **6 Third term of reference: NICE's evaluation process and Speed of publishing guidance**

### **6.1 Document Structure**

- (66) NICE took two years to formulate these proposed Draft Guidelines. The ME stakeholders/sufferers were limited to two months in which to respond with comments, despite the fact that their illness severely limits what they can do. Little consideration of the condition of pwme, whose cognitive abilities are affected by the illness, has been included within the planning schedule.
- (67) It is over five years since the Chief Medical Officer's (CMOs) report on ME was published and four years since the Medical Research Council (MRC) working group published recommendations. These Draft Guidelines have been universally rejected by the ME community and so the situation is not being improved.
- (68) The full version of the Draft Guidelines document is poorly structured and cumbersome to read. It is considered very unwieldy and the shortened version is probably the only version that will be read fully. This will then lead to the fuller guidelines being ignored as regards supporting evidence. But, if this evidence is flawed, then the whole document becomes suspect.
- (69) The structure of the document, with recommendations spread all over, references everywhere, sections which should be broken down into more manageable entries and tables and page sets of varying formats are an indication that the whole document is badly formatted. Even a healthy person would find it difficult to read the full version.

## 6.2 Implementation

- (70) One section included in the short version, but not present in the full version, was entitled Implementation. As far as the cost of all of the psychological therapies (posing as treatments) are concerned it is difficult to understand how this will be paid for with an estimated 250,000 people suffering from ME/CFS in the UK. This is of especial concern considering the low priority and lack of funding given to ME in the past. To have sparse resources squandered on psychological therapies, which the ME community do not need or want, is considered to be an appalling waste.
- (71) Perhaps implementation should consider what the need of the medical community is, especially clinicians who need assistance with the diagnosis of ME and the exclusion of related non-specific fatiguing conditions. One of the biggest issues with ME is the lack of a clear diagnostic tool and the mixing of patient cohorts with numerous fatiguing conditions. The use of the WHO ICD-10 G93.3 definition for Myalgic Encephalomyelitis and the development of a "fingerprint test", possibly based on the elevated levels of Choline in the brain blood chemistry, which has been the only unique identifier found to-date, could be used and validated.

## 6.3 Objectives

- (72) Finally, when looking at NICE's evaluation process, IIME suggest that NICE has failed to evaluate if their guidelines have achieved the stated objectives and offers the following observations against the defined objectives.

### 6.3.1 Objective: Increasing the recognition of CFS/ME

- (73) Not achieved as the Draft Guidelines provide nothing new for sufferers and carers. Essential research showing the multi-system nature of ME is not discussed, e.g. enteroviruses, orthostatic intolerance, oxidative stress. Yet without a basic understanding or awareness of the pathology of the illness how are healthcare staff supposed to recognise the true nature of ME? Increasing the recognition of ME can only be achieved by increasing the knowledge of the illness itself.
- (74) The NICE recommendations once again force non-functional and biased psychiatric therapies as management techniques and will lead to more harm and probably contribute to fostering even more antagonism between healthcare staff (especially those who are untrained in ME) and the patient/carer. Increasing recognition of the illness could also have been assisted by the use of the correct terminology – as detailed by the WHO. IIME consider that ME/CFS is the correct term and Myalgic Encephalomyelitis is the correct name for the acronym ME. By pandering to organisations and individuals, who have a vested interest in using other terms, NICE will be considered to have failed and the consensus amongst ME patients will be that NICE cannot be trusted.

