National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
SH	25% M.E. Group	1	NICE	General		In General: These guidelines are too broad in their scope and the diagnostic criteria and suggested management options are not relevant to ME. Most ME patients would not recognise their illness as described in this document. All the way through it appears to imply that patients with ME/CFS are able to make choices and decisions about their illness at will and not based on the severity of their symptoms. The guidelines acknowledge that CFS/ME	The diagnostic section of the guideline has been revised to make this clearer. While it is generally recognised that it is heterogeneous, the evidence does not allow distinctions between subgroups. The Guideline Development Group reviewed the results of the questionnaire. Please refer to the results of the questionnaire, which are published in the full guideline. The evidence supports the use of CBT and GET. However, we have recommended that the preference and needs of the individual should be taken into account and there be an individualised programme.

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						is heterogeneous but then ignore the need for subgroups. They then recommend CBT and GET as the two therapies of choice for all the patients, when patient evidence and surveys suggest that these two therapies are not suitable for many and indeed may cause harm to a significant proportion of patients. In our experience, CBT and GET are the least favoured the least requested and the least helpful for patients with ME. Patient evidence, testimonies and responses to the NICEquestionnaire appear to be totally ignored.	

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						As these guidelines will almost certainly form the basis for the treatment and care of ME/CFS patients in primary, secondary and tertiary care, it is essential that this draft is rejected. In their present form the guidelines will expose ME/CFS patients to further psychologising of their illness and all that implies in terms of treatments and welfare.	
SH	25% M.E. Group	2	NICE	General		As many illnesses are unfortunately covered by the term ME/CFS, it is unhelpful to treat every condition in the same way. One size does not fit all. The mildest form of Post Viral Fatigue Syndrome	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						cannot and should not be lumped together with most types of ME. This goes for other chronic illnesses with fatigue-states, which can vary in severity and can carry with them a myriad number of debilitating symptoms which accompany such illnesses. There should be more emphasis made on the extreme fatigue; pain/neurological problems; hormonal imbalances; cardiovascular abnormalities; IBS; allergies/intolerances to food/drugs and multiple chemical sensitivities that people with full blown ME experience.	
SH	25% M.E. Group	3	NICE	Genera		To look at the medical	The evidence supports the use of CBT

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				l		definition of CBT; *"Method of treating mental disorders based on the idea that the way we perceive the world and ourselves (our cognitions) influences our emotions and behaviour."* What has this got to do with a physical illness? NICEstates that M.E/CFS is a physical condition and yet wish only to treat the illness as a psychological one. The NICEdraft document is littered with references to the 'psychological aspect' of the illness and therefore it gives a clear indication to everyone reading it that that IS the way this condition should be treated.	and GET. However, we have recommended that the preference and needs of the individual should be taken into account and an individual strategy developed based on the individual's current activity levels. To date there is no evidence for the effectiveness of pacing.

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						That is in total conflict to all the biomedical research findings and the WHO’s classification of M.E/CFS, as a disease of neurological (physical) origin. The thought is still there that people with M.E. are making themselves ill or are perpetuating their illness through negative thought processes. Nothing could be further from the truth. The terminology used in the NICE document still implies that thought patterns are influencing negative thoughts in patients and stopping them from recovering. Everyone I know with this terrible illness is very motivated and we ALL want to get	

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						well. Positive thinking is part of our lives. CBT and GET will set progress back 20 years and ignore the potential benefits of future drug/therapies, as and when they are available. The NICE Guidelines are totally patronising to people with M.E. and I've no doubt this is as a result of pressure from certain psychiatrists/psychologists who will not let go of the myth/theory that M.E. is personality based, which is totally damning and totally inaccurate…this is what was being touted 15 years ago…move on please! Will a diagnostic blood test also be ignored as physical proof of illness?	

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						♦ CBT should not be seen or indeed treated as though it a cure for M.E. when it is not. This will exclude other treatments, which will directly target areas such as pain control, allergies, hormonal imbalances and IBS etc, until such time a cure is forthcoming. These would be far more beneficial to sufferers, who at present often have to pay for testing/treatments or go to the expense of seeking them out, as GPs cannot always offer help in these areas. Supplements	

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						and natural remedies also come at a price to the patient and many people find benefit from these, where there is extreme sensitivity to proprietary drugs. ♦ GET in many cases can do more harm than good. Pacing is a much better option to adopt…, as there is a very fine line between improving mobility and doing lasting damage. Will patients be able to sue for compensation should health professionals give inappropriate advice? Cycling or brisk walking for most M.E. sufferers	

