

National Institute for Health and Clinical Excellence
CFS/ME consultation draft
29 September – 24 November 2006
Comments on Chapter 1

| Status | SH organisation | Order no. | Document | Page No. | Line no. | Comments | Responses |
|--------|-----------------|-----------|----------|----------|----------|---|---|
| SH | 25% ME Group | 55 | FULL | 13 | | The glossary of terms does not include the word relapse, which is an omission. | Noted: GDG decided to use term 'setback/relapse'. |
| SH | 25% ME Group | 56 | FULL | 13 | | 'Rest' – for severely affected patients this can be for a long time. In any case rest enforced by the illness can feel very long subjectively. | Please see Chapter 6 and the recommendations for a more complete explanation. We have clarified both the definition and the recommendations on this. |
| SH | 25% ME Group | 57 | FULL | 13 | | The phrase 'wheelchair dependent' is not PC and oversimplifies the situation of many severely affected people. | We have used the definitions in the CMO's report |
| SH | 25% ME Group | 58 | FULL | 21 | GENERAL | I am extremely concerned that the draft guidelines propose that 'the therapies of first choice should be CBT or GET'. This is a reflection of the fact that there is a paucity of biomedical research and that the very limited research that has been undertaken has been limited to the fields of CBT or GET. It is shocking that this has led to a document disproportionately weighted to promoting these two practices. Research shows the dangers of GET, eg oxidative stress, very importantly the problems with the heart, muscle problems, mitochondrial problems again backed up with gene expression research etc etc. | Please see the revisions in the complete list of recommendations. |
| SH | 25% ME Group | 59 | FULL | 21 | 2 | The issuing of NICE Guidelines at this stage is premature. - Not enough research has yet been done on diagnoses, | NICE was commissioned by the Department of Health to develop a guideline on CFS/ME. There is a formal process for reviewing and updating NICE guidelines |

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causes and treatments (especially biomedical treatments) to justify the issuing of definitive guidelines

(see Chapter 15, Guidelines Manual available from NICE website).

- Anything produced at this stage will necessarily be an interim document, which must be subject to review in the NICE and long term.

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|----|--------------|----|------|----|-------|--|---|
| SH | 25% ME Group | 60 | FULL | 21 | 8 | <p><i>The Guideline Development Group developed this guideline with the aim of increasing recognition of CFS/ME:</i></p> <p>If the guidelines stand as they are at present, then the TRUE recognition of ME will not be attained, in fact these guidelines will do much damage to the reality of the disease.</p> <p>Why has the definition been widened?</p> <p>- widening the definition is bound to distract attention from the most severely affected and those who have been ill for a long time.</p> | The definition and term is based on that used in the CMO's report. |
| SH | 25% ME Group | 61 | FULL | 21 | 9 | <p>Very concerned about the real outcome of the practical issues in this document and that, if implemented will cause more damage and distress than is presently being experienced by ME sufferers; if that was possible!</p> | ... |
| SH | 25% ME Group | 62 | FULL | 21 | 13-14 | <p>"BEST PRACTISE" is not always 'good practise' and it is surprising that such weak, 'evidence based medicine' is being promoted as a reliable method of management and treatment for children and the severely affected.</p> | We have used the guideline development methodology as defined by NICE, and described in the Methods chapter |

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|----|--------------|----|------|----|---------|--|---|
| SH | 25% ME Group | 63 | FULL | 21 | 20 | "When the adult or child's main goal is to return to normal activities." This sounds as though you are insinuating that not all people with ME want to get better. These are not people who have a depressive illness; although I am sure these sufferers also wish to be 'normal' .I do not know any one who does not want to be better again. But they are mostly conscious that the forms of treatments on offer i.e. CBT/GET are not reliable. | Noted and please see revisions in the full recommendations. |
| SH | 25% ME Group | 64 | FULL | 21 | 20 - 21 | Seems to conflict with page 22, lines 2, 6 and 12. Patients should be able to choose the therapy. 'Return to normal activities' is a desirable outcome for all patients but should not be called a 'goal' because it is often not achievable. To call it a 'goal' can lead to a sense of failure in patients who are unable to meet this target. | Noted and please see revisions in the full recommendations. |
| SH | 25% ME Group | 65 | FULL | 21 | 21-23 | Clearly, CBT and GET are at best useless and at worst extremely harmful for M.E. patients. According to numerous patient survey results – summary results of 4 surveys for the CMO's WG Report were submitted to the GDG – on a total of 3074 patients; 707 (48%) of 1467 patients found GET made them worse, another 235 (16%) found it made no difference; 232 of 423 patients found CBT made no difference, and 91 (22%) found it made them worse. These are results on significant numbers of patients – more than in any RCTs'. Besides, RCTs are not suitable for patients | Noted and please see revisions in the full recommendations. |

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with ME/CFS, whose individual history requires an individualized and person-focused therapeutic approach, frequently multi-faceted'.

Despite this, people with M.E. are routinely being recommended these treatments while also being assured that they are completely safe.

These treatments are also not just being offered to M.E. patients solely on a voluntary basis; many have been treated as psychiatric patients against their will. (Or against the will of the parents of children with M.E., as described previously). In some cases it is a condition of receiving medical insurance entitlements that M.E. patients first undergo 'rehabilitation' such as CBT and GET programs. This is also true of government welfare entitlements as Professor Malcolm Hooper explains:

[In the UK] many patients are simply too sick to be forced to attend psychiatric units and to participate in compulsory "management strategies" which involve exercising, but if they fail to attend, they are deemed not to want to get better and their State benefits are withdrawn because of Wessely's dogmatic advice to Government that ME is nothing more than an "aberrant illness belief". There are many such known cases, including those in which ME patients have been threatened with being sectioned (ie. compulsorily detained under the Mental Health Act) unless

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they comply with psychotherapy.
(2003, [Online])

The 'evidence for the efficacy of the proposed 'treatments' are extremely weak and unreliable in reality.

Subclassifying Chronic Fatigue Syndrome through Exercise Testing. Vanness JM, Snell CR, Strayer DR, Dempsey L 4th, Stevens SR. Med Sci Sports Exerc. 2003 Jun;35(6):908-913. [PDF Format]

Response to Exercise

Healthy People

ME/CFS Patients

Sense of well-being

Invigorating, anti-depressant effect

Malaise, fatigue, worsening of symptoms.

Resting heart rate

Normal

Elevated

Heart rate at maximum workload

Elevated

Reduced heart rate

Maximum oxygen uptake

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Elevated

Approximately ½ of sedentary
controls

Age-predicted target heart rate

Can achieve it

Can **NOT** achieve it

Heart functioning

Increased

Sub-optimal

Cerebral blood flow

Increased

Decreased

Body temperature

Increased

Decreased

Respiration

Increased

Decreased

Cognitive processing

Normal, more alert

Impaired

Oxygen delivery to the muscles

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Increased

Reduced

Gait Kinematics

Normal

Abnormalities

Recovery period

NICE

Days or weeks

**ME/CFS Post-Exertional Malaise /
Fatigue and Exercise** by Marjorie van
de Sande B.Ed, Grad. Dip. Ed.

An excerpt:

Even though post-exertional malaise is a hallmark feature of ME/CFS, exercise programs are often prescribed with little thought to the effect they may have on patients. The panel of experts for the ME/CFS clinical consensus document(1) stressed that a thorough evaluation of patients and their total illness burden, optimizing medical management, and a careful evaluation of pain generators and risk factors must be done before even considering an exercise program. As much care must be taken in prescribing appropriate exercise for ME/CFS patients as in prescribing pharmaceuticals.(5)

[Note that recovery may be incomplete in some patients even

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after 'days or weeks' as this chart states. Symptom exacerbation or progression may in fact persist for many months or years following (over)exertion, and/or may be irreversible]

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| SH | 25% ME Group | 66 | FULL | 21 | 21 -23 | There is a wealth of biomedical research that shows a different picture and outcome for strategies in how to manage and treat ME, that has not been highlighted in this Guideline – SEE Individual submission presented to NICE, which details a lot of this research | Noted and please see revisions in the full recommendations. Also please see responses to the specific comments. |
| SH | 25% ME Group | 67 | FULL | 22 | 4-8 | <p>“CFS/ME” is not the same disorder as ICD-10 ME/CFS (and as defined in the Canadian criteria)</p> <p><i>“To facilitate shared decision-making the healthcare professional should provide information on the aetiology, nature, course and approaches towards CFS/ME”</i> The Draft Guideline fails to provide any information on the biomedical anomalies that have been demonstrated in ME/CFS and it fails to mention that ME/CFS is classified in the WHO ICD-10 as a neurological disorder. These are significant omissions, and are exactly the same omissions as in the “independent” Report by the Chief Medical Officer’s Working Group in 2002</p> | We have used the term as in the CMO’s report. |
| SH | 25% ME Group | 68 | FULL | 22 | 5 | This should be extended: “...and inform patients of the WHO’s classification of the condition as a neurological illness” | We have stressed the need for informed discussion around diagnosis. |

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|----|--------------|----|------|----|-------|--|--|
| SH | 25% ME Group | 69 | FULL | 22 | 6 - 7 | <p>The range of strategies outlined in this guideline are limited, unreliable and narrow i.e. there is no reference to Pacing therapy, as recommended by the CMO Report, published in 2002.</p> <p>There is a strong possibility that the outlined approaches in this Guideline, will actually be unhelpful and even harmful to ME patients in the long term.</p> | Noted and please see revisions in the full recommendations. |
| SH | 25% ME Group | 70 | FULL | 22 | 10 | Should continue: 'and consider other possible treatments' | We have noted the need for the range of treatment options to be discussed. |
| SH | 25% ME Group | 71 | FULL | 23 | 6-8 | <p>"Adults and children who are severely affected should be able to access the same diagnostic and therapeutic options as those who are not severely affected, as appropriate."</p> <p>This will only work if enough resources are made available to visit the severely affected in their homes. At present this rarely happens.</p> | This has been referred to the NICE implementation team. |
| SH | 25% ME Group | 72 | FULL | 23 | 11 | <p>Many patients have no choice but to stay in bed and this is very difficult for them when they want to be up and about. To emphasise the risks of bed rest is inappropriate, as it will only add to their fears. This sentence implies that there is no risk involved with avoiding bed rest when it is well known that activity beyond a person's ability is a main cause of relapse in this illness. Any risks associated with inactivity are a complication of the illness itself and should not be seen as being under patients' control. In the above mentioned 4 patient</p> | This recommendation has been deleted |

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surveys on 3074 patients submitted to the CMO's Working Group, bed rest was the most frequently cited helpful approach: 2165 of 2426 patients (89%) found bedrest helpful. They cannot all have been wrong or laboured under an illusion. It is a misguided view of certain UK psychiatrists which has resulted in this erroneous notion that bedrest in ME/CFS patients results in a deterioration in their condition.

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|----|--------------|----|------|----|---------|--|---|
| SH | 25% ME Group | 73 | FULL | 23 | 12 | Instinctively, all patients yearn to get back to a previous (better) level. To say that 'advice should focus on ...a gradual return to normal ...' belittles the severity of the condition and implies that setting the goal of recovery is sufficient to induce it. The statement should also include "circulatory problems". | This recommendation has been deleted. |
| SH | 25% ME Group | 74 | FULL | 28 | General | There should be research done to assist in diagnosis of psychologically ill people who have been misdiagnosed with ME/CFS, so that they can be referred to mental health services and not use up valuable resources set aside for people with ME/CFS. | The GDG did not consider this to be a key research recommendation (please see the NICE Guidelines manual for criteria used when drafting research recommendations). |
| SH | 25% ME Group | 75 | FULL | 29 | 10 | The following needs clarification. 'It is not known how much improvement is important for patients with CFS/ME.' | These have been revised after the consultation and such questions on the most appropriate way to measure 'effectiveness' are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an |

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|----|--------------|----|------|----------------|--------------|---|--|
| SH | 25% ME Group | 76 | FULL | 23 | 9 -12 | Are we talking about recovery from a normal viral infection or patients who have been damaged by having a weakened immune response and then contracted ME? | improvement in pain? This recommendation has been deleted. |
| SH | 25% ME Group | 77 | FULL | 26 | Top left box | Why should 'management for children who are severely affected follow the same principles as for those who are mildly/moderately affected'? Particularly CBT and GET as there is evidence that these techniques may be inappropriate in severe CFS/M.E. ALL the charities that have carried out membership surveys have shown that CBT and GET management therapies are largely, unhelpful and harmful to ME sufferers. (see above for details) | The care pathways have been revised – also see the detailed recommendations on the care for people with severe CFS/ME. |
| SH | 25% ME Group | 78 | FULL | 26 | Top left box | Hospital admission is problematic for children who are severely affected due to the nature of the hospital environment – noise, light, chemicals, drugs etc. | Please see the detailed recommendations on the care for people with severe CFS/ME. |
| SH | 25% ME Group | 79 | FULL | 26 and General | | 'Activity management' is not another term for 'pacing' which is how it seems here and elsewhere in the document. | We have made the use of language more consistent – please also see the recommendations and Chapter 6 for a full discussion of activity management. |
| SH | 25% ME Group | 80 | FULL | 27 | Top left box | AGAIN, why should 'management for adults who are severely affected follow the same principles as for those who are mildly/moderately affected'? Particularly CBT and GET. Severely affected required home visits from GPs, practical help in the home with personal care, housework, shopping, cooking etc. This all too | The care pathways have been revised – also see the detailed recommendations on the care for people with severe CFS/ME. |

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| | | | | | | often is not happening. | |
| SH | 25% ME Group | 81 | FULL | 28 | 11 | <p><i>“Patient experience suggests that some of these interventions may be harmful and/or not effective”.</i></p> <p>Despite acknowledging their harm and ineffectiveness, the Draft Guideline nevertheless promotes these interventions and stipulates (on page 181) that they should be offered to ALL adults and children with “CFS/ME”.</p> | We have revised the recommendations to clarify their use. |
| SH | 25% ME Group | 82 | FULL | 29 | 1 | <p><i>“We need reliable information on prevalence and incidence to plan services”</i></p> <p>What is needed is that due attention be paid to the Canadian definition.</p> | Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. The GDG considered the research recommendations to be appropriate. |
| SH | 25% ME Group | 83 | FULL | 29 | 10 - 11 | <p>It is important to all patients to gain as much improvement as they possibly can! This sentence sounds patronising to patients, or thoughtless.</p> | These have been revised after the consultation and such questions on the most appropriate way to measure ‘effectiveness’ are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an improvement in pain? |
| SH | 25% ME Group | 84 | FULL | 30 | 8 | <p><i>“The guideline provides recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness”</i></p> <p>This has been shown to be profoundly untrue.</p> | ... |

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|----|--------------|----|------|----|-----|--|---|
| SH | 25% ME Group | 85 | FULL | 31 | 16 | Also children under 5 years are not covered. | The GDG agreed that it is very rare in young children and there is likely to be very little evidence. The considered opinion of the GDG was that the management of younger children is likely to be similar to that of older children. This was reflected in the scope. |
| SH | 25% ME Group | 86 | FULL | 31 | 25 | The Draft Guideline fails to inform its clients that there are now 10 case definitions for ME/CFS and that the Oxford criteria (on which the Guideline relies) specifically excludes those with neurological disorder but specifically includes those with psychiatric disorder, or that the most accurate and informed case definition is the Canadian definition. | Please see the chapter on diagnosis for a full discussion of the evidence, and the relevant recommendations. |
| SH | 25% ME Group | 87 | FULL | 35 | 4-5 | The term myalgic encephalomyelitis (means muscle pain, my-algic, with inflammation of the brain and spinal cord, encephalo-myel-itis, brain spinal cord inflammation) was first coined by Ramsay and Richardson and has been included by the World Health Organisation (WHO) in their International Classification of Diseases (ICD), since 1969. The currently version ICD-10 lists ME under G.93.3 - neurological conditions. It cannot be emphasised too strongly that this recognition emerged from meticulous clinical observation and examination (Hooper 2006) ¹ . It is also worth noting that the term, Myalgic Encephalopathy, is | The title of the guideline was amended to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (encephalopathy) following the scope consultation with stakeholders. |

¹ Hooper M. (2006) Myalgic Encephalomyelitis (ME): a review with emphasis on key findings in biomedical research. JCP Online First, published on August 25, 2006 as 10.1136/jcp.2006.042408 jcp.bmjournals.com

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|----|--------------|----|------|----|-----|--|---|
| SH | 25% ME Group | 88 | FULL | 35 | 4-5 | <p>not mentioned at all in the WHO ICD classification document.</p> <p>The symptom list in this guideline is very limited compared to those experienced by sufferers of Myalgic Encephalomyelitis and perhaps a separate list should be included:</p> <p>Myalgic Encephalomyelitis is primarily neurological, symptoms may be manifested by: cognitive, cardiac, cardiovascular, immunological, endocrinological, respiratory, hormonal, gastrointestinal and musculo-skeletal dysfunctions and damage.</p> <p>More than 64 distinct symptoms have been authentically documented in M.E (See the symptom list below for further information.) Symptoms are also caused by a loss of normal internal homeostasis; the body becomes unable to make all the appropriate physiological adjustments that allow it to maintain homeostatic equilibrium in response to the many changes to the internal and external environment that are part of everyday life. The body/brain no longer responds appropriately to homeostatic pressures, including (to varying extents): physical activity, cognitive exertion, sensory input, orthostatic stress, emotional stress and infectious stress.*</p> <p>When certain levels of each of these homeostatic pressures occur (or are applied), homeostatic disequilibrium</p> | <p>We have revised the recommendations on diagnosis. The view of the GDG, was that at this point the evidence did not support the presence of clusters of symptoms as useful in diagnosis. The symptoms listed in the guideline are not intended as a comprehensive list, but those that are helpful in recognising the condition. The view of the GDG was that a list of all symptoms was potentially confusing as symptoms may then be attributed to CFS/ME rather than investigated further. .</p> |
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results. **The result of this homeostatic disequilibrium is a period of time in which the patient experiences:**

A combination of: profound cognitive dysfunctions (and various other neurological disturbances), muscle weakness (or paralysis), burning eye pain, subnormal temperature or low-grade fever, sore throat or painful lymph nodes (and/or other signs of inappropriate immune system activation), faintness or vertigo, loss of co-ordination, dyspnea, an explosion of sensory phenomena, cardiac and/or blood pressure disturbances, facial pallor and/or a slack facial expression, widespread severe pain, nausea or feeling as if poisoned, feeling cold and shivering one minute and hot and sweating the next, anxiety or even terror (as an organic part of the attack itself rather than as a reaction to it) and hypoglycaemia. Often the patient will feel an urgent need to retreat from all homeostatic pressures. The types of symptoms triggered vary widely from patient to patient, but some combination of these is common. There may also be an accompanying exacerbation of other symptoms. **These symptoms combine to create an indescribable and overwhelming experience of terrible illness that is unique to M.E, and can be profoundly incapacitating.** At its most severe, the patient feels as if they are about

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to die.

In the severely affected neurological symptoms are usually more prominent and severe. The CMO's Report in 2002 also raised concerns about the difficulties associated with care for the severely affected (section 4.2.1.2 of the CMO report)

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|----|--------------|----|------|----|-------|--|--|
| SH | 25% ME Group | 89 | FULL | 35 | 5-7 | Even though purporting to include "ME", the cardinal feature of the disorder is omitted. | ... |
| SH | 25% ME Group | 90 | FULL | 35 | 15 | <i>"the MRC has made research on CFS/ME a priority"</i> On the contrary, the MRC has not made research on ME/CFS.- a priority but has focused on funding yet more research into behavioural disorders that disingenuously claim to be studying ME. | Noted – the MRC noted CFS as a strategic priority. |
| SH | 25% ME Group | 91 | FULL | 35 | 16 | To be added. 'Despite this priority the MRC have funded no biomedical research. The MRC should be proactive in seeking research proposals due to the urgency of need, and the fact that that necessary research will need to cross traditional medical boundaries' | Noted – the MRC noted CFS as a strategic priority. |
| SH | 25% ME Group | 92 | FULL | 35 | 23-27 | There is also little mention of the Epstein Barr virus and other triggers of this illness...all physical.... And little constructive advice regarding viral onset, adequate rest and symptom management, let alone chronic phases, relapses and secondary illnesses/conditions associated with having M.E. | ... |

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We would like to add that countless vaccines are given to infants and children to avoid potential serious complications arising from many varied viral (and bacterial) infections. It is very curious that when such complications occur as a result of certain viruses, both in children and adults, the resultant consequences (i.e. ME or CFS etc) are interpreted as somehow being due to psycho-social causes or personality traits etc.

SH 25% ME Group 94 FULL 36 5-10

There is long standing debate concerning the appropriateness of the Oxford criteria, especially for diagnosis of ME. This is because of the wide ranging use of this tool in psychiatry.

Please see the revised recommendations on diagnosis.

Many feel that really emphasising the serious problems of the definition of the illness are absolutely central to the whole issue.

If they haven't got the definition correct then how can the guidelines be correct? There are papers by Prof Jason and DR Spence and co etc etc showing that the definition is far too loose and as such includes people with a wide range of disparate illnesses.

The Canadian criteria are more appropriate for helping to diagnose ME, which automatically eliminates conditions like chronic fatigue and other psychological conditions.

There is a danger that ME will continue to be a 'dust-bin' diagnosis

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for the medical profession who are uncertain how to diagnose a patient with truly defined ME. Using the diagnostic tools highlighted in this Guideline will only continue to confuse medical personnel.

Someone else commented that; They should be using the Canadian Criteria which as you well know was written by doctors with vast *clinical* experience of treating ME patients over many years. They know the difference between ME and chronic fatigue. I don't wish to be disparaging to those with chronic fatigue, I am merely pointing out that it is a different illness and the guidelines for treatment for ME need to be for ME NOT for any one and everyone with fatigue. Fatigue is a symptom of innumerable illnesses (including cancer and MS).

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|----|--------------|----|------|----|--------|--|------------------------|
| SH | 25% ME Group | 95 | FULL | 36 | 11 | <i>"the Oxford criteria"</i> | This has been revised. |
| | | | | | | The Oxford criteria are not "frequently used": they have been shown to have no predictive validity; they are used by only a handful of UK psychiatrists and have been rejected by world experts on the disorder. | |
| SH | 25% ME Group | 96 | FULL | 36 | 11 -16 | These definitions are used for research but are in the 'Diagnosis' section without qualification. The Canadian guidelines are more suitable for diagnosis. | This has been revised. |
| SH | 25% ME Group | 97 | FULL | 36 | 23 | Should say: "excluded all other KNOWN causes" | Noted and revised. |

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|----|--------------|----|------|----|------|--|--|
| SH | 25% ME Group | 98 | FULL | 36 | 5-27 | <p>A paper produced by Dr Byron Hyde gives his take on how to diagnose ME</p> <p><i>MYALGIC ENCEPHALOMYELITIS (ME)</i></p> <p>The term <i>myalgic encephalomyelitis</i> was based on clinical descriptions of an illness that has occurred both sporadically among the General population and in clusters, or epidemics, usually in hospitals or schools. Over 60 such epidemics have been described in the medical literature (Acheson, 1992; Henderson & Shelokov, 1992; Hyde, 1992) since Sandy Gilliam, Assistant Surgeon General of the United States and later Dean of Medicine at Johns Hopkins, first described the 1934 epidemic in the Los Angeles County General Hospital (1938). B. Sigurdsson et al. (1950) in Iceland, D. A. Henderson, and A. Shelokov, in the United States (1959a, 1959b); A. Wallis, in 1955, and A. M. Ramsay, in 1988, and John Richardson, in England (1992); and P. Behan, in Scotland (Behan & Behan, 1988; Behan, Behan, & Bell, 1985), have all added to this growing literature. This group of illnesses has been given many names, but these have distilled down to myalgic encephalomyelitis (ME), a term used primarily in the United Kingdom, Canada, and Australia.</p> <p>These various clinical descriptions include these characteristics:</p> <ul style="list-style-type: none">• A sporadic and epidemic | Please see the revised recommendations on diagnosis. |
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postinfectious illness most frequently occurring in the late summer or early autumn, with an incubation period from 4 to 7 days. The epidemic illness is most commonly acquired in hospitals, schools, or domiciliary institutions at a time when an increase of similar sporadic illness occurs among the General population. Although the illness is seen in diverse occupations, health care workers, teachers, and students are the most commonly affected.