### 6.3.2 Objective: Influencing practice in the “real world”

- (75) This objective is not met. By immediately stating that CBT and GET are the most useful therapies or treatments NICE has shown it is not willing to move the issue of ME into an area that offers any real hope of progress. These Draft Guidelines will not influence practice but will lead to already established myths being perpetuated. The lack of a decision on endorsing one set of diagnostic guidelines – the ‘*more stringent*’ Canadian guidelines – is seen as a travesty. It seems that NICE is intent on maintaining as broad a definition for ME as possible. This will result in little change in the “*real world*”. The absence of emphasis on the lack of funding for biomedical research into ME will not help to alter the government’s/MRCs position on this subject and, therefore, gives little to change the current unsatisfactory position where patients are subjected to possible harmful GET. It will not inform healthcare staff of the missing link in research into ME – funding for biomedical research. The Draft Guidelines state that a patient/carer can refuse any therapy without it impacting the relationship with the healthcare practitioner(s). In the face of insurance companies and Department of Work and Pensions (DWP) staff forcing an ME patient to undergo potentially harmful or useless GET or CBT, then we doubt if these Draft Guidelines will prevent this from happening. In such instances, recourse to litigation will be the only possibility for pwme. It would have been useful for these Draft Guidelines to detail what avenues are open for legal aid for pwme who wish to challenge insurance companies and healthcare staff who insist on ME patients undergoing GET or CBT against their will.
- (76) In summary:
- The guidelines make little headway in influencing ‘real world’ issues such as insurance companies forcing claimants with ME to undergo psychiatric therapies.
  - The guidelines do little to influence ‘real world’ issues such as the requirements from the DWP that people with ME go through elaborate processes to prove they are ill.
  - The guidelines do little to influence ‘real world’ issues such as the need for parents to battle with schools for the rights of their children with ME.

### 6.3.3 Objective:

*Improving access to appropriate services, and supporting consistent service provision*

- (77) It is doubtful this has been met as NICE provide nothing new for sufferers and carers. Little is given in support of pwme in their dealings with DWP staff and no reference is made regarding how pwme are meant to deal with the harassment and bias of insurance companies who propose psychiatric treatment for ME.

### 6.3.4 Objective: Emphasising the need for multidisciplinary working

- (78) These guidelines patently fail to achieve this due to the concentration on psychological therapies at the expense of real research of published biomedical research papers. Although there are a few statements stating that multi-disciplinary working is required in dealing with pwme the bias toward psychological therapies, and the amount of space given to these therapies (masquerading as treatments) in these guidelines, means that there is little credit given to non-psychiatric disciplines in treating and managing ME.

### 6.3.5 Objective: Improving care for patients, and particularly for those severely affected

- (79) The guidelines offer little for severely affected pwme. There is no provision for specialist treatment – simply rehashed dogma relating to therapies which are entirely inappropriate for severely (and moderately) affected pwme. There is little support defined for carers.

#### 6.3.6 Objective: Providing guidance on 'best practice' for children with CFS/ME

- (80) Here the Draft Guidelines fail abjectly. The best practice is not psychiatric therapies, where the onus is on the patient to attend meetings with psychiatrists. NICE have failed the children of this country with ME.

#### 6.3.7 Objective:

Balancing guidance with the flexibility and tailored management, based on the needs of the patients

- (81) By emphasising GET and CBT as primary treatments it is not possible to state that these Draft Guidelines help in basing management on the needs of patients. Its predilection for asserting that activity and exercise help pwme already undermines any confidence that the ME community may have about the impartiality of these guidelines.

#### 6.3.8 Objective:

Facilitating communication between practitioners and patients, and their families or carers

- (82) It cannot be said this objective was achieved, as the emphasis on psychological therapies posing as treatments using heavily skewed data will inevitably influence GPs and paediatricians – especially if they have little time available for pwme. A multitude of fatigue-related patients are included in this study. If it purports to be for ME then the studies need to use pwme – not CFS or other fatigue conditions.

(83)

## **7 Any recommendations for action by the Government or others which the submitter would like the committee to consider for inclusion in its report to the House**

- (84) The psychological approach has been comprehensively covered in this initial proposal for a NICE Guideline. Any future iteration needs to clearly demonstrate a balanced approach and include the compelling biomedical research that shows the organic nature of ME and which will likely dictate the diagnosis and treatment of ME.
- (85) If NICE attempt to implement these Draft Guidelines without substantial change or revision following the consultation process, without having accepted the depth and breadth of the failures and omissions in the Draft Guidelines, then rejection by the community of pwme is likely and IiME could postulate that a judicial review would be inevitable.
- (86) NICE state in these Draft Guidelines that they wish for the patient and medical community to work together. IiME consider that the exact opposite will be achieved if these Draft Guidelines are not subject to a severe review and re-write.
- (87) IiME would submit that, as Ellen Piro of the Norwegian ME Association reminds us of the old adage –

*"If the map doesn't match the terrain, it is the map that is wrong and not the terrain."*