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						is totally absurd to suggest and very dangerous, yet we have all trusted health professionals to make decisions on our behalf. From a patient's perspective, pacing has improved my mobility and that is from personal experience… but I am a long way from being able to lead a 'normal' life, because of problems with severe IBS; pain; allergies; intolerances; hormonal imbalances etc. I do not think for one moment CBT and GET will cure or help these problems. The NICEguidelines also	

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						ignore the delicate balancing act that has to be considered when treating anyone with M.E. This condition fluctuates hourly/daily/weekly and new symptoms can crop up when least expected, as well as long standing ones disappearing without apparent reason!	
SH	25% M.E. Group	4	NICE	General		Graded Exercise Therapy should not be prescribed without a health warning and in the context of the caveats stipulated by the medical defence unions. Why is this not dealt with in the guidelines? I feel this should only be undertaken in M.E. under the guidance	The guideline makes it clear that professionals should be qualified and gives details of the programme.

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						of qualified fitness instructors or suitably qualified physiotherapists. This is a charter for litigation and yet again potential for a huge hole in public finances.	
SH	25% M.E. Group	5	NICE	1	1	It's unclear what is meant by 'relatively common'– although it does seem to set the scene for the all-inclusive broad diagnostic criteria that follows.	The prevalence is detailed in the next paragraph.
SH	25% M.E. Group	6	NICE	1	16	"… poses 'real problems', seems perhaps deliberately ambiguous and should be substituted by the word 'serious'.	The wording has been changed to reflect this comment.
SH	25% M.E. Group	7	NICE	2	5	It can be all too easy to overrule patients, especially children, if their parents do not agree with treatment protocols that	This is standard text in all NICE guidelines.

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						have no evidence to support them ie, CBT & GET. This has caused much abuse of parents' and childrens' rights and has even led to removal of children from their parents. There has to be protection for parents who will not submit their children to dangerous or unhelpful treatments as defined by them, the parents.	
SH	25% M.E. Group	8	NICE	2	14–15	'Communication should be supported by the provision of evidence-based information offered in a form that is tailored to the needs of the individual patient.' It is important to just offer information on the current level of understanding of	Comment noted but no action is required.

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						the condition at **international level**.	
SH	25% M.E. Group	9	NICE	3	6	As mentioned above the "evidence" for CBT is much weaker than is portrayed– counselling may be just as effective as an illness management tool. Where will the necessary money come from to finance the required legions of CBT therapists with appropriate "expertise" in ME/CFS?	Issue 1. Counselling: In the view of the Guideline Development Group the evidence was stronger for CBT than counselling. Issue 2. Funding: Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.
SH	25% M.E. Group	10	NICE	3	10	As above–the "evidence" for GET is remarkably weak. There is strong evidence that people with ME/CFS respond abnormally to exercise. There is a very fine line between improving mobility and doing lasting damage. **Will patients be able to**	The evidence supports the use of GET; however, we have recommended that the preference and needs of the individual should be taken into account.

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						sue for compensation should health professionals give inappropriate advice? Doctors and healthcare professionals must prescribe exercise with exactly the same degree of care as with a prescription drug. The Medical Defence Union has repeatedly advised GPs to take the same care with recommending GET as when prescribing drugs.	
SH	25% M.E. Group	11	NICE	3	6–15	CBT and GET have been disputed by many patients as effective forms of treatment for true ME/CFS. The evidence for their usefulness was derived by using a very "woolly" &	The evidence supports the use of CBT. However, we have recommended that the preference and needs of the individual should be taken into account and there are many other strategies in the guideline. The Guideline Development Group

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						disputed definition of ME. However, they seem to be the only treatments on offer, in various forms. Patient's experience is denied or seen as a product of unhelpful beliefs – based on no evidence of this.	recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches.

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SH	25% M.E. Group	12	NICE	4		Welcome patient centred care concept–but question whether patient will have opportunity to make 'informed' decisions when information supplied is to be 'evidence based' It is somewhat reassuring to read that patients will be consulted at all times about their treatment, but as there is a strong psychological slant to it, I would hope that there will not be any pressure for patients to comply with everything that may be suggested to them. I also hope that there will not be any psychological profiling of patients who refuse any specific treatments, when his/her	Noted with thanks. There is a recommendation that patients can withdraw from treatment at any time without detriment (please see recommendation for full wording)

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						health is at stake…. After all they have to live with the consequences!	
SH	25% M.E. Group	13	NICE	5	1	The phrase usually STOPPED work is totally inappropriate. It suggests there was a choice. For the vast majority, of people, this was certainly not the case. With many being dismissed by their employers on the grounds of medical incapacity or had to give up work. Many have tried to return, but major relapses have meant they reluctantly ended their careers.	These are based on those of the Chief Medical Officer's report.
SH	25% M.E. Group	14	NICE	6	1	'WHEN the adult's main goal is to return to normal activities …'–What other goal would there be? This is entirely unacceptable	This wording did not clearly reflect what was intended. It has been changed to make it clearer.

