



Invest in ME

August 2007

Invest in ME Response to the

NICE CHRONIC FATIGUE SYNDROME / MYALGIC ENCEPHALOMYELITIS (CFS/ME) diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis in adults and children GUIDELINE

Invest in ME



August 2007

1. Background

Invest in ME (IIME) is a UK charity which was registered in May 2006 by people with Myalgic Encephalomyelitis (ME/CFS) or parents of children with ME/CFS. The work we perform is unpaid and voluntary and the charity has no paying subscribers. We therefore are independent and do not have any ties to NHS or government departments which could influence our opinions when analysing these guidelines.

Invest in ME have examined the Full version of the NICE guidelines

“Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) in adults and children”

which are meant for healthcare professionals. We have also looked at the other documents produced by NICE in all the categories (for patients, careers and the public).

A summary of our comments is supplied here.

The objectives of IIME in reviewing the NICE Guidelines are to ensure that people with Myalgic Encephalomyelitis (ME) and their families receive appropriate treatment. Due to the severity and consequences of this illness ME/CFS needs to receive whatever public funding is necessary to allow proper diagnosis, treatment based on scientific evidence and not vested interests, and for a cure for this devastating illness to be developed.

IIME reviewed the NICE Draft Guidelines (Chronic fatigue syndrome/Myalgic encephalomyelitis: diagnosis of chronic fatigue syndrome/Myalgic encephalomyelitis in adults and children) in 2006 and produced a comprehensive, 38,000 word review of the full and short versions of the Draft Guidelines.

NICE took over two years to formulate the Draft Guidelines. IIME, along with the ME/CFS community, were limited to two months to respond with comments to the Draft Guidelines and received no advance warning of the final contents of the NICE guidelines released in August 2007.

Where necessary IIME have drawn on our review of the NICE Draft Guidelines for those areas where our concerns not been satisfactorily addressed or have been ignored by NICE (full comments to the draft guidelines with references are available



Invest in ME

August 2007

at <http://tinyurl.com/375t5t>. These references are able to back up the quotes and research in this document also).

IIME welcome the fact that at least some of our recommendations and requests for changes have been accepted by NICE.

We are dismayed that many have been left unanswered or unsatisfactorily answered, or ignored.

These guidelines relate to CFS/ME. NICE incorporate all of the existing forms of chronic fatigue within this document and include ME or ME/CFS – myalgic encephalomyelitis.

We would prefer to use the term ME for the illness but recognise that ME/CFS is used widely. The true term for ME/CFS is myalgic encephalomyelitis and IIME have used the correct WHO IDC 10 G93.3 classification of this neurological illness – ME/CFS – within this document in our comments in order to standardise.

IIME's interest is ME/CFS – a neurological illness.

2. IIME Comments on These Guidelines

In the Preface Professor Richard Baker states that

"The publication of this guideline presents an opportunity to improve care for people with CFS/ME. "

That was a very true statement.

It is a sad failing of NICE, however, that these guidelines fail to grasp this opportunity and instead deliver a weak and ineffectual document that seemingly attempts to retain much of the ignorance and prejudice existing within healthcare provision for ME/CFS.

We believe these guidelines provide little to further the treatment of ME/CFS and this is an opportunity missed by those entrusted with the responsibility for producing these guidelines.

The NICE guidelines lack any vision in moving forward the treatment of people with ME/CFS.

NICE have chosen only to use the evidence which satisfied a predetermined view that CBT and GET are preferred methods of treatment for ME, that there is doubt about the true nature of ME/CFS and that CFS incorporates ME/CFS within its catchment.

We dispute the statement by Baker that



Invest in ME

August 2007

"A recent two-year programme to set up demonstration services has shown what can be achieved, and we wish to encourage development of care based on the experience of these schemes."

The overwhelming majority of the CNCC Clinics are generally nothing more than psychiatric-led chronic fatigue therapy centres, often headed by psychiatrists and achieving nothing to help people with a neurological illness. The money on setting these clinics up has been wasted.

Baker's comments are typical of the NICE spin on the true facts surrounding ME/CFS.

Baker continues –

"Development of recommendations about the cause of CFS/ME was outside the scope of the guideline."

Yet surely a diagnostic test should not be outside the scope!
How else is it possible to overcome this *"poor understanding"* of the illness.

Baker states that -

"In developing the guideline, we kept in mind the overall goal of improving care for people with CFS/ME, that is, improving diagnosis, enabling patients to receive therapy appropriate for, and acceptable to them, and providing information and support, with the patient's preferences and views firmly driving decision-making."

Yet how can diagnosis be improved if NICE refuse to adopt consistent, standard guidelines and deem diagnostic tests to be out of scope and do not call for research in finding a diagnostic test.

NICE have ignored the overwhelming evidence showing the organic nature of the illness and use a deplorable spin on the facts which does not serve ME/CFS patients, their families or healthcare staff who are genuinely interested in helping.

It is also rather short-sighted to ignore all of the politics which have been going on for years as the vested interests of psychiatrists, including the original Beard analysis back in the seventies, have effectively clouded the issue of ME/CFS and allows the myths (which are perpetuated in the guidelines) to distort thinking and action and so adversely affect the chance of ME/CFS patients to get sensible and proper consideration for the underlying biological illness.



Invest in ME

August 2007

We dispute the continued characterisation of ME/CFS as being '*poorly understood*'. There are over 4000 biomedical research papers on the illness which the NICE searches should have seen and analysed.

Views by ME/CFS support groups show that ME/CFS must be seen as a distinct and separate illness from CFS. This, we feel, is part of the problem with healthcare staff and others – by broadening the view of what ME/CFS is it will inevitably dilute the requirements for diagnosing and treating ME/CFS patients.

The guidelines are 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.

It also attempts to subjugate ME/CFS into a bag of common illnesses all falling under the term CFS. In this NICE have done a major disservice to people with ME/CFS who are needlessly suffering from the perceptions of biased healthcare professionals who maintain their views with little good scientific evidence.

This questions the impartiality of NICE and the Guidelines.

People with ME/CFS wish that this illness is taken seriously by the medical profession as the neurological illness that it is and that research is publicly funded to provide early diagnosis, treatment, and eventually a cure.

liME agree, and welcome the areas of the guidelines which state that the patient/carer is in control of actions and decisions relating to the illness. The statement that -

"treatments which are offered allow the person with the CFS/ME to refuse without compromising the further therapeutic relationship" ,

which appear frequently in the NICE guidelines, must apply always.

Decision-making lies with the patient/carer - this needs to be emphasised so that insurance companies are also aware that people with ME/CFS may refuse any inappropriate treatment without any consequences or denial of benefits.

liME analysed the full version of the guidelines. We also examined the short version (the version most people, including healthcare staff, will look at).

Below we comment on the major areas of the guidelines.

Research



Invest in ME

August 2007

NICE state that "*The research recommendations were chosen to prioritise those areas that would most directly inform future guidelines.*"

Yet no biomedical research is highlighted which will help future guidelines. The current and previous biomedical research is seemingly ignored.

The literature searches referred to by NICE seemingly failed to find the abundance of biomedical research into ME/CFS and we wonder whether they were conveniently ignored?

We cannot accept that these guidelines still use as broad a section of fatigue states as possible in describing ME/CFS.

Terminology

The terminology may be crucial in dealing with ME/CFS, especially as GPs, paediatricians, other healthcare personnel and the media use different terms.

Let us be unequivocal - Chronic Fatigue is a symptom, not a disease or illness. The correct term currently to be used is ME/CFS.

NICE have quoted the CMO working group

"The CMO working group called for a consensus to be reached on terminology and definition, and while awaiting this, suggested that the composite term CFS/ME is used and that it is considered as one condition or a spectrum of disease for the purpose of the report."

But the CMO working group is now 5 years old and little or none of the recommendations from the CMO report have been implemented (see <http://tinyurl.com/2vtqr5>).

A new direction is required.

We need to subgroup CFS/ME so that ME/CFS is separate from the various fatigue states which have so benefited the psychiatric lobby and their unscientific trials and so rewarded them with the near totality of available funding.

The MRC did not complete a research strategy (<http://tinyurl.com/2mxwmw>) and has failed to make any breakthrough due to its persistence in refusing to fund biomedical research.

NICE do nothing to address the issue of terminology and instead seem satisfied to perpetuating the terminological mess around ME/CFS.



Invest in ME

August 2007

Perhaps the principal problem is that ME/CFS is not 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" or "ME/CFS", they use CFS since the 1994 definition of CFS - flawed though it is - has come to be the dominant catch-all definition.

NICE call for "*Avoidance of dogmatic belief in a particular view.*"

Yet this is itself biased as all of the evidence and recommendations made by NICE are using psychiatric paradigms for treatment.

The NHS maintains a systemic corruption in its classification of ME/CFS as a mental illness. The MRC refuse to fund biomedical research yet pay millions for psychiatric trials. NICE is entirely disingenuous in this statement.

How could there be any progress, for example, in understanding MS if all research was performed on coping strategies of MS sufferers?

These guidelines could have moved this issue on by using and recommending the term recognised and used by the WHO – under ICD 10 G93.3. However, NICE refer to the WHO classification only once and then fail to accept this and then totally ignores this international definition. The persistence in retaining as broad a band of fatigue states to be included with a neurological illness invalidates any claims by NICE to be impartial or scientific.

NICE also allows "*encephalopathy*" to be used, which merely serves certain organisations or individuals who benefit from having as wide a set of paying subscribers/patients as possible or who have vested interests in maintaining vagueness.

The title is misleading and incorrect.

Dr. B. Saraceno of the WHO clarified the classification in writing on October 16, 2001.

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

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



Invest in ME

August 2007

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

IIME believe that NICE should have had the courage, and the morals, to demand that the proper terminology is to be used by all healthcare staff. ME/CFS is the name that should be used. This alone undermines the guidelines and the integrity of NICE.

The problem lies in the lack of separation of ME/CFS from the various fatigue states which NICE seem happy to live with under one definition.

IIME asked for biomedical terms which have been proven to exist in pwme to be documented? This document is supposedly aimed at healthcare professionals so terms common to many ME/CFS patients and to serious ME/CFS researchers ought to be here to help educate healthcare staff.

We asked why the concentration of terms connected to psychiatric paradigms and therapies were present? Why not others? NICE chose to ignore our recommendation to add other terms such as Orthostatic intolerance, Oxidative stress and other biomedical terms which have been proven to exist in pwme?

NICE commented "*We have not included definitions of all medical terms in the guideline as this is not text book but a guideline for healthcare professionals – therefore only some terms have been included.*"

This didn't answer the question and poses the next question why is NICE intent on supplying only limited and biased reference data?