- The epidemic illnesses have been associated with infrequent deaths involving CNS (central nervous system) changes. Many of these changes have been subcortical brain changes. Deaths in sporadic cases have been rare but have been associated with acute cardiac arrest, with no signs of coronary disease, and frequently suicide. Deaths other than suicide are uncommon.
- Onset of the primary ME illness usually follows abruptly during the recovery phase of an often banal infection (if an infection is noted at all) or within 4 to 20 days of an immunization. Frequently one observes the onset of an ME-like illness after multiple infectious episodes. The primary infectious illness and the ME illness do not resemble each other. Most

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infectious illnesses are described as upper respiratory tract, flu-like, gastrointestinal and, less commonly, hepatic illness or pneumonia. Traumatic incidents associated with minor infectious illness or travel to foreign countries. These associations often follow within 30 days of a series of immunizations.

- ME illness in adults is associated with measurable changes in the CNS and autonomic function and at times injury to the cardiovascular, endocrine, and other organs and systems. It is described as (1) a systemic illness often of subnormal temperatures; (2) marked muscle fatigability; (3) an acute onset of CNS changes of memory impairment, mood changes, sleep disorders, irritability, and reactive depression; (4) involvement of the autonomic nervous system resulting in tachycardia, coldness of the extremities, urinary frequency, bowel changes, pallor, and sweats; (5) diffuse and variable involvement of the CNS leading to severe headaches, visual problems, ataxia, weakness, cramps, and sensory changes; (6) muscular and neck pain, acute fleeting spasmodic pain and tenderness, and myalgia.
- In children in the acute phase,

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there is depression with weeping, significant loss of energy, retardation and impairment of thought and memory process, disorders of sleep, behavioral disorders, acute onset of school problems, often of a serious nature, with a reluctance to attend school, and with a significant weight loss. Children are usually diagnosed as hysterical or school phobic.

- The initial period of illness lasts from weeks to up to two years and tends to be more severe. During this period, the patient either recovers, remains, or relapses in a chronic phase of variable severity. The chronic phase is often sufficient to prevent return to school or work for either long periods or permanently.
- Dr. Michael Goldberg, of Tarzana, California, believes that this illness often results in children being rejected, abused, and abandoned to the street or to juvenile criminal activity. Dr. John Richardson (1992), of Newcastle, and others have documented significant associated cardiac and cardiovascular injury as well as other organ injuries associated with the usual CNS and autonomic changes in this group of patients. Dr. Seymour Grufferman (1992), of Pittsburgh,

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has described an increased incidence of malignancies, often lymphomatous, associated with individuals in clusters of ME/CFS. A similar finding was initially described in some of the patients in the Lake Tahoe epidemic (Daugherty et al., 1991; Peterson et al., 1992).

All ME descriptions were concerned with chronic or recurrent acute onset illnesses. The ME descriptions deal with primarily CNS and autonomic changes and, at times, with easy fatigability and with poor or delayed recovery of CNS or muscular abilities. Although ME clinical descriptions noted the infectious onset and infrequently the postimmunization history of ME illness, neither pharyngitis nor involvement of lymph nodes was ever mentioned in any of the clinical descriptions of the actual chronic illness manifestations.

Host factors are important in ME. At the time of the initial illness, the patient often appears to be either temporarily or chronically immune-compromised by one or more of the following:

- Exhaustion from overwork or night shifts
- Repetitive infectious disease
- Recent immunization
- Significant illness or trauma

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- Toxic chemical exposure

As in all diseases, there is a significant variation in the degree and range of injury. Those who are least injured often simply return to school or work and operate at a lower productivity and escape diagnosis. Those who are most injured or die are easily recognized at disease onset or nicely after as CNS, cardiovascular, or organ injury. Because of their overwhelming illness and the specificity of the end-organ injury, they are never diagnosed as ME except in epidemic or cluster situations. Overwhelming fatigue is often a feature of the chronic illness phase (Fukuda et al., 1994). After a few months, however, this profound fatigue often changes and some patients begin to feel normal until they are challenged by any physical, intellectual, emotional, or sensory stress. In this new phase, the patient has rapid fatigability and poor recovery after any stressor. These patients begin to feel they inhabit a body and mind significantly different from usual, and sometimes they panic. The adult patient with moderate to major illness rarely recovers totally, but usually does improve (Joyce, Hotopf, & Wessely, 1997). It is an unacceptable improvement. Those adults who are still significantly ill at two years can still improve but only a few ever return to any degree of normal function. Unlike adults, the majority of children

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and adolescents, even those seriously injured, who have proper care and are in a positive economic environment, tend to recover substantially or at least improve significantly over time (Marshall, 1999).

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|----|--------------|-----|------|----|--------|---|---|
| SH | 25% ME Group | 99 | FULL | 36 | 25 | <p>It is nonsense to suggest that at present “there are no physical signs that identify CFS/ME” – this effectively ignores swathes of international biomedical research evidence.</p> <p>As Harvard physician/researcher Anthony Komaroff stated in a CDC press conference earlier this month, there are over four thousand refereed journal articles attesting to physical abnormalities found in patients with CFS-Fukuda. Given that the criteria for M.E. are more restrictive than for CFS-Fukuda, one would assume that many of these articles would apply.</p> | Please see Chapter 5 for a fuller discussion of diagnosis. |
| SH | 25% ME Group | 100 | FULL | 37 | 8 - 11 | Reference to Canadian Criteria here – but then no mention of what they actually say anywhere! | We have added in reference to the Canadian guidelines as appropriate. |
| SH | 25% ME Group | 102 | FULL | 37 | 23 | <p>ANOTHER STORY: My dear friend XXXX lost her son XXX at the age of [x] last year to this damn disease - they lived near a major university, but no doctor would believe he had anything physically wrong with him. The autopsy showed that he died in his sleep of a heart attack, and that his heart had been destroyed by old and new viral damage. The mother was diagnosed with [x] two years before xxxx was born. She has been</p> | ... |

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| | | | | | | ill for [x] years, but the only name for her illness that the U.S. CDC will recognize is "CFS". | |
| SH | 25% ME Group | 103 | FULL | 37 | 17-25 | The evidence for improvement is very sketchy and any improvement is often limited, even the CDC highlight how rare complete recovery occurs. If you are advocating (and healthcare professionals implement) the treatments in this Guideline, then we will not see recovery, but rather significant numbers of <u>ME patients being made worse, as also reported by all the major charities.. Including the 25% ME Group Surveys http://www.25megroup.org/Group%20Leaflets/Group%20Leaflets.htm</u> We also (as the MEA has said), that the Guideline Development Group should refer to the information on prognosis that is provided in section 1.4.3 of the CMO report. | Noted |
| SH | 25% ME Group | 104 | FULL | 37 | 23 | In surveys carried out by the 25% ME GROUP, it is highlighted that many severely affected sufferers have had the condition for most of their lives i.e. up to 50 years. <u>http://www.25megroup.org/Group%20Leaflets/Group%20reports/May%2002%20Generic%20GRAPH%20Report.doc</u> | We have noted that some people may become severely and permanently disabled. |
| SH | 25% ME Group | 105 | FULL | 37 | 23 | There are approx 60,000; based on an estimate of 240,000 of ME sufferers in the UK. This is almost as many MS sufferers in the UK. | ... |

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|----|--------------|-----|------|----|------|---|---|
| SH | 25% ME Group | 106 | FULL | 38 | 4-11 | M.E. can occur in both epidemic and sporadic forms and over 60 outbreaks of the illness have been recorded worldwide since 1934. M.E. can be extremely disabling and in some cases the illness is fatal. (Hyde 1992 p. xi) (Hyde & Jain 1992 pp. 38 - 43) (Dowsett 2001, 2000, 1999.b, b [Online]) Less than 1% of the population has Myalgic Encephalomyelitis. | Noted |
| SH | 25% ME Group | 107 | FULL | 38 | 23 | On page 38, line 23, the Draft Guideline states that CBT is a psychological therapy and at line 27 states that it “ <i>is used in many health settings including cancer</i> ”. Whilst it is not disputed that psychological support can be helpful (and even essential) in any illness for those upon whom the demands imposed by events exceed their ability to cope, that is very different from stipulating that psychotherapy should be the firstline management regime, which is what is happening with ME/CFS. For the record, several cancer charities, including Cancer Research UK, have confirmed that CBT/GET is not routinely used as part of cancer patients’ rehabilitation programmes. Equally, the MS charities have confirmed that it is not used as a first-line management approach. Since there is no specific psychiatric service providing compulsory corrective behaviour regimes upon fatigued cancer sufferers in order to compel them to change their “illness | Not clear which section this refers to – but the section on management (Chapter 6) and the associated recommendations on CBT have been revised. |

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beliefs” that they are sick, or upon those with lupus, or on those with multiple sclerosis or other neurological disorders, how can it be justified to impose such a regime on those with ME/CFS? The answer is because Wessely School psychiatrists advise Government bodies that ME does not exist except in the minds of those who think they suffer from it, and that CFS is a behavioural disorder.

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| SH | 25% ME Group | 108 | FULL | 39 | 1-17 | There is great concern about the various specialist service centres, that were originally supposed to be set-up for ME patients. These centres have been taking patients with various conditions that are not related to ME and thus have created a confusing picture, especially when it has come to those who have experienced improvement with the 'treatments' on offer i.e. mainly psychological approaches. | Noted |
| SH | 25% ME Group | 109 | FULL | 39 | 2 | Rheumatology should also be referred to here. | Noted and added |
| SH | 25% ME Group | 110 | FULL | 39 | 7-17 | These (new CFS/ME) centres are discredited because they employ cognitive behavioural therapy (CBT) and graded exercise therapy (GET) when there is significant publicly available evidence that such regimes may be actively harmful to those with ME / CFS because they are based on the psychiatrists' discredited assertion that “CFS/ME” is a “faulty belief system” that can be “corrected” by | ... |

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CBT and incremental aerobic exercise regimes.(Williams 2004²)

- Stephen Ralph (2006) points out :
 “80% figure of individuals do not present to these “Fatigue” Clinics with the specific signs and symptoms of G93.3 Myalgic ...
 The **vast majority** of "CFS/ME" patients are almost certainly seen by intentionally vague (but to the ignorant impressively sounding) “multidisciplinary teams” at "Fatigue" clinics set up using the Functional Psycho-Somatoform Disorder model and an ideology handed down to them by their puppet masters in the form of Wessely/Sharpe/White/Chalder et al. As we have already seen here on ME ActionUK - the majority of these clinics have people running them who do what they do based on their interests in Somatoform Psychiatry even if they are not psychiatrists themselves. ...The vast majority will be treated as though they have mental health disorders of which fatigue and non-specific pain are key treatable symptom using CBT and Graded Exercise Therapy.”

SH Action for M.E. 4 FULL 21 9

With regard to “...influencing practice in the real world”, sufficient specialist services should be available, along with suitably trained health professionals, otherwise false hopes

The aim of the guideline is to improve care, including in those areas noted here.

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and expectations are raised.

In addition, of particular concern is the lack of knowledge and expertise in Primary Care. In our survey, 36.5% disagreed and 19.6% strongly disagreed with the statement that Primary Care professionals could identify M.E./CFS. In a recent study, 811 GPs (77%) responded to a questionnaire intended to obtain baseline data and identify the factors associated with GPs' attitudes and knowledge of M.E./CFS. 48% of GPs did not feel confident with making a diagnosis of M.E./CFS; and 41% did not feel confident in treatment (Ref: Primary healthcare provision and Chronic Fatigue Syndrome: a survey of patients' and General Practitioners' beliefs. BMC Family Practice. 6:49, 2005).

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| SH | Action for M.E. | 5 | FULL | 21 | 13 | <p>There is a limited amount of detailed information in the guideline on support for the severely affected, although the FULL guidelines do contain more information.</p> | <p>Also see the recommendations on people with severe CFS/ME.</p> |
| SH | Action for M.E. | 6 | FULL | 21 | 17 | <p>A key problem in facilitating communication between practitioners and patients is the fact that terminology still lacks clarity. For example, the phrase and definition of Graded Exercise Therapy concerns many of our constituents. Unfortunately, the use of ambiguous language has led to concern and confusion amongst our constituents as we note below.</p> | <p>Noted and we have stressed the need for consistency in the language used, and have provided definitions in the Glossary and detailed descriptions of interventions in the recommendations and appropriate chapters.</p> |

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| SH | Action for M.E. | 7 | FULL | 21 | 19 | Priority Recommendation, 'when the main goal is to return to normal activity'. Many constituents found this an insensitive comment as they felt it implied that they didn't want to return to normal. This needs to be rewritten. | Noted and please see revisions in the full recommendations. |
| SH | Action for M.E. | 8 | FULL | 22 | 14 | Some of our constituents have noted that they have been advised not to engage with self-help groups, as this encourages 'sick beliefs'. Such issues need to be addressed. | Please see the recommendations on information and support. |
| SH | Action for M.E. | 9 | FULL, Research Reccs | 28 | | <p>The scientific study of M.E./CFS is a rapidly developing field where little is known at present.</p> <p>The guidelines are inconsistent with the phrase "there is little good research evidence for most aspects of CFS/M.E." being used, which contradicts the claim made in both the FULL and NICE guidelines that there is 'clear evidence' for the effectiveness of CBT and GET. A transparent representation of the research context is needed.</p> <p>No explicit recommendation for biomedical research is made – which we consider essential. In our survey, 73.6% strongly agreed and 14.9% agreed that the most important research for people with M.E./CFS is biomedical.</p> <p>No mention is made of the M.E. Research Observatory, which will look at epidemiological issues.</p> <p>No rigorous evaluation of Pacing was identified, though patient experience</p> | <p>These have been revised after the consultation.</p> <p>Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. We have also added some detail to this section to describe the general approach.</p> <p>Therefore, although such research may be valuable, this is not intended as a list of all possible research relevant to people with CFS/ME.</p> |

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supports this technique and this was clearly supported by the CMO report (A RCT on Pacing is now taking place in specialist services and is due for completion in 2009).

Research into symptom management as part of a portfolio approach to the illness needs to be undertaken. In our survey 68.1% strongly agreed and 22.4% agreed with the need for such research.

We would wish to see a recommendation for research into case definition. Research into sub group analysis was also supported by our constituents; 57.9% strongly agreed and 34.5% agreed that such research is required to see how effective different management methods are with different groups.

A recommendation for research into the information needs of patients and practitioners would also be welcomed.

All of the above should be recommended as future and/or on-going research activity and noted as opportunities for future development in diagnosis and treatment.

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| SH | Action for M.E. | 10 | FULL | 28 | 6 | The research question stated here is itself open to question. | ... |
| SH | Action for M.E. | 11 | FULL | 37 | 13-16 | The principles of pain management should be highlighted in both guidelines and should be more detailed, as it is often a significant feature of M.E./CFS. | Noted and added – please see the revised recommendations. |

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| SH | Action for M.E. | 12 | FULL | 37 | 17-25 | There is a considerable difference in the comments made here, in lines 21–25, and those in the nicer guidelines (p161.2.3.3). The nicer guidelines should reflect the more comprehensive understanding of the illness given in the full guidelines. | Noted, but the NICE version includes only the recommendations – however we have stressed the need throughout for accurate communication, including around prognosis. |
| SH | Action for M.E. | 13 | FULL | 38 39 | | The limited availability and vulnerability of services is noted... this needs to be highlighted further to ensure that the guidelines can be properly met. This does not appear to be referred to in the NICE guidelines. | Noted and service provision is not normally highlighted in the NICE version, although it is key background information. We have also passed this onto the NICE Implementation team. |
| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 2 | FULL | 9 | | counselling is not defined as an evidence based treatment, though elsewhere p. 152, p.269 it is acknowledged that there is better evidence for counselling than CBT in the only relative efficacy RCT referred to here - why is counselling not defined as an evidence - based treatment here? | Ridsdale 2001, as noted in the health economic discussion, is not a trial in people with CFS, but people with chronic fatigue, of whom only 28% has CFS. |
| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 3 | FULL | 14 | | counsellors and psychotherapists have not been included in the list of professionals, though there is good evidence to show that these professionals can make a significant contribution to the care of patients with CFS - why have they not been included? | The list is not intended as a complete list of all possible healthcare professionals. |
| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 4 | FULL | 21 | 21 - 23 | it is highly misleading to state that CBT is the therapy of first choice, since the only relative efficacy RCT quoted in the guideline (p. 152, p. 269 Ridsdale et al Br J Gen Pract 2001 51(462)19-24) shows that counselling has better outcomes than CBT (as | Noted and please see revisions in the full recommendations. Also the participants in the trial cited had chronic fatigue, not CFS/ME (only 28% met diagnostic criteria for CFS/ME). |

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well as being more cost effective - see Chisholm et al op cit) equally, this recommendation seriously conflicts with the recommendation (see 4.1.1.1 p. 78) that patient choice and preference needs to be uppermost in the collaborative approach to care - and the finding that 45% of patients report either being made worse or not helped at all by CBT (p. 55) and, elsewhere, only 7% of patients surveyed report being helped by CBT (p. 58) - why is a misleading recommendation being made?

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| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 5 | FULL | 26 27 | | referral to the practice counsellor should be included as a primary care treatment intervention, since there is good evidence for this supportive psychotherapy should be offered as a choice, given the absence of any evidence that CBT has better outcomes than psychotherapy - what would be the reasons these are not added? | The care pathways have been revised – also see the detailed recommendations on the treatment options. However, no evidence was identified on the use of supportive psychotherapy. |
| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 6 | FULL | 28 | 14-20 | further trials of CBT and counselling and psychotherapy should be conducted, given the higher costs associated with employing CBT specialists, and the absence of any evidence that CBT is superior to other psychological interventions - what is the reason this hasn't been added? | Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. The GDG considered the research recommendations to be appropriate... |
| SH | Association for Psychoanalytic Psychotherapy in the NHS (APP) | 7 | FULL | 29 | 9-12 | we do not know how much patient preference contributes to better outcomes, so that if the patient's preference of therapy is put first (eg. counselling, eg. homeopathy etc.) | This was not considered a key research recommendation. |

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| | | | | | whether this is the key variable to recovery / improvement, as opposed to the treatment method per se - what is the reason this hasn't been included as a research recommendation? | |
| SH | Association of British Neurologists | 6 | | | There is no known intervention that is effective in severely affected patients and children; therefore there is no issue of denial of access to intervention. The statement "Denying these two patient groups access to appropriate and effective care increases inequality" is a meaningless political statement that suggests that denial of CBT and GET in these groups is responsible for inequality in health care. The statement should be rephrased to simply state that the role of CBT and GET in these patients should be subjected to proper research. | These have been revised after the consultation. |
| | | | FULL | 28 | 12 -13 | |
| SH | Association of British Neurologists | 7 | | | There is evidence that Group CBT is not as effective as individual CBT; this is not a priority research question. There is no validated model of "telephone or computer CBT or GET" for CFS/ME-so this cannot be a priority research question. Only research using validated tools should be recommended; alternatively, research should be used first to validate new tools (e.g.computerised CBT) | These have been revised after the consultation. |
| | | | FULL | 28 | 14 -16 | |
| SH | Association of British Neurologists | 43 | | | The distinction between mild/minimally symptomatic CFS/ME. and severely disabled CFS/ME has been intentionally blurred in case | We have used the definitions from the CMO's report. |
| | | | FULL | 8 - 14 | 11, 12 | |

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| SH | Association of Young People with ME | 2 | FULL | 21 | 20 | <p>definition and treatment recommendations</p> <p>'CBT and GET should be the first choice of therapies'</p> <p>This prescriptive statement does not sit with the rest the recommendations on page 22.</p> <p>If the 'Main Recommendations' could begin with a more Generalised statement – as below, AYME feels that the excellent recommendations which follow on page 22 will then be read thoroughly, and maybe the entire Guideline given a fair study.</p> <p>AYME suggests that the Guidelines begin with one, over-riding recommendation (see below) to replace Page 21 Line 20:</p> <ul style="list-style-type: none"> • In order for a child or adult to return to normal activity, evidence-based research indicates that CBT and GET – when carried out in a flexible, collaborative dialogue with patients by therapists with relevant training and experience – have some success for those mildly or moderately affected with CFS/ME. However, as there is a dearth of research in the severely affected patient and children, management of these patients in particular should be based on establishing a cautious and | <p>We have revised the full recommendations to reflect this and other concerns – including the need for dialogue and informed consent.</p> |
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controlled, rehabilitative approach, ensuring that a solid and sustainable baseline is maintained in the first instance before cautiously increasing activity slowly and careFULLy within the patient's functional capacity.

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| SH | Association of Young People with ME | 3 | FULL | 22 | 6 12 14 | <p>The following recommendations are very good, particularly:</p> <ul style="list-style-type: none"> patients given information on a range of therapies consider patient preference patients given information on support groups | Noted. Thank you. |
| SH | Association of Young People with ME | 6 | FULL | 24 | 78 4.1 6 | <p>Recommendation – very good</p> <p>Ongoing medical support.</p> <p>Many patients are diagnosed and then forgotten in an 'out of sight, out of mind' scenario. It is vital that clinicians are aware of the need for ongoing medical support following diagnosis.</p> <p>An additional recommendation is suggested for Pg 24 Ln 6</p> <ul style="list-style-type: none"> • Once a diagnosis has been made it is important that the medical team makes arrangements for continued and regular support, which may mean domiciliary visits for severe and very severely affected patients. | Please see the recommendations specific to the care for people with severe CFS/ME. |

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|----|-------------------------------------|---|------|---------|----------|--|--|
| SH | Association of Young People with ME | 7 | FULL | 13 | Glossary | Severely and Very Severely affected patient | We have used the definitions in the CMO's report |
| | | | | Pg 190 | 6.3.6.17 | The very severely affected are grouped together with the severely affected, which we feel is inappropriate. Mildly and moderately affected patients have been separated, but it is AYME's experience that in terms of management, there is actually bigger difference between the severely affected and the very severely affected, than there is between the mildly and moderately affected. For example, Pg 190, 6.3.6.17 mentions that 'sitting up in bed could be a good starting point'. For the very severely affected, a starting point is often as low as wiping a cloth around the face which has been soaped by a carer, with sitting up in bed as the NICE-term goal. | |
| | | | | Pg 260 | Ln 4-6 | | |
| | | | | Page 13 | Glossary | | |
| | | | | Pg 256 | Sec 7 | | |
| | | | | Pg 258 | 7.3 | | |
| | | | | | | In addition, Pg 260, line 4-6, discusses the support needs of the severely affected adult (food preparation & shopping). For the very severely affected, bed-bound, tube-fed child, these examples are totally inappropriate. | |
| | | | | | | AYME suggests that where the description of Severely and Very Severely affected is printed (Page 13) it might read better as either: | |
| | | | | | | <ul style="list-style-type: none"> • Severely affected tends to be rated between 20% and 30% functional ability (see www.ayme.org.uk/article.php) | |

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?sid=10&id=11), with the
Very Severely affected
between 0% and 20%.

OR

- Severely affected patients are Generally housebound, whilst Very Severely affected patients are bedbound.