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						and should be removed, wherever it appears in the document.	
SH	25% M.E. Group	15	NICE	6	8	“…acknowledge the reality and impact of the condition” – this seems to indicate that the patient needs to be reassured that people believe their condition is real.	The Guideline Development Group wished to encourage a sympathetic approach to managing the condition.
SH	25% M.E. Group	16	NICE	7	9	“excessive fatigue” – needs defining–it’s not clear if this is mental or physical. Suggest replace ‘excessive fatigue’ with ‘severe post-exertional fatigue’.	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.
SH	25% M.E. Group	17	NICE	7	11	“Risk of prolonged bed rest …” In acute phase of the illness especially, this may be absolutely necessary. ‘Patient survey results invariably show that	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.

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						patients find bed rest helpful (89% of 2426 patients in 4 surveys done for the CMO's Working Group)'.	
SH	25% M.E. Group	18	NICE	8		Object to 'when an adult or child's main goal is to return to normal activities' This is insulting and implies that we may not wish to return to 'normal' Also object to 'it is not known how much improvement is important for patients with CFS/ME' for the same reason [p38 4.4]	Noted. This was not the intention and has been revised.
SH	25% M.E. Group	19	NICE	9	[1.1.1.1]	Approve 'be aware that all adults and children with CFS/ME have the right to refuse any component of care without detriment to	Noted with thanks.

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						the provision of other aspects of care' but would prefer 'without detriment' so that his would hopefully include benefits etc.	
SH	25% M.E. Group	20	NICE	9	18 1.1.1.1	We're not convinced that they *could* provide an aetiological explanation. Especially as the guidelines suggest that aetiology isn't properly understood!	Agreed and changed.
SH	25% M.E. Group	21	NICE	10	[1.1.1.2]	I question how many skilled and expert healthcare professionals there are for ME/CFS.	Noted.
SH	25% M.E. Group	22	NICE	10	3	Refusal of the care plan should not affect welfare benefits etc. and homehelps (carers) either. The care plan is based on GET & CBT. This is disputed as effective treatment and seen by	The guideline emphasises the patients' involvement with care.

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						many as potentially harmful.	
SH	25% M.E. Group	23	NICE	11	[1.1.3.6]	I am very concerned about the inclusion of work related rehab and advice in a health guideline (ie. NHS Plus booklets (Guidelines) on Occupational Aspects of CFS ….?) These links are already in place in our CNCC area and I feel they put both clinicians and patients under pressure to achieve 'positive' outcomes. These measures are in my opinion political and have no place in a health guideline.	The view of the Guideline Development Group is that generally people want to return to their previous activities. While recognising that this will not be possible for everyone, it is part of the management plan of those who are able.
SH	25% M.E. Group	24	NICE	12	[1.2]	The diagnostic criteria are much too broad for ME/CFS. A prevalence of 0.2-0.4% but this figure would be much higher	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						using these criteria. No mention of sub groups. No good saying CFS/ME is heterogeous and then treating them all the same.	
SH	25% M.E. Group	25	NICE	13	1.2.1.2	Diagnostic criteria have been further broadened here. Ref: Canadian Guidelines, (to which there appears to be no reference in "NICE" version)? Crucially "New Onset" also appears to be missing?	Wording as been changed to reflect this comment.
SH	25% M.E. Group	26	NICE	13	1.2.1.1 Line 3	'CFS/ME is recognised on clinical grounds alone.' There is good evidence to suggest that ME/CFS CAN be recognised from a characteristic constellation of abnormal lab data – IF	The Guideline Development Group did not find evidence that CFS/ME could be diagnosed by a series of tests.

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						the correct tests are carried out. (Ref Jacob Teitelbaum's work on lab testing).	
SH	25% M.E. Group	27	NICE	13	19	'lymph nodes painful not enlarged' – as EBV may cause enlarged lymph nodes – so are we then to conclude that EBV is excluded as a causative factor of ME/CFS? (See comment below P16)	Wording has been clarified.
SH	25% M.E. Group	28	NICE	14	1.2.1.8	We're not convinced it would be possible, or necessary, for ME/CFS patients to receive a mental health assessment within the 4 months that a diagnosis should be made in. These services already seem to be hard-pressed, with long waiting lists.	Any implementation issues regarding recommendations will be raised with the NICE implementation team.
SH	25% M.E. Group	29	NICE	14	Line 3,	This suggests that ME/CFS	This is not a comprehensive list of