Why have NICE decided to concentrate on terms connected to psychiatric paradigms and therapies and deliberately choose to ignore others?

The real NICE agenda surfaces yet again.

Sub-Grouping

The guidelines ask "*What are the best ways of sub grouping patients to aid in diagnosis and management?*" and then fail to discuss sub grouping or even mention it again.

NICE make no mention of the need for sub-grouping of the current ME/CFS patients and separation from chronic fatigue.

Professor Leonard Jason of DePaul University, Chicago published in 2005 an excellent review on the need for sub-grouping of the over-broad "diagnostic category" CFS which can catch widely different groups of patients in its net. As he said,



"This review suggests that there is a need for greater diagnostic clarity and that this might be accomplished by subgroups that integrate multiple variables including genetic, neurological, psychological and biological domains."

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"."

This is a major failing of NICE as no recommendation on sub grouping is made. The guidelines fail to address a key element in the treatment of this illness and so fail all ME/CFS patients as well as healthcare staff.

Sub-grouping is indeed one of the big issues and NICE could have done more by calling for this to happen and basing the sub-grouping on up-to-date and valid criteria for diagnosis such as the Canadian guidelines.

Epidemiological Data

The NICE guidelines admit that there is a lack of epidemiological data for the UK. So why is the UK DoH not collecting epidemiological data?

The CMO working group produced the figure that states "prevalence of at least 0.2–0.4%"? That report was from 2002. What is the latest estimate for the UK?

It has been reported by one study (Dowsett, Colby; 1997) that ME/CFS is the leading cause of long-term absence from school for children. Yet this is not addressed in these NICE Guidelines. Why?

Why does NICE not take the opportunity to join Invest in ME in calling for ME/CFS to be made a notifiable illness in schools to allow epidemiological studies to be augmented? This would help the epidemiological analysis as well as ensuring that schools take this illness seriously. It also would reduce stress on children and their families as it would likely be taken more seriously. NICE fail to even recognise the problem.

Vaccinations



Invest in ME

August 2007

Despite IIME informing NICE of the absence of comment on the link between vaccinations and ME/CFS the guidelines do not carry a single reference to vaccinations despite research being present from over ten years ago.

Why?

The recent investigations in Norway (published prior to NICE's August 2006 review of new research information) reveal the extent of ME/CFS cases linked to vaccinations and there is research appearing over 10 years ago which documents the connection (<http://tinyurl.com/2os5h2>).

None of this has been mentioned by NICE.

Why?

Epidemics

The NICE guidelines do not carry one reference to epidemics despite strong evidence to support this from numerous references.

Why?

NICE failed to make any changes to the draft guidelines in this respect and ignored IIME's questions relating to this despite IIME supplying at least 12 references as evidence.

Why?

Organo-Phosphate poisoning

The NICE guidelines do not carry any reference to organo-phosphate poisoning despite the evidence indicating it being linked to ME/CFS.

Why?

These are all major oversights by NICE.

IIME consider that these links 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/CFS.

IIME suggests that research ought to be performed on historical evidence from epidemics and vaccinations that have resulted in similar conditions to ME/CFS and the NICE GDG ought to have analysed these topics sufficiently to include comment as the information can directly affect diagnosis and management.



Invest in ME

August 2007

NICE could have taken the initiative here, but yet again another opportunity to provide leadership has been lost.

There are many other comments in the guidelines which carry a lack of evidence to support their inferences.

The definition states that the majority of individuals with mild CFS/ME will still be working. Where is the evidence for this? No epidemiological studies can substantiate this. Studies by ME Research UK show that around 50% are employed but struggling to maintain their lives, with another 40% existing on benefits. This is a different spin on the facts.

Most *"mildly affected"* will not *"use the weekend to cope with the rest of the week"*. This is so generic as to be unusable. Many students for example will use the weekend to make up for lost time during the week.

NICE state that *"Higher depression scores were noted among CFS/ME patients in some studies but it was unclear whether depression occurred before or after CFS/ME symptoms began."*

How would this compare to other chronic illnesses?

This is a skewed spin which NICE use to trash ME/CFS patients.

NICE state that *"Most people with CFS/ME will improve over time and some people will recover and be able to resume work and normal activities."*

Where is the evidence to support this?

No epidemiological studies have been performed to determine the accuracy of this statement.

NICE state that *"No definitive studies have been carried out in the UK to determine the prevalence of severe CFS/ME in people with CFS/ME"*.

Would it not be possible to extrapolate these figures from those statistics of people claiming incapacity and DLA benefit due to ME/CFS?

Making ME/CFS a notifiable illness in schools would also assist in collating statistics of prevalence of ME/CFS in children. For an illness that is recognized as the leading cause of long-term absence from school (Dowsett, Colby; 1977) this would seem to be a relatively easy procedure to effect.

NICE fail to progress these areas. Another opportunity missed.

Diagnosis



Invest in ME

August 2007

There are at least ten definitions of Chronic Fatigue Syndrome. In these guidelines and the so-called supporting evidence base 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.

This is too broad a view of fatigue states and underlines the heart of the problem with the way this illness is treated and perceived as it includes far too broad a range of illnesses.

IIME feels that the use of the Oxford criteria for any discussion/diagnosis or treatment for ME/CFS has long since reached its sell-by date and its usage should be terminated forthwith.

Most sections of the ME/CFS community, who have no desire to retain as wide a selection of subscribers for their own financial gain, now ignore the Oxford guidelines as they believe them to be worthless.

Even NICE state that the Canadian guidelines are more detailed than the Oxford.

There is little unequivocal evidence to show that CBT or GET has good evidence of benefit and much which shows the contrary result. Most of these studies have also used the flawed Oxford criteria for selection of participants in the programme where neurological symptoms of the illness disqualify patients from being included!

At this time there is no evidenced-based proof that these therapies are appropriate which has been accepted as rigorous and independent from the psychosocial approach to ME/CFS by some experts.

The NICE guidelines should not be using research based on these criteria as they are flawed and biased – something which will cause all results based on these criteria to be worthless.

The 2003 Canadian definition states that cardinal symptoms are no longer optional and that patients must have neurological, immune and/or neuroendocrine manifestations.

NICE recognise that -

"The 2003 Canadian definition¹¹ is more stringent and was developed by an international clinical CFS team."

yet then fail to take any leadership and recommend their usage.

NICE should have used the Canadian guidelines to differentiate between true ME/CFS and other conditions. The criteria used by NICE to diagnose ME/CFS can include almost anybody.



Invest in ME

August 2007

The number of varying diagnostic guidelines is a problem that the ME/CFS community has been criticising for a long time.

NICE state that "*The evidence review concluded that no current case definitions are established as being superior to the others. The Canadian criteria are based on expert opinion, and not research*".

This is incorrect. The research base is comprehensive.

The Gibson Inquiry recently reviewed diagnostic criteria and concluded that the Canadian criteria were a useful contribution to defining the clinical condition of CFS/ME. They are more detailed than the Oxford criteria, for example.

This is central to the whole issue of diagnosis. The Canadian guidelines will differentiate between those who have neurological ME/CFS and those who have a collection of symptoms which will be classified as idiopathic chronic fatigue.

Correct diagnosis allows each group to be treated accordingly.

From Canadian guidelines: 'Idiopathic chronic fatigue: if the patient has unexplained prolonged fatigue (6 months or more) but has insufficient symptoms to meet the criteria for ME/CFS, this should be classified as idiopathic chronic fatigue.'

IIME feel that NICE have again lost an opportunity here to bring discipline and consistency to this area by not adopting the latest and most **stringent** (the word used by NICE themselves in the Canadian Guidelines) guidelines available – the Canadian Guidelines. This would have led to a substantial shift in the diagnosis and treatment of ME/CFS in the UK.

NICE have failed in this respect.

The NICE guidelines state that "*several factors have been suggested (as to the cause), including: immunological, genetic, viral, neuroendocrine and psychological.*" If this is accepted as a biological illness then why is the report slanted at psychological paradigms to manage the illness?

From this approach, IIME can only conclude that the basis of the NICE Guidelines is in viewing as broad a section of fatigue states as possible, where high quality biomedical research into ME/CFS has been ignored. Essential research showing the multi-system nature of ME/CFS has been ignored and is not considered or discussed, e.g. enteroviruses, orthostatic intolerance and oxidative stress.

There is little in the guidelines that would persuade a GP to conduct a proper and full medical examination before diagnosis.



Invest in ME

August 2007

Imaging is mentioned once as regards recommendations. It is never mentioned anywhere else, although many doctors now believe proper medical examination to exclude other illnesses should include SPECT scans.

This potentially allows this illness to take a hold whilst opening the door to ineffective and dangerous psychiatric treatments set up by ignorant healthcare staff.

NICE state that persistent fatigue is that which lasts for at 3 or 4 months and substantially outlives its precipitating cause. How is it possible to say this? If the cause is unknown how can it be stated that the precipitating cause has been outlived?

ME/CFS is an acute onset illness and 3-4 months may be too long. This section advises that *"Advice on symptom management should not be delayed until a diagnosis is established."* IIME feel that tests and treatment must be possible earlier (example – mycoplasma is implicated in ME/CFS – early usage of antibiotics may treat this but delayed usage will compromise recovery).

Why should there be a difference in the timescale for children compared to adults? Is there a different symptomology or aetiology?

The guideline does not address the management of co-morbidities.

Why? These are as important as the illness

NICE state that *"At present, there are no physical signs that identify CFS/ME specifically."*

Yet NICE exclude a range of symptoms?

The psychological approach has been comprehensively retained from the draft guidelines and these guidelines failed to address this with a balanced approach by excluding the compelling biomedical research that shows the organic nature of ME/CFS and which will likely dictate the diagnosis and treatment of ME/CFS.

For example, the work of Prof Puri at the Hammersmith Hospital is indicating a "fingerprint" marker using elevated Choline levels in brain chemistry SPECT-scan results. There is also the work by Dr Spence at ME Research UK that shows post-exertional oxidative stress that appears to be unique to neurological ME/CFS.

NICE seem content to retain a number of related psychological and clinical illnesses together even though the differentiation should clearly distinguish ME/CFS from other fatiguing syndromes and illnesses. It should be remembered that ME/CFS has been found to have inflammation of the brain and central nervous system and that pathology will provide increasing evidence.



The list of symptoms does not include orthostatic intolerance. Yet Dr Peter Rowe found as long ago as 1994 that ME/CFS patients had significant cardiovascular responses to standing upright, manifested by changes in vascular volume/heart rate/blood pressure. An article entitled "Standing Up For ME" in *The Biologist* in 2004, Professor Julian Stewart and Dr Vance Spence outlined some of the "physical" arguments surrounding this aspect of the illness.