We feel that some examples would be helpful from each category: Mild, Moderate, Severe and Very Severe, such as included in AYME's Functional Ability Scale, www.ayme.org.uk/article.php?sid=10&id=11 (Moss, J.I. (2005) 'Development of a functional ability scale for children and young people with myalgic encephalopathy (ME)/chronic fatigue syndrome (CFS)' *Journal of Child Health Care* Vol 9 (1) 20-30)

Differences in children from adults. Whilst AYME approves of the breadth of information and excellent advice in Section 7 on the severely affected, we felt that it does not reflect the needs of the very severely affected, particularly the very severely affected child. Anecdotally, more children and young people than adults seem to drop down to the very bottom of the ability scale and need very careful management, especially those who require tube feeding. If this anecdotal evidence is correct, then this is an area where children and young people differ from adults. The

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resulting isolation and lack of education can have very serious repercussions on their social and emotional development.

Page 137, line 13, mentions the need for 'one named clinician'. For all severely affected people, but children in particular, we would wish for this recommendation to be added under 7.3 Page 258.

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| SH | Association of Young People with ME | 10 | FULL | 26 | box top left | <p>Please add: Under activity management: that a</p> <ul style="list-style-type: none"> “...baseline of activity is maintained in the early stages, and then increments must be very small (10%-15%) and achievable”. | Please see the detailed recommendations and chapter 6 for a fuller explanation of activity management. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 16 | FULL | 21 | 8 | <p>By depending so heavily upon the psychiatric model of ME/CFS, the Guidelines totally fail to increase recognition of an illness, that the writers do not appear to neither recognise, nor understand, themselves. This is evident by their lack of recognition of ME/CFS as a neurological illness, as recognised by WHO, Royal Society of Medicine and the DOH. This document will not increase the recognition of the true neurological illness which is ME/CFS, but instead it will reinforce the erroneous, outdated and non-evidence based psychiatric model of the illness.</p> | The Diagnosis chapter has been revised and now includes a reference to the WHO classification. |
| SH | BRAME Blue Ribbon for the | 17 | FULL | 21 | 9 | <p>It needs to be recognised that the only 'influence' this document is likely to have is that it will continue to</p> | ... |

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| | Awareness of ME | | | | | promote bad practice and will probably harm more people with ME/CFS than it will help. | |
| SH | BRAME Blue Ribbon for the Awareness of ME | 18 | FULL | 21 | 10 | <p>We agree that we need appropriate services and consistent provision, however this needs to be done by providing more specialised clinics which utilise the biomedical approach to diagnose and manage this illness, and not the psychiatric bias seen in most clinics today.</p> <p>At present there are only 12 specialist ME/CFS clinics in England, and only a few of these are run with the correct bio-medical approach to managing ME/CFS, with most regrettably being purely psychiatrically led, despite the DOH recognizing that ME/CFS is a neurological illness. It is therefore imperative that these NICE guidelines are urgently rewritten, to give a true reflection to medical professionals for the diagnosis and management of ME/CFS. We are also very aware that some SHAs in East Anglia, possibly replicated nationwide, where when they are not aware of, or there are none, local/regional ME/CFS services, then these patients are automatically referred to mental health services – how many other neurological conditions are treated in this disrespectful and unprofessional manner?</p> | Although service provision is outside the scope of this guideline, local commissioning services should use the recommendations within this guideline to provide appropriate services. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 19 | FULL | 21 | 13 | <p>Whilst we agree with the intentions of this statement our concern is that this document will not improve care, particularly if CBT and GET are the</p> | We have clarified the recommendations for people with severe CFS/ME. |

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| | | | | | | management protocols of choice, and especially if they are used on the severely affected. | |
| SH | BRAME Blue Ribbon for the Awareness of ME | 20 | FULL | 21 | 14 | We have serious concerns that this will not provide guidance on best practice for children with ME/CFS. | Throughout the guideline, children with CFS/ME have been considered as a separate group, and specific recommendations made, as appropriate. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 21 | FULL | 21 | 20-23 | We have 2 main problems with this recommendation 1 – The inappropriate use of language – To suggest that it is not all ME/CFS patients' main goal to return to normal activities is an insult. This implies and reinforces that erroneous belief by some medical professionals that patients take on the 'sick role'. There is ample evidence that all patients want to go into remission, or for their health to improve sufficiently to lead a semblance of a normal life. To infer that those who do not improve enough to do this 'do not want to get better', is offensive, and shows a complete ignorance of both ME/CFS and the people who suffer the illness. 2 – To advise medical professionals that the therapies of 'first choice' should be CBT and GET shows again a complete misunderstanding of ME/CFS, and to say these should be first choice conflicts with your recommendation for patient choice, if they should wish to try other management strategies, and most will want to do this. Once again this implies that those who do not wish to undertake CBT and GET do not wish | Noted and please see revisions in the full recommendations. |

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| | | | | | | to return to normal activity. | |
| SH | BRAME Blue Ribbon for the Awareness of ME | 22 | FULL | 22 | 6 - 7 | We have serious concerns about the information that will be given, and whether information will be able to be given on therapies and management strategies that are not detailed in this guideline eg energy management/pacing, counselling – strategies that patients themselves have found to be the most effective in managing their illness. This recommendation also conflicts with the following recommendation (line8-10), which states that information should be provided on any therapy. | Noted and please see revisions in the full recommendations. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 23 | FULL | 22 | 8 | To state that information on aetiology should be given when there is little, if any, information about this in the document, and which until money is put into biomedical research into this illness is as yet unknown, is disingenuous – although many pieces are now falling into place through privately funded research eg abnormalities in gene expression | Noted...please see Chapter 5 for a further discussion on aetiology and diagnosis. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 24 | FULL | 22 | 12-13 | Patient preference, experience and previous outcomes should not just be 'considered'. They should be paramount when making joint decisions about management of this illness. To use the term 'consider' implies that the medical professional does not have to listen to, or comply with, the patient's preferences. | We have stressed the need for these factors to be part of the decision making process throughout the recommendations. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 25 | FULL | 23 | 1-5 | I do not agree with diagnosis for adults when symptoms have only been present for 4 months, there may | The GDG considered 4 months to be an appropriate timescale. |

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be an argument for this for the severely affected, but not the mildly and moderately affected. I believe that before 6 months there can be a provisional diagnosis, plus appropriate advice and management until the 6 months listed by all diagnostic criteria – but the clinicians should always be mindful of possible alternative diagnoses.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 26 | FULL | 23 | 6-8 | We agree with the intentions of this recommendation, however we fear that this will mean the severely affected will be forced into inappropriate management strategies ie CBT and GET | Please see the revisions to the full recommendations. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 27 | FULL | 23 | 9 -12 | <p>We have concerns about this recommendation as it is not just the excessive fatigue but the overwhelming ‘flu-like symptoms’, severe head ache/pain, joint/muscle pain etc experienced by patients.</p> <p>Advice should focus on energy management, rest and symptom/pain management. A gradual return to normal daily routine should only be where possible.</p> <p>Most ME/CFS specialists state there is very little evidence of deterioration in muscle function through prolonged bed rest. Advice should be given about the concerns of circulatory problems for prolonged bed rest eg pressure sores and DVT, there are also problems relating to poor nutrition and dehydration.</p> | This recommendation has been deleted. |

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| SH | BRAME Blue Ribbon for the Awareness of ME | 28 | FULL | 23 | 23 | “...fitness for work and education ...” should be followed by ‘for the mildly affected’, and with the caveat of ‘when they are able to’ and ‘with provision for flexibility and awareness of the illness’. There is a real fear that more patients will be forced back into work, sooner than they are able to physically cope with it, because doctors are now being given bonuses for each patient they return to work, and the DWP’s effort to get 1million people off incapacity benefit. | The DWP state that their reforms aim to enable those with illness or disability who could work to become independent, and are not about forcing people back to work. We are not aware of any “bonuses” to doctors as described. Education and work are important issues also for the moderately affected, who may want to return to modified part time work, or even do a small amount of work from home. The important point about health professionals engaging jointly with patients (not forcing them) and making individual treatment plans is well made earlier in these guidelines. It is worth emphasising the concept of flexibility, and the need for an individualised approach has been noted throughout. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 29 | FULL | 24 | 6 | Add ‘SKILL’ here as they are an excellent source of information for disabled students in further and higher education | This list is not intended to be exhaustive. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 30 | FULL | 26 27 | Severely affected box | Elements of CBT and GET should not be offered to the severely affected as they are not appropriate for the severely affected. | The care pathways have been revised – also see the detailed recommendations on the care for people with severe CFS/ME. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 31 | FULL | 26 27 | Specialised Care Box | Management options: We do not agree with GET and CBT being present here at all, but activity management should at least precede them, as this is the least harmful of these three. Where are pacing/energy management and person-centred counselling? These should be before AM/CBT/GET. | The care pathways have been revised – also see the detailed recommendations on the treatment options. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 32 | FULL | 28 | 6 -13 | There is a conflict of fact within this statement. It starts by stating that ‘there is no evidence’ and then refers | These have been revised after the consultation. |

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to patient evidence, although it is hidden under the term 'experience'. There is evidence. Patient evidence. There are surveys of thousands of patients, including both children and the severely affected. The research evidence for the severely affected, shown by the 25% ME Group surveys, as well as those done by other patient groups, explicitly show that there is harm done by GET, and that both GET (95%) and CBT (93%) were found to be either harmful or unhelpful. Therefore to state that there is no evidence, given that patient evidence is one third of any decision made on evidence based medicine, is a total failure to give all the facts.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 33 | FULL | 28 | 14-20 | <p>Cost effective/efficient methods – how can you make this research recommendation into finding more cost effective and efficient ways of delivering the two forms of management therapy that patients have found to be the most harmful/least effective? Surely money should be put into finding the cost effectiveness of management strategies that patients have found to be most helpful such as symptom/pain management, pacing/energy management and person-centred counselling.</p> <p>It beggars belief that NICE can make recommendations of treatments/management strategies that the majority of ME/CFS patients</p> | <p>Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. We have also added some detail to this section to describe the general approach.</p> |
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have found to be unhelpful/harmful. Would they make this same recommendation for heart or cancer patients?

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| SH | BRAME Blue Ribbon for the Awareness of ME | 34 | FULL | 29 | 5 -12 | <p>We have 2 comments to make on this recommendation</p> <p>1 - There is no mention of the Karnofsky Scale which is extremely helpful in defining functioning ability, and for monitoring any improvements or deterioration.</p> <p>2 -To state that “it is not known how much improvement is important for patients for CFS/ME” is insulting, derogatory and offensive. To imply that improvement is not important is to imply that these extremely ill people, whose only wish is to get better, do not want to return to normal activities.</p> | <p>These have been revised after the consultation and such questions on the most appropriate way to measure ‘effectiveness’ are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an improvement in pain?. The best method of determining appropriate outcomes, e.g. whether to use the Karnofsky Scale, would be part of designing the study.</p> |
| SH | BRAME Blue Ribbon for the Awareness of ME | 35 | FULL | 30 | 8-9 | <p>This sentence just proves that the recommendations of ‘good practice’ are not based in any way on patient evidence, and therefore the recommendations throughout are against patient experience. Surely promoting practice which will harm patients more than help them is unethical?</p> | <p>Please see the Methods chapter for details of how the evidence was used.</p> |
| SH | BRAME Blue Ribbon for the Awareness of ME | 36 | FULL | 31 | 5-8 | <p>The consensus method is not appropriate for illnesses with such diametrically opposed opinions and approaches to the illness. With such opposing views, a patient rep, with all of the patient evidence, can vote/mark one way, and have their point completely obliterated by ‘the</p> | <p>Please see the Methods chapter for details of the different methods used throughout the guideline.</p> |

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| | | | | | | majority'. | |
| SH | BRAME Blue Ribbon for the Awareness of ME | 37 | FULL | 31 | 25 | <p>You do not give recommendations on the clinical case definition, you give a revised Oxford research criteria. You mention the out-dated, non-peer reviewed and woefully inadequate Oxford research Criteria and have pushed the one clinical case definition, criteria and guideline – the Canadian Clinical Guidelines – to the side. We know for a fact that the Canadian Guidelines were seen and research showing it in comparison to the Fukuda criteria was also seen, and yet this guideline was ignored.</p> <p>One of our respondents said:</p> <p><i>“Both the Fukuda and the Oxford criteria are for research purposes, whilst the Canadian Guidelines are for clinical diagnostic purposes. Surely the latter are appropriate for clinical guidelines and should be used here?”</i></p> | Please see the chapter on diagnosis for a full discussion of the evidence, and the relevant recommendations. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 38 | FULL | 32 | 14 +16 | Graded exercise and CBT are not helpful, and can be harmful – as proven by the patient evidence. | Please see the chapter on management for a full discussion of the evidence, and the relevant recommendations. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 39 | FULL | 32 | 15 | We are delighted to see pacing mentioned, but apart from a brief mention in the glossary there is no explanation or advice on pacing throughout the document. This needs to be rectified as pacing/energy management has been found by patients, after symptom/pain management, to be the most effective form of management for their illness. | Please see the revised recommendations. |
| SH | BRAME Blue | 40 | FULL | 33 | 7 | We realise that advice cannot be | We have noted that any identified co- |

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given on the management co-morbidities, but the fact that there are complications with treating co-morbid illnesses in people with ME/CFS needs to be recognised and highlighted. In particular for the long-term severely affected for whom the illness has become multi-system, multi-organ and are more likely to have adverse reactions to medication and treatment/management programmes, therefore advice should be provided within this document for this.

morbidities should be managed as per other guidelines or standard clinical care (see also the recommendations on investigations and review).

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| SH | BRAME Blue Ribbon for the Awareness of ME | 41 | FULL | 35 | 4 | 1.1 Introduction: This is a perfect opportunity to state that “ME/CFS is a chronic neurological illness as recognised by the World Health Organisation and the Dept of Health.” | Noted and added. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 42 | FULL | 35 | 6 | Should read “malaise/post-exertional malaise”. | We have used ‘fatigue’ here to allow for the wide variation of fatigue – please see the diagnosis recommendations for further details. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 43 | FULL | 35 | 7 | Should read “muscle and joint pain.” | Noted and added. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 44 | FULL | 35 | 9 | Should read “triggered by minimal activity, with characteristically delayed onset and long recovery time.” | Noted and added |
| SH | BRAME Blue Ribbon for the Awareness of ME | 45 | FULL | 35 | 15-16 | We would argue that the MRC has not made research into ME/CFS a priority. To date it has only funded two research programmes the disputed PACE and FINE trials. We are not aware of any funding being given to the bio-medical research into the aetiology and pathogenesis of | Noted – the MRC noted CFS as a strategic priority. |

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Me/CFS, despite very clear recommendations to do so in the CMO Report (2002).

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| SH | BRAME Blue Ribbon for the Awareness of ME | 46 | FULL | 35 | 24-26 | 1.3 Aetiology: Research has not shown any evidence of ME/CFS being a psychological illness, instead research has shown, not suggested, that this is indeed an organic illness. | We have noted several factors have been suggested. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 47 | FULL | 36 | 1 | Would not agree that there is a 'spectrum on illness', but rather, at present, the label of ME/CFS is used as an umbrella term for many different illnesses of similar symptomology such as Myalgic Encephalomyelitis, Fibromyalgia, Post Viral Fatigue Syndrome, Brucellosis/Lyme Disease, Multiple Chemical Sensitivities, Chronic Pain Syndrome and Chronic Mononucleosis. | Noted.... |
| SH | BRAME Blue Ribbon for the Awareness of ME | 48 | FULL | 36 | 9-10 | 1.4 Diagnosis: The debate about which diagnostic criteria to use is irrelevant. The Oxford criteria have now been discredited. The Fukuda criteria were not designed to be diagnostic criteria. The Canadian Clinical Criteria are therefore the only appropriate ones for diagnostic purposes, as they acknowledge the serious organic illness that this is, and creates a more homogeneous group. Diagnostic criteria are of vital importance to sufferers, as they do not wish to be diagnosed with the wrong illness. Nor do they wish people with other illnesses to be misdiagnosed with ME/CFS because the criteria are so wide that they can be included by mistake, leading to | This has been revised – also see the revised recommendations and Chapter 5 |

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people with illnesses, sometimes fatal, being misdiagnosed, mismanaged, and occasionally losing their life. Everyone with respiratory conditions will perhaps suffer from the same core symptoms eg. shortness of breath, but they are then given different diagnoses eg. from asthma to lung cancer. This does not however stop them from being investigated and managed according to their specific diagnosis. Why is it that, with ME/CFS the opposite principle is applied and it is argued that you need wide criteria in which to manage everyone? As a result, those who truly fit the criteria are not managed at all. Criteria that are clearly defined and that create an homogeneous group are not a bad thing, because they allow for people to be treated accordingly.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 49 | FULL | 36 | 11-12 | <p>We are disgusted to see that once again the disputed Oxford Criteria are being given such a high profile. These are not clinical diagnostic criteria and should not be used within the diagnostic process by medical professionals. The Oxford Criteria, created by psychiatrists, are purely used within research and should be discredited because they have never been peer reviewed. They bear no resemblance to ME/CFS in any format, they are simply a description of chronic fatigue. Their use within research has lead to the research being flawed, as the inclusion group through using the Oxford Criteria</p> | This has been revised. |
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basically includes anyone with undiagnosed non-specific chronic fatigue. It includes people with multiple illnesses, creating such a huge heterogeneous group that therefore the conclusions cannot be extrapolated and used for the ME/CFS community. We strongly recommend that all mention of the Oxford Criteria is removed from this document.

NICE has not helped the situation by creating its own diagnostic criteria, based on the Oxford criteria, by only requiring fatigue and one other symptom for diagnosis.

We acknowledge that the Fukuda criteria have, until recently, been used within clinical settings as the criteria utilised by doctors for diagnosis. However more and more doctors are now adopting the Canadian Clinical Criteria, as the Fukuda still creates too heterogeneous a group, and the Canadian Criteria allows patients who do not fulfil the diagnosis of ME/CFS to be diagnosed as idiopathic ME/CFS, thus allowing them to continually monitor and manage these patients whilst distinguishing between those who do, and do not, fulfil the diagnostic criteria.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 50 | FULL | 37 | 13-16 | 1.5 Management: As detailed by the Canadian guidelines in their tables of pharmacological symptom control ME/CFS has to be treated differently in some respects, due to their predisposition for adverse reaction, | Please see the revised recommendations. |
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ignoring this is dangerous. The Canadian Guidelines state which drugs are more likely to help and which are likely to elicit the worst reactions. You must start the drugs off at a lower dose and then gradually build up if tolerated.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 51 | FULL | 37 | 23 |
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1.6 Prognosis:

We are pleased that you acknowledge the estimated 60,000 sufferers, who become severely affected and often permanently disabled. Research shows that those who have been severely affected for more than five years have a 2% chance of remission, as acknowledged in the CMO report.

However the guidelines fail to mention that this group is also extremely likely to develop co-morbid conditions, as their illness becomes even more multi-system/multi-organ, and that for them there is a real concern of these conditions becoming fatal. Recent research by Jason et al (2006) has shown that those who suffer from ME/CFS are more likely to die of eg. heart complications (cardiomyopathy and chlamydia pneumoniae), and rare or unusual cancers. Those who do die from these conditions, do so at a younger age than would be expected within the wider population. This therefore must be red-flagged, so that doctors are ultra aware of the problem, and can look out for the warning signs. The Canadian Clinical Guidelines say "*Progressive*

Please see Chapter 7 and the revised recommendations.

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degeneration of end organs, particularly cardiac or pancreatic failure, may result in death”.

We recommend that there is added to this statement the following advice:

- The prognosis for the severely affected is significantly poorer than the rest of the patient population.

And:

- That for some this condition can be fatal through complications and co-morbid conditions associated with ME/CFS.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 52 | FULL | 37 -38 | 24-2 |
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The CDC states, in relation to prognosis, that *“Improvement rates varied from 8% to 63% in a 2005 review of published studies, with a median of 40% improving during follow-up (BRAME – therefore 60% showed no sign of improvement). However FULL recovery from ME/CFS may be rare, with an average of only 5% to 10% sustaining total remission”*

We are pleased to see the CDC statistics here (the FULL quote from the CDC we have included above), which given the research evidence we have seen, is optimistic. It is also worth noting that the CDC now state that ME and CFS are two similar, but different, conditions, something that the ME community has long held as true.

We were not able to find the CDC statement that the conditions were different? The CDC glossary states: myalgic encephalomyelitis - A synonym for chronic fatigue syndrome in common usage in the United Kingdom and Canada.

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| SH | BRAME Blue Ribbon for the Awareness of ME | 53 | FULL | 38 | 14 | 1.8 Incidence and Prevalence: Research has shown that the most likely reason that ME/CFS affects more women than men is down to genetics/hormones – so an explanation of this would be appropriate here. | We are simply referring to the different prevalences in different groups – not the possible underlying reasons. |
| SH | BRAME Blue Ribbon for the Awareness of ME | 54 | FULL | 39 | 7-17 | 1.9 Existing Service Provision: Most of the 12 CNCCs set up are run inappropriately, and are unhelpful to patients. The emphasise a psychiatric/behavioural bias to care/diagnosis/management, rather than the correct biomedical care/diagnosis/management, which addresses the physical illness ME/CFS is. We recognise that the withdrawal of funding is a problem, and this situation needs to be reviewed to allow the continuation of ME/CFS services. However we feel very strongly that those services which take the psychiatric/behavioural approach need to be reappraised, and replaced, with bio-medical services, run by doctors who truly understand the illness, and money is needed to do this. This is what the patients' need, proper care by those who truly understand this chronic neurological illness, not those who base their practice on flawed research which is harmful and outdated. | ... |
| SH | British Association for Counselling and Psychotherapy | 2 | FULL | 21 | 20 - 23 | We note that when the adult or child's main goal is to return to normal activities then the therapies of first choice should be CBT or GET | Noted and please see revisions in the full recommendations. |

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| (BACP) | 58 | 3 | because there is good evidence of benefit for this recommendation. |
| | 22 | 2 - 19 | However, we see responses to the 'Action for ME Membership survey (p. 58) rate CBT and GET as the least helpful of a range of interventions. |
| | 21 | 20 - 23 | |
| | 22 | 17 | This finding underlines the potential conflict between health professionals and patients which the GDG has gone to great lengths to minimise when making evidence based recommendations. |
| | | | BACP suggests that when making recommendations about managing CFS/ME, that the first recommendation is about 'Shared decision making' (p.22, lines 2 - 19) and the second recommendation is about CBT and GET (p. 21, lines 20 - 23). |
| | | | Through re-ordering these statements, it puts the patient/health professional relationship as the priority, from which other agreed treatment plans, based on recommendations from the knowledge reviews, may follow. |
| | | | It would be a shame to antagonise patient groups, which are often not convinced by the benefits of CBT as demonstrated in clinical studies. (We refer again to the Action for ME survey findings above). By putting the shared care recommendation first, the guideline underlines its commitment to good communication and the patient staying in control of their |

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treatment, etc.