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					1.2.1.4	is not a serious disease! In severe cases ME/CFS DOES produce 'abnormal neurological signs'. There may be significant overlap with all of the following and in addition to those listed, investigations and screening should also be carried out to exclude: Addison's Disease, Hypothyroidism, Multiple Sclerosis, Lyme Disease/ Borreliosis, Fybromyalgia, Sarcoidosis, Lupus, Hughes Syndrome and Parvovirus infection.	alternative diagnoses. The Guideline Development Group's view was that there were a very large number of illnesses that could be considered. As the guideline cannot be a medical textbook, there was a concern about mentioning only a handful. We have clarified this section, which is included to ensure that patients in need of urgent medical treatment receive it.
SH	25% M.E. Group	30	NICE	16	1.2.2.3	It seems very odd to suggest that EBV should not be routinely tested for when this is widely acknowledged to be one of	Testing is only not recommended when there is no indication of that the individual previously had an infection as, without an indicative history, this is extremely unlikely according to statistics.

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						the precipitating causes of ME/CFS? A patient may have been an asymptomatic carrier for many years. There is also documented evidence to that EBV can initiate neurological damage. Viral tests should also be carried out for Coxsackie B,& RNase L for which there is good evidence that these might also help to validate the diagnosis, confirm an organic origin, and may help discriminate ME/CFS from other illnesses.	Therefore patients who have had symptoms of an infection will be appropriately tested.
SH	25% M.E. Group	31	NICE	18	1.3.1.3 Line 3	'WHEN the adults goal …' See comment for page 6. This is offensive & should be removed.	This wording did not clearly reflect what was intended. It has been changed to make it clearer.

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SH	25% M.E. Group	32	NICE	18	[1.3.1.3]	I would not consider CBT and GET to be the first choice for patients wishing to return to normal activities. I can see no evidence for this being justifiable. If it were so then PWME would not be ill for many years. In all surveys we have done [including one with the CNCC] CBT and GET were found to be the least favoured, least requested and least helpful therapies. Many people also reported being harmed by these therapies Activity management doesn’t seem to be very different from GET?	The Guideline Development Group found good research evidence for improvements with CBT and GET.

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SH	25% M.E. Group	33	NICE	19	[1.3.1.9]	Management programmes delivered by practitioners with no experience in the condition' Agree totally – but who is monitoring this?	This would be an issue for the professional bodies and appropriate audit. We have also fed this back to the Implementation team.
SH	25% M.E. Group	34	NICE	19	[1.3.1.10]	Disagree totally with both these statements. Patient evidence proves otherwise. There is a great deal of rhetoric about listening to the patients, yet we are ignored and so is our often substantial experience. There is a great deal of evidence (albeit anecdotal) from patients that this approach works. There is not experimental evidence because the research has not been done. This does not mean this can be discounted. Our evidence	There are the general risks and deleterious effects of bedrest such as DVTs, chest infections, muscle wastage, etc., which should be avoided if possible.

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						is constantly discounted. There is no evidence to suggest this approach does not work and no evidence to suggest deconditioning is a major problem. Yet it is constantly being assumed that these things are true. This is offensive and patronising to patients. For me, and many others, this approach was the one that really did and does work and I have yet to meet someone with ME/CFS that it has not helped. Lack of rest is detrimental. The need to rest is determined by listening to the body, not the programme.	
SH	25% M.E. Group	35	NICE	20	[1.3.1.12 and 13]	The CBT programme seems focused on illness beliefs and perpetuating	These sections have been revised.

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						factors. Is there any evidence for 'fear of activity' and 'perfectionist beliefs'? This is opinion and not fact.	
SH	25% M.E. Group	36	NICE	21	1.3.1.13 (Lines 4–5)	To talk about 'symptom over-vigilance' is offensive and should be removed. Does this appear in the M.S. NICEguidelines?	The wording has been changed as a result of the consultation.
SH	25% M.E. Group	37	NICE	21	Line 4	'decreasing somatic attributions' and address symptom over vigilance …' This is offensive and based upon misguided opinion rather than evidence.	The wording has been changed as a result of the consultation.
SH	25% M.E. Group	38	NICE	21	1.3.1.14	It is wrong to try and prescribe for mild & "moderately" affected in the same way. There may be a world of difference. Also, as mentioned previously, how many people that were	The emphasis is on an individual programme based on the person's situation and symptoms. There is a great deal of detail on other recommendations on the development of the programme.

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						once mildly/moderately affected have become severely affected due to inappropriate prescribing of GET?	
SH	25% M.E. Group	39	NICE	22	1.3.1.15 Line 5	“How (&who) would explain the symptoms and “benefits of exercise in a physiological context “? The illness is not sufficiently well understood! There are certainly too few experts within the NHS.	As with all treatments a full explanation should be offered by the healthcare professional with experience of CFS/ME.
SH	25% M.E. Group	40	NICE	22	1.3.1.16 Lines 12–13	Whilst we realise that this *may* be the (or an) ‘ultimate goal’: Many will find advocating a “daily brisk walk” … and CYCLING for “moderately affected”, an utterly absurd thing to suggest, and potentially very dangerous. This is the	The recommendations have been revised and expanded to reflect this and other concerns.