"The first thing to recognise is that the blood pressure in most ME/CFS patients is maintained by a significant increase in heart rate, at least in the early stages of upright posture."

Professor Stewart of New York has published some interesting data on what happens to ME/CFS patients when they are upright, and it shows that there is a group of patients whose leg blood is low when lying down and it *increases* when upright, a wholly abnormal response and indicative of a shift of vascular volume towards the legs. Images of the leg of an 18 year old woman suffering from ME/CFS were shown when in the supine and upright position to illustrate the increased blood flow.

This whole area of orthostasis is extremely complex and indicates that there might be a problem with peripheral blood vessels in ME/CFS patients. Since 2000, the group at the University of Dundee has been looking at how skin blood vessels respond to the endothelium-dependent vasodilator, acetylcholine. In ME/CFS patients, blood vessels are sensitive to acetylcholine driven through the skin; i.e. the skin blood vessels dilate more than expected, a novel if not unique finding (i.e. most diseases show the opposite response to acetylcholine, which is a blunted or decreased blood flow). A review of this work has been published, and ME Research UK continue to fund research on this aspect of ME/CFS especially given its importance to understanding some of the unusual vascular phenomena which characterise the illness.

Dr Vance Spence has highlighted a finding of increased isoprostanes in the bloodstream of ME/CFS patients, and the fact that these were correlated with symptoms. This was the first investigation to measure isoprostanes in patients, which are now recognised as one of the most reliable approaches to assessing in vivo oxidative stress and which seem to be a biomarker of great potential in the assessment of cardiovascular risk. There are several possible sources for these oxidants, including blood vessel endothelium, inflammatory/immune cells and muscle, and a range of precipitating factors can be involved.

The high degree of correlation of increased isoprostane levels associated with post-exertional myalgia from a sample of 29 patients shows the grades of post-exertional fatigue in patients reporting mild, moderate and severe symptoms after exercise. It may be that the muscle pain experienced by ME/CFS patients after exercise is due to the elevated levels of isoprostane and oxidation in the muscle,



but further work is required to understand the mechanisms. This is not shown in the guidelines.

It is interesting to note that NICE state they are concerned about the effect of repeated testing on patients yet happily subscribe to the view that GET is acceptable for ME/CFS patients despite the danger inherent in its use and the poor record of research.

How can these claim to be guidelines for healthcare staff if no comprehensive list of symptoms or investigations is given?

NICE recommend that viral serology should not be carried out in the absence of a recent history suggesting viral infection as it was *"difficult to establish a link between CFS/ME and serology indicating past viral infection, and that serological evidence of past infection would not alter the patient's management"*.

In the early stages of illness it is important to identify viral or bacterial causes and treat them early with relevant antimicrobials.

After receiving a diagnosis of ME/CFS people are too often told that all of their consequent symptoms are 'just ME' and no investigations are undertaken. Many people go on suffering unnecessarily as treatable conditions/co morbidities go undiagnosed. ME/CFS should not be seen as a dead end diagnosis where all investigations stop and patients are only called in for note taking.

Adoption of the Canadian Guidelines for diagnosis, which are comprehensive and stringent and accepted by leading biomedical experts on ME/CFS, would define the critical symptomology in a clear and concise manner that permits objective assessment. The NICE definition does not define the "symptoms".

Treatments & Management

IIME find the information on management the most disappointing – and quite biased. The true agenda for these guidelines seems to be illustrated in this section.

A recommendation for treatment of ME/CFS in the NICE Guidelines for those who are "mild to moderately affected" are Cognitive Behavioural Therapy (CBT) and GET. In making this recommendation, the Guideline Development Group seem to be ignoring credible evidence that such treatments are potentially dangerous for those who suffer from this illness, particularly in the case of GET.

The comments on the management are often worthless as they seem to be dealing with patients suffering from burn-out rather than from a neurological illness. They also seem to be contradictory with a great deal of print sometimes emphasizing the



Invest in ME

August 2007

use of psychological therapies such as GET and CBT and at other times stating that the choices are the patients'.

The complete disparity between the amount of space given to non-psychological treatments/therapies as compared to psychological treatments/therapies shows an obvious and unscientific bias in these guidelines and undermine the value of these documents. The information on CBT and GET in these guidelines often seems to read more like propaganda than a scientific, analytical review of management aids.

The guidelines contain an inordinate number of pages on management using psychological therapies compared to other management aids. Apparently so much time has been spent with cherry-picked research from psychiatrists, most of whom have no credit or respect in the ME/CFS community, yet little effort was made to analyse the biomedical research. It appears that the biomedical research is dealt with in a limited, dismissive and unscientific manner.

The membership of the Guideline Development Group appears to have very little expertise in the clinical definition, analysis and research of neurological ME/CFS 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 biomedical experts in ME/CFS are included.

In the Guideline Development Group there is one neurologist but 2 psychiatrists? Why for a neurological illness?

There is still obvious bias in these guidelines – so much that it is impossible to take some of the statements seriously. The huge amount of coverage given to psychiatric therapies contrasts sharply with the limited analysis given to pharmacological and dietary interventions and complementary therapies. This is indicative of the bias behind these guidelines. The objectives and the result were already predetermined before the publication.

The emphasis in this document on psychological therapies as treatments for ME/CFS only retain the same old myths that ME/CFS is a somatoform illness.

IIME strongly disagree with the recommendation that the therapies of first choice should be Cognitive Behaviour Therapy (CBT) or GET. It is incredible that this should be a recommendation at all, since the Guidelines document a lack of evidence.

NICE state that "*CBT is used as part of the overall management for many conditions, including cardiac rehabilitation, diabetes and chronic pain.*"

Yet compare the NICE guidelines for other illnesses such as MS, Parkinson's etc.



For Dementia [[CG42 Dementia NICE](#)]

Carers of people with dementia who experience psychological distress and negative psychological impact should be offered psychological therapy, including cognitive behavioural therapy, conducted by a specialist practitioner. For people with dementia who have depression and/or anxiety, cognitive behavioural therapy, which may involve the active participation of their carers, may be considered as part of treatment.

No GET was found.

For Epilepsy [[CG20 Epilepsy NICE](#)]

Psychological interventions (relaxation, cognitive behaviour therapy, biofeedback) may be used in conjunction with AED therapy in adults where either the individual or the specialist considers seizure control to be inadequate with optimal AED therapy.

Psychological interventions (relaxation, cognitive behaviour therapy) may be used in children with drug resistant focal epilepsy.

No GET was found

For MS [[CG8 Multiple Sclerosis NICE](#)]

Specific antidepressant medication, or psychological treatments such as cognitive behavioural therapy, should be considered, but only as part of an overall programme of depression management.

No GET was found

For Parkinson's [[CG35 Parkinson's NICE](#)]

No mention of CBT or GET

For mental health and behavioural conditions one can see the following -

CG51 Drug misuse: psychosocial interventions: NICE guideline

Cognitive behavioural therapy and psychodynamic therapy

Cognitive behavioural therapy and psychodynamic therapy focused on the treatment of drug misuse should not be offered routinely to people presenting for treatment of cannabis or stimulant misuse or those receiving opioid maintenance treatment.



Invest in ME

August 2007

Evidence-based psychological treatments (in particular, cognitive behavioural therapy) should be considered for the treatment of comorbid depression and anxiety disorders in line with existing NICE guidance for people who misuse cannabis or stimulants, and for those who have achieved abstinence or are stabilised on opioid maintenance treatment.

CG22 Anxiety: NICE guideline

*Cognitive behavioural therapy (CBT) should be used.
CBT should be delivered only by suitably trained and supervised people who can demonstrate that they adhere closely to empirically grounded treatment protocols.*

CBT in the optimal range of duration (7–14 hours in total) should be offered.

For most people, CBT should take the form of weekly sessions of 1–2 hours and should be completed within a maximum of 4 months of commencement.

Briefer CBT should be supplemented with appropriate focused information and tasks.

Where briefer CBT is used, it should be around 7 hours and designed to integrate with structured self-help materials.

For a few people, more intensive CBT over a very short period of time might be appropriate.

This shows the disingenuous intentions behind the NICE guidelines when they have applied them to a neurological illness such as ME/CFS.

NICE state that "*The significant physical and psychological risks associated with prolonged bed rest should be taken into account.*"

So should the dangers of not resting enough, especially during the early stages of the illness. Even results from patient group surveys ("*Rest, including bed-rest, helped 90%.*") which show rest made people feel better and GET made them worse, are given a spin which skews the result.

NICE ignore this!

lIME are left wondering 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 use of other treatments such as supplements and alternative medicines are not recommended even though patient experiences, as evidenced in this document and elsewhere, show them to be useful to some ("*51% said nutritional supplements had helped symptoms*"). Yet NICE refuse to recommend these.



The recommendations for CBT and GET seem to ignore what ME/CFS patients themselves are saying.

NICE's advice is so generic as to be unusable. NICE discourage complete rest (cognitive, physical and emotional) during a setback/relapse.

Elsewhere NICE *"supported the view that people with CFS/ME need to learn to 'listen to' body energy levels in order to manage their daily life and that sudden large increases in activity were not advisable."*

The guidelines contain a lot of bland statements which actually just seem like common sense - e.g. *"For people with moderate or severe CFS/ME, providing or recommending equipment and adaptations (such as a wheelchair, blue badge or stairlift) should be considered "... This may help them to maintain their independence and improve their quality of life."*

Do we really need guidelines and over two years of preparing this set of guidelines, together with their enormous costs, just to repeat the obvious?

CBT

Cognitive Behaviour Therapy (CBT) is being recommended as a management technique and therapy for ME/CFS. NICE state that *"an evidence-based psychological therapy used in many health settings, including cardiac rehabilitation and diabetes management. It is a collaborative treatment approach."*

This is not so – the evidence base is very poor. Even NICE's own document gives a poor evidence level for effectiveness of CBT in reducing symptoms and improve quality of life.

CBT is not a treatment for moderately-affected people with ME/CFS either. *"Cognitive behavioural therapy and/or graded exercise therapy should be offered to people with mild or moderate CFS/ME and provided to those who choose these approaches, because currently these are the interventions for which there is the clearest research evidence of benefit."*

Cognitive behavioural therapy and graded exercise are entirely inappropriate methods of treatment for patients suffering from a neurological illness.

Especially the statement that *"currently these are the interventions for which there is the clearest research evidence of benefit"* is an outright distortion of the truth and has no place in any guidelines purporting to treat ME/CFS. There is only modest evidence from RCTs for these therapies.



Invest in ME

August 2007

NICE have not listened, or chosen to ignore the overwhelming evidence from patient surveys that show these therapies are unhelpful or harmful.