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| SH | British Dietetic Association | 5 | FULL | 17 | 264 | Particular attention to Vitamin D intake should be paid in this group, not only for long term health, but also effects of low intake on lower extremity weakness and immune system | Please see the revised recommendations on dietary interventions. |
| SH | Cambridgeshire Neurological Alliance | 3 | FULL / NICE | 1 1 | 3 of title 3 of title | For clarification, it is noted the Draft Guidelines use the term “encephalopathy” in relation to “M.E.” within the documents title. Yet, there is no such medical term. “M.E.”, as WHO clearly states, purports to Myalgic Encephalomyelitis, only. And although, WHO list “Encephalopathy” also under a “neurological disorder”. The coding is entirely different and, there is no “M”. Simply, a stand alone “E” for Encephalopathy. Therefore, “Encephalopathy” cannot under any circumstances, be termed in relation to “M.E.” Please remove the “Encephalopathy” in order for this Draft Guideline document to be considered credible in relation to the correct and proper term for “M.E.” | The title of the guideline was amended to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (encephalopathy) following the scope consultation with stakeholders. The WHO classification has been referred to in the chapter on diagnosis. |
| SH | Cambridgeshire Neurological Alliance | 11 | FULL | 6 | All | Throughout the “Acknowledgements” on Page 6, there lacks reference to leading researchers in the field of M.E. Those listed, appear mostly to have had positions with the Government, yet non pertain to the those with current scientific Research studies i.e. Professor Basant Puri, Head of Brain Lipid and Neurosciences MRI Unit, Hammersmith Hospital, Dr Jonathan | The acknowledgements recognise people who have been involved with the development of the guideline. |

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| SH | Cambridgeshire Neurological Alliance | 12 | FULL | 9 | All | <p>Kerr, Activity” It states:</p> <ul style="list-style-type: none"> ➤ “which may lead to an increase in symptoms and a decrease in function” <p>This quite simply, does not make sense and requires clarifying as to what it is suppose to be mean and what it is referring to and why“</p> | Noted and revised, as considered appropriate by the GDG. |
| SH | Cambridgeshire Neurological Alliance | 13 | FULL | 9 | All Line 3, 4, 5, 6, | <p>“Breathing techniques” It clearly states:</p> <ul style="list-style-type: none"> ➤ “Breathing techniques are used to reduce the respiratory rate, promoting parasympathetic activity therefore stimulating relaxation.” And gives two types of breathing techniques <p>However, there appears no understanding, certainly no acknowledgement or reference here, of the impact of any exertion over and above that, that the now compromised central nervous system, which, is the hallmark of CFS/ME, has on someone with CFS/ME.</p> <ul style="list-style-type: none"> ➤ The parasympathetic mechanism is actually affected and when overexerted, the breathing can become very shallow where the diaphragm muscles and lung muscles | Please see the revised recommendations for details on how the strategies should be used, including the recommendation for a detailed discussion of the potential harms and benefits of any intervention. |

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capacity have been become
“fatigued”.

- The weakness is “transient” and in the milder cases, restore to its former state – however, it is well documented that that “former state” can be as much as 40% or 50% below the lung and diaphragmatic strengthen of a healthy person.
- Something that is often overlooked in CFS/ME and similar to that experienced in Post Polio Syndrome. Although these patients can access “investigative tests” often leading to Non-invasive Night time Ventilation –
- Something, that has yet to be recognised, diagnosed, investigated and quite simply, accessed, as could assist this much misunderstood symptom in CFS/ME.

NICE, should therefore, be cautionary in its “promotion of GET/CBT/ET” in respect of “Exercise Programmes”. In particularly, in the hands of “novice GET/CBT/ET Therapists”.

There have been documented litigation cases in the NH, where exercise programmes have been administered without the knowledge

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or understanding of how “therapy” can impact on a number of conditions, especially neurological conditions, including MS, ME. CFS/ME, Myasthenia, Dystonia, Ataxia, Muscular Dystrophy. And, until these conditions are better understood and as to what role the central nervous system plays on the lung, diaphragm and parasympathetic system. Use the breathing technique for “Anxiety” where anxiety exists – but bare caution, where it does not.

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| SH | Cambridgeshire Neurological Alliance | 14 | FULL | 9 | All | <p>“Cognitive Behavioural Therapy (CBT)”</p> <p>It clearly states “CBT is a psychological therapy and collaborative treatment approach which aims to reduce the levels of symptoms, disability and distress associated with CFS/ME”</p> <ul style="list-style-type: none"> ➤ NICE would need to have a better understanding of the central nervous system dysfunction and abnormalities, before they endorse any such “treatments” in CFS/M.E. And of course, how and what “CBT” therapist <li style="margin-left: 20px;">Expect from their CFS/ME patients. ➤ “CBT” is not just about “Talking Therapies”. It is about “Doing”. “Doing Physical Exercise,” “Doing Graded Exercise Therapy | <p>Please see Chapter 6 for a more complete explanation.</p> |
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(GET) “Doing Exercise Therapy (ET)”. It is about “Physical Tasks”. “CBT” is not just about sitting and talking”. Please cast your minds to Page 11, where the NICE definition of “Mild CFS/ME” and its clear understanding of “can do light housework with difficulty” often takes days off work”

NICE need to put this into perspective when promoting “GET/CBT/ET” because if even a “Mild CFS/ME” patient cannot even carry out “light housework” without “difficulty”. And “often takes time of work” just trying to keep a job. how then, are they expected to have the additional “CBT” programme

- Are they to be given time off work to cope with the extra physical impact of “GET/CBT/ET”?
- Paid benefits to forfeit their wage loss?
- Allowed time off work in order to recover and therefore not to risk losing their jobs?

NICE need to think this through further, to make sense and not risk to be seen as contradicting themselves, which, appears clearly, to have happened in paragraph after paragraph throughout this draft

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| SH | Cambridgeshire Neurological Alliance | 15 | FULL | 11 | All Line 2, 3, 4, 5, 6, | <p>document.</p> <p>“Mild CFS/ME” Page 11</p> <p>It clearly states:</p> <ul style="list-style-type: none"> ➤ “Individuals who are mobile, can care for themselves and can do light domestic tasks with difficulty” ➤ “The majority will still be working. ➤ However, in order to remain in work they will probably have stopped all leisure and social pursuits, often taking days off.” ➤ Most will use the weekends to cope with rest of the week” <p>Then, how and more to the point, why is it NICE propose that even these “Mild CFS/ME” patients can – in addition to their carrying out “light tasks with difficulty,” “stopped all leisure pursuits, often taking days off”, most will use the weekends to cope with the rest of the week” will actually be expected to – in addition to their “difficulties” attend “Clinic” and keep to a “GET/CBT/ET” “Exercise Programme” week on week. In addition, to the travelling to and from that clinic/setting, which, may well be several hundred miles away, at least and potentially set within another health authority region”</p> | We have used the definitions as in the CMO’s report. |
| SH | Cambridgeshire | 16 | FULL | 11 | All | “Moderate CFS/ME” Page 11 | We have used the definitions as in the |

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| | Neurological Alliance | | | | Line 15, 16, 17, 18, 19, 20 | <p>It clearly states “Individuals who have reduced mobility and are restricted in all activities of daily living”</p> <ul style="list-style-type: none"> ➤ Then how is it NICE appear to expect these patients to attend “GET/CBT/ET” clinics/settings? ➤ Often, many miles away? <p>NICE clearly need to grasp the implications of the neurological aspects of CFS/ME and the impact on symptoms, to even understand that their “merit” for “GET/CBT/ET” is just wide off the mark with this illness. PACING, yes, as it encompasses the fluctuating symptoms, the very hallmark of CFS/ME.</p> | CMO’s report |
| SH | Cambridgeshire Neurological Alliance | 17 | FULL | 11 -12 | All 7, 20, | <p>“Pacing” Page 12</p> <p>It clearly states:</p> <p>“People with CFS/ME frequently like this approach because they feel in control”.</p> <ul style="list-style-type: none"> ➤ More to the point, is that when someone affected by CFS/ME operate within their systems limitations, they are less likely to sufferer from profound exhaustions, in which the nervous system risks increase in symptoms. Therefore, the system is calmer and the reason for feeling “in control”. | Noted |
| SH | Cambridgeshire Neurological | 18 | FULL | 12 | 11, 12, 13, 14, | <p>“Perceived exertion /Rate of perceived exertion / Borg rating”</p> | Please see Chapter 6 for a more complete explanation of GET. |

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| Alliance | | | | | 15, 16, 17, 18, | (RPE) It clearly states” The RPE commonly reduces as the CFS/ME patient continues with a GET programme and may therefore, become more reliable as they get better”. ➤ This remark appears nonsensical in that it tries to imply the “RPE” is “cured” by “GET” In: “the RPE commonly reduces as the CFS/ME patient continues with a GET programme” ➤ And: “and may become more reliable as they get better” For NICE to make and accept this “tick box” tactic to “promote “GET, is simply a “Quango”. The above paragraph should simply be removed. It appears to be there just to “support GET” and the words “may become more reliable” is more akin to a “wish-list” rather than a NICE Health Guideline. Please ensure this is removed. | We have also removed this definition. |
| SH | Cambridgeshire Neurological Alliance | 19 | FULL | 13 | All 5, 6, | “Rest” It clearly states “NICE periods of time when the individual is neither sleeping or engaged in physical or mental activity” ➤ “Rest” in CFS/ME can actually mean anything from | Please see Chapter 6 and the recommendations for a more complete explanation. We have clarified both the definition and the recommendations on this. |

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30 minutes, an hour, several hours, or even several days or weeks,

- NICE does not appear to appreciate or understand, that “rest” in CFS/ME has nothing to do with the everyday “rest” a healthy individual experiences.
- NICE, again, must understand the consequences of CFS/ME on the impact on what “rest” now means to a CFS/ME patient.

“Rest” means doing absolutely nothing and resting eyes with a mask and even ear-plugs, laying flat and well supported with cushions so that every muscle is in the “resting” phase, including the brain and mind.

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| SH | Cambridgeshire Neurological Alliance | 20 | FULL | 13 | All | <p>“Severe / very severe CFS/ME”</p> <p>It clearly states:</p> <p>“A person whose functioning will only allow them to carry out minimal daily tasks”</p> <ul style="list-style-type: none"> ➤ This appears to imply that the person “functioning” is disallowing them to do things ➤ When in fact, it is as a result of the impairment / abnormalities of the central nervous system that is causing the dysfunction, | We have used the definitions in the CMO’s report. |
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enough to impede on the level of functioning – not the other way round, as NICE has incorrectly stated.

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| SH | Cambridgeshire Neurological Alliance | 21 | FULL | 15 | All | <p>“Guideline Development Group (GDG)”</p> <p>It clearly states a number of people involved with the GSG. However, none of those listed appear, to operate or be involved on a national or international and only “regionally”. How is it they can be expected to bring in that wide range of experience or knowledge, except for one national CFS/ME charity?</p> | <p>The Guideline Development Group is a multidisciplinary group comprising clinicians, professionals, technical experts and patient representatives with a range of experience, beliefs and values. The members do not represent the view of their nominating organisations but represent the perspective of healthcare workers involved in the care of patients affected by CFS/ME and patient/carer issues and choices. The guideline goes out for a public consultation whereby national organisations have an opportunity to comment on the draft recommendations. For further information please see Chapter 4, Technical Manual, available on the NICE website.</p> |
| SH | Cambridgeshire Neurological Alliance | 22 | FULL | 16 | All | <p>“Guideline Development Group expert co-optees”, and “Methods Team”, also appear to have a rather regional representation, than national</p> | <p>The National Collaborating Centre has technical expertise and skills in guideline development and is commissioned by NICE to produce clinical guidelines. The expert co-optees are individuals who have expertise in the clinical area and have been co-opted onto the group for specific discussions.</p> |
| SH | Cambridgeshire Neurological Alliance | 23 | FULL | 17, 18, 19, 20, | All | <p>“Registered stakeholder organisations”</p> <p>There appears a clearly stated disproportionate representation of “Mental Health Trust” within this list</p> | <p>Any organisation which fits the definition of a stakeholder (available on page 15, Guideline development process: an overview for stakeholders, the public and the NHS) is able to register for the guideline at any point during the development process.</p> |
| SH | Cambridgeshire Neurological | 24 | FULL | 21 | All | <p>“Executive summary and recommendations” 1 – 18</p> | <p>These have been the GDG’s aims throughout the guideline development</p> |

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| | Alliance | | | | | “Increasing the understanding of the impact of CFS/ME on the patient, carer, family” needs to be included in this list | process, but the impact on the carer/family has been acknowledged throughout the guideline. |
| SH | Cambridgeshire Neurological Alliance | 25 | FULL | 21 | All 19, 20, 21, 22, 23, 24, | <p>“Priority recommendations”</p> <p>“When the adult or child’s main goal is to return to normal activities”</p> <ul style="list-style-type: none"> ➤ NICE would need to change this paragraph, as it appears to simply that all CFS/ME people need to do is “want to return to normal activities” and then find “CBT or GET”, to “return to work” ➤ All the good will and determination in the world will not make “CFS/ME” “go away” and NICE “must not be sold” to service providers, NHS or the public. | Please see the revisions in the complete list of recommendations. |
| SH | Cambridgeshire Neurological Alliance | 28 | FULL | 29 | All 5, 6, 7, 8, 9, 10, 11, | <p>“What is the best way of measuring outcome in search studies” Which outcomes accurately reflect functional ability? Which outcomes are important to patients and how much change in outcomes are clinically significant?”</p> <ul style="list-style-type: none"> ➤ NICE should change this paragraph or remove it as; <p>It would appear the words are skewed to reflect the “results” from the “GET/CBT/ET” in which the focus appears on “return to work” only and the recognition.</p> | These have been revised after the consultation and such questions on the most appropriate way to measure ‘effectiveness’ are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an improvement in pain?. |

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i.e. “Which outcomes are important to patients and how much change in outcomes are clinically significant?”

And answers “It is not known how much improvement is important to patients with CFS/ME”.

- This apparent silly question should be removed.
- A straight forward survey or questionnaire that

Includes the most affective would serve this

Purpose.

- NICE should appreciate, that for a very severely affected person may have improved enough to sit up I bed for five minutes, or have been able to speak for a few minutes.
- NICE appears to not the correct information on severely affected people with CFS/ME.
- With the “Future research studies to investigate cost effectiveness of treatment require functional outcomes, such as return to work”. Again, this appears to hide the true nature of the severely affected and their profound symptoms and gives the impression, NICE have no

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experience of the very
 severely CFS/ME and
 their symptoms.

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| SH | Cambridgeshire Neurological Alliance | 29 | FULL | 39 | All 17, | “Questions therefore remain about access to appropriate care for all who need it”. This is the NICE opportunity to have a well balanced and fair CFS/ME Guidelines and trust you will amend copies. | Noted. |
| SH | CFS/ME Clinical Network Coordinating Centre | 1 | FULL | 8 | | No definition of ‘biopsychosocial’ | This is considered to be an accepted, and understood term. |
| SH | CFS/ME Clinical Network Coordinating Centre | 2 | FULL | 18 | | CFS/ME Clinical Network Coordinating Centre, Royal Victoria Infirmary should read ‘Northern CFS/ME Clinical Network’ | Noted and passed to NICE. |
| SH | CFS/ME Clinical Network Coordinating Centre | 3 | FULL | 23 | | Incorporate concept of multi-agency working as focus rather than just ‘liaison’ | Please see the full recommendations for further detail on multi-agency working, although detailed service delivery is outside the scope of this guideline. |
| SH | Chronic Fatigue Research Unit at King’s College London | 2 | FULL | 28 | General, ex page | We do not agree with what is written about the care of those with severe disability and CFS, and the best treatment options for that group. For example, on page 28 it is stated that “patient experience suggests that some of these interventions may be harmful or ineffective”. We are of course familiar with such observations, and accept that some sufferers report that, and that you need to place some caveat in the text at this point. But first, we would argue on the basis of our extensive experience listening to patients, that what is being reported in these | Please see the revised recommendations for this patient group. |

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negative accounts is rarely either CBT or GET, a point you accept elsewhere in a more General context. Second, it would be more accurate to state that “some patients” rather than “patient experience” since the latter seems to imply that it is all patient experience, which is definitely not the case. We have treated a small number of severely affected patients, confined to bed and/or wheelchair, with CBT, with good results.

There is also a small peer reviewed literature that speaks to the fact that some severely affected patients have benefited from either CBT or GET. We reported a case series some years ago from the National Hospital for Neurology of the successful treatment of a small number of the severely afflicted – (Chalder T, Butler S, Wessely S. In patient treatment of chronic fatigue syndrome. Behavioural Psychotherapy 1996;24:351-365). We were unable to continue the programme when the service moved to King’s because of lack of inpatient beds, but have just resumed it on a home visit/outreach basis. We are currently preparing a paper describing the results of treating a second series of adolescents too disabled to come to outpatients using the same treatment techniques that we use in the clinic, and have already reported in two papers, one uncontrolled (Chalder et al Family cognitive behaviour therapy for chronic fatigue syndrome: an

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uncontrolled study. Arch Dis Childhood 2002;86:95-97) and the other an RCT (Chalder T, Deary V, Husain K, Walwyn R. Family focused cognitive behaviour therapy versus behaviourally oriented psycho-education for chronic fatigue syndrome in 11-18 year olds: a randomised controlled treatment trial). There are other reports of successful treatment of severely affected patients using CBT and GET techniques –(Cox D, Findley L. Is chronic fatigue syndrome treatable in an NHS environment? Clinical Rehabilitation 1994;8:76-80. Wachsmuth J, MacMillan H. Effective treatment for an adolescent with chronic fatigue syndrome. Clinical Pediatrics 1991;30:488-490. Powell P, Edwards R, Bentall R. The treatment of wheelchair-bound chronic fatigue syndrome patients: two case studies of a pragmatic rehabilitation approach. Behavioural and Cognitive Psychotherapy 1999;27:249-260. Essamme C, Phelan S, Aggett P, White P. Pilot study of a multidisciplinary inpatient rehabilitation of severely incapacitated patients with chronic fatigue syndrome. J Chronic Fatigue Syndrome 1998;4:51-60.

True, these are not RCTs, but the numbers of patients in this category is small, and the logistical difficulties of ever launching an RCT in this situation, means it is unlikely that one, let alone several, RCTs will ever be

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done in this group. Given that the uncontrolled results so closely mirror the results in the RCTs, then it seems likely that the same approach that works in outpatients would also be successful in severely afflicted. As you already report uncontrolled, anecdotal observations that GET/CBT makes some severely disabled patients worse, it seems illogical and inconsistent not to at least acknowledge published peer reviewed evidence that speaks to the contrary.

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| SH | Chronic Fatigue Research Unit at King's College London | 3 | FULL | 23; 181 (6.3.6.3): 188 (6.3.6.14) : bottom of 203 and elsewh e |
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We disagree with the numerous statements in the guidelines that those patients in the published CBT/GET trials are “mild to moderate”. Nearly all of the published studies (Deale et al; Wearden et al, Fulcher and White; Prins et al; Wallman et al; Sharpe et al; O Dowd et al) came from secondary or tertiary care. One would expect that these will be patients with high morbidity, and the data indeed shows that to be the case. The statement on “mild to moderate” can indeed be used to describe primary care samples, but not secondary/tertiary care (see Euba R, Chalder T, Deale A, Wessely S. A comparison of the characteristics of chronic fatigue syndrome in primary and tertiary care. Br J Psychiatry 1996;168:121-126).

Please see Chapter 6 for a full discussion of the evidence and the revisions to the recommendations (made in light if these and other comments).

For example in the first King's trial (Deale et al, 1997) those who took part in the trial were characterised, as

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the paper says, by “long illness durations and marked disability and exhaustion” The group had “near maximum scores on measures of functional impairment and fatigue” and the mean scores on the relevant disability measures confirm that this was not a “mild or moderate” group – see Table 3 for example for the SF 36 scores. Very few were working and many were members of patient organisations.

In the Barts GET trial (Fulcher and White) Fulcher and White, 1997, the mean (SD) SF36 physical function subscale scores were 48.5 (22) and 47 (19) in the two randomised groups. Only 39% of all 66 patients were working or studying FULL- or part-time at randomisation. In the Sharpe et al Oxford CBT trial three quarters were unable to work or study because of illness and the participants spent an average of two days per week in bed totally inactive. In the Powell et al 2001 BMJ trial all participants had an SF 36 below 25., and 88% were not working.

The Australian trial (Wallman et al; Randomised controlled trial of graded exercise in chronic fatigue syndrome. Med J Australia 2004;180:444-448) also included patients who could not be considered “mild/moderate”. Of the 61 subjects, 12 needed to be supplied with a taxi in order to bring them into the university for testing each week. A number spent most of their days in

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bed, only getting up to attend the treatment centre. All of these subjects improved with gentle, individually paced GET as compared to the 'better' CFS subjects who improved, but not as dramatically (see paper and Wallman, pers comm.).

The only primary care GET study is the New Zealand Moss Morris paper, where indeed the levels of disability were less than those found in the secondary and tertiary care studies, but even then 22% were not working because of CFS. The only primary care CBT study comes from King's (Ridsdale et al, 2001, Br J Gen Practice) and showed that in that population, in which levels of disability were certainly less than in secondary care, and also few patients either believed they had "ME" or made other physical attributions for their symptoms, CBT was as effective as counselling.

Finally, all the studies use the 1994 CDC criteria, which is far and away the most accepted international criteria, and which includes disability as a criterion.

Overall, then, this is strong evidence that the published work on CBT and GET concerns those with chronic illness and substantial disability. This needs to be addressed since if this is not corrected, there is a danger that NICE will inadvertently give credence to the oft expressed but erroneous view that that CBT/GET only works in

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those who do not have “real ME”, those who have “psychiatric disorders”, or who are not very disabled. The evidence from the trials speaks to the opposite.

SH Chronic Fatigue Research Unit at King's College London

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FULL

28, 38 and others; page 90 5.2.4.2

There are several mentions of the need for prospective population based studies to assess such factors as the risk factors, incidence and prognosis of the condition. There are several recent studies that have used just such a model. For example, the Swedish twin study is a study of 19,192 twins born between 1935 and 1958, a complete sample, in which there are prospective measures taken at intervals, and a standardised assessment of CFS as outcome measure (Kato K Sullivan P, Evengard B, Pedersen NL. Premorbid predictors of chronic fatigue. Arch General Psychiatry 2006;63:1-6.). In this most recent paper from that cohort the authors show that “elevated premorbid stress is a significant risk factor for chronic fatigue like illness, the effect of which may be buffered by genetic factors. Emotional instability assessed 25 years earlier is associated with chronic fatigue through genetic mechanisms contributing to both personality style and expressions of the disorder”. This adds to the existing evidence that personality and depression increases the risk of CFS and/or post infective fatigue. The statement on page 90 5.2.4.2 should reflect this new and definitive

We will consider current research in progress for the updates as appropriate.

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research.

Likewise, there is now population based epidemiological evidence on the prevalence, incidence and risk factors for CFS in children, taken from the ONS study of mental health in children aged 5-15. Incidence rates over 4-6 months were 20% (95% CI: 17.3 to 22.7) for fatigue, 1.1% (0.04 to 1.8) for CF and 0.5% (0.01 to 0.9) for CFS. Point prevalence rates for fatigue were 34.1% (30.9 to 37.3) at Time 1 and 38.1% (34.8 to 41.5) for Time 2, for CF were 0.4% (0.0 to 0.8) and 1.1% (0.04 to 1.8), and for CFS were 0.1% (-0.1 to 0.4) and 0.5% (0.01 to 0.9). Higher risk of developing CF at Time 2 was associated with Time 1 anxiety or depression (30.2; 7.75 to 117), conduct disorder (7.13; 1.42 to 35.7), and maternal distress (OR 1.18; CI 1.01-1.38); in multivariate analysis, baseline anxiety or depression remained a significant predictor of CF. Increased risk of developing fatigue at Time 2 was associated Time 1 anxiety or depression (4.88; 1.80 to 13.2), conduct disorder (3.16; 1.36 to 7.36), and older age (1.30; 1.14 to 1.49); in multivariate analyses these factors and female gender (1.77; 1.20 to 2.61) were all significant predictors of fatigue. Three of the four adolescents who developed CFS at Time 2 had had at least one psychiatric diagnosis at Time 1.

(See Chalder et al. Epidemiology of

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chronic fatigue syndrome and self reported myalgic encephalomyelitis in 5-15 year olds: cross sectional study. British Medical Journal 2003; 327:654-655 and Rimes K et al. Incidence, prognosis and risk factors for fatigue and chronic fatigue syndrome in 11-15 year old adolescents: prospective community study; Pediatrics, in press (e pre print available).