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						sort of poor quality and inappropriate advice that has made people severely affected, who were not so previously.	
SH	25% M.E. Group	41	NICE	23	1.3.1.18	Those with properly diagnosed M.E. DO NOT experience normal stiffness/fatigue; it is one of the defining characteristics of the illness as described by Dr Melvin Ramsay. Many previously fit & active people with this illness know exactly what it is like to experience normal muscle fatigue response to exercise and IT IS NOT THE SAME. [A. Melvin Ramsay. Myalgic Encephalomyelitis and Postviral Fatigue States: The Sage of Royal Free	This recommendation has been revised to reflect concerns.

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						disease. 2nd edition. Gower Medical Publishing, London 1988. See http://www.cfs-news.org/me.htm]	
SH	25% M.E. Group	42	NICE	23	1.3.1.19	'IF the patient would like to progress!' What other goal would there be! See comment for page 6. (Line 1) This should be removed. It is offensive.	This refers to the patient progressing *further.* Different individuals will have different activity goals, all may not want to progress their activity beyond their GET goals.
SH	25% M.E. Group	43	NICE	23	1.3.1.20	'Deconditioning and withdrawal from activity' is much less relevant to ME/CFS than is being presented here – the risks of exacerbating the illness through over-exertion is more likely.	This recommendation has been revised to reflect concerns. However the Guideline Development Group wished to reflect the general risks and deleterious effects of bedrest such as DVTs, chest infections, muscle wastage, etc., which should be avoided if possible.
SH	25% M.E. Group	44	NICE	26	1.3.2.1	As mentioned above, during the acute phase of the illness "excessive sleep" may be exactly what	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.

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						is required?!" It is the body's natural way of trying to regain homeostasis, i.e. recover from an infection or injury etc.	
SH	25% M.E. Group	45	NICE	27	1.3.2.2 (Line 17)	'Excessive alcohol' -This gives real cause for concern that we might not actually be talking about the same illness here?! Most people with ME/CFS cannot tolerate alcohol AT ALL. Ref paper by Woolley, Allen & Wessely (2003).	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.
SH	25% M.E. Group	46	NICE	30	1.3.3.5 Line 27	'A GET programme should be delivered by an appropriately trained professional with experience of GET with CFS/ME' – As above, there are very few of those.	This comment will be referred to the NICE implementation team.
SH	25% M.E. Group	47	NICE	31	1.3.4.4	Thyroid hormone may	This may be part of an individual

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						occur, thus causing the patient to appear eurthyroid or hypothyroid on lab data, when clinically hypothyroid due to tissue insensitivity. Comprehensive thyroid function tests should be done to reveal any problems. Thyroid functioning is a highly complex process, but vitally important in proper metabolic functioning of the body.	management strategy. The Guideline Development Group has recommended that investigations and diagnosis are regularly reviewed in CFS/ME, and that investigations are repeated if there is no improvement, particularly in the severely affected.
SH	25% M.E. Group	48	NICE	32	1.3.5	As mentioned previously, with so many people with ME/CFS experiencing food intolerances /digestive problems, sometimes acute, it is hard to believe that this is all these guidelines are going to say about diet/nutrition.	Managing food intolerances was beyond the scope of the guideline. The guideline now cross-refers to the NICE IBS guideline, which has more in depth guidance on this matter.

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						A number of people with ME/CFS have found an exclusion diet to be an important part of their treatment protocol. There appears to be no mention of the importance of good fluid intake? Also no mention of appropriate symptom control for nausea.	General dietary advice and advice for nausea is now given.
SH	25% M.E. Group	49	NICE	33	1.3.6	The guidelines are unacceptably dismissive of complementary therapies. There appears to be plenty of evidence that they may help with treating symptoms of ME/CFS.	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS.

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						(Because of the individual nature of treatment, it may never be possible to carry out RCTs to test this, in a way that would be acceptable to NICE, even if sufficient funding was forthcoming.) A number of people with ME/CFS are reporting improvements on EPA/Omega-3 supplements. There is also some evidence to suggest that B12 & magnesium may also have a role to play in some patients.	The Guideline Development Group found insufficient evidence to recommend nutritional supplements routinely. It is acknowledged, however, that some individuals may find these approaches helpful.
SH	25% M.E. Group	50	NICE	34	1.4 .1.1	It is not clear exactly how the severely affected would access “the same diagnostic and therapeutic options”–even if they wanted to!	The intention of Recommendation 1.4.1.1 is to make it clear that those who are severely affected should have treatment regardless of whether they can get to hospital or clinic. The wording has been revised to make this clear.