This is an unscientific and highly erroneous guidance.

The "*evidence base*" for CBT is extremely weak and shows an example of NICE "cherry-picking" diverse pieces of research to justify their strategy whilst ignoring other research which totally contradicts and disproves the NICE agenda. The NICE "research" is based on the flawed Oxford criteria as they use all states of fatigue. The description of CBT is confusing. Is it treatment or therapy? The CBT offered for ME/CFS patients, differs from the one offered for cardiac, cancer, diabetes or chronic pain patients. There is a big difference between CBT for somatoform illnesses and CBT for physical illnesses such as ME/CFS.

The glossary definition states that CBT does not imply that symptoms are psychological, 'made up' or in the patient's head. Yet later in the document it refers to "*..The CBT programme ...designed to 'attempt to modify thoughts, beliefs and behavioural responses to symptoms and illness with a view to increasing adaptive coping strategies'.*"

The guidelines are inconsistent and disingenuous.

If this 'therapy' is to be included then Reflexology, Bowen Technique, Acupuncture, and host of other therapies need also to be included – as none of these provide a cure yet all may be used to try to ameliorate some part of ME/CFS.

The evidence base is poor for CBT. Even NICE's reference show the Evidence level at 1+. All of the statements on CBT/GET show poor evidence (1+-2) yet CBT/GET are recommended without any doubt.

NICE state "*(CBT) is a collaborative approach that aims to reduce the levels of symptoms, disability and distress associated with CFS/ME. CBT or psychological approaches to CFS/ME do not imply that symptoms are psychological, 'made up' or in the patient's head. CBT is used as part of the overall management for many conditions, including cardiac rehabilitation, diabetes and chronic pain.*"

We are glad that NICE removed the erroneous suggestion from the Draft Guidelines that CBT is stated to be a treatment for ME/CFS for cancer and heart disease. Yet NICE seem to repeat the myths around ME/CFS, supported by those vested interests who promote ME/CFS as a somatoform illness, by fallaciously making the implication that ME/CFS patients can change their illness beliefs explaining '*the relationship between thoughts, feelings, behaviours and symptoms, and the distinction between causal and perpetuating factors*'.

In NICE's own words these guidelines have stated that –



Invest in ME

August 2007

'trials (to) look at the effect of CBT performed over only 6 sessions... did find considerably poorer outcomes from 6 sessions of CBT in people with CFS/ME than with general chronic fatigue'.

This has no place in a set of guidelines meant to be used for a neurological illness and certainly has no place being used as the only treatment.

From the IIME response to the NICE Draft guidelines we have reused the comments on human rights provided by R. Mitchell and V. Mitchell. The guidelines should have had a significant increase in evidence-based assessment and treatments beyond the psychosocial model and CBT/GET treatments before it can be accepted as an independent, expert guideline for the treatment of ME/CFS (see [Human Rights](#) later).

As an MRC Report stated psychological treatments raise a number of issues about consent and coercion. How much information should patients be given about the possible effects of therapy on their brain?' and concludes that 'further research is needed to determine whether such therapies are reversible, or if there are persistent adverse effects', noting: There is already evidence that in certain situations psychotherapy can do harm.

There are therefore serious ethical concerns about whether this type of therapy is 'acceptable to Society', as well as outstanding safety issues. Where are the safeguards for this form of treatment? The guidelines maintain a deafening silence on these issues.

Drugs undergo exhaustive testing over an extended period of time overseen by an independent body thus ensuring their safety and efficacy. Comprehensive information on the intellectual foundation of the treatment, its effects and counter effects are provided to clinicians and patients. In the US, *'It takes 12 years on average for an experimental drug to travel from lab to medicine chest. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.'* Similar rigorous testing processes apply to the UK under European Community regulations. The MHRA UK Regulatory Authority website states:

'Safety, quality and efficacy are the only criteria on which legislation to control human medicines is founded where experts assess all applications for new medicines to ensure they meet the required standards. This is followed up by a system of inspection and testing which continues throughout the lifetime of the medicine. Safety monitoring is also continuous and the doctors and patients receive up-to-date and accurate information about their medicines. This is achieved by ensuring that product labels, leaflets, prescribing information and advertising meets the required standards laid down by the Regulations.'

Contrast the intellectual and scientific rigour applied in the approval process for the licensing of drugs for clinical use, with the lack of scientific and intellectual rigour applied in the NICE guidelines with regard to the recommendations for the use of



Psychological Therapy in CFS/ME. When compared with the extensive clinical trialling over many years and the independent scrutiny a drug therapy is subjected to, the small and heavily criticised evidence base used to justify the recommendation of CBT and GET for CFS/ME in the NICE guidelines is seen to be totally inadequate.

The report on ME/CFS from the Chief Medical Officer of 2002 stated that 65% of patients trialled using CBT found that it was of no value. An even more alarming figure of 50% stated that GET had made them worse. Reference was also made to the most recent study on CBT (ref: Cognitive behaviour therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme. Health Technology Assess. 2006 Oct; 10 (37): 1-140) which had failed to demonstrate any major overall benefit when CBT was compared to either education and support or standard medical care.

Results from the trials listed by NICE even show the poor results from CBT.

- *'13% were made worse by CBT, 32% were not helped at all, 37% were helped a little and 18% were helped a lot.'* (Report on Survey of Members of Local ME Groups, Cooper 2000)
- *93% found CBT unhelpful. (25% ME Group, Analysis Report, 2004)*

This is unequivocal - CBT is unhelpful. Yet still NICE persist in enforcing this on patients.

In a survey of 3074 ME/CFS patients conducted between 1998 – 2001, 55% of patients said that CBT had made no difference to their illness, whilst 22% said CBT had made their illness worse. 16% of patients said that Graded Exercise had made no difference to their illness whilst 48% said it had made their illness worse.

A survey by the 25% ME Group (for severe sufferers) of 437 patients, demonstrated that of the 39% of group members who had used graded exercise, 95% had found this therapy unhelpful, whilst - reported their condition had been made worse by graded exercise. Some patients were not severely ill with ME until after graded exercise.

In the same survey - those who had undergone Cognitive Behavioural Therapy had found it unhelpful.

Professor Kenny De Meirleir mentioned [International ME/CFS Conference 2007 in London – [<http://tinyurl.com/2we4b7>]] that in trials in Belgium only 6% of patients found CBT helpful – and that a placebo would have given better results!

The amount of space given to CBT shows the lack of vision in this document, the lack of analysis carried out on biomedical research available and the true agenda behind NICE and this document.



Invest in ME

August 2007

NICE describe CBT as “a specific psychological therapy, based on underlying theoretical principles, with a broad evidence base across a variety of conditions”.

NICE are not really aiming to treat the underlying pathology in any way.

Professor Malcolm Hooper says that CBT experts themselves have stated that any improvement from CBT is not sustainable.

NICE state that *“These are evidence statements agreed by the GDG, based on the evidence reviewed.”*

This again shows the NICE spin as it has ignored valid evidence showing the lack of effect of CBT.

NICE state that “The aim of the CBT was to enable patients to address negative beliefs regarding symptoms, self-expectations and self-esteem. GET was tailored to each patient’s physical capacity and aimed for a gradual increase in aerobic activities, especially walking, and was delivered by physiotherapists”

and

“Explaining the CBT approach in CFS/ME, such as the relationship between thoughts, feelings, behaviours and symptoms, and the distinction between causal and perpetuating factors.”

and

“CBT for a person with CFS/ME should be planned according to the usual principles of CBT, and should include: Challenging thoughts and expectations that may affect symptom improvement and outcomes.”

This is revealing and shows the true nature and purpose of these guidelines. To associate a neurological illness with comments such as ‘attempt to modify thoughts’. Is this the type of CBT which is given to cancer and diabetes patients?

Again NICE force upon patients the same old psychiatric therapies that it has just stated are not mandatory! It again lets slip its true agenda by concentrating on feelings and behaviours – straight from the psychiatrists text book!

GET

Recommendations for using GET for shows a totally irresponsible and blinkered and biased approach to treating people with ME/CFS. Abundant research has at the very least cast serious doubt on its effects. ME/CFS patient groups reject its usage. But



Invest in ME

August 2007

NICE refuses to listen and carries on with its dedicated agenda to enforce psychiatric paradigms on a vulnerable section of the community using policy-based evidence selection. How can a recovery be an objective with the use of GET when the causes of ME/CFS are 'unknown'?

NICE are totally discredited with these tactics.

Graded Exercise Therapy (GET) has been shown to be harmful or useless yet it is wrapped up into a psychiatric paradigm to allow vested interests to perpetuate the same old myths about ME/CFS. The guidelines explicitly state that *"There was strong agreement that persistent, debilitating, post exertional fatigue characterised the condition"* - yet the Guidelines still recommend GET as a therapy/treatment.

"An evidence-based approach to CFS/ME that involves physical assessment, mutually negotiated goal-setting and education."

There is poor quality evidence submitted by NICE to justify this claim and much evidence to the contrary which has been excluded.

GET is a proposed self-management technique that is not appropriate for patients with severe ME, where post-exertional oxidative stress can cause more serious problems. *"Increases in duration of exercise"* are very dangerous, as blood pressure can drop and patients can be subject to numerous adverse reactions to any forced exercise. *"Aiming towards recovery"* implies that recovery is possible with increased exercise, which is unproven and fallacious.

A blanket recommendation of graded exercise therapy is imprudent for such a heterogeneous group of patients (NICE *"there is growing evidence that the condition is heterogeneous, and may not have a single or simple aetiology"*) most of which are likely to respond negatively to physical activity.

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.

GET, as practiced today with ME/CFS patients, does not take into account a patient's preferences. How can a recovery be an objective with the use of GET when the causes of ME/CFS are unknown? Yet this is what the NICE guidelines disingenuously propose.

GET cannot be recommended for severely, or even moderately affected ME/CFS patients. It is tantamount to inviting diabetics to take more sugar. This is where the NICE agenda for imposing psychological therapies onto ME/CFS patients shows the basic irresponsibility behind the policy.



Invest in ME

August 2007

Whilst activity management is essentially a common-sense approach to managing symptoms GET is totally unacceptable. What benefit does GET hold for a tube-fed, incontinent, bed bound patient? The proposition is risible.

It is well known that those who perform GET studies "cherry-pick" their patients (i.e., choose only those patients well enough to be able to exercise in the first place and thus contribute to the overall 'success' of the trials).

No severely affected ME/CFS patients have ever been shown to benefit from the use of GET.