King's has completed a series of studies on CFS using the 1946 birth cohorts to assess pre morbid risk factors for CFS. These are currently under review, which we assume means that they cannot as yet be considered, but NICE may wish at least to acknowledge that these will be appearing soon. Harvey S, Wadsworth M, Wessely S, Hotopf M, Does prior psychiatric disorder predict chronic fatigue? Evidence from a National Birth Cohort. Submitted for publication (but the answer is yes it does); Harvey S, Wadsworth M, Wessely S, Hotopf M, The aetiology of chronic fatigue: findings from a National Birth Cohort, submitted for publication.

On the same subject, we also note the omission of any reference to what is now a well cited and accepted body of research on the role of psychiatric disorders and CFS, which is definitely of interest to clinicians considering treatment options. Because CFS is a condition associated with

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impairment/disability, it is sometimes said that in any given patient any psychiatric disorder such as depression and/or anxiety is merely a consequence of disability. However, there is now a well replicated body of evidence that shows this is not to be the case. In a series of studies in both adults and children that compare rates of psychiatric disorder between patients with CFS and patients with other medical conditions, it has been established that the rates of psychiatric disorder in the CFS patients are too high to be explained as a simple reaction to disability – the absolute rates vary from study to study, determined by the criteria/instruments used, but what is consistent across all studies is that the relative risk of psych disorder is increased in the CFS patients compared to the controls (RRs between 2 and 6). Such is the consensus in this area that such studies are no longer being performed. See Katon W et al. Psychiatric illness in patients with chronic fatigue and rheumatoid. *Journal of General Internal Medicine* 1991;6:277-285. ; Wood G, Bentall R, Gopfert M, Edwards R. A comparative psychiatric assessment of patients with chronic fatigue syndrome and muscle disease. *Psychological Medicine* 1991;21:619-628. Wessely S, Powell R. Fatigue syndromes: a comparison of chronic 'postviral' fatigue with neuromuscular

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and affective disorder. *J Neurology Neurosurgery Psychiatry* 1989;52:940-948. Walford et al. Fatigue, depression and social adjustment in children with chronic fatigue syndrome. *Arch Dis Childhood* 1993;68:384-388; Pepper et al. A comparison of neuropsychiatric characteristics in chronic fatigue syndrome, multiple sclerosis and major depression. *Journal of Neuropsychiatry and Clinical Neurosciences* 1993;5:200-205 ; Johnson et al. Depression in fatiguing illness: comparing patients with chronic fatigue syndrome, multiple sclerosis and depression. *J Affective Disorders* 1996;38:21-30. Pelcovitz et al. Psychosocial correlates of chronic fatigue syndrome in adolescent girls. *J Develop Behavioral Paediatrics* 1995;16:333-338. Carter BD, Kronenberger WG, Casuey D. Psychological symptoms in chronic fatigue and juvenile rheumatoid arthritis. *Pediatrics* 1999; 103:975-979. Brace M, Smith M, McCauley E, Sherry D. Family reinforcement of illness behavior: A comparison of adolescents with chronic fatigue syndrome, juvenile arthritis, and healthy controls. *J Develop Behavioral Pediatrics* 2000; 21:332-339. Garralda M, Rangel L. Impairment and coping in children and adolescents with chronic fatigue syndrome: a comparative study with other paediatric disorders. *Jf Child*

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Psychology and Psychiatry and Allied Disciplines 2004; 45:543-552.
 Fischler et al Generalised anxiety disorder in chronic fatigue syndrome; Acta Psychiatrica Scandina 1997; 95: 405-413.

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| SH | College of Occupational Therapists | 2 | FULL | 8 | Activity | Current definition given excludes social aspects. | Noted and revised, as considered appropriate by the GDG. |
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Suggestion:

Activity is “a specific goal-orientated behaviour directed toward the performance of a task. Completion of activities requires sensor motor, cognitive, perceptual, emotional and social abilities” or skills.

Reference: Trombly (1995)
 Occupation: Purposefulness and meaningfulness as Therapeutic Mechanisms. *American Journal of Occupational Therapy*, 49(10).

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| SH | College of Occupational Therapists | 3 | FULL | 8 | Activity Analysis | This appears to be a one-dimensional view of a complex process; it is vital to consider the activity within the context of the individual. | Noted, and we have stressed throughout the whole guideline that the needs, preferences etc of the individual are key. |
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Suggestion:

To identify an activity’s component parts to determine which skills and abilities are necessary to complete the task. Secondly, to examine the context in which it is performed. Thirdly, to consider the context of the person’s age, occupational roles, cultural background, gender, interests and preferences that may influence the meaningfulness of the activity to

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the individual.

Reference: American Occupational Therapy Association (OTA) (1993) Position Paper: Purposeful Activity, *American Journal of Occupational Therapy*, 47(12) 1081-2

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| SH | College of Occupational Therapists | 4 | FULL | 8 | Activity Management | <p>This is described as a strategy for symptom management.</p> <p>The adaptation of activity as a therapeutic modality is a core skill of occupational therapists and is used to evaluate, facilitate, restore or maintain an individual's abilities to function independently. It may reduce symptoms, such as fatigue, but can also be used to improve functioning and well-being within the context of continuing symptoms.</p> <p><u>Reference:</u></p> <p>OTA (1993) Position Paper: Purposeful Activity, <i>American Journal of Occupational Therapy</i>, 47(12) 1081-2</p> <p>Suggestion:</p> <p>Would 'manage the condition and its impact on the individual' be more appropriate than just symptoms?</p> <p>Also analysis should always come before grading. This is important as many professionals in this field are now 'prescribing' activity with this condition who do not have the skills and training in understanding and analysis of activity on which to base this.</p> | <p>Noted and revised, as considered appropriate by the GDG.</p> |
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|----|------------------------------------|---|------|----------|-----------------|---|--|
| SH | College of Occupational Therapists | 5 | FULL | 8, 9, 10 | | Activity management/CBT/GET all need to be facilitated by a therapist knowledgeable in CFS/ME. | Noted and this is included in the recommendations. |
| SH | College of Occupational Therapists | 6 | FULL | 10 | Graded Activity | The current definition oversimplifies the process. The complexities of grading activity are given one line in comparison to graded exercise and CBT, giving the impression that this is a simple technique to apply. Suggestion: Grading activity is one aspect of using activities to promote health, well being and function by analysing, selecting, synthesising, adapting, grading and applying activities for specific therapeutic purposes. This is a core principle of occupational therapy. <u>Reference:</u> Creek J (2003) <i>Occupational therapy defined as a complex intervention</i> . London: College of Occupational Therapists. | Please see Chapter 6 and the detailed recommendations for a more complete explanation of how these should be used. This is simply a brief definition. |
| SH | College of Occupational Therapists | 7 | FULL | 11 | Pacing | Definition for Adapted Pacing Therapy is incorrect; it is not about reducing activity. In addition the definitions are becoming confusing because, in effect, 'pacing' is another name that has evolved for the same processes as activity management. It would, therefore, be helpful to make this connection in the definition to reduce the confusion. Also 'pacing' is a self-management strategy. Suggestion: Adapted Pacing Therapy (APT) as defined in the PACE Trial is; <i>an energy management strategy to</i> | Noted and revised, as considered appropriate by the GDG. |

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monitor and plan of activity with the aim of balancing rest and activity in order to avoid exacerbations of fatigue and other symptoms. This can be used by some people as another name for activity management and is a self-management approach.

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|----|------------------------------------|----|------|----|---------|---|--|
| SH | College of Occupational Therapists | 8 | FULL | 13 | | Severe/ Very severe may require use of rehabilitative / compensatory equipment (e.g. wheelchair). | We have used the definitions in the CMO's report. |
| SH | College of Occupational Therapists | 9 | FULL | 14 | 14 | As there are more occupational therapists working in the specialist multi-disciplinary teams than many of the other professional groups listed, it is disappointing to see that they are listed second from last in the list of relevant professionals. | The list is in no particular order |
| SH | College of Occupational Therapists | 10 | FULL | 8 | General | Suggestion: It would also be helpful to have definitions of 'de-conditioning', 'needs-led' service, and 'envelope theory'. To also use either 'person centred' or 'patient centred', not interchanging, and provide a definition. Person centred is the usual term. | Noted and revised, as considered appropriate by the GDG. We have added in Deconditioning and used person-centred. |
| SH | College of Occupational Therapists | 11 | FULL | 21 | 13 | Improving care for patients and carers? | These have been the GDG's aims throughout the guideline development process, but the impact on the carer/family has been acknowledged throughout the guideline. |
| SH | College of Occupational Therapists | 12 | FULL | 21 | 14 | For children and adults with CFS/ME? Facilitating dissemination of current theory, evidence base and clinical expertise. | These have been the GDG's aims throughout the guideline development process, with children considered as a specific group, and recommendations made, as appropriate. |

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|----|------------------------------------|----|------|---------|--------------------------|---|---|
| SH | College of Occupational Therapists | 13 | FULL | 21 | Priority recommendations | The order of the recommendations appears confused and difficult to follow. Suggestion: It would be helpful if they could follow the care pathway from diagnosis in primary care to specialist treatment. | Noted and revised. |
| SH | College of Occupational Therapists | 15 | FULL | 21 | 19-23 | <i>“When the adult or child’s main goal is to return to normal activities then the therapies of first choice should be CBT or GET”.</i> This seems a somewhat unpalatable phrase, as most people would say that they want to return to normal activities. It also provides little by way of choice for the patient, particularly in respect of current scepticism by some patients of these two treatments. | Noted and please see revisions in the full recommendations. |
| SH | College of Occupational Therapists | 16 | FULL | 22 | 15 | Will NHSdirect be the best source of information on self-help groups for this condition? | We have revised this recommendation. |
| SH | College of Occupational Therapists | 17 | FULL | 23, 125 | 2 8 | Why <u>4</u> months – Current criteria (e.g. Oxford & CDC) as discussed state 6 months; even though there may be debate at how this was arrived at, there does not seem to be any clinical evidence presented to support reducing the time period either for adults. The only reason given is delaying access to specialist care. This places an additional burden on still under resourced services and ignores the opportunity to develop the role that primary care could be playing in helping people manage fatigue (not just for those with CFS/ME). The RCPCH guidelines are | The GDG considered 4 months to be an appropriate timescale. |

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only for children and therefore are not a useful reference as the only evidence upon which to change adult criteria.

Suggestion:

Maintain the timing of diagnosis for CFS/ME in adults at 6 months but make recommendations about access to General fatigue management when fatigue is persisting past 2-3 months within primary care, enhancing the skills and training of existing staff, such as community nurse or utilising the Expert Patient Programme.

| | | | | | |
|----|------------------------------------|----|------|------------|----|
| SH | College of Occupational Therapists | 18 | FULL | 23, 106 | 19 |
|----|------------------------------------|----|------|------------|----|

In other NICE guidelines a tiered approach to treatment has been used, for example with depression, so that certain interventions can be carried out in primary care, and for those where further specialist input is required referral onto secondary care services.

Please see the full, revised recommendations on diagnosis and referral. Also those on management where we have tried to clarify the approach (generalist/specialist care).

These recommendations appear to largely ignore the role of primary care, which may be due to the fact that the recommendations do not follow the care pathway. It states that symptom management should not be delayed, but does not highlight sufficiently that this should be available in the primary care setting as a first line. There appears to be too much emphasis on referrals to specialists, which seems to be contradictory to the direction of the NHS in delivering more treatments through local services.

This would be an opportunity to

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emphasise the need for more rehabilitation services in the community, which could use the existing skills of OTs, physiotherapists, nurses etc, to deliver help for General problems, such as fatigue, pain etc, with support from specialist services and referral on if required.

| | | | | | | | |
|----|------------------------------------|----|------|----|-------|--|--|
| SH | College of Occupational Therapists | 19 | FULL | 24 | 3 | Also condition management services where these are available. | The guideline does not cover service configuration. |
| SH | College of Occupational Therapists | 21 | FULL | 30 | 18 | There are implications for Social Services if the current criteria for recommending equipment does not correspond with the guidance given for CFS/ME. | Noted, and this was the scope agreed before the guideline development and cannot therefore be changed. |
| SH | College of Occupational Therapists | 22 | FULL | 32 | 11 | The list separates out self management techniques from other approaches, such as lifestyle management but later refers to them all as self management techniques. | We have revised the recommendations and the chapters to be consistent in the use of terminology. |
| SH | College of Occupational Therapists | 23 | FULL | 32 | 12 | Return to work/employment is a goal of care rather than an intervention, should this be vocational rehabilitation? On page 33 it repeats 'advice on returning to work/education'. | This was the scope agreed before the guideline development and cannot therefore be changed. |
| SH | College of Occupational Therapists | 24 | FULL | 35 | | Should the controversy attached to the condition be acknowledged? | We have noted throughout the different views and perspectives. |
| SH | College of Occupational Therapists | 25 | FULL | 38 | 12 | CDC (?Year) | The reference is cited. |
| SH | Department of | | FULL | 11 | 22-23 | Adaptive Pacing is characterised as | Noted and revised, as considered |

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| | | | | | | | |
|----|--|---|------|----|---------|--|--|
| | Health, Peninsula Medical School | | | | | reducing activity, which is incorrect. Adaptive Pacing adapts the level activity to tolerable levels, which may involve an initial reduction, stabilisation and then can include an incremental increase, subject to tolerability. | appropriate by the GDG. |
| SH | Department of Health, Peninsula Medical School | 3 | FULL | 14 | 2-6 | Some relevant medical specialities are left out. Rheumatology and General medicine should certainly be mentioned. I would also suggest adding: "and other relevant clinical specialities". | Noted and revised, as considered appropriate by the GDG but this list is not intended as exhaustive. |
| SH | Department of Health, Peninsula Medical School | 4 | FULL | 21 | 20 -23 | This statement is in the wrong place. It is a treatment recommendation (re GET and CBT) that applies only to a subset of patients whose condition is informed by RCT evidence (see below). Its location here gives inappropriate emphasis, which could be misinterpreted. If it were located after line 24 on page 22, it would put it in the appropriate context and sequence (diagnosis through to treatment). | The key priorities are now listed in the order of the guideline. |
| SH | Department of Health, Peninsula Medical School | 5 | FULL | 27 | Diagram | The diagram/algorithm needs a structural change. At present, the boxed layout seems to imply (in contrast to the boxed text and the main text) that, after diagnosis, the patient's treatment would be through specialist care teams after 6 months, even if mild. In reality, many straightforward patients can and should increasingly continue to be managed within primary care (indeed that is the purpose of such guidelines!). This would be made | The care pathways have been revised as in the QRG. |

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more evident and explicit by putting ongoing treatment etc in parallel boxes, one for primary care and one for specialist care. There should be arrows with text indicating the sort of issues that would most likely characterise the two care pathways, apart from severity. For example:
 Primary: lack of co-morbidity, difficulty with adjustment, lack of adverse personal/social factors, good initial adherence to an appropriate treatment programme. Specialist: substantial co-morbidity that interacts, diagnostically or therapeutically; severe specific symptoms that are hard to manage, difficulty in adjustment; adverse personal/social circumstances. See also below.

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|----|--|---|------|----|------|--|---|
| SH | Department of Health, Peninsula Medical School | 6 | FULL | 28 | 2-4 | It may be worth making more explicit that NICE is only looking at those aspects of research that would most directly inform its own compass, and its ability to make recommendations within the defined scope of the NICE Guidance for CFS/ME. Of course, there is a need for wider research, for example on the aetiology and pathogenesis, that would be vitally important, and that could substantially affect treatment approaches, albeit indirectly. | Noted and added. |
| SH | Department of Health, Peninsula Medical School | 7 | FULL | 28 | 20 + | It would seem appropriate to add research that compares outcomes of treatment in primary and secondary care, where appropriate. This would have a major impact on care pathway recommendations. | These have been revised after the consultation. |

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|----|--|---|------|----|----|--|------------------------|
| SH | Department of Health, Peninsula Medical School | 8 | FULL | 36 | 12 | “Centers”. However, CDC do point out that the “Fukuda” criteria were drawn up by an expert panel, which CDC helped to convene, but are not in fact CDC criteria per se. It may be worth getting a precise form of words from CDC. | This has been revised. |
| SH | Department of Health, Peninsula Medical School | 9 | FULL | 36 | 27 | This is a non-sequitur. The lack of physical signs and laboratory tests do not mean that the diagnosis is one of exclusion. This is a common, but erroneous assumption. Diagnosis of any condition is made through the characteristic features on clinical history, supported by features (or their absence) on clinical examination and laboratory tests. Differential diagnosis of course involves excluding other conditions, but that is true of many well established conditions (with or without specific physical or laboratory findings). It is vitally important that clinicians characterise the symptoms, both in their range and in how they are affected by other factors, as a means to establishing a positive diagnosis, in which the normal differential diagnostic process of excluding other things that are similar is used. This is also especially important in respect of co-morbidity, where multiple diagnoses may co-exist. A patient may have CFS/ME and another clinical condition that shows up on examination and laboratory tests, as well as those that do not. The commonest co-morbidities that are well documented in the literature are depression and | Noted and revised. |

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anxiety. These may also lack physical signs and laboratory tests. However, there are established means of diagnosing them with a reasonably high level of certainty. Not only must the same be the case for CFS/ME, pending new knowledge and tests, but also must enable clinicians to be able to diagnosis co-morbid CFS/ME and mood disorder. This section needs substantial rephrasing to make this clear.

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|----|--|----|------|----|-------|--|---|
| SH | Department of Health, Peninsula Medical School | 10 | FULL | 37 | 13-16 | <p>The approach taken on symptom management as stated here is a problem. The scope of the guideline specifies symptom management, yet the line taken here and within the body of the Guideline is very limited, partial and unbalanced. Pain is a major feature of the lives of many people with CFS/ME, and its appropriate management is vital to an integrated treatment strategy. Similarly, sleep, mood, gastrointestinal symptoms, vertigo, etc. In many instances, the approaches are indeed similar to those used elsewhere, but a) non-specialist clinicians are often reluctant to apply them, because of a sense that CFS/ME is different, and b) the approaches need to be adapted to certain characteristics of CFS/ME, for dose and type of intervention (eg poor tolerability of more activating antidepressants, especially in respect of sleep and activity management; inability to benefit from the Cooksey-Cawthorne physiotherapy exercises</p> | <p>We have revised the recommendations and clarified that healthcare practitioners should have expertise in the management of CFS/ME.</p> |
|----|--|----|------|----|-------|--|---|

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for vertigo, probably because of physical and cognitive constraints). The NICE guideline is the proper place to outline these differences, and the better tolerated interventions to consider, as well as routing non-specialist clinicians to the main relevant generic guidance. Unfortunately, it also seems that the consensus process did not adequately utilise the specialist clinical experience available from physicians who do work in this field, partly by the nature of the questions asked, and partly because perhaps insufficient emphasis was given to those who had the relevant expertise and experience, as this is quite a specialist area.

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|----|--|----|------|----|------|---|---|
| SH | Department of Health, Peninsula Medical School | 11 | FULL | 38 | 5-17 | CDC studies have also shown a consistently higher population prevalence in rural areas. This should be mentioned for planning purposes. | We have made a research recommendation that good epidemiological studies are needed to plan services. |
| SH | Department of Health, Peninsula Medical School | 12 | FULL | 39 | 1 | Replace “are” by “have been” to make sense of the following section about the Service Investment Programme. | This has been changed. |
| SH | Department of Health, Peninsula Medical School | 13 | FULL | 39 | 11 | It s worth emphasising that some of the remaining 35% are covered by the pre-existing services | This has been changed. |
| SH | Department of Health, Peninsula Medical School | 14 | FULL | 39 | 15 | “However, the initial set-up phase of the Investment ..” | This has been changed. |
| SH | Department of Health, Peninsula Medical School | 15 | FULL | 39 | 16 | “..of some of these services ..” | This has been changed. |
| SH | Department of | 16 | FULL | 39 | 16 | Add: “at risk, even though the | This has been changed. |

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|----|----------------------------------|----|------|----|----|---|--|
| | Health, Peninsula Medical School | | | | | necessary funding to continue them has been provided to the NHS.” | |
| SH | Invest in ME | | FULL | 23 | 16 | <p><i>Priority recommendations</i></p> <p>liME Comment: What is the element of “partnership” and does this indicate agreement being necessary by all parties prior to proceeding with treatment? How is this different from normal procedures? If there is agreement by the medical profession on aetiology and treatments for ME, then specialised care could be provided in an agreed manner that includes biomedical treatment rather than psychological interventions.</p> | Partnership implies the use of shared decision making. |
| SH | Invest in ME | 19 | FULL | 8 | | <p>Definition of Activity and Activity management</p> <p>liME Comment: This needs to be revised. For some patients even 5 minutes is long. Some ME patients have remained bed bound for years without sitting up. An increase in activity might be one minute in a week.</p> <p>“<i>Activity Management</i>” is exactly what the title suggests, i.e. a scheme for a patient to proactively manage activity levels. The definition given, which includes “<i>to enable patients to improve and or maintain their function</i>” is totally misleading for a patient with severe ME, where it is not possible to perform Activity Management.</p> | <p>A full explanation of activity management is given in Chapter 6.</p> <p>We have also revised this definition.</p> |
| SH | Invest in ME | 20 | FULL | 8 | | <p><i>Boom-bust / activity cycling / over-under- activity</i></p> | This wording was considered appropriate by the GDG. |

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These terms describe fluctuating activity levels and symptoms, as a common feature to CFS/ME. People with CFS/ME may be over-active when they are feeling better, which may lead to an increase in symptoms and a decrease in function.

liME COMMENT: This is completely without foundation and would be far too generic a labeling in any case.

SH Invest in ME 21 FULL 9

Glossary of Terms:

Cognitive Behavioural Therapy (CBT)

liME Comment: This is not true – CBT is not a treatment for severe ME and it has been proven to be positively dangerous to such patients. Maybe CBT is used in other health settings, however, not where post-exertional oxidative stress can cause more serious problems.

The evidence base for CBT is poor and based on research using 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.

How can a therapy also be a treatment? Is NICE stating that CBT cures ME? The glossary definition states that CBT does not imply that symptoms are psychological, 'made up' or in the patient's head. Yet later

Please see Chapter 6 for a more complete explanation.

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in the document it refers on page 202 to 'CBT or other behavioural treatments...'. The guidelines are inconsistent.

It is also proven to be ineffective. 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.

SH Invest in ME 22 FULL 10

Glossary of Terms:

Graded Exercise Therapy (GET)
 IIME COMMENT: Evidence-based? Evidence has shown this is of no help.

Please see Chapter 6 for a more complete explanation.

It 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.

SH Invest in ME 23 FULL 11

Glossary of Terms:

Mild CFS/ME
 IIME COMMENT: 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.

We have used the definitions as in the CMO's report.

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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 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.

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|----|--------------|----|------|----|--------------------|--|---|
| SH | Invest in ME | 24 | FULL | 11 | Glossary of Terms: | <p><i>Pacing</i></p> <p>IIME COMMENT: Please also add COMMON SENSE. If anybody is ill then they do not run a marathon the day their symptoms improve. Let us include CST – COMMON SENSE THERAPY.</p> <p>Pacing is not necessarily about adoption of a psychological paradigm with expensive and unnecessary people making their living from this. Pacing is also common sense.</p> <p>The CMO report has been criticised for their definitions and conclusions by organisations and charities involved with Severe ME sufferers.</p> | Noted and revised, as considered appropriate by the GDG. |
| SH | Invest in ME | 25 | FULL | 13 | Glossary of Terms: | <p><i>Severe / very severe CFS/ME</i></p> <p>IIME COMMENT: They may also not be able to do anything (literally) for years. This needs to show the whole range of effects.</p> | We have used the definitions in the CMO's report. |
| SH | Invest in ME | 26 | FULL | 13 | Glossary of Terms: | <p><i>Specialised care</i></p> <p>IIME Comment: What is the defined specialised care, when there is no</p> | The GDG considered the definition to be appropriate, please see the recommendations for more information on |

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agreed definition of ME or treatment protocols? care.