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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SH	25% M.E. Group	51	NICE	34	1.4.1.3	We do not believe, or accept, that "GET may be an appropriate addition …" for the severely affected.	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or

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							gentle stretches, informed by the principles of GET.
SH	25% M.E. Group	52	NICE	37	4.1	If there is no evidence to suggest that GET/CBT is effective in severely affected adults & children then why is it even being mentioned in this context?	To encourage research in this area.
SH	25% M.E. Group	53	NICE	38	4.4	'It is not known how much improvement is important for patients with CFS/ME.' This in an incredible (and perhaps very telling) statement to make–it suggests that we do not know the best way of measuring outcomes in research studies, yet CBT & GET are put forward with a degree of certainty that we do not have.	This question could be asked of most serious chronic illnesses. In studies on hip replacement, there are disputes about whether the better outcome is being able to walk again without pain or that the x-ray shows a good placement of the device. In looking at the CFS/ME research, there were a wide variety of outcomes with little indication of their relative benefits.
SH	Action for ME	86	NICE	1		It would be helpful to insert the word 'physical' into the	This has been revised.

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						first sentence and to add that it is defined by WHO and classified by the Department of Health as a long-term neurological condition.	
SH	Action for ME	87	NICE	3		"CBT is an evidence-based treatment…." We have already commented on concerns r. the level of research evidence available and the importance of noting that this statement is true within the current research situation.	The evidence supports the use of CBT. However, we have recommended that the preference and needs of the individual should be taken into account.
SH	Action for ME	88	NICE	6	Bullet point 1	We have already mentioned concerns re. the phrase 'therapies of first choice'. M.E./CFS is not a 'one size fits all' illness.	This wording did not clearly reflect what was intended and has been changed to make it clearer.
SH	Action for ME	89	NICE	6	Bullet point	Comments regarding	Noted. This a key principle throughout.

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					2	shared decision-making are welcome but it would be appropriate to add that patients are in control of goals and pace of management programmes. This is so important it must be reiterated whenever necessary.	
SH	Action for ME	90	NICE	7	Bullet 5	"When an acute infection is followed by…". As so many of our constituents have a problem with pain management this should be included as a requirement for special focus.	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.
SH	Action for ME	91	NICE	7	Bullet 7	"Referral to specialist care should be based on needs and symptoms…" An acknowledgement of the limited geographical spread and the vulnerability of the	Noted with thanks. These will be referred to the NICE implementation team.

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						specialist services is made in the full guidelines but not in the NICEguidelines. What can the primary healthcare worker do if there are no services in their area or they cannot refer out?	
SH	Action for ME	92	NICE	7, 8	Bullet 8	"In the absence of a specialist diagnosis..." Who will provide this advice and symptom management? There is concern regarding the level of expertise amongst GPs and other primary healthcare providers.	We have revised this. The intention is to ensure that people get appropriate symptom management early in the pathway.
SH	Action for ME	93	NICE	9		The statement regarding the patient being in charge of their goals and pace of treatment should be included under General Principles of Care.	Added.

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SH	Action for ME	94	NICE	10	1.1.1.2	Again, appropriate skill and expertise needs to be clarified.	The guideline has provided some information on competencies, but detailed work should be undertaken by local commissioners and by the professional organisations to ensure the skills and expertise of healthcare professionals.
SH	Action for ME	95	NICE	10	1.1.2.2	This comment re. continuity of care is welcomed.	Noted with thanks.
SH	Action for ME	96	NICE	11	1.1.3.5/6	Concern has been expressed in relation to how any refusal of a management component may be used in relation to employers or benefits. It should also be noted that the healthcare professional needs to properly understand the illness and its impact on daily life and take the patient view into account.	One of the aims of the guideline is to raise awareness of the condition and its impact and it does specify the involvement of patients.
SH	Action for ME	97	NICE	12	1.1.1.4	Particularly welcome here is support negotiating the	Noted with thanks.