There has been much research on muscle and immune cells. Christopher Snell in 2005 reported that the results of exercise capacity and immune function in male and female patients with CFS "implicate abnormal immune activity in the pathology of exercise intolerance in CFS and are consistent with a channelopathy involving oxidative stress and nitric oxide-related toxicity". This could explain why people with ME/CFS can't exercise, as there is a limit, beyond which one cannot train.

Lane et al have found evidence of abnormal muscle physiology in a significant number of ME/CFS patients that could not be explained by physical de-conditioning or muscle disuse.

Jammes et al make a connection between such muscle dysfunction and increases in oxidative stress observed in people with ME/CFS when subjected to incremental increases in exercise activity, a finding corroborated by Nijs et al.

Magnetic Resonance Imaging (MRI) brain scans compared between control patients and patients with ME/CFS indicated areas of reduced blood flow - indeed, myalgic encephalomyelitis might be a good name for such "brain-muscle" anomalies.

Professor Malcolm Hooper takes this one step further by making the association between increased oxidative stress and generation of free-radicals. Given the link between free-radicals, aging and cancer this is surely a matter of particular concern for those with ME/CFS. To put things succinctly, excessive exertion has the potential to cause premature aging and increased risk of cancer in those with ME/CFS.

The work of Chia establishes a link between enterovirus re-activation through over-exertion (exercise is mentioned as a specific example). This itself further supports the work of Lane who states -

"we have correlated abnormal lactate responses to exercise with the detection and characterisation of enterovirus sequences in muscle."



It is therefore possible to state that over-exertion by those with ME/CFS has the potential to lead to enterovirus re-activation as a result of faulty muscle metabolism.

An additional concern involves measurable cardiac insufficiency in those with the illness. Peckerman et al have demonstrated a link between symptom severity and cardiac dysfunction. This work is backed up by that of Vanness, Snell et al, who go so far as to state that:

"The blunted heart rate and blood pressure responses in the 'mild' through 'severe' groups are similar to those seen in chronic heart failure."

It is also worth noting that in their study, they accounted for any potential "lack of effort" on the part of their subjects:

"it was felt that the multiple testing protocol employed in this study was sufficient to ensure that the results obtained accurately reflect patients' functional capacities."

With regard to cardiac function and exercise therapy, Carruthers and van de Sande issue the following warning:

"Externally paced 'Graded Exercise Programs' or programs based on the premise that patients are misperceiving their activity limits or illness must be avoided."

Thus we have several health risks for those with ME/CFS which may be exacerbated by exercise: excessive oxidative stress and resultant generation of free-radicals, enterovirus reactivation, and cardiac dysfunction. All three have the potential to cause serious harm, and arguably have lethal potential. Given this situation, it is surely irresponsible to recommend exercise therapy for this particular patient group.

Every medication has to have a list of side-effects – these need to be stated here also with reference to GET. GET needs to carry a government health warning for ME/CFS patients.

As NICE continue to recommend GET then they have to shoulder some of the responsibility for the consequences. 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 risks increasing the burden of illness posed by ME/CFS on society at large.



The weight of empirical evidence indicates that exercise has direct and persistently negative impacts on the physiology and quality of life of a significant subgroup of ME/CFS patients. Any universally applied therapy is unlikely to address the heterogeneity of ME, and graded exercise is particularly unsuitable as it may worsen the condition, and should not be generally recommended without a high degree of confidence that it will not be applied to susceptible patients. It is difficult to conceive of a more inappropriate therapy for ME/CFS. By increasing the risk of relapse and overall health risks, rather than reducing them, graded exercise therapy also risks increasing the burden of illness on society at large. The present review suggests that an approach based on treatment of the underlying physiological dysfunction will be more fruitful.

NICE chose to ignore what patients say about CBT and GET. We are left to wonder about the litigation that will follow if these guidelines ever see the light of day as a standard method for treatment of ME/CFS patients.

If ME/CFS is a severe fatiguing condition, then performing exercises will exacerbate the fatigue condition. In research published by the University of Dundee, ME/CFS patients have shown that severe reactions to exercise can occur. In fact Dr Vance Spence, has expressed concerns that undertaking aerobic exercise could lead to fatal consequences. Is NICE in a position to recommend GET in the face of this evidence? Is NICE willing to face the potential legal consequences of proposing GET should a patient with ME/CFS suffer fatal after-effects in following the proposed NICE Guideline? Has NICE taken any legal advice to accept the publishing of this proposed guideline?

Will the chair of these NICE guidelines be willing to be held responsible for any damage that will inevitably result from using GET on moderately or severely affected patients by healthcare staff who will likely still be unconvinced of the biological nature of ME?

These guidelines emphasise the psychological nature of GET. However, if ME/CFS patients were able to perform exercise, then they wouldn't have ME/CFS according to this fallacious argument. The failure of ME/CFS patients to achieve a return to FULL health using CBT and GET indicates that ME/CFS is not a psychological illness. Patient cohorts that do recover as a result of CBT and GET undoubtedly include patients with other fatiguing states. By not selecting patients correctly, and then claiming benefits for exercise strategies and discounting failures or withdrawals, this does not indicate that an "*evidence-based*" approach is being used correctly.

Finally, on the subject of CBT and GET, all ME/CFS patients should remember the NICE statement that -



Invest in ME

August 2007

"Healthcare professionals should be aware that – like all people receiving care in the NHS – people with CFS/ME have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their care, or future choices about care."

This should effectively remove unnecessary and dangerous psychiatric paradigms from the treatment of ME/CFS patients. Though we doubt whether this will influence some insurance companies who will persist in their discrimination against people with ME/CFS.

Not only severely affected people with ME/CFS will be at risk from GET. Also moderately affected people with ME/CFS can relapse due to this advice. 2 * 15 minute brisk daily walks are impossible for some mildly affected patients. This is more like a treatment for burn-out or over-training syndrome than for an illness where infection may play a part. ME/CFS is a neurological illness. NICE took IIME's objections to this and stated that they were noted and clarified. They fail to do this.

NICE also ignore what happened to other patients who did not benefit. Maybe the frequency and propensity for relapse ought to be monitored. Despite NICE revising these comments after IIME objected they are still misleading. NICE state "We have revised this to 'be of benefit to some patients.' We have noted the concerns of patients regarding the safety of GET, but research evidence reviewed for this guideline supports the use of GET. "

This is disgraceful spin and obfuscation. NICE have chosen only to use the evidence which satisfied their predetermined view that GET is a method of treatment for ME/CFS. They have ignored the overwhelming evidence showing the harm it can do. Legal implications of this will need to be ascertained as patients are destined for great harm.

Management

The descriptions of Activity management needs to be revised. For some patients even 5 minutes is too long. Some ME/CFS patients have remained bed bound for years without sitting up. An increase in activity might be one minute in a week. "Activity Management" is exactly what the title suggests, i.e. a scheme for a patient to proactively manage activity levels. The definition given, which includes "to enable patients to improve and or maintain their function" is totally misleading for a patient with severe ME, where it is not possible to perform Activity Management.

NICE state that "Setbacks/relapses are to be expected as part of the normal course of CFS/ME. With effective management, the frequency, severity and duration of setbacks/relapses should reduce".



Invest in ME

August 2007

Where is the evidence of this? What is effective management? Is this common sense applied to the situation? Or is NICE inferring that this is due to psychological therapies?

NICE stated that they revised this section from the draft guidelines document – we see no revision.

NICE state that *"Setbacks/relapses appear to be caused by different things; triggers can include, for example, sleep disturbance, overactivity, stress or an active infection (such as a common cold). However, it may not always be possible to identify a cause."*

One could also argue that setbacks are caused by graded exercise, CBT, lack of knowledge of the biological nature of ME/CFS by GPs, efforts performed having to argue with DLA officials etc.

NICE state that *"Advice on managing setbacks/relapses may vary according to the cause. For example, it may be advisable to maintain an exercise programme, in agreement with the patient, if stress has been a causative factor, but not if there is an active infection."*

This contradicts earlier statements by NICE. Dr. Jonathan Kerr's research has shown that active infection is still prevalent in ME/CFS patients without other causative factors – i.e. an infection present from the start of the ME/CFS which is still ongoing may be the cause of relapse.

NICE state that *"Difficulty may arise in distinguishing symptoms caused by CFS/ME from those of an active infection, as such symptoms are often similar (for example, increased fatigue, myalgia, headache, sore throat). In this situation, measurable evidence can be helpful (such as taking temperature with a thermometer, evidence of sputum). If an active infection is present, a different approach would then be used."*

What different approach would this be? What is the evidence to substantiate that anything but rest and recovery from the infection is necessary?

The example of 2 * 15 minutes daily brisk walks to the shop for an ME/CFS patient, either mild, moderate or severely affected is palpably ridiculous – this could be extremely dangerous to a mildly/severely affected pwme. It needs to be removed! Even healthy people might not be able to manage 2*15 minute brisk walks. There is no basis for this. If someone could manage this then one wonders why any intervention is necessary.

NICE recommend against resting after a relapse or during the illness. This shows little understanding of the real world.

During the early onset of ME/CFS rest is of paramount importance.



Invest in ME

August 2007

IIME agree with the statement that healthcare professionals should provide accurate information to people at all stages of CFS/ME, starting from when a diagnosis is first being considered and that it should be tailored to the person's circumstances, including the stage and duration of the condition.

This is important – stage and duration can mean different requirements.

IIME disagree with the statement that "sleep management strategies should not include encouraging daytime sleeping and naps. People with CFS/ME should be advised that excessive sleep does not generally improve physical or mental functioning, and excessive periods of daytime sleep or frequent napping may further disrupt the sleep-wake cycle. This is totally erroneous. See earlier IIME comments from draft.

IIME disagree that strategies for managing CFS/ME should not include prolonged or complete rest or extended periods of daytime rest in response to a slight increase in symptoms.

It depends on the patient and the stage of the illness.

"37% said they were helped a lot by doing this. Total bed rest helped a total of 74% of respondents who had done this." (Report on Survey of Members of Local ME Groups, Cooper, 2000). In another survey *"Rest, including bed rest, helped 90%."* It is important for patients to listen to their own body.

IIME feel NICE are irresponsible in stating that *"it is very important that work and education are addressed early in the care pathway for CFS/ME"*.

It is of more importance that early diagnosis and correct advice is addressed early. Work and education need to follow health in priority.

Perhaps some of the most illuminating parts of the guidelines, and seemingly unused in many of the recommendations, are within the personal testimonies from people with ME/CFS - some clearly demonstrating how dangerous the recommendation to get people active and back to work is without real consideration of the condition of the patient.

Such results are only too familiar to the patients with ME/CFS. Yet these guidelines want to enforce more graded exercise and force people to be active rather than take adequate rest.