“Ideally this will be provided by a multidisciplinary team and members may include General practitioners with a special interest” where is the evidence to indicate that a multi-disciplinary team is the correct approach?

If ME is related to elevated levels of chemicals (e.g. choline) in the brain and there are modified gene expressions as noted by Prof Puri and Drs Kerr and Gow, then there is physical evidence of damage to the endocrine system. Therefore, shouldn't an endocrinologist be the first port of call for the medical profession?

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|----|--------------|----|------|-------|--|---|---|
| SH | Invest in ME | 27 | FULL | 8 -14 | Glossary of Terms: | <p>We would like to see the following terms added as they need to be used later in the document:</p> <p style="padding-left: 40px;">Orthostatic intolerance</p> <p style="padding-left: 40px;">Oxidative stress</p> <p>Why not also include other biomedical terms which have been proven to exist in pwme?</p> <p>Why the concentration of terms connected to psychiatric paradigms and therapies? Why not others?</p> | <p>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.</p> |
| SH | Invest in ME | 28 | FULL | 15 | <p><i>Guideline Development Group members</i></p> <p>liME Comment: liME would like to see a lawyer added to the consultation group. The lawyer would be there to</p> | <p>Guideline Development Group members were selected for their experience in the clinical area to develop clinical guidelines. Please see the NICE website for details on stakeholder registration.</p> | |

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represent ME patients as, undoubtedly, there will be litigation against the people making these recommendations when yet another patient dies from such guidelines

SH Invest in ME 29 FULL 15

Guideline Development Group members

It should be noted that the make-up of this Guideline Development group was as follows –

- Patient representatives -
4
- Physiotherapists -
1
- Paediatrician -
3
- General practitioner -
2
- Dietitian -
1
- Neurologist -
1
- Clinical psychologist -
1
- Infectious disease consultant physician -
1
- Psychiatrist -
2
- Occupational health physician/therapist -
2

The list is not correct, the GDG members are listed in the guideline and are available from the NICE website. Co-optees are not members of the GDG but may attend a meeting for specific discussions. Please refer to the 'Guideline development process: an overview for stakeholders, the public and the NHS' available on the NICE website for further information.

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- Nurse -
2
- Immunologist -
1

liME Comment: For a neurological illness there is one neurologist but 2 psychiatrists? Why?

SH Invest in ME 30 FULL 21

Executive summary and recommendations Aims of the guideline

Noted...

“increasing the recognition of CFS/ME”

liME Comment: If this were so, it would then be useful to use the recognized term as per WHO consistently.

SH Invest in ME 31 FULL 21 20

Priority recommendations

Noted and please see revisions in the full recommendations.

- When the adult or child's main goal¹ is to return to normal activities then the therapies of first choice should be CBT or GET² because there is good evidence of benefit for this condition in mild to moderately affected adults and some evidence in mild to moderately affected children.

¹liME Comment: Obviously any child's or adult's main goal is to return to normal activities. This needs to be removed as it is insulting.

²liME Comment: There is little unequivocal evidence to show that CBT or GET have good evidence of benefit and much which shows the contrary result. Most of these studies have also used the flawed Oxford

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criteria for selection of participants in the programme.

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 by some experts.

liME Comment:

The report on ME 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.

CBT and Graded Exercise can worsen ME symptoms

In a survey of 3074 ME/CFS patients conducted between 1998 – 2001, 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

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[Appendix 6 – 3].

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*
[Appendix 6 – 4].

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 [Appendix 5 - 1] 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 [Appendix 5 – 2] make

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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 [[Appendix 5 – 3](#)].

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.

Hooper [[Appendix 5 – 4](#)] 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 [[Appendix 5 – 5](#)] 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 [[Appendix 5 - 1](#)] who states -

"we have correlated abnormal lactate responses to exercise with the detection and characterisation

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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 [[Appendix 5 – 6](#)] have demonstrated a link between symptom severity and cardiac dysfunction. This work is backed up by that of Vanness, Snell et al [[Appendix 5 – 7](#)], 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 [[Appendix 5 – 8](#)] issue the following warning:

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"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.

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|----|--------------|----|------|----|-----|---|--|
| SH | Invest in ME | 32 | FULL | 22 | 2-4 | <p><i>Priority recommendations</i></p> <p>liME Comment: We welcome line 2-4 on page 22 stating that decision-making lies with the patient/carer.</p> | Noted. Thank you. |
| SH | Invest in ME | 33 | FULL | 22 | 6 | <p><i>Priority recommendations</i></p> <p>liME Comment: This guideline needs to include 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</p> | Noted and please see revisions in the full recommendations. |
| SH | Invest in ME | 34 | FULL | 22 | 12 | <p><i>Priority recommendations</i></p> <p>liME Comment: This needs to be 'Allow patient preference...'. All the way through the document repeats that the patient should be able to</p> | We have noted the right of the patient to refuse care at any time. |

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decide. If so then this wording needs to change. See also Page 93 lines from 1 onwards where allows is used.

SH Invest in ME 35 FULL 22 14

Priority recommendations

- offer information about access to self-help groups and support groups for adults and children, families and carers (see www.nhsdirect.nhs.uk, and also the NHS Expert Patient Programme [ww.expertpatients.nhs.uk/](http://www.expertpatients.nhs.uk/))

Noted and this has been revised. The public and patient version of this guideline will also provide contact details for a number of national charities.

liME Comment: We welcome this but feel that the NHS direct web site contains incorrect and dangerous information and cannot be used as a reference in its current form. A list of local and national support groups, charities should be available.

SH Invest in ME 36 FULL 22 17

Priority recommendations

- be aware that all adults and children with CFS/ME have the right to refuse any component of a care plan without detriment to the provision of other aspects of care.

Health insurance is beyond the scope of NICE guidelines.

liME Comment: It is to be welcomed that patients are in control. Also health insurance needs to be an area to be looked into. This includes any or all of the therapies used by psychiatrists.

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

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|----|--------------|----|------|----|----|--|--|
| SH | Invest in ME | 37 | FULL | 22 | 22 | Benefits or Disability Benefits. <i>Priority recommendations</i> liME Comment: Why is the inference always on the emotional state, by having “emotional” and “emotional impact” at the start and end of this statement? Surely, it could be better worded not to cause possible offence by stating “achieve a return to normal health and capabilities for the patient”. | We have also listed physical and cognitive capacity. |
| SH | Invest in ME | 38 | FULL | 23 | 1 | <i>Priority recommendations</i> liME Comment: Why are the Canadian Guidelines not adopted for this diagnosis, which are comprehensive, evidence-based and accepted by leading biomedical experts on ME? They also define the critical symptomology in a clear and concise manner that permits objective assessment. The above definition does not define the “symptoms”. | Please see Chapter 5 for a full discussion of the evidence for the different diagnostic criteria. |
| SH | Invest in ME | 39 | FULL | 23 | 3 | <i>Priority recommendations</i> liME Comment: Why should there be a difference in the timescale for children compared to adults? Is there a different symptomology or aetiology? | A different timeframe was first suggested by the CMO report. There is a dramatic difference in prognosis for adults and children which is important and it is considered that missing 6 months in the old definition was far too long for children. Even missing 3 months of school can have dire consequences so there is a push on getting an early diagnosis. |
| SH | Invest in ME | 40 | FULL | 23 | 9 | <i>Priority recommendations</i> “• When an acute infection is followed by excessive fatigue, the adult or child should receive advice on how to promote recovery. The advice should focus on sleep management, risks of | This recommendation has been deleted. |

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prolonged bed rest (for example, deterioration in muscle function), and a gradual return to a normal daily routine.”

liME Comment: This cannot be allowed. Advice has to be specific to each patient – gradual return to normal daily routine is not advice.

It cannot apply if the condition/infection is still present.

All patients should receive advice on how to promote recovery, irrespective of the starting symptoms or aetiology? If sleep disturbances are experienced, then the nature should be investigated before appropriate advice given, since sleep management may not be appropriate, or possible. Also, severely affected ME patients may not be able to avoid prolonged bed-rest, therefore, dangers should be managed but not be a focus of treatment. Curative treatments are required, but no basis is given in this text apart from possible scare-mongering!

The assumption that an ME patient can always do more is an erroneous one. There are overwhelming international research findings on ME, which support multi-system involvement particularly of the immune, endocrine, cardiovascular and neurological systems [[Appendix 6 – 5](#)]. Also, there is evidence indicating pathology of the central nervous system and immune system

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[Appendix 6 – 6] and evidence of metabolic dysfunction in the exercising muscle [Appendix 6 – 7]. Also, Dr. Jay Goldstein has demonstrated through SPECT scans the severely decreased brain perfusion of an ME patient 24 hours after physical exercise [Appendix 6 – 8]. The Canadian Criteria (2003) states that *the worsening of symptoms after exertion is a principal symptom of ME* [Appendix 6 – 9]. Raised levels of noxious by-products of abnormal cell membrane metabolism, associated with exercise and correlating with patients' symptoms have been demonstrated [Appendix 6 – 10].

Dr Byron Hyde M.D. of the Nightingale Research Foundation for ME in Canada, who has studied ME since 1984 [Appendix 6 – 13] states that

“Patients who improve after physical exercise programmes do not have ME/CFS.” .

Dr. Hyde stresses that ME is primarily a disease of the Central Nervous System [Appendix 6 – 14].

Priority recommendations

liME Comment: Why not also advice/help regarding DWP? One of the biggest stresses on patients with ME is the necessity to prove that they are ill to DWP staff who have little real knowledge of the illness and the aetiology. If the objective is to make it

This is outside the scope of the guideline, but we have noted that healthcare professionals should be proactive in supporting patients accessing the benefits system.

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| SH | Invest in ME | 41 | FULL | 23 | 22 |
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better for the patient then why cannot healthcare staff defend the patient's need for understanding from DWP?

Healthcare professionals should recognise the biological nature of ME (P 22 line 5) and advise disability services departments of the inappropriateness and inability of pwme to be forced into return to activity or work if they are not able to.

Also healthcare staff should be able to advise insurance companies of the above.

Part of stress on parents/carers also relates to education as schools are often apathetic and ignorant toward pwme.

One could also ask why should this be even noted, since it should be within the bounds of normal practice? However, if there is a psychosocial element to be addressed then this should be removed from the treatment of a biomedical physical illness.

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|----|--------------|----|------|----|----|
| SH | Invest in ME | 42 | FULL | 23 | 19 |
|----|--------------|----|------|----|----|

Priority recommendations

“In the absence of a definite diagnosis and/or while waiting for referral, advice and symptom management should not be delayed until a diagnosis is made.”

liME Comment: This is a most unusual statement, as if there is a missing diagnosis, then the best course of medical treatment cannot be defined. Is the NHS routinely

Please see the full, revised recommendations on diagnosis and referral.

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encouraged to prescribe treatments where the diagnosis is not clear?

SH Invest in ME 43 FULL 23 22

Priority recommendations

liME Comment: Surely, healthcare professionals should be proactive in the diagnosis and application of appropriate treatments to return the patient with ME back to a healthy, normal standard of living? Shouldn't this include the provision of advice on rehabilitation from professional experts on rehabilitation that includes experience of ME at all the grades of severity? Is the medical profession responsible for inputs to JobCentres or the Connexions service independent of requests for input from those services or the patient?

The objective of appropriate treatments is to return the patient to normal function. For those who worked prior to their illness, this would include a return to appropriate work. This recommendation is intended to remind health professionals to consider work rehabilitation early as part of the overall management plan. Although Jobcentre plus and other services are usually accessed through self-referral, the health professionals have an important role in signposting these resources.

SH Invest in ME 44 FULL 28 14

Research Recommendations

liME Comment: If this is about research then why aren't more demands being made to fund biomedical research into ME.

Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. We have also added some detail to this section to describe the general approach.

SH Invest in ME 45 FULL 28 14

Research Recommendations

liME Comment:

What are standard methods? Why is the only standard method CBT or GET – for a neurological illness – what are standard methods? This is not the same CBT offered to cardiac patients. The Canadian guidelines have a chapter on this – why does this document not refer to that?

Why focus on these two methods? Why not alternative medicines? This

These have been revised after the consultation.

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is already skewed and reasserts the old myths that CBT/GET can help (treat) ME.

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|----|--------------|----|------|----|-----|---|--|
| SH | Invest in ME | 46 | FULL | 28 | 17 | <p><i>Research Recommendations</i></p> <p>liME Comment: Sub-group analysis needs to be explored. Why are there no research recommendations into sub-grouping?</p> | These have been revised after the consultation and this has been added. |
| SH | Invest in ME | 47 | FULL | 28 | 21 | <p><i>Research Recommendations</i></p> <p>liME Comment: What about previous studies showing epidemics, contraction after vaccination etc?</p> <p>Research ought to be on epidemics and vaccinations.</p> <p>ME is now the leading cause of long-term absence from school for children. Why not make ME a notifiable illness to allow epidemiological studies to be augmented?</p> | We have recommended the need for good epidemiological studies. |
| SH | Invest in ME | 48 | FULL | 29 | 2-5 | <p><i>Research Recommendations</i></p> <p>liME Comment: We agree with this. Well constructed epidemiological studies are required.</p> | Noted with thanks |
| SH | Invest in ME | 49 | FULL | 29 | 21 | <p><i>Research Recommendations</i></p> <p>“It is not known how much improvement is important for patients with CFS/ME.”</p> <p>liME Comment: This is a ludicrous and insulting comment – which patient wants to be ill? It needs to be removed.</p> | These have been revised after the consultation and such questions on the most appropriate way to measure ‘effectiveness’ are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an improvement in pain? |

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|----|--------------|----|------|----|--|--|---|
| SH | Invest in ME | 50 | FULL | 29 | 21 | <p><i>Research Recommendations</i></p> <p>“Future research studies to investigate cost effectiveness of treatment require functional outcomes such as return to work.”</p> <p>liME Comment: Again a ludicrous comment – getting health back is the most important thing – everything follows from that. Only biomedical research will provide a cure for ME.</p> | These have been revised after the consultation. |
| SH | Invest in ME | 51 | FULL | 29 | <p><i>Research Recommendations</i></p> <p>liME Comment: Look at the number of pages made for management techniques as opposed to anything related to biomedical research. The document is skewed.</p> <p>Why is there not a single recommendation for more biomedical research?</p> <p>This shows extremely poor quality analysis and indicates a lack of vision from this group.</p> <p>CBT and GET are reported to be dangerous and hazardous to health for severe ME – has this been examined? If yes, where is the reference material to support the view that CBT and GET are safe? All of the questions noted miss the key questions for research: Aetiology; Diagnostic test; Valid treatments (i.e. successful medical interventions with pharmaceuticals or other treatments); Epidemiology (how the illness is transferred from patient to patient); Demography (are there patient</p> | Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. We have also added some detail to this section to describe the general approach. | |

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|----|--------------|----|------|----|----|--|---|
| | | | | | | clusters?). | |
| SH | Invest in ME | 52 | FULL | 30 | 5 | liME Comment: Encephalopathy needs to be removed as this was not in the 2004 commission statement. | The title of the guideline was amended to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (encephalopathy) following the scope consultation with stakeholders. |
| SH | Invest in ME | 53 | FULL | 32 | 2 | <i>Clinical management</i> liME Comment: Imaging is mentioned here 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. | Please see the chapter on diagnosis and investigations for a full discussion of the evidence, and the relevant recommendations. |
| SH | Invest in ME | 54 | FULL | 32 | 10 | <i>Clinical management</i> liME Comment: Regarding return to work – this needs to be balanced with advice on dealing with DWP when somebody is being harassed or being intimidated from insurance companies. | Noted – and please see the recommendations on support for patients. |
| SH | Invest in ME | 55 | FULL | 33 | 6 | “the management of co-morbidities “ liME Comment: How can these be ruled out? Who knows which came first if diagnosis has taken 3-4 months, or longer? Also ME produces other co-morbidities over time which need to be looked at. This guideline itself recommends other examinations on Page 27. (a review of the diagnosis especially if signs and symptoms change). Therefore this document is already lacking in precision. “service provision or models of care. “ | We have noted that any identified co-morbidities should be managed as per other guidelines or standard clinical care (see also the recommendations on investigations and review. We have recommended throughout the need for patient choice and the right to refuse any component of care. |

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liME Comment: Is this not impacted by the management techniques being forced on pwme by these guidelines? Surely forcing someone to do GET has a bearing on models of care as the results of GET will affect directly the amount of care which a pwme will require when it causes deterioration in the health of pwme.

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|----|--------------|----|------|----|---|---|--|
| SH | Invest in ME | 56 | FULL | 34 | 1 | liME Comment: By whom is new information checked? Who decides what is new evidence? | There is a formal process for reviewing and updating all NICE guidelines (see Chapter 15, Guidelines Manual available from NICE website). |
| SH | Invest in ME | 57 | FULL | 35 | 2 | liME Comment: Please remove encephalopathy | The title of the guideline was amended to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (encephalopathy) following the scope consultation with stakeholders. |
| SH | Invest in ME | 58 | FULL | 35 | 4 | <p><u>liME Comment:</u> Why not document that this is a multi-system biological illness? See press-release. Also state that this is a multi-system illness.</p> <p>Why exclude other symptoms? For example 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</p> | We have revised the recommendations on diagnosis. The view of the GDG, was that at this point the evidence did not support the presence of clusters of symptoms as useful in diagnosis. The symptoms listed in the guideline are not intended as a comprehensive list, but those that are helpful in recognising the condition. The view of the GDG was that a list of all symptoms was potentially confusing as symptoms may then be attributed to CFS/ME rather than investigated further. |

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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 were shown when in the supine and upright position to illustrate the increased blood flow (redness of colour).

This whole area of orthostasis is extremely complex. Might there 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 ([Appendix 6 - 1](#)), and ME Research UK continue to fund research on this

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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 ([Appendix 6 -2](#)) 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 we have work to do to understand the mechanisms. This is not shown in the guidelines.

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|----|--------------|----|------|----|--------|---|------------------------|
| SH | Invest in ME | 59 | FULL | 35 | 9 / 10 | <u>liME Comment:</u> These issues affect so called 'mildly affected' patients | Noted – text clarified |
|----|--------------|----|------|----|--------|---|------------------------|

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also – being at home for years with little contact can also be classified as severe.

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|----|--------------|----|------|----|-----|---|--|
| SH | Invest in ME | 60 | FULL | 35 | 14 | liME Comment: It should be stated that the MRC has refused to fund biomedical research and this needs to be mentioned. | Noted, but not added |
| SH | Invest in ME | 61 | FULL | 36 | 2-5 | 1.3 Aetiology liME Comment: Current research is defined. Will this include research underway by Dr. Jonathan Kerr, by the projects being sponsored by ME Research UK or by other biomedical research projects? | It would be inappropriate to list details of ongoing research here. |
| SH | Invest in ME | 62 | FULL | 36 | 6 | <i>Diagnosis</i> liME Comment: Are we discussing CFS or CFS/ME? | The Royal Australian College of Physicians refer to CFS and not CFS/ME. However, in this guideline we refer to CFS/ME. |
| SH | Invest in ME | 63 | FULL | 36 | 11 | <i>Diagnosis</i> liME Comment: The Oxford criteria are now discredited as they are based on too broad a range of patients. Why aren't Canadian criteria mentioned? | This has been revised. |
| SH | Invest in ME | 64 | FULL | 36 | 25 | "It is also clear that, at present, there are no physical signs that identify CFS/ME and there are no diagnostic laboratory tests that can confirm a diagnosis of CFS/ME Therefore a diagnosis of CFS/ME is one of exclusion." liME Comment: This is contradictory. See Page 35 lines 6-7 – there are physical signs. The Canadian Guidelines list the range of symptoms and NICE should be using that data. | Please see Chapter 5 for a fuller discussion of diagnosis. |

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|----|--------------|----|------|----|---------|---|--|
| SH | Invest in ME | 65 | FULL | 37 | 12 - 16 | liME Comment: yet the title includes diagnosis – if not every symptom is analysed then why have you included those chosen? How can the title include diagnosis if not all symptoms are to be examined? | Please see Chapter 5 for a fuller discussion on diagnosis. |
| SH | Invest in ME | 66 | FULL | 38 | 8 | liME Comment: Why is the UK DoH not collecting epidemiological data? How old is this data that states “prevalence of at least 0.2–0.4%”? What is the latest estimate for the UK? This lack of data means that the basis for this document is also suspect as are much of the data from trials. | We have made a research recommendation that good epidemiological studies are needed. |
| SH | Invest in ME | 68 | FULL | 39 | 11 | liME Comment: There is no indication or evidence of them being successful or useful. These clinics are called fatigue clinics and will include a wide range of fatigue states which are not ME. | ... |
| SH | LocalME | 64 | FULL | 9 | | Glossary of Terms: It is stated that “CBT or psychological approaches to CFS/ME do not imply that symptoms are psychological, ‘made up’ or in the patient's head. It is used in many health settings including cardiac, cancer, diabetes and chronic pain as well as with mood disorders such as anxiety and depression.” This comparison is highly misleading as CBT is normally used as a back up for cardiac, cancer, diabetes and Multiple Sclerosis treatments and only used when the patient has problems coping with their illness or changes to | Noted and revised, as considered appropriate by the GDG. |

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lifestyle. To promote the automatic referral of PWME for CBT is tantamount to treating them as suffering with a behavioural disorder. This view has already been witnessed in the UK when the Collaborating Centre for the Institute of psychiatry deliberately misclassified ME/CFS under the erroneous WHO classification of F48.0 (mental, behavioural disorders) in order to include it in the UK version of WHO Guide to Mental Health in Primary Care. If NICE know of no other way to treat ME/CFS - it is obviously too early to publish these guidelines.

| | | | | | | | |
|----|---------|----|------|----|----|---|---|
| SH | LocalME | 65 | FULL | 15 | | <p>We understand that GDG Group “patient representatives” were there in an individual capacity and not representing groups of PWME - perhaps this should be made clear.</p> <p>There were only 3 patients on the GDG panel and their input was not given enough weighting in decision making.</p> <p>It appears that little notice was paid to the comments made by patients who did complete the questionnaires.</p> | <p>Please see the NICE Guidelines Manual on the website for details of the process for patient involvement in guidelines. Guideline Development Groups usually have 2 patient representatives and this guideline had 3. Chapter 2 details of the Methods used and the objectives of the wider , wider questionnaire. which was to inform the GDG who had the responsibility for developing the guideline.</p> |
| SH | LocalME | 66 | FULL | 22 | 5 | <p>This should be extended: “...and inform patients of the WHO’s classification of the condition as a neurological illness”</p> | <p>We have stressed the need for informed discussion around diagnosis.</p> |
| SH | LocalME | 67 | FULL | 22 | 10 | <p>This should continue: ‘and consider other possible treatments’</p> | <p>We have noted the need for the range of treatment options to be discussed.</p> |
| SH | LocalME | 68 | FULL | 23 | 12 | <p>This should certainly mention: circulatory problems</p> | <p>This recommendation has been deleted.</p> |

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|----|---------|----|------|----|--------|---|---|
| SH | LocalME | 69 | FULL | 28 | | There should be research carried out to assist in diagnosis of psychologically ill people who have been misdiagnosed with ME/CFS. They can then be referred to mental health services and not use up valuable resources set aside for people with ME/CFS. | The GDG did not consider this to be a key research recommendation (please see the NICE Guidelines manual for criteria used when drafting research recommendations). |
| SH | LocalME | 70 | FULL | 35 | 21 | Despite countless research papers highlighting crucial differences, GPs seem to have difficulty differentiating between ME/CFS and depression. For clarification read Psychiatrist, Dr Eleanor Stein, MD FRCP(C), .“Assessment and Treatment of Patients with ME/CFS: Clinical Guidelines for Psychiatrists” www.fm-cfs.ca/Psychiatry-overview.pdf . The Canadian guidelines cover this effectively. “Reactions to exercise ... are helpful in distinguishing ME/CFS from depression. Ref. P9 found in: “An Overview of the Canadian Consensus Document”. | Please see the revised recommendations on diagnosis. |
| SH | LocalME | 71 | FULL | 36 | 23 | This should say: “excluded all other KNOWN causes” | Noted and revised. |
| SH | LocalME | 72 | FULL | 36 | 25 | It is nonsense to suggest that at present “there are no physical signs that identify CFS/ME” - This statement effectively ignores swathes of international biomedical research evidence to the contrary. | Please see Chapter 5 for a fuller discussion of diagnosis |
| SH | LocalME | 73 | FULL | 37 | 8 - 11 | Reference to Canadian Criteria here - but hardly any mention of what they | We have added in reference to the Canadian guidelines as appropriate. |

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| | | | | | | actually say anywhere! | |
| SH | LocalME | 74 | FULL | 38 | 2 | Prognosis | Noted |
| | | | | | | “... FULL recovery being rare (5-10% achieving total remission)” as highlighted in General comments – this is not made at all clear in the NICE. In fact this is one of the few areas of the document where (quite rightly) the word remission appears. | |
| SH | LocalME | 75 | FULL | 37 | 23 | ... and some may even die of this illness. | We have used the CMO’s findings here. |
| SH | LocalME | 76 | FULL | 39 | 2 | Rheumatology should also be referred to here. | Noted and added |
| SH | Mid Staffordshire General Hospitals NHS Trust | 6 | FULL | 9 | | Glossary of Terms: It is stated that “CBT or psychological approaches to CFS/ME do not imply that symptoms are psychological, ‘made up’ or in the patient’s head. It is used in many health settings including cardiac, cancer, diabetes and chronic pain as well as with mood disorders such as anxiety and depression.” This comparison is highly misleading as CBT is normally used as a back up for cardiac, cancer, diabetes and Multiple Sclerosis treatments and only used when the patient has problems coping with their illness or changes to lifestyle. To promote the automatic referral of PWME for CBT is tantamount to treating them as suffering with a behavioural disorder. This view has already been witnessed in the UK when the Collaborating Centre for the Institute of psychiatry deliberately misclassified ME/CFS | Please see Chapter 6 for a more complete explanation. |

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under the erroneous WHO classification of F48.0 (mental, behavioural disorders) in order to include it in the UK version of WHO Guide to Mental Health in Primary Care. If NICE know of no other way to treat ME/CFS - it is obviously too early to publish these guidelines.