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						healthcare, benefits and social services systems.	
SH	Action for ME	98	NICE	12	1.1.4.4	The listing under a line referring to it as a support that 'should be considered' is inappropriate and contradicts a key recommendation that all those with M.E./CFS should have equity of access to treatment.	1.1.4.4 The wording has been changed to reflect this comment.
SH	Action for ME	99	NICE	13	1.2.1.2	There is significant concern that primary healthcare professionals are not familiar with the presenting features of M.E./CFS.	One of the aims of the guideline is to raise awareness of presenting symptoms.
SH	Action for ME	100	NICE	14	1.2.1.7	A timeframe relating to this discussion with a specialist should be provided? There are also resource issues to be considered here.	The Guideline Development Group wishes to encourage discussion where there is concern at any time. Timescales for referral are given later.
SH	Action for ME	101	NICE	15	1.2.11	Reference to the patient being in control of goals	This is overarching advice given at the beginning of the guideline. We have tried

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						and timeframe, as per our previous comments.	to make it clearer that this applies throughout the guideline. The view of the Guideline Development Group is that is would make the document excessively wording to repeat it with every recommendation.
SH	Action for ME	102	NICE	16	1.2.3.3	A prognosis of cautious optimism was Generally welcomed. However, it should be noted that when we asked respondents to our survey to indicate which definition they agreed with–'People with M.E. can go into remission' OR 'people with M.E. can recover'–84.1% considered 'remission' the more accurate description (comments have already been made regarding the disparity between this section and the full	This has been reworded based on your comment.

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						guidelines).	
SH	Action for ME	103	NICE	17	1.2.4	This recommendation was welcomed but people wondered if it would be possible to implement, given lack of resources. Our survey showed that 76.8% strongly disagreed and 12.9% disagreed with the statement that there are sufficient specialist services available.	Any implementation issues regarding recommendations will be raised with the NICE implementation team.
SH	Action for ME	104	NICE	17	1.2.4.3	While clarification of waiting times for a referral have Generally been welcomed, a concern has been raised. A GP may wait the recommended time for the referral but then an additional wait is required to see a specialist, which could exacerbate diagnosis in a condition where early	The Guideline Development Group was clear that the management of symptoms should start early and in primary care. The guideline has been restructured to make this clearer.

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						diagnosis can be crucial. It is important that treatment is provided as soon as possible within the primary care setting (See also Action for M.E.’s ‘Guidance on the management of M.E./CFS’).	
SH	Action for ME	105	NICE	17	1.3.1	Much of this section is welcome but 1.1.1.3 is not. CBT is not necessarily the first choice of people with even mild or moderate M.E./CFS (although we would not argue that many would gain benefits from it).	This recommendation has been re-worded to make the meaning clearer.
SH	Action for ME	106	NICE	19	1.3.1.11	A clearer understanding of CBT would be provided if comments re. the research context were provided.	This is provided in the full guideline.
SH	Action for ME	107	NICE	19	1.3.1.10	General feedback which we	The The wording has been revised to

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						have received via our survey indicates that this statement is regarded as particularly contentious when it has been compared to the overall lack of research data and clear evidence.	reflect patient views.
SH	Action for ME	108	NICE	21	Bullet 2	Many of our constituents were extremely disturbed by the phrase "somatic attributions and symptoms over-vigilance," which is regarded as patronising and ignores the patient voice. An expressed concern for over-exertion is understandable given how some with this illness have been affected by exercise regimes. Though we	The wording has been changed as a result of the consultation.

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						understand the necessity of moving people away from self-limiting beliefs, this statement could be better expressed.	
SH	Action for ME	109	NICE	23	1.3.1. 20	Constituents have noted that both guidelines have a dominant tone emphasising the need for exercise and to challenge patients' fear of it. Many people over extend themselves and yet there is only one reference to it (P20 1.3.1.3). This imbalance in the document could lead to misinterpretation.	The recommendations have been revised and expanded to reflect concerns.
SH	Action for ME	110	NICE	23	1.3.1.21	The guidelines need to clarify what sort of support might be made available to enable the patient to reinforce learning and lifestyle changes.	This has been revised.

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SH	Action for ME	111	NICE	31	1.3.4	Pharmacological interventions should include some reference to helping with pain and offer a toolkit or portfolio of interventions to suit patient needs.	Referral to a pain management clinic has now been added as an option. The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. Where the management of symptoms is the same as that of people who do not have CFS/ME it is not addressed. The Guideline Development Group did not have the time or remit to write a guideline on each symptom.
SH	Action for ME	112	NICE	31	1.3.4.4	The warning re. lower tolerance and potential impact of medication is welcomed.	The Guideline Development Group was concerned about sub-optimal doses being prescribed that would not benefit the patient. As an in-depth search of the literature yielded no evidence for greater intolerance, this recommendation has been redrafted as part of an individual management strategy.

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SH	Action for ME	113	NICE	33	1.3.6	While there is little available research into complementary medicine or the benefits of supplements, a number of constituents feel they have derived benefits from both. Research is needed in this area and more detailed information on balancing individual benefits and cost. In our survey, 53% of respondents found a complementary therapy useful in managing M.E./CFS.	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS. It is acknowledged, however, that some individuals may find these approaches helpful.
SH	Action for ME	114	NICE	33	1.3.6.2	How this could link into specialist clinics should be considered. Patient feedback at individual clinics, in relation to this issue, should be	This comment will be referred to the NICE implementation team.