How many patients might have recovered had they followed sound advice to rest until their bodies told them it was possible to be active?

The wording by NICE is easily able to be misconstrued, or misunderstood, by healthcare staff lacking in real knowledge of ME/CFS and will severely impact many ME/CFS patients if promoted via these guidelines.



The emphasis on exercise at the expense of proper rest is appalling. Guidelines such as these ought to be for the benefit of the patient. These guidelines do not fulfil this objective.

Implementation

As for 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 CFS/ME in the UK, especially considering the low priority and lack of funding given to ME/CFS in the past. To have sparse resources squandered on therapies which the ME/CFS community do not need or want is an appalling waste.

Perhaps implementation should consider what is the need of the medical community, especially clinicians to assist in the diagnosis of ME/CFS and the exclusion of related non-specific fatiguing conditions.

The greatest factor in the UK and the Rest of the World 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 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.

Supplements and Alternative Medicines

The NICE guidelines provide an incredibly poor and limited summary on supplements as aids in managing ME/CFS.

Supplements are dismissed with little research or attempt to analyse.

Yet they can be a useful part of the diet for pwme who cannot cook always or who cannot eat properly and could benefit from such supplements (fish oils, vitamin C, multi-vitamins etc.) - surely this is a negligent oversight from NICE.

In terms of supplements, two "essential fatty acids" studies had positive results and very high rankings - 16 and 17 respectively. Carnitine, liver extract, and magnesium also scored as high as CBT in terms of therapies (10, 10, and 15).

The highest validity scores in the data presented by NICE was for an alternative therapy.

Fish oils score as highly or better than CBT so why does NICE not recommend this as a therapy/treatment?



Invest in ME

August 2007

Professor Puri's analysis of long chain fatty acids has resulted in his assessment of EPA products being useful for ME/CFS but this is not listed or discussed.

In some places the use of supplements is rejected and is not considered worthy of more investigation –

"evidence is insufficient to support a beneficial effect of dietary supplements"

and -

"the GDG agreed that they could not be recommended for the management of CFS/ME"

Yet in other places in these guidelines it is stated that there may be a use for them -

"There may be a need for use of prescribable supplements where requirements cannot be met by conventional means."

It becomes totally confusing which recommendations are meant to be used.

Imagine how GPs must react when reading these guidelines!!

The inconsistency undermines the guidelines and the standard modus operandi for NICE comes to the fore again with its predictable motto - save money at the expense of improving health.

What about the one high quality study – shouldn't people be given a choice instead of CBT and GET? And it would be easier for ME/CFS patients if these therapies were available on NHS.

Isn't this where one listens to patients for evidence?

Human Rights

The recommendation from NICE to use psychological therapies for treating ME/CFS contravenes the human rights of patients with ME/CFS.

It has been stated that by ignoring the serious issues with regard to CBT and GET the NICE guidelines would 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, apart from major concerns about the efficacy of use of CBT or about the danger in the use of GET.



Invest in ME

August 2007

There is no regulatory framework governing the development and use of CBT and GET thus leaving ME/CFS patients vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice.

IIME would state that this is already the case, as frequent letters to our information mailbox attest to this fact.

In respect of informed consent for using these therapies the issue does not arise. There simply cannot be informed consent since there are important ethical, safety and regulatory questions arising from these treatments, to be addressed.

Ethical and safety questions such as those raised in the MRC Neuroethics Report 2005 should be paramount.

It is hard to envisage any Independent authority clearing a drug for Human testing or use without ethical and safety issues, like those surrounding Psychological Therapy, being resolved.

By ignoring these serious issues with regard to Psychological Therapy the NICE guidelines violate the right of clinicians and patients to the highest, safest standards of Medical practice and care, amounting to a violation of their Human Rights.

This is a Human Rights issue.

Without an answer to whether this type of therapy is 'acceptable to Society' and if it is, without an effective Regulatory framework governing its development and use, there is the serious risk that sick and vulnerable people everywhere will be vulnerable to exploitation and abuse at the hands of the vagaries of power, politics and prejudice.

NICE (its chairman and CEO and the chair of these guidelines) should be accountable in a court of law for any harm done to patients given these treatments/therapies.

It is a pity that Sophia Mirza could not have given evidence or participated in these studies as we are sure that her experience would also have been compelling.

Unfortunately, Sophia Mirza is dead. The Cause of Death was noted to be ME/CFS on the Death Certificate.

IIME believe the NICE Guidelines should state unequivocally that it is unacceptable for patients with ME/CFS to be subjected to "sectioning" by psychiatrists, supported by Social Services and the Police, simply because the person has ME/CFS. Instead the NICE guidelines add to the obfuscation and NICE, at best, sit on the fence.

The section added "Sectioning under the Mental Health Act" indicates how irresponsible these guidelines are.



Invest in ME

August 2007

NICE state that *"mental health professionals may have a role to play in the treatment of CFS/ME, both in assessment and management of the condition"*.

We disagree entirely with this statement.

Psychiatrists have no role to play in assessment of patients with a neurological illness. NICE are again showing their true agenda by inferring that depression, psychosis or other forms of severe mental illness are applicable to ME/CFS.

This is an appalling distortion of the true facts and the NICE chair ought to be ashamed of his allowance of inclusion of this in these guidelines.

There is ACTUAL evidence of ME/CFS patients being sectioned because they refuse to accept the treatments that NICE are recommending in this document.

There is still no valid reason why an ME/CFS patient is sectioned. This is ludicrous and these guidelines would not help a patient who found themselves in the same situation as Sophia Mirza.

It is not for sensation that IIME requested that a lawyer be added to the NICE consultation group. The lawyer would be there to represent ME/CFS patients as, undoubtedly, there will be litigation against the people making these recommendations for use of GET/CBT when yet another patient dies from putting into practice such guidelines.

Despite introducing the semi-platitudinous comment that the patient can refuse treatments without compromising further therapeutic relationship we feel the lack of knowledge by healthcare staff and patients of the effects of these therapies will likely cause further infringements of human rights. The NICE guidelines will allow such exploitation to continue.

Support Information

IIME are happy that NICE have taken IIME's suggestion to inform people with ME/CFS of support organisations as these groups often know far more about the illness than healthcare staff, CNCC clinics and official government bodies deliberating on how to treat ME/CFS. IIME welcome the chance to be able to inform patients of correct information regarding ME/CFS.

However, the NHS direct web site contains incorrect, erroneous and dangerous information and cannot be used as a reference in its current form.



Invest in ME

August 2007

We are glad that NICE accepted our recommendation to attach a reference to local and national support groups and charities and IiME are happy to be included in this. However, looking at the list of charities which NICE have included in the Patient version we note that both Invest in ME and a number of other national and regional groups are omitted.

We have grave reservations regarding the listing of two of the organisations whom we believe are unrepresentative of people with ME/CFS and young people with ME/CFS as they receive finance by the Department of Health to support the non-functioning psychiatric CNCC Clinics which have wasted so much scarce funding. Blind acceptance of NHS and government policies do not serve ME/CFS patients or their families. The lack of impartiality and the track record of some of these organisations means that support and information available to patients reading these documents may be skewed.

The salient point here, though, is that the number of organisations listed here needs to be broadened and regional organisations ought to be included.

We call on NICE to update this list with all national ME/CFS charities and regional groups so that patients have access to the fullest and unbiased information possible.

Document Structure

We find the full version of the guidelines document still poorly structured and cumbersome to read. They are very unwieldy and the shortened version is probably the only version which will be read fully. This would then lead to the fuller guidelines being ignored as regards supporting evidence. But if this evidence is flawed then the whole set of documents are suspect.

Summary of Comments on the Short Version Analysis

Below we summarise comments on the short version.

IiME agree with the following-

- *"ME is a relatively common illness"* something that needs to be emphasized so that adequate funding can be given to real scientific research
- That *"the physical symptoms can be as disabling as multiple sclerosis, systemic lupus erythematosus, rheumatoid arthritis, congestive heart failure and other chronic conditions"*



Invest in ME

August 2007

- That "*CFS/ME places a substantial burden on people with the condition, their families and carers, and hence on society*"
- that "*There is a lack of epidemiological data for the UK*"
- that "*the recommendations in this guideline emphasise the importance of ... making an accurate diagnosis, ensuring that significant clinical features are investigated, and working in partnership with people with CFS/ME to manage the condition.*"
- that "*Carers and relatives should also be given the information and support they need.*"
- That "*the healthcare professional should: Acknowledge the reality and impact of the condition and the symptoms.*"
- that "*Healthcare professionals should be aware that – like all people receiving care in the NHS – people with CFS/ME have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their care, or future choices about care.*"

This is probably the single most positive aspect of these guidelines as it should effectively remove unnecessary and dangerous psychiatric paradigms from the treatment of ME/CFS patients.

IIME welcome this statement and hope that healthcare staff in all forms will no longer play a role in assisting insurance companies from enforcing deplorable tactics against a vulnerable section of society.

Refusal of (possibly inappropriate) treatment has also been proposed as a means of reducing Incapacity Benefits or Disability Benefits.

It is to be welcomed that patients are in control.

- that "*Healthcare professionals should provide diagnostic and therapeutic options to people with CFS/ME in ways that are suitable for the individual person. This may include providing domiciliary services (including specialist assessment) or using methods such as telephone or email.*"
- that "*Information should be available in a variety of formats if appropriate (printed copy, electronic and audio), which people with CFS/ME and their carers can refer to at home and in the clinical setting.*"

Providing this information represents the true nature of ME/CFS and reflects patients' experiences then it could be a useful addition.



IIME disagree –

- that *"this guideline offers best practice advice on the care of people with CFS/ME."*
It fails to do this due to the absence of a comprehensive analysis of research into ME/CFS.
- that healthcare professionals should *"Offer information about local and national self-help groups and support groups for people with CFS/ME and their carers (see also the NHS Expert Patients Programme)."*

if this is limited to those organisations selected by NICE at the expense of other ME/CFS charities and regional organizations.
Some of these organisations have been part of the problem with ME/CFS for years.
- that *"Advice on symptom management should not be delayed until a diagnosis is established."*
Is NICE stating that symptoms really should be treated without knowing exactly what the illness is? Is this applied to other illnesses?
A symptom of fatigue can be indicative of almost anything.
- that *"An individualised, person-centred programme ...offered to people with CFS/ME... (should have)... the objectives of...(being able to)..sustain or gradually extend, if possible, the person's physical, emotional and cognitive capacity and manage the physical and emotional impact of their symptoms."*

We disagree with this phraseology.

This is based on selective and flawed research.

Why is this automatically offered?

If a patient has no emotional problems then why is this highlighted?

Irresponsible and costly and dangerous advice.