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|----|---|----|------|----|----|---|---|
| SH | Mid Staffordshire General Hospitals NHS Trust | 7 | FULL | 15 | | <p>We understand that GDG Group “patient representatives” were there in an individual capacity and not representing groups of PWME - perhaps this should be made clear.</p> <p>There were only 3 patients on the GDG panel and their input was not given enough weighting in decision making.</p> <p>It appears that little notice was paid to the comments made by patients who did complete the questionnaires.</p> | <p>Please see the NICE Guidelines Manual on the website for details of the process for patient involvement in guidelines. Guideline Development Groups usually have 2 patient representatives and this guideline had 3. Chapter 2 details of the Methods used and the objectives of the wider , wider questionnaire. which was to inform the GDG who had the responsibility for developing the guideline.</p> |
| SH | Mid Staffordshire General Hospitals NHS Trust | 8 | FULL | 22 | 5 | <p>This should be extended: “...and inform patients of the WHO’s classification of the condition as a neurological illness”</p> | <p>We have stressed the need for informed discussion around diagnosis.</p> |
| SH | Mid Staffordshire General Hospitals NHS Trust | 9 | FULL | 22 | 10 | <p>This should continue: ‘and consider other possible treatments’</p> | <p>We have noted the need for the range of treatment options to be discussed.</p> |
| SH | Mid Staffordshire General Hospitals NHS Trust | 10 | FULL | 23 | 12 | <p>This should certainly mention: circulatory problems</p> | <p>This recommendation has been deleted.</p> |
| SH | Milton Keynes Primary Care Trust | | FULL | 28 | | <p>There should be research carried out to assist in diagnosis of psychologically ill people who have been misdiagnosed with ME/CFS.</p> | <p>The GDG did not consider this to be a key research recommendation (please see the NICE Guidelines manual for criteria used</p> |

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| | | | | | They can then be referred to mental health services and not use up valuable resources set aside for people with ME/CFS. | when drafting research recommendations). |
| SH | National CFS Network Executive Committee | FULL | 35 | 21 | Despite countless research papers highlighting crucial differences, GPs seem to have difficulty differentiating between ME/CFS and depression. For clarification read Psychiatrist, Dr Eleanor Stein, MD FRCP(C), .“Assessment and Treatment of Patients with ME/CFS: Clinical Guidelines for Psychiatrists” www.fm-cfs.ca/Psychiatry-overview.pdf. The Canadian guidelines cover this effectively. “Reactions to exercise ... are helpful in distinguishing ME/CFS from depression. Ref. P9 found in: “An Overview of the Canadian Consensus Document”. | Please see the revised recommendations on diagnosis. |
| SH | National Institute for Mental Health in England (NIMHE) | FULL | 36 | 23 | This should say: “excluded all other KNOWN causes” | Noted and revised. |
| SH | National ME Centre, The | FULL | 36 | 25 | It is nonsense to suggest that at present “there are no physical signs that identify CFS/ME” - This statement effectively ignores swathes of international biomedical research evidence to the contrary. | Noted and revised. |
| SH | National Patient Safety Agency | FULL | 37 | 8-11 | Reference to Canadian Criteria here - but hardly any mention of what they actually say anywhere! | We have added in reference to the Canadian guidelines as appropriate. |
| SH | National Public | FULL | 38 | 2 | Prognosis | Noted |

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|----|--|---|------|----------|---------|---|--|
| | Health Service - Wales | | | | | “... FULL recovery being rare (5-10% achieving total remission)” as highlighted in General comments – this is not made at all clear in the NICE. In fact this is one of the few areas of the document where (quite rightly) the word remission appears. | |
| SH | National Tremor Foundation | | FULL | 37 | 23 | ... and some may even die of this illness. | We have used the CMO’s findings here. |
| SH | National Youth Advocacy Service | | FULL | 39 | 2 | Rheumatology should also be referred to here. | Noted and added |
| SH | North Staffordshire Combined Healthcare NHS Trust | 7 | FULL | 9 | 22 | The aetiology remains uncertain. | Please see Chapter 5 for a more complete discussion of aetiology. |
| SH | North Staffordshire Combined Healthcare NHS Trust | 8 | NICE | 11 | 1.1.3.6 | It is important to maintain therapeutic optimism and to stress that any adjustments may be modified as individuals improve. | ... |
| SH | North Staffordshire Combined Healthcare NHS Trust | 9 | FULL | 14,15,16 | | These investigations are essential to exclude other conditions. It should be stressed that, should these be normal, no further investigations would be useful unless the presentation changes. | Please see Chapter 5 and the recommendations for details on the investigations. |
| SH | PRIME Project (Partnership for Research in ME/CFS) | 1 | FULL | 29 | 5 | PRIME welcomes the acknowledgement that there are insufficient studies using outcomes that are important to patients. A review of published Patient Reported Outcome Measures (patient completed measures, or questionnaires, of health status and | Noted with thanks, and current research will be considered for the update of the guideline as appropriate. |

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quality of life) will be completed in February 2007; we refer the Guidelines Development Group to this work. The review will identify the wide range of patient-reported outcomes used in published studies of people with ME/CFS, and the associated evidence of measurement quality – in terms of important measurement properties.

Preliminary findings suggest the following:

- A lack of guidance to inform the selection of core health domains and associated methods of assessment.
- The result of which is a lack of measurement standardisation. A large number of measures of health and health status have been identified; heterogeneity of measurement has important implications for evaluating and communicating the impact of disease and health care.
- However, this is associated with a limited focus across important health domains: most studies include the assessment of symptoms (often fatigue and sleep). Few studies include outcome measures that explore the wider impact of ME/CFS, and

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issues considered important by patients, such as physical function, social well-being, work instability/disability, and personal constructs.

- Moreover, there is limited evidence of important measurement properties, such as measurement reliability, validity and responsiveness – particularly across the wide spectrum of disease impact – for many of the identified measures. The results of assessments should therefore be interpreted with caution.
- Few, if any, studies provide guidance in support of score interpretation: evidence in support of what may be considered clinically important change in score (minimal important difference) is very limited.

There is a clear need for:

- Well developed patient-reported outcome measures: such measures provide an essential resource to ensure that patient experience of health and health care is appropriately captured within the evaluation of treatment effectiveness.
- Consensus, between health professionals and

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representative patients, to identify core outcomes of relevance across interventions and settings, and the identification of appropriate outcome measures. Standardisation across measurement outcomes and selected methods of measurement supports data meta-analysis, treatment comparison, enhances familiarity and may improve communication between health care providers and consumers.

- Where gaps in assessment are identified, appropriate, well-developed methods of assessment are required. Patient experience and patient involvement should be central to the development / evaluation of patient-reported outcome measures
- The rigorous assessment of key measurement and practical properties is essential across the range of health care settings and population groups.

The Royal College of Nursing Institute team who are conducting this review may be able to give some preliminary results to the GDG before they report early in 2007

SH Royal College of 2 FULL 36 4 After FULL stop add new para:- This is intended as a brief introduction to

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General
Practitioners
Wales

The conceptual time-line of CFS/ME begins with the definition of the syndrome 3-6 months after onset of symptoms. Thus early pathogenesis is missing and this gap provides opportunities for competing hypotheses about aetiology. This may be important to drive research, but it also has a downside: it fuels worried patient and carer searches for explanatory models to fill the knowledge gap and this will inevitably raise questions that some physicians find unsettling. We return to the issue on page 135, but it must be said that a guideline based on dysfunction and disability will inevitably remain focussed on rehabilitation rather than on the more difficult areas of cure and prevention that evade scientific understanding.

At number of theories about aetiology are in circulation and clinicians need to be aware that their patients may be subscribing to one or more of these explanatory models:

1. An initial self-limiting acute illness caused by a variety of infective agents is followed by a prolonged period of physiological dysfunction despite resolution of the primary infection. Psychosocial factors may contribute to this process and complications of disuse will follow (weakness, autonomic dysfunction, neuroendocrine disorder, muscle wasting). This

the guideline and not a detailed background explanation to the issues around diagnosis. The guideline scope did not cover aetiology

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theory fits best with pragmatic definition adopted in this guideline after symptoms have been present for 3-4 months.

2. An initial acute viral infection progresses to a slow or latent phase of viral infection in which the organism lies dormant for months or years before reasserting itself as the syndrome CFS/ME. The evidence for this hypothesis is weak but it is plausible.
3. An initial infection by *Borrelia burgdorferi* causes a primary infection (in 50% of cases localised erythema chronicum migrans) that is treatable if diagnosed early. Later stages due to dissemination of the spirochaete produce a less well known systemic disease with disabling neurosensory symptoms that may be indistinguishable from CFS/ME. (Donta ST. Late and Chronic Lyme Disease. *Med Clin North Am* 2002; 86(2): 341-349. Donta S. Macrolide therapy of chronic Lyme Disease. *Med Sci Monit* 2003; 9(11): 136-142. Steere AC, Sikand VK, Schoen RT, Nowakowski J. Asymptomatic infection with *Borrelia burgdorferi*. *Clin Infect Dis* 2003; 37:528-532. Evidence-based guidelines for the management of Lyme disease. *Expert Rev Antiinfect Ther* 2004;2(1 Suppl):S1-13.).

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Unreliable immunological results can lead to confusion about causality and we note that the US Centres for Disease Control and Prevention warns clinicians not to depend on conventional immunology for the diagnosis of chronic borreliosis +/- co-infections.

4. These hypotheses are not mutually exclusive so combinations are conceptually possible.

| | | | | | | | |
|----|--|----|------|----|----|--|---|
| SH | Royal College of General Practitioners Wales | 3 | FULL | 36 | 27 | At end of sentence add before FULL-stop: And it is essential to include serious consideration of patient and carer beliefs or concerns about aetiology in this process. . | Please see the recommendations for communication between healthcare practitioners and patients. |
| SH | Royal College of Nursing | 14 | FULL | 16 | | List of GDG Expert co-optees Should read 'Ms Anna Gregorowski' not 'Dr...' | This has been changed. |
| SH | Royal College of Nursing | 15 | FULL | 21 | 19 | As with the NICE – these priorities need to be put in a sensible order | The priorities are now listed in order of the full guideline document. |
| SH | Royal College of Nursing | 16 | FULL | 22 | 2 | Parents should be included with 'child' – i.e. child and parents – in decision making partnerships. | Noted and this is covered in the Patient Centred Care section. |
| SH | Royal College of Nursing | 17 | FULL | 22 | 11 | It is best practise to provide clear and correct information about recovery to all patients. | Noted and this has been recommended. |
| SH | Royal College of Nursing | 18 | FULL | 24 | 4 | Direct liaison with schools and home tutors should be included here as examples. | We have recommended home tuition in later recommendations and also liaison with schools. |
| SH | Royal College of | 19 | FULL | 26 | | Include use of e-mail, alongside | Please see the detailed recommendations |

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|----|--------------------------|----|------|----|----|--|--|
| | Nursing | | | | | telephone, as an additional way to deliver care to severely affected children. | on the care for people with severe CFS/ME. |
| SH | Royal College of Nursing | 20 | FULL | 26 | | As stated earlier, hospital admission is often the best and most effective way to deliver the intensive help and support that severely affected children need. This is especially the case where travel to access an outpatient rehabilitation programme is causing increased fatigue. The hospital admission needs to be viewed as an additional care option to be offered to children and young people wherever appropriate. | Please see the detailed recommendations on the care for people with severe CFS/ME. |
| SH | Royal College of Nursing | 21 | FULL | 27 | | The dark blue box – principles of management of CFS/ME: The line “whether a definite diagnosis has been made or not” - does not make sense within this box. | The care pathways have been revised as in the QRG. |
| SH | Royal College of Nursing | 22 | FULL | 31 | 13 | Most of affected children fall in adolescent population and have different needs to those of younger children. Also there is little evidence to support diagnosis of CFS/ME in children under 10 years of age. | Noted, and this was the scope agreed before the guideline development and cannot therefore be changed. Please see the recommendations for children and young people. |
| SH | Royal College of Nursing | 23 | FULL | 33 | 7 | This guideline does not address co-morbidities. It would be good if the most commonly occurring co-morbidities could be referred to. | Please see the relevant recommendations. |
| SH | Royal College of Nursing | 24 | FULL | 36 | 22 | Suggest the term ‘post viral fatigue’ is useful for those with under 3 months fatigue. | This is a quote from the RCPCH guidelines. |
| SH | Sheffield South | 1 | FULL | 10 | | Glossary of Terms. Graded Exercise | Please see Chapter 6 for a more complete |

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|----|--|----|------|----|------------|--|--|
| | West Primary Care Trust | | | | | Therapy (GET) Need to clarify what is meant by physical assessment as part of the definition of GET | explanation. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | | FULL | 23 | 22 thru 27 | Sometimes acting as an intermediary between patient and employer may encourage dependence rather than fostering recovery via empowerment. We therefore suggest adding the word "may" on line 24 to read, "This may include..." | Facilitating a dialogue with employers about adjustments to work often helps to remove barriers for the patient. However, the approach will vary between patients. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 14 | FULL | 8 | | Definition of adult at 19. We believe most adult services are based on 18+. | This definition has been changed. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 15 | FULL | 8 | 7 | For accuracy, would be best to keep definition to "To break activities down into their component parts". Activity analysis has many uses – for example it can be used to eliminate steps based on values not skills. | Noted and revised, as considered appropriate by the GDG. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 16 | FULL | 9 | 8-9 | This sentence does not make sense. What about: "using the diaphragm to breath rather than the rib-cage" | This has been changed. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 17 | FULL | 9 | 10 | What is the evidence base for this 7/11 breathing? It is a long cycle, and may be difficult for some patients to achieve. | We have simply noted in the definition that there are several techniques, including 7/11, that may be used. However, in the recommendations we have not recommended specific techniques. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 18 | FULL | 10 | 8 | What is the evidence base for this definition of graded activity? We think this is more accurate: "an approach that involves the patient increasing their physical and mental activities, in graded steps, mutually negotiated between patient and therapist." | Please see Chapter 6 for a more complete explanation of the evidence. |
| SH | St Bartholomew's Hospital Chronic | 19 | FULL | 10 | 11 | GET is not a self management approach; it requires close | Noted and revised. |

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|----|--|----|------|----|---------|--|---|
| | Fatigue Services | | | | | supervision and guidance. | |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 20 | FULL | 11 | 15 - 20 | Definition of "moderate" is inadequate and mixes symptoms and disability-- and is based on contradictory quasi-functional differentiations: eg. to be able to be mobile, work and yet have difficulty with light domestic tasks. Sleep symptoms define neither degree of illness nor disability. We suggest you define severity solely by disability. | We have used the definitions as in the CMO's report. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 21 | FULL | 12 | 4, 8 | It is unclear what is meant by this definition of pacing. It is designed to achieve a balance of what? We suggest: "Pacing is aimed at managing activity and rest to achieve a balance <i>between them</i> ." | We have clarified both the definition and the recommendations on this. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 22 | FULL | 13 | 10 + | Severity: again the guideline mixes symptoms and disability, which is not supported by the literature. There is no reliable evidence to support for separating "severe" from "very severe", and including this would make CFS/ME unique in the whole of medicine! See our suggestion above. We suggest only defining severity by disability, taking out symptoms, and amalgamating "severe" and "very severe". | We have used the definitions in the CMO's report. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 23 | FULL | 21 | 15 | Providing an individualised approach to the management of each patient, based on best available evidence. | These have been the GDG's aims throughout the guideline development process, with an individualised approach, based on evidence, being key to care. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 24 | FULL | 21 | 20 + | "When the adult or child's main goal is <i>to return to normal activities</i> "... There is no current evidence that CBT and GET are more effective when this is | Noted and please see revisions in the full recommendations. |

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the case, and can also help when the patient simply wants to improve his/her health. This statement is rather odd and prejudicial, as it implies there are patients who do not want to get back to normal activities. We suggest you delete this clause.

“..there is good evidence of benefit for this condition in *mild to moderately* affected adults..” We do not think this is consistent with the published evidence. As the York University CRD updated FULL systematic review (NICE: Chambers D et al. JRSM 2006;99:506-20) shows, most of the RCTs were in secondary care with measures consistent with severely disabled patients, often unable to work. None could have been considered to be mildly affected. We suggest you omit “mild to” and add “and severely” after “moderately”.

There are also several open studies (RCTs being very difficult to do) that suggest benefit with these and similar approaches in those patients who are severely affected and unable to attend outpatients for treatment. For instance, Essame CS, Phelan S, Aggett P, White PD. Pilot study of a multidisciplinary inpatient rehabilitation of severely incapacitated patients with the chronic fatigue syndrome. *Journal of Chronic Fatigue Syndrome* 1998;4:51-60. Also: Chalder T, Butler S, Wessely S. In patient treatment of chronic fatigue syndrome. *Behavioural*

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Psychotherapy 1996;24:351-365; Powell P, Edwards R, Bentall R. The treatment of wheelchair-bound chronic fatigue syndrome patients: two case studies of a pragmatic rehabilitation approach. Behavioural and Cognitive Psychotherapy 1999;27:249-260; Burgess M. & Chalder T. Telephone / postal cognitive behaviour therapy for chronic fatigue syndrome in secondary care: a pilot study. Behavioural and Cognitive Psychotherapy 2001;29:447-455. We suggest you add, “..and some evidence of benefit in the most severely disabled”.

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| SH | St Bartholomew's Hospital Chronic Fatigue Services | 25 | FULL | 22 | 14 | The The draft guideline mentions access to support for people with CFS and families & carers. We think support both <i>for and from</i> carers could be made more explicit. We know that social support is a key variable in recovery & adjustment process across chronic & life-threatening conditions and conversely can have a detrimental effect if lacking (Taylor, S (1995): Part 5: Management of Chronic & Terminal Illness, in <i>Health Psychology</i> . McGraw-Hill Inc). We suggest adding the statement, “Carers should be encouraged to provide support for the patient undertaking treatment aimed at recovery or improvement.” | Please see the revisions on support in the full recommendations. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 26 | FULL | 23 | 9-12 | We warmly welcome this important recommendation on how to recover more quickly from viral and other | This recommendation has been deleted. |

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infections. This is based on an open study (Dalrymple W, 1964. Add reference) and an RCT (Bridget Candy, Trudie Chalder, Anthony J Cleare, Simon Wessely, Matthew Hotopf. A randomised controlled trial of a psycho-educational intervention to aid recovery in infectious mononucleosis. *Journal of Psychosomatic Research* 2004;57:89–94.) We suggest that you add, “there is some evidence that this approach prevents prolonged fatigue after an infection.”

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| SH | St Bartholomew's Hospital Chronic Fatigue Services | 27 | FULL | 23 | 16-18 | Referral to specialist care should depend on the severity of disability, not severity of symptoms. | The GDG considered the wording to be appropriate, however we have noted that referral should be based on need, however defined. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 28 | FULL | 28 | 9 | “There is no evidence for the use or effectiveness of these strategies in these two patient groups.” This is not strictly true. There is evidence in several open studies for the use of CBT and other active rehabilitation approaches in the severely affected (see references given above). There is also one RCT published finding that CBT was efficacious in adolescents (Maja Stulemeijer, Lieke W A M de Jong, Theo J W Fiselier, Sigrid W B Hoogveld and Gijs Bleijenberg. Cognitive behaviour therapy for adolescents with chronic fatigue syndrome: randomised controlled trial. <i>BMJ</i> 2005;330;14-18). Having stated that, we agree that we need more research in these patient groups. We suggest omitting the word | These have been revised after the consultation. |

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| | | | | | | “no” and substituting “limited”. | |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 29 | FULL | 28 | 11 | “Patient experience” suggests an almost universal phenomenon, which is not the case and we would qualify this statement by saying “some patients’ experience...” | These have been revised after the consultation. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 30 | FULL | 29 | 1-2 | “We need reliable information on prevalence and incidence of this condition <i>to plan services</i> .” Do we really? Services are always planned, or more likely, delivered on the basis of patient presentations to primary care and referrals onwards, not on the basis of epidemiological studies. Epidemiological studies that are sufficiently large and prospective to measure prevalence and incidence would be very expensive, and we suggest it might be better to spend such money as is available on other more worthwhile studies. | Please see the Guidelines Manual for the process and criteria the GDG used when identifying the research needs. The GDG considered the research recommendations to be appropriate. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 31 | FULL | 28, 29 | General | Apart from our lack of support for epidemiological studies in order to plan services, we strongly agree with the GDG about the need for the other studies you suggest. | Noted with thanks (please note there have been some revisions). |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 33 | FULL | 35 | 1.3 | Aetiology: The GDG may not all be aware of two recently published important studies of early risk factors from stressful life events for CFS and CFS-like illness, one of which was a large cohort study. Christine Heim, Dieter Wagner, Elizabeth Maloney, Dimitris A Papanicolaou, Laura Solomon, James | Thank you for this. We have removed the background to the prognostic indicators as the GDG considered none were informative in developing recommendations on diagnosis or management |

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F Jones, Elizabeth R Unger, William C Reeves. Early Adverse Experience and Risk for Chronic Fatigue Syndrome: Results From a Population-Based Study Arch Gen Psychiatry 2006;63:1258-1266

<http://archpsyc.ama-assn.org/cgi/content/abstract/63/11/1258?etoc>

Kenji Kato, Patrick F Sullivan, Birgitta Evengard, Nancy L Pedersen. Premorbid Predictors of Chronic Fatigue. Arch Gen Psychiatry 2006;63 1267-1272

<http://archpsyc.ama-assn.org/cgi/content/abstract/63/11/1267?etoc>

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|----|--|----|------|----|-----|---|--------------------|
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 34 | FULL | 37 | 8 | The Health Council of the Netherlands have also written guidelines on management, which have been accepted by the Dutch government. (Health Council of the Netherlands. Chronic fatigue syndrome. The Hague: Health Council of the Netherlands, 2005; publication no. 2005/02E. ISBN: 90-5549-558-1. www.healthcouncil.nl) | Noted and added. |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 35 | Full | 37 | 17+ | It should be made explicit that these studies determining outcome and prognosis were based on the natural course, without using evidence based treatments. | Noted and revised. |
| SH | St Bartholomew's | 35 | FULL | 37 | 17+ | | ... |

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| | Hospital Chronic Fatigue Services | | | | | | |
| SH | St Bartholomew's Hospital Chronic Fatigue Services | 36 | FULL | 38 | 4+ | <p>The prevalence of 0.2 – 0.4% of the population is based on the CDC definition, which is narrowly defined. The CDC's own studies show that this excludes up to twice that number of individuals who have chronic disabling fatigue, but with less than 4 associated symptoms. Therefore, particularly since the GDG is appropriately using a looser definition of CFS/ME, the guideline should use a figure of between two and three times that proportion.</p> <p>Reyes M, Nisenbaum R, Hoaglin DC, Unger ER, Emmons C, Randall B, et al. Prevalence of chronic fatigue syndrome in Wichita, Kansas. Arch Intern Med 2003,163:1530-6.</p> | We have used the figures as cited in the CMO's report – and noted that these figures are a minimum. |
| SH | Stockport PCT | 1 | FULL | 23 | 1 – 5 | Diagnosis made in adults after 4 months. Preferred timescale should be 3 months for adults. | The GDG considered 4 months to be an appropriate timescale. |
| SH | Stockport PCT | 2 | FULL | 19 | | Diagnosis made in children after 3 months. Preferred timescale should be 6 weeks for children. | The GDG considered the timeframe to be appropriate. |
| SH | Stockport PCT | 3 | FULL | 23 | 19 – 21 | This is absolutely crucial to prevent further deterioration both physically and psychologically. | Noted |
| SH | Stockport PCT | 5 | FULL | 29 | 12 | Outcomes not only 'return to work' but also important are 'return to normal family life', 'resumption of social activities', 'increased self esteem / self worth'. (All of the above outcomes | These have been revised after the consultation. |

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are obviously inter-related).