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						considered.	
SH	Action for ME	115	NICE	35		Summary of each consultation: this would be best practice, whatever the degree of severity.	Noted, but the Guideline Development Group did not think that it would be generally necessary for all mild/moderate patients.
SH	Action for ME	116	NICE	37	4	The research recommendations are not to be found in section 5 of the full guidelines.	They will be added.
SH	Action for ME	117	NICE	36–37		The implementation process was outlined during the NICEImplementation Planning Meeting. A number of issues were raised relating to the need for tailored information for a variety of audiences. Unfortunately, this useful discussion was not reported in any detail in relation to the feedback notes, as certain comments	Noted with thanks. This will be referred to the NICE implementation team.

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						raised would have been useful in making further comment on this section.	
SH	Association for Psychoanalytic Psychotherapy in the NHS (APP)	9	NICE	General		as there is no evidence that CBT has better outcomes than any other psychological therapy (eg. counselling, psychotherapy) and some evidence from RCT studies of the opposite–it is highly misleading for this to be the main recommendation, as well as contradictory of the two following recommendations (page 6) which emphaises individual patient choice and preference; it is also disappointing that this is not included as a research recommendation–both a need for relative efficacy	The evidence supports the use of CBT. However, we have recommended that the preference and needs of the individual should be taken into account. Please refer to the evidence review. There was no evidence on the effectiveness of counselling for people with CFS/ME.

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						studies of different psychological therapies, plus a study of whether patient preference is the key variable related to better outcomes for patients with CFS	
SH	Association of British Neurologists	8	NICE	28–29		Why there is no research recommendation on biomarkers and brain imaging (MR Spectroscopy or functional MRI) in CFS/ME which would allow objectivity in the diagnosis and treatment outcome?	The research on biomarkers and brain-imaging reviewed by the Guideline Development Group was unconvincing and we did not find any research avenue in this field which merited special attention at present.
SH	BRAME Blue Ribbon for the Awareness of ME	262	NICE	37–39	4	Where are the recommendations for bio-medical research into the aetiology and pathogenesis of ME/CFS?	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope of the guideline.
SH	BRAME Blue Ribbon for the Awareness of ME	263	NICE	37	4.1	Patient evidence has already shown that CBT and GET are not suitable	The Guideline Development Group identified these areas as the most important in informing updates of the

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						for the severely affected and children. To put these vulnerable groups through damaging research trials, is irresponsible and unethical. If you read the bio-medical evidence we have included in this response you will see that you are playing Russian Roulette with patient's lives.	guideline. The Guideline Development Group does not commission research and the protocol would be subject to the same rigour as any research study.
SH	BRAME Blue Ribbon for the Awareness of ME	264	NICE	38	4.2	CBT is not effective, therefore whatever format it takes the form of, it will not be cost effective – so why waste money that is vitally needed into the bio-medical research on something that patients say does not help them?	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope of the guideline.
SH	BRAME Blue Ribbon for the Awareness of ME	265	NICE	General		The NICE guidelines do not contain so much important information eg. that there is	The NICE guidelines are not intended to have the detailed background information but to list the recommendations.

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						no cure, and that CBT and GET are not cures, and only suitable for some patients – although we feel that they are not suitable for this illness. There is no comprehensive information on prognosis, in particular that the CDC state that only 5-10% achieve remission. Considering that the only real description of the illness is found in the patient evidence section – and this is missing from the NICE document. How are doctors to learn about the real illness? There is also large sections describing the life of the severely	

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						affected which would helpful to be included in the NICE document.	
SH	British Dietetic Association	6	NICE	32	19–24	The importance of regular eating, especially slow release starchy foods, needs to be emphasised, also the physiological consequences of not doing so.	Acknowledged. The recommendation has been changed accordingly.
SH	British Dietetic Association	7	NICE	33	19–28	As there is growing evidence around the importance of vitamin D for all patients, we feel this should be included in this section. A routine supplement of 10mcg Vit D is suggested as sensible for all patients due to it’s importance in immune function and prevention of osteoporosis.	The Guideline Development Group found insufficient evidence to recommend nutritional supplements routinely. It is acknowledged, however, that some individuals may find them helpful.
SH	British Dietetic Association	8	NICE	33	3–9	Many patients experience	This section has been substantially

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						food intolerances and find a clinically supervised exclusion diet a helpful tool in identifying those symptoms (not just bowel symptoms) which may be related to foods. We feel that this should be reflected here.	revised.
SH	British Dietetic Association	9	NICE	1.3.5		People with ME/CFS are very interested in dietary approaches and are going to ask questions about what