The objectives should be to be treated with no emphasis on extending capacity until ready.

- that *"Cognitive behavioural therapy and/or graded exercise therapy should be offered to people with mild or moderate CFS/ME and provided to those who choose these approaches, because currently these are the interventions for which there is the clearest research evidence of benefit."*
This is fallacious and also discriminates against moderately affected patients who are not necessarily better equipped to withstand unnecessary, expensive and flawed psychiatric treatments which are not proven to be useful, have been proven to be dangerous and are an infringement of people's human rights. From an economic point of view



offering these failed psychiatric therapies will also be unachievable. Already there are year-long waiting lists for CBT, irrespective of whether it is effective or not.

Where does the NHS get the money to supply this unwanted psychiatric therapy regime to patients yet NICE and the NHS deny life-saving drugs for other illnesses?

- that a diagnosis can be made if *"fatigue with all of the following features: ..and one or more of the following symptoms: .."* .
This is too broad a view of fatigue states and underlines the heart of the problem with the way this illness (ME/CFS) is treated and perceived as it includes far too broad a range of illnesses. Almost anybody can fit into these broad criteria.
NICE should have used the Canadian guidelines to differentiate between true ME/CFS and other conditions.
- that *"Sleep management strategies should not include encouraging daytime sleeping and naps. People with CFS/ME should be advised that excessive sleep does not generally improve physical or mental functioning, and excessive periods of daytime sleep or frequent napping may further disrupt the sleep-wake cycle."*.
This is too generalised. Where is the research for this? Surely it all depends on what stage of the illness a person is?
- that *"Limiting the length of rest periods to 30 minutes at a time."*.
The patient needs to listen to their body. This is far too generalized a statement and actually means nothing. Patients in different stages of the illness need different procedures. This is simply pointless generalized recommendations. As NICE state later under the definition of pacing *"The keys to pacing are knowing when to stop and rest by listening to and understanding one's own body, taking a flexible approach and staying within one's limits;"*. This then negates the earlier statement that patients should limit their rest periods. Again NICE show inconsistency in their documents by their own contradictory statements. How are healthcare staff supposed to form a clear idea of treatment using these guidelines.
- that *"the ability of a person with CFS/ME to continue in education or work should be addressed early and reviewed regularly."*
What needs to be performed early is diagnosis and recovery – not an insistence on returning to work or school.
- the statement *"Strategies for managing CFS/ME should not include: • Prolonged or complete rest or extended periods of daytime rest in response to a slight increase in symptoms."*.



Invest in ME

August 2007

This is a dangerous assumption to make that "*a slight increase in symptoms*" is to be ignored. Such generalisations are meaningless and allow patients to be put at risk.

- that CBT is given to include "*Developing awareness of thoughts, expectations or beliefs and defining fatigue-related cognitions and behaviour.*" and "*Identifying perpetuating factors that may maintain or exacerbate CFS/ME symptoms to increase the person's self-efficacy (sense of control over symptoms).*"

These are insulting and NICE repeat the same myths about ME/CFS and continue to be peddled throughout the UK healthcare system. These are disgraceful comments.

Does a ME/CFS patient have control over their symptoms?

Does a cancer patient also have this divine attribute?

- the whole emphasis on use of GET. This should be removed completely as no valid trials exist which show any benefit and the evidence which NICE suggest is of good quality is based on flawed criteria for selection of patients. To suggest that "*People with mild or moderate CFS/ME should be offered GET*" is ridiculous as moderately affected patients can easily turn into severely affected patients.

IIME fail to understand –

- Why NICE state in the short guideline that "*Treatment and care should take into account patients' individual needs and preferences*" yet in the full guideline state that the patient is in control. The patient/carer must always be in control.
- Why NICE state in the short version that "*enables people with CFS/ME (and their families and/or carers as appropriate) to participate as partners in all decisions about their healthcare,*" yet in the full guideline state that the patient is in control.
- Why NICE advise that serological testing should not be carried out unless the history is indicative of an infection. Yet the Canadian guidelines state "*It is also essential to exclude ... infectious diseases such as tuberculosis, chronic hepatitis, Lyme disease,..*" . As ME/CFS is commonly follows an infection this ought to be mandatory.
- Why NICE advise that "*Healthcare professionals should work closely with social care and education services to ensure a common understanding of the goals of the person with CFS/ME.*"
What goals characterise patients with ME/CFS compared with other illnesses?
Isn't any patient's goal to recover?



Invest in ME

August 2007

Why does NICE persist in continuing these disparaging implications about ME/CFS patients?

- The statement "Although there is considerable support from patients (particularly people with severe CFS/ME) for the following strategies, healthcare professionals should be aware that there is no controlled trial evidence of benefit: • Encouraging maintenance of activity levels at substantially less than full capacity to reserve energy for the body to heal itself (sometimes known as the envelope theory). • Encouraging complete rest (cognitive, physical and emotional) during a setback/relapse."

The patient needs to listen to their own body. These are foolish recommendations that surely no doctor could endorse.

- The statement that "*There is insufficient evidence that complementary therapies are effective treatments for CFS/ME and therefore their use is not recommended. However, some people with CFS/ME choose to use some of these therapies for symptom control, and find them helpful.*"

This paragraph contradicts itself. Who knows better than patients what helps them?

- The statement that "There is insufficient evidence for the use of supplements – such as vitamin B12, vitamin C, co-enzyme Q10, magnesium, NADH (nicotinamide adenine dinucleotide) or multivitamins and minerals – for people with CFS/ME, and therefore they should not be prescribed for treating the symptoms of the condition."

As NICE state in the following sentence "*some people with CFS/ME have reported finding these helpful as a part of a self-management strategy for their symptoms.*"

Again why aren't patients being listened to?

Later NICE state "*Some people with CFS/ME need supplements because of a restricted dietary intake or nutritional deficiencies.*"

So they can't be prescribed but NICE admit they can be helpful.

Isn't this just a way NICE use to avoid having any medication paid for by the NHS – the classic *raison d'être* for NICE.

- The statement that "*The following drugs should not be used for the treatment of CFS/ME: • thyroxine • antiviral agents.*" Surely these should be used if and when required. To exclude them seems pointless. Especially as NICE state that aetiology of ME/CFS is unknown.



Invest in ME

August 2007

- The statement that *"The aetiology of CFS/ME was outside the scope of the guideline and therefore a systematic search of the area was not carried out. For that reason, the GDG has not made a research recommendation about the causes of CFS/ME, but it recognises that research in this area would be very helpful."*

It should emphasize that biomedical research is lacking. If aetiology is outside the scope of these guidelines then how can comment be passed on what is beneficial for people with ME/CFS. What about research on biological markers?

Surely this is the essence of what is required! How can one continue to advise on treatment but avoid recommending cause to be discovered?

- That *"People with CFS/ME should be advised that setbacks/relapses are to be expected as part of CFS/ME."* when NICE elsewhere recommend GET as a treatment. Relapses are to be expected if GET is forced on patients
- The statement that *"The guideline does not cover the management of comorbidities,"* yet earlier NICE state that they can treat the symptoms without knowing the underlying cause of the illness. This seems to be bordering on the clinically negligent.
- Why sub grouping is not recommended.
- Why the most stringent of guidelines – the Canadian guidelines – are not recommended as a standard – except we probably already know why NICE has not recommended them – because it would exclude those with ME/CFS from being grouped into a wide group of fatigue states. This would impact a lot of vested interests....
- How an ME/CFS *"specialist"* is defined.
Currently this definition of a specialist is nowhere to be found. It should be a clinician who knows and understands the biomedical nature of the illness. What is the defined specialised care, when there is no agreed definition of ME/CFS or treatment protocols?
- From the quick reference guide for patients –

"If a treatment described in this booklet appears suitable for you, but it is not available, you should talk to your local Patient Advice and Liaison Service (PALS) in the first instance. If they are not able to help you, they should refer you to your local Independent Complaints Advocacy Service."



Why therefore can it not be stated that if a treatment appears suitable for you and is available, but it is NOT described in this booklet, you should talk to your local Patient Advice and Liaison Service (PALS) in the first instance?

Then patients could ask for supplements, ATP testing, complementary therapies etc.

What Is Required for ME/CFS

- Correct and standard diagnostic criteria – the Canadian Guidelines to be used to separate chronic fatigue and ME/CFS
- Sub grouping within ME/CFS
- Proper terminology – use of ME or ME/CFS for the neurological illness
- Protocols for medical examinations of ME/CFS patients
- A diagnostic test
- Biomedical research into the pathogenesis of ME/CFS
- Epidemiological studies into ME/CFS
- ME/CFS to be made a notifiable illness in schools
- A correct biomedical service model that could be used by all PCTs

Comments on the Guideline objectives

Below we examine the stated aims of the document as written in the Executive summary and recommendations.

However, these were the aims given to NICE prior to the guidelines being produced (see <http://guidance.nice.org.uk/download.aspx?o=111640>)

Remit: "To prepare for the NHS in England and Wales, guidance on the assessment, diagnosis, management of adjustment and coping, symptom management, and the use of rehabilitation strategies geared towards optimising functioning and achieving greater independence for adults and children of CFS/ME."

So it was all pre-decided. A pointless exercise produced by people with little conscience for the effects that their "work" will have on ME/CFS patients and their families.

Where is the objective to "treat" and "cure" the illness? Without this objective, the guideline becomes psychological intervention/management only. If this is the case,



then NICE should clearly define the limitations (and should be ashamed of such a minor ambition and role in the approach to treatment of ME/CFS).

It is appropriate to determine if these objectives were met by this document.

The Guideline Development Group developed this guideline with the aims of -

Increasing the recognition of CFS/ME

It is doubtful if this has been met as it provides nothing new for sufferers and carers. Instead it has just caused more confusion.

The few places where the document has requested that healthcare professionals take the illness seriously and that the recognition of this is paramount is good.

However, essential research showing the multi-system nature of ME/CFS is not discussed – enteroviruses, orthostatic intolerance, oxidative stress – none of these are allowed to be discussed in detail. 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/CFS?

Increasing the recognition of ME can only be achieved by increasing the knowledge of the illness itself.

However, the recommendations that once again force non-functional and biased psychiatric therapies as a management technique will lead to more harm and probably contribute to fostering even more antagonism between healthcare staff (especially those who are untrained in ME/CFS) 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. ME/CFS is the correct term and myalgic encephalomyelitis is the correct name for the acronym ME/CFS. By pandering to organisations and individuals, who have a vested interest in using other terms, NICE does nothing but harm to itself as the consensus amongst patients will be that NICE cannot be trusted.