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| SH | Stockport PCT | 6 | FULL | 36 | 17 – 19 | Agree with this statement except fatigue durations should be <u>6 weeks</u> and <u>8 weeks</u> . | These are durations cited in the RCPCH guidelines. |
| SH | Stockport PCT | 7 | FULL | 38 | 1 – 2 | Prognostic outcomes – this is often an important question asked by CFS/ME sufferers at initial assessment or at an early stage in their illness. 8% - 63% is such a wide variation it is almost meaningless. It doesn't help the 'professional' to offer any 'concrete' answer to the question. An area for further research? | Please see the revised recommendations. |
| SH | The Association for Family Therapy | 1 | FULL | 22 | 2, 17, 21 | Shared decision making in relation to children should include parents/carers. It is important to emphasise the age appropriate autonomy for children and the involvement of parents. | Noted and this is covered in the Patient Centred Care section. |
| SH | The Association for Family Therapy | 2 | FULL | 23 | 26 | This could include liaison with child and adolescent mental health services. It is generally important to involve parents/carers in negotiating with schools in order not to disempower them | Please see the full recommendations on education. |
| SH | The British Psychological Society | 20 | FULL | 21 | 22, 23 | We acknowledge that there is evidence for the efficacy of CBT and GET in the treatment of some adults with CFS/ME,. However, we note that there is limited information for the effectiveness in patients with symptoms other than fatigue and depression, and recent studies indicate that the GET component may not be effective for patients who are | We have stressed the need throughout for the patient's needs and abilities to be considered in the choice and treatment options presented. |

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| | | | | | already operating at their maximum tolerance levels (cf. work by Bleijenberg et al). | |
| SH | The British Psychological Society | 26 | FULL | 9 | We miss a reference to counselling, shown to be as effective as CBT and included in the first CRD review (see later). | Ridsdale 2001, as noted in the health economic discussion, is not a trial in people with CFS, but people with chronic fatigue, of whom only 28% has CFS. |
| SH | The British Psychological Society | 27 | FULL | 10 | Graded activity. This definition is similar to that of pacing. In the literature on CFS, the word 'graded' is usually associated with pre-determined increases. | Please see Chapter 6 for a more complete explanation. |
| SH | The British Psychological Society | 28 | FULL | 11 | This definition does not refer to the most commonly used and arguably most helpful version, which does not include increases in activity (see above). Pacing, by definition, means adaptation to circumstances. It takes account of the phenomenon of the 'plateau' and is supported by research. It does not require monitoring by others, and does not involve goals. On what evidence is the notion of balancing rest and activity based? Is there research showing that matching 20 minutes of activity with 20 minutes rest is more effective than pacing, GET, or graded activity? If we are to be rigorous, we should avoid recommendations based on anecdotal reports and untested concepts. We should be consistent and objective. If patient groups have good evidence for this particular balancing theory, they should publish this. | We have clarified both the definition and the recommendations on this. |

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Pacing is not being assessed by the PACE trial. Adaptive Pacing Therapy is. Aside from the lack of evidence for APT, no person has claimed authorship or has taken responsibility for it. There are no details in the public domain for us to study and assess. The only trial so far (the pilot for PACE, cited in the CMO's report) showed that it was ineffective. We do not recommend other therapies based on an untested theory, for which there is no evidence and no scientific literature to study. Perhaps information about APT can be added when there is sound evidence from the PACE trial. In the meantime, it is worth differentiating the original version of pacing (in the public domain, studied and with scientific references) from the more anecdotal concepts.

| | | | | | | | |
|----|-----------------------------------|----|------|----|--|---|--|
| SH | The British Psychological Society | 29 | FULL | 23 | 1 | Again, the 4 months minimum excludes epidemic cases. | From the group's discussions epidemic cases seems to be regarded as unusual, and it may be contentious that these such epidemics are CFS/ME. Although they do indeed occur, they are rare events, and the diagnostic interval does not preclude an interim presumed diagnosis, which could be helpful should there be an epidemic. |
| SH | The British Psychological Society | 30 | FULL | 34 | There are currently 2 MRC funded randomised controlled trials underway. The PACE Trial is testing CBT vs GET vs adaptive pacing therapy in patients in secondary care, and the FINE trial {Wearden is the principal investigator} is testing a nurse-led pragmatic self-help | There is a formal process for reviewing and updating all NICE guidelines (see Chapter 15, Guidelines Manual available from NICE website). | |

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treatment vs a non-directive counselling treatment for patients in primary care. We would suggest that the evidence should be re-evaluated, and the guidelines updated if necessary, after the results of the PACE and FINE trials are known.

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| SH | The British Psychological Society | 31 | FULL | 35 | 1 | Given the recent research findings, one can be more precise than this. It is a heterogeneous condition and subgroups have been identified (e.g. the one with evidence of an encephalopathy, Natelson et al 2005). With triggers as varied as pathogens, organophosphates, food sensitivities and stress, we need to consider the most effective strategies for each. | However the evidence on interventions does not allow the identification of subgroups – we do recommend that the management should be tailored to the individual. |
| SH | The British Psychological Society | 32 | FULL | 35 | 6 | Replace ‘fatigue’ with ‘exhaustion’, rewrite to differentiate it from neurasthenia, as above (NICE, p1), unless these guidelines are for neurasthenia as well as CFS/ME. If precision is valued, it is worth keeping them apart. | We have used ‘fatigue’ as the preferred term. The guidelines are for CFS/ME only. |
| SH | The British Psychological Society | 33 | FULL | 36 | 11 | These criteria are for research only. This needs to be pointed out and underlines the importance of the proposed guidelines in the draft. | This has been revised. |
| SH | The British Psychological Society | 34 | FULL | 38 | 5 | Prevalence. A more realistic range is .1 to 2.6%. | We have used the figures as cited in the CMO’s report – and noted that these figures are a minimum. |
| SH | The Chartered Society of Physiotherapy | 1 | FULL | 10 | GET | The term is not clearly defined and is a term used by different people with different meanings. GET is not only a self-management approach to CFS/ME. This definition implies physical activity only when mental | Please see Chapter 6 for a more complete explanation. Some revisions have also been made. |

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activity needs to be included. Must also take into account any reaction to increased activity before progressing further which is not stressed enough.

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| SH | The Chartered Society of Physiotherapy | 2 | FULL | 11 | Pacing | Clearer definition of which pacing method used in this document is needed | We have clarified both the definition and the recommendations on this. |
| SH | The Chartered Society of Physiotherapy | 3 | FULL | 27 | General | Concern re emphasis on GET | Noted and please see the detailed recommendations. |
| SH | The Chartered Society of Physiotherapy | 17 | FULL | 19 | 6.3 19 | Where has the magic figure of “20%” increases come from? | This is based on the protocols used in the trials. Also this is recommended as a maximum increase if appropriate, not a required one. |
| SH | The Chartered Society of Physiotherapy | 18 | FULL | Chapter 6.3 | General | Everything is covered in very discrete “bundles” e.g. CBT/GET/activity management, but there is little discussion that these approaches can actually be used in conjunction with one another, and this may enhance the guideline further. | Please see the revised recommendations and Chapter 6 |
| SH | University of Manchester | 1 | FULL | 21 | 22,23 | We would agree with priority recommendation 1 that there is good evidence for the efficacy of CBT and GET in the treatment of adults with CFS/ME, but would suggest that there is some, albeit limited, evidence for the efficacy of these approaches with severely affected adults. While, to our knowledge, there has been no trial of CBT or GET for severely affected adults alone, as far as one can tell from baseline scores on the outcome measures used, many of the treatment trials which have been carried out to date have included patients with a range of illness | Noted and please see revisions in the full recommendations. |

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severity and functional disability. Illness severity has not, however, been classified according the mild/moderate/severe/very severe rubric suggested in the NICE guidelines. Our treatment, pragmatic rehabilitation, which, while neither GET nor CBT, contains elements of both of them, has been successFULLy used to treat wheelchair-bound patients (Powell et al., Behav Cog Psychother 1999,27:249-260).

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| SH | University of Manchester | 3 | FULL | 34 | We would suggest that the evidence should be re-evaluated, and the guidelines updated if necessary, after the results of the PACE and FINE trials are known. | There is a formal process for reviewing and updating all NICE guidelines (see Chapter 15, Guidelines Manual available from NICE website). |
| SH | Welsh Association of ME & CFS Support | 2 | FULL | 8 | "It has physical." Change wording to can have | Noted and revised, as considered appropriate by the GDG. |
| SH | Welsh Association of ME & CFS Support | 3 | FULL | 8 | "NB: In housebound/bedbound patients an appropriate increase in activity can be small e.g. sitting up in bed for 5 minutes or talking on the phone." This is not in the right section - move to graded activity section. | This has been removed from the definitions and additional details given in other definitions as appropriate. |
| SH | Welsh Association of ME & CFS Support | 4 | FULL | 8 | Remove 'sense of well being' this is inappropriate wording | Noted and revised, as considered appropriate by the GDG. |
| SH | Welsh Association of ME & CFS Support | 5 | FULL | 8 | The Boom/bust cycle can also happen because of unexpected activities be they mental or physical. And not necessarily when a person | Noted and revised, as considered appropriate by the GDG. |

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| SH | Welsh Association of ME & CFS Support | 6 | FULL | 9 | <p>feels better.</p> <p>CBT cannot be described as evidence based for all patients as it has not been trialled on the severely affected. At best it can be described as a therapy which has helped a <i>small number of</i> patients to secure a modicum of improvement in a <i>small number of</i> symptoms. It's affect on a wide range of symptoms has not been measured and it is totally untested on a wide range of patients, including the severely affected. This is misleading.</p> <p>This is a misleading statement This type of CBT is not used with other patient groups.</p> | Noted and revised, as considered appropriate by the GDG |
| SH | Welsh Association of ME & CFS Support | 7 | FULL | 9 | <p>This type of goal setting is normally referred to as SMART Specific, measurable, attainable, realistic and timed. This is not suitable for the majority of patients with CFS/ME and should therefore be removed from these guidelines</p> | Noted, and we have given details on how the process of goal setting should be undertaken. However, the wording of the definition was considered appropriate by the GDG. |
| SH | Welsh Association of ME & CFS Support | 8 | FULL | 10 | <p>Change wording to relapse not setback</p> | Noted: GDG decided to use term 'setback/relapse'. |
| SH | Welsh Association of ME & CFS Support | 9 | FULL | 10 | <p>GET cannot be described as evidence based and therefore this statement is misleading. GET has not been trialled on some patient groups i.e. the severely affected and this should be made clear in the Glossary and elsewhere. The implication that GET can facilitate recovery through improving symptoms and functioning is also unproven and this should be</p> | Please see Chapter 6 for a more complete explanation and details of the evidence can be seen in Appendix 1. |

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| | | | | | reworded. | |
| SH | Welsh Association of ME & CFS Support | 10 | FULL | 11 | Change the wording to 'may' be working | We have used the definitions as in the CMO's report. |
| SH | Welsh Association of ME & CFS Support | 11 | FULL | 11 | This is the same statement repeated twice but said in different ways and is not a true reflection of the meaning of pacing as practised by the majority of pwme. | We have clarified both the definition and the recommendations on this. |
| SH | Welsh Association of ME & CFS Support | 12 | FULL | 11 | This describes adaptive pacing therapy for which there have been no research trials. This statement is therefore misleading and needs to be removed or reworded to reflect the true meaning of what you are describing. | We have clarified both the definition and the recommendations on this. |
| SH | Welsh Association of ME & CFS Support | 13 | FULL | 12 | This statement is misleading. The trial which is currently running is into adaptive pacing therapy and is not the same as the pacing described in this paragraph. | We have clarified both the definition and the recommendations on this. |
| SH | Welsh Association of ME & CFS Support | 14 | FULL | 12 | This is a treatment for anxiety states and may not be suitable for all people with CFS/ME. | ... |
| SH | Welsh Association of ME & CFS Support | 15 | FULL | 13 | The terminology in use here is relapse not 'setback' | Noted: GDG decided to use term 'setback/relapse'. |
| SH | Welsh Association of ME & CFS Support | 16 | FULL | 13 /14 | Include Counsellors in this list | The list is not intended as a complete list of all possible healthcare professionals. |
| SH | Welsh | 17 | FULL | 21 | It is doubtful that the guidelines | These have been the GDG's aims |

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| | Association of ME & CFS Support | | | | | can succeed in meeting most of the stated aims. | throughout the guideline development process. |
| SH | Welsh Association of ME & CFS Support | 18 | FULL | 21 | 10 | It is doubtful that the guidelines can succeed in meeting most of the stated aims, particularly 'improving access to appropriate services' due to the 2 therapies of first choice being so expensive and the shortage of practitioners. Also the guidance given to GPs on diagnosis and pharmacological interventions is inadequate and there are no specialists in Wales for patients to be referred to. | This has been referred to the NICE Implementation Team. |
| SH | Welsh Association of ME & CFS Support | 19 | FULL | 21 | 19 | It is doubtful that the guidelines can succeed in meeting most of the stated aims, particularly 'influencing practice in the real world' because the 2 therapies of first choice are expensive and there is a shortage of practitioners. Also the guidance given to GPs on diagnosis and pharmacological interventions is inadequate and there are no specialists in Wales for patients to be referred to. | This has been referred to the NICE Implementation Team. |
| SH | Welsh Association of ME & CFS Support | 20 | FULL | 21 | 15, 16 | The wording here is not clear so this section needs to be reworded. | Noted and revised. |
| SH | Welsh Association of ME & CFS Support | 21 | FULL | 21 | 20 | This comment is offensive and implies an unwillingness on the part of the patient not to want to recover. | Noted and please see revisions in the full recommendations. |
| SH | Welsh Association of | 22 | FULL | 21 | 21 | Treatment cannot be standardised across the whole spectrum of patients | Noted and please see revisions in the full |

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| | ME & CFS Support | | | | | because the evidence base is not there. These treatments have not been trialled on the severely affected therefore there is no evidence as to their efficacy. | recommendations. |
| SH | Welsh Association of ME & CFS Support | 23 | FULL | 22 | 3 | Although this is good in theory this should also be patient centred. | We have noted the need for care to be patient centred throughout. |
| SH | Welsh Association of ME & CFS Support | 24 | FULL | 23 | 13 - 15 | This is good in practice as long as it is patient centred | Noted... |
| SH | Welsh Association of ME & CFS Support | 25 | FULL | 23 | 19 | Between 'referral', and 'advice' add: A preliminary diagnosis should be made | Please see the full recommendations on diagnosis and referral |
| SH | Welsh Association of ME & CFS Support | 26 | FULL | 23 | 19 | Where is the guidance for doctors on which advice to offer? Would it be exactly the same as if a full diagnosis or specialist assessment was made? That would be unwise | This has been revised. |
| SH | Welsh Association of ME & CFS Support | 27 | FULL | 23 | 20 - 21 | There are no guidelines for symptom management in the interim period. | Please see the full, revised recommendations on diagnosis and referral, and interim symptom management. |
| SH | Welsh Association of ME & CFS Support | 28 | FULL | 24 | 4 | England only | We have revised this recommendation. |
| SH | Welsh Association of ME & CFS Support | 29 | FULL | 28 | 1 | should include an exploration of the role of rest at all stages of the illness, a study of relapses, assessments of drugs and alternative treatment in order to have something to compare the studies of CBT and GET, the role | The GDG did not consider this to be a key research recommendation (please see the NICE Guidelines manual for criteria used when drafting research recommendations). |

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of energy management and activity management at all stages of illness.

It should also include A statement reinforcing the need for the MRC to fund biomedical projects to aid diagnosis and treatment

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| SH | Welsh Association of ME & CFS Support | 30 | FULL | 29 | 10/11 | This comment is insulting. This implies patients do not want to recover. | These have been revised after the consultation and such questions on the most appropriate way to measure 'effectiveness' are standard research questions when outcomes are not clear for a specific area – for example, is an improvement in fatigue an important outcome alone, or is it meaningless to patients unless there is also an improvement in pain? |
| SH | Welsh Association of ME & CFS Support | 31 | FULL | 29 | 12 | Ability to work is only one aspect of functioning, much more basic is the ability to dress oneself, cook meals, go shopping, hold conversations with family etc | These have been revised after the consultation. |
| SH | Welsh Association of ME & CFS Support | 32 | FULL | 32 | 15 | This description is the same as GET but is labelled differently | This was the scope agreed before the guideline development and cannot therefore be changed. |
| SH | Welsh Association of ME & CFS Support | 33 | FULL | 32 | 15 | Put pacing in a line of it's own as it is a stand alone therapy which most people with CFS/ME find beneficial | This was the scope agreed before the guideline development and cannot therefore be changed. |
| SH | Welsh Association of ME & CFS Support | 34 | FULL | 32 | 16 | Add counselling | This was the scope agreed before the guideline development and cannot therefore be changed. |
| SH | Welsh Association of ME & CFS | 35 | FULL | 33 | 6 | Would it be possible to at least mention the main comorbid | Please see the relevant recommendations. |

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|----|---------------------------------------|----|------|----|--------|--|--|
| | Support | | | | | conditions, to help doctors out? | |
| SH | Welsh Association of ME & CFS Support | 36 | FULL | 35 | 6 | Characterised by post exertional fatigue | We have used 'fatigue' here to allow for the wide variation of fatigue – please see the diagnosis recommendations for further details. |
| SH | Welsh Association of ME & CFS Support | 37 | FULL | 35 | 7 | Include IBS etc | This is not intended as a complete list – note 'including' |
| SH | Welsh Association of ME & CFS Support | 38 | FULL | 35 | 9 | Add in Physical or mental activity | Noted and added |
| SH | Welsh Association of ME & CFS Support | 39 | FULL | 35 | 11 | It needs to be specified that this was then CMO for England's Report | Noted and revised |
| SH | Welsh Association of ME & CFS Support | 40 | FULL | 35 | 24 -27 | o say that a number of factors have been <i>suggested</i> for the aetiology of CFS/ME is to trivialise the significance of the research findings which point to serious dysfunction in the body. A FULLer summary of the main finding should be included as these form the context in which the illness should be understood. The WHO classification should also be reported. The word heterogeneous is used to describe the illness - there is certainly 'evidence' for sub-groups and this should be made clear. | We have revised the introduction and referred to the WHO classification. |
| SH | Welsh Association of ME & CFS | 41 | FULL | 36 | 2 - 4 | These guidelines are based on evidence yet you are quoting pending research findings as fact. This is | We have noted the need to be aware of any new research on aetiology. |

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| | Support | | | | | | misleading. | |
| SH | Welsh Association of ME & CFS Support | 42 | FULL | 36 | 11 | | The Oxford criteria exclude patients with any neurological signs or symptoms. | This has been revised. |
| SH | Welsh Association of ME & CFS Support | 43 | FULL | 36 | 24 - 27 | | Currently there is research going on into biological markers and tests on treatments will nicely be underway. | Noted and revised. |
| SH | Welsh Association of ME & CFS Support | 44 | FULL | 37 | 13 - 15 | | what is the evidence that the symptoms of people with CFS/ME will respond in the same way to treatment as people with other conditions? | We have noted that established principles should be followed, and in the recommendations we have stressed the need for specialist input as appropriate with detailed review and monitoring |
| SH | Welsh Association of ME & CFS Support | 45 | FULL | 38 | 23 | | Specify English CMO | Revised |
| SH | West Midlands Consortium | 64 | FULL | 22 | 5 | | This should be extended: “..and inform patients of the WHO’s classification of the condition as a neurological illness” | We have stressed the need for informed discussion around diagnosis. |
| SH | West Midlands Consortium | 65 | FULL | 22 | 10 | | Should continue: ‘and consider other possible treatments’ | We have noted the need for the range of treatment options to be discussed. |
| SH | West Midlands Consortium | 66 | FULL | 23 | 12 | | Should mention: circulatory problems | This recommendation has been deleted. |
| SH | West Midlands Consortium | 67 | FULL | 28 | | | There should be research done to assist in diagnosis of psychologically ill people who have been misdiagnosed with CFS/ME. They can then be referred to mental health services and not use up valuable resources set aside for people with CFS/ME. | The GDG did not consider this to be a key research recommendation (please see the NICE Guidelines manual for criteria used when drafting research recommendations). |

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| SH | West Midlands Consortium | 68 | FULL | 35 | 4 | Should mention that it is a neurological illness | Noted and added. |
| SH | West Midlands Consortium | 69 | FULL | 36 | 23 | Should say: "excluded all other KNOWN causes" | Noted and revised. |
| SH | West Midlands Consortium | 70 | FULL | 36 | 25 | It is nonsense to suggest that at present "there are no physical signs that identify CFS/ME" - This effectively ignores swathes of international biomedical research evidence. | Noted and revised. |
| SH | West Midlands Consortium | 71 | FULL | 37 | 8 - 11 | Reference to Canadian Criteria here - but then no mention of what they actually say anywhere! | We have added in reference to the Canadian guidelines as appropriate. |
| SH | West Midlands Consortium | 72 | FULL | 37 | 23 | ... and some may even die of this illness. | We have used the CMO's findings here. |
| SH | West Midlands Consortium | 73 | FULL | 39 | 2 | Rheumatology be referred to here. | Noted and added |