We are happy that NICE have listened to iME's objections to the lax terminology and removed references to CFS alone. However, using CFS/ME rather than the more commonly accepted term (ME/CFS) leaves open further opportunities for misunderstanding, deception and mendacity by certain vested interests – both within the medical arena and within the ME/CFS community itself.

Result: FAILURE



Influencing practice in the 'real world'

It is doubtful if this has been met as it provides nothing new for sufferers and carers.

By immediately stating that CBT and GET are the most useful therapies NICE has shown it is not willing to move the issue of ME/CFS into an area which offers any real hope of progress.

These 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 a travesty. It seems that NICE is intent on using as broad a definition for ME/CFS 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/CFS will not help to alter the government's position on this subject and therefore gives little to change the current unsatisfactory position where patients are given possible harmful GET. It will not inform healthcare staff of the missing link in research into ME/CFS – funding for biomedical research.

The guidelines show little awareness of other biomedical research being carried out or performed in the past. It should include references to new research in this area so that healthcare staff can be aware of the overwhelming evidence of the neurological source of this illness.

The guidelines state that a patient/carer can refuse any therapy without it impacting the relationship with the healthcare practitioner(s). We would like to see this occur but we are afraid that it will not.

In the face of insurance companies forcing an ME/CFS patient to undergo potentially harmful or useless GET or CBT or DWP staff refusing to accept the authenticity of the illness then we doubt if these guidelines are forceful enough to influence the '*real world*' and avoid this from happening.

In such instances recourse to litigation may be the only possibility for ME/CFS patients.

It might have been useful for these guidelines to detail what avenues are open for legal aid for ME/CFS patients who wish to challenge insurance companies and healthcare staff who insist on ME/CFS patients undergoing GET or CBT against their will.

The guidelines make little headway in influencing '*real world*' issues such as insurance companies forcing claimants with ME/CFS to undergo psychiatric therapies.



The guidelines do little to influence '*real world*' issues such as the need for people with ME/CFS to pass the continual DWP 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/CFS.

Will NICE state that nobody should be refused insurance and sickness benefits if they refuse to take anti-depressants or CBT/GET?

Result: FAILURE

Improving access to appropriate services, and supporting consistent service provision

It is doubtful if this has been met as it provides nothing new for sufferers and carers. Little is given in support of ME/CFS patients in their dealings with DWP staff and no reference is made regarding how ME/CFS patients are meant to deal with the harassment and bias of insurance companies who propose psychiatric treatment for ME/CFS.

If the service provision is providing treatments which are unfit for ME/CFS then consistency is meaningless.

Result: FAILURE

Emphasising the need for multidisciplinary working

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 ME/CFS patients the bias toward psychological therapies, and the amount of space given to these therapies in these guidelines, means that there is little credit given to non-psychiatric disciplines in treating and managing ME/CFS.

Result: FAILURE

Improving care for patients, particularly for those with severe CFS/ME

The guidelines offer little for severely affected. 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 here for carers.

Result: FAILURE

Providing guidance on 'best practice' for children with CFS/ME

The guidelines add little new of relevance which doctors would not already know today. The best practice is not psychiatric therapies where the onus is on the patient to attend CBT meetings. It does little to move the debate on for children or their families.

Result: FAILURE

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

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

It fails to recommend prescription supplements which can be tailored to manage symptoms of the illness, based on the needs of the patient. There is nothing flexible with the continued advocacy of useless or dangerous psychiatric therapies.

Result: FAILURE

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

The guidelines cannot be said to achieve this 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 ME/CFS patients. The subject matter is skewed to allow a multitude of fatigue-related patients to be included in this study. If it purports to be for ME/CFS then the studies need to use patients with ME/CFS – not CFS or other fatigue conditions.

Result: FAILURE



Comments on other stakeholders' comments

IIME have welcomed some of the changes which NICE made based on IIME's submission to the Draft guidelines.

We are left perplexed as to why NICE has not published all of our comments.

IIME have also viewed the comments from other stakeholders to these guidelines.

While there are some organizations, such as IIME, who wish for ME/CFS to be taken seriously and proper biomedical research performed we also note the comments from some other organisations, including surprisingly some charities purporting to represent ME/CFS sufferers, and we can clearly see that their intentions are not the same. In fact they are clearly viewing some other illness – not ME/CFS – or selling short the people they claim to represent.

And here we have a major failing of NICE. By pre-determining the result based on its requirements to view this illness as a broad chronic fatigue illness NICE has failed to grasp the reality, failed to analyse and use proper research, failed to respond to patients' demands and requirements and produced a document that will continue to allow this illness to be blended into a nebulous fatigue syndrome which only benefits psychiatrists interested in funding and other organisations who depend for their existence on paying members.

Conclusion

NICE had a real opportunity with these guidelines to improve the future for patients with ME/CFS. After all, over two years and unknown costs were expended in their preparation. Extensive comments to the draft guidelines were provided by the ME/CFS community and revisions could have removed the fallacies within the revised documents.

Yet 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 continue to be a collection of perpetuated myths, psychiatric dogma, outdated practices and prejudice.

The guidelines provide a lot of words without actually saying much.

NICE have no vision and no ideas with which to progress the treatment and perception of ME/CFS.

This is a mediocre effort by an organisation which again fails the people to whom it purports to provide instructions and information.



Invest in ME

August 2007

The document shows little new thinking and is clearly lacking in impartial analysis of all areas of research into ME/CFS.

One can only ask was it sensible to have these guidelines made at all at this stage without better analysis and research?

If much of the evidence was of poor quality then perhaps these guidelines are premature.

We should compare these guidelines with those produced for other neurological illnesses.

The inconsistency in these guidelines coupled with fallacious arguments used in favour of psychological therapies all undermine the supposed impartiality and credibility of NICE.

The lack of comment on epidemics and vaccinations shows how lacking in vision, scope and thoroughness has been the work carried out by NICE. The lack of analysis of the extensive biomedical research also shows a lack of rigorous control exercised in the formulation of these guidelines.

NICE state that *"We accept the Gibson Inquiry's view that the origins and nature of CFS/ME are poorly understood and that more high quality biomedical research is required."*

So it is even stranger that so little/no biomedical research is quoted in the NICE guidelines.

The Preface to the guidelines states that *"Several factors have contributed to the neglect of CFS/ME. Firstly, the illness is poorly understood."*

These guidelines do not make it any more understandable as they refuse to standardise on the *"most stringent"* guidelines (the Canadian Consensus) and continue to avoid the issue of including as broad a range of fatigue states as possible into the CFS/ME group – something only of benefit to psychiatrists and the ever-pervasive lobby of vested interests who have no wish for ME/CFS to be treated as a neurological illness).

The NICE guidelines end up as a confusing pile of notes which has no clear directive and no sense of understanding what this illness is.

IIME cannot endorse these guidelines as they condemn people with ME/CFS to a false and perilous future which will again be dominated by psychiatrists and the



Invest in ME

August 2007

institutionalised psychiatric dogma which pervades many organisations and healthcare departments.

NICE state in their 52 page short version for healthcare staff -

"The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer and informed by the summary of product characteristics of any drugs they are considering."

This is true – these guidelines are best left on the shelf when treating patients with ME/CFS.

NICE state that clinical guidelines are updated as needed so that recommendations take into account important new information. NICE claim to check for new evidence 2 and 4 years after publication, to decide whether all or part of the guideline should be updated.

We hope they do a better job than has been done in looking at existing evidence. In our view these guidelines are incomplete and a "rapid update of some recommendations" are required immediately.

At the time of this document it will be nearly two years since Sophia Mirza died from ME/CFS. It is a sobering thought that in this century, in the UK, such an event could occur. These NICE guidelines will do nothing to prevent more deaths.

Invest in ME are left dismayed, exhausted and totally fed up after reading this document (the full guidelines for healthcare professionals). It is unwieldy and unuseable.

It does nothing to progress either the perception or treatment of patients with ME/CFS. Whilst acknowledging that this must be treated properly and with respect by healthcare professionals it then proceeds to act out its pre-determined agenda and offer failed and expensive psychiatric solutions for a neurological illness.

It fails to subgroup, diagnose properly or even demand proper research.

It is a hopeless document considering how much time has been spent on its formulation.

Finally we quote some of the principal architects behind the NICE policy toward ME/CFS.



Invest in ME

August 2007

Andrew Dillon, Chief Executive at NICE and Executive Lead for the guideline, states:

“Until now there have been uncertainties about the diagnosis and management of this condition, but this new guideline will help health professionals make an accurate diagnosis, whilst considering other conditions that may be present”

It will do no such thing.

Professor Richard Baker, Chair of the Guideline Development Group, GP and Head of the Department of Health Sciences at the University of Leicester, states:

“The publication of this CFS/ME guideline is an important opportunity to change the current situation for the better, helping both healthcare professionals and individuals by providing clear advice on how best to manage this disabling condition. ”

It will not help individuals or healthcare staff.

It must be a sobering thought for the chair of the group these guidelines, and for many of those people who are responsible for the final product, that despite the cost and resources used these guidelines are a lame, biased and short-sighted attempt to keep ME/CFS patients and their families/carers just where they have been for the past thirty years, with little hope of proper treatment.

These guidelines have taken over two years to prepare and it will be another two years before they are revised.

Invest in ME believe they should be revised immediately.

These NICE guidelines are a poor collection of outdated theories and attempts at treatment.

They do nothing to help either GPs or patients deal with this illness. They add nothing to improve the situation for patients who are wasting their lives without any sign of a radical change in the way biomedical research into ME/CFS is initiated.

They fail the severely affected people with ME/CFS by offering them nothing but a referral to specialist care. NICE fail to define what this specialist care means.

Looking at the aims and objectives with these guidelines it is clear one can come away with only one conclusion.



Invest in ME

August 2007

With these guidelines NICE have failed in every respect.

Failure and dissatisfaction now seem to be synonymous with NICE and it seems that NICE are constantly in opposition with what patients and patient groups need and want.

Why this constant misrepresentation is occurring with NICE is something the government ought to look in to.

Certainly the management at NICE seem to attract attention for all of the wrong reasons.

At the Invest in ME International ME/CFS Conference 2007 in London Annette Whittemore (from the Whittemore-Peterson Institute in Nevada) stated that, with ME/CFS, second best is not good enough.

We urge all ME/CFS patient groups, organisations, individuals and healthcare staff to reject these guidelines as not good enough. For ME/CFS patients who have suffered from prejudice, outdated myths, ignorance and apathy for all of these years we say –

2ND BEST IS NOT GOOD ENOUGH

These guidelines are unacceptable.

NICE has failed in delivering anything worthwhile.

These guidelines are unfit for purpose.

NICE has shown itself unfit for purpose.

INVEST in ME
Charity Number 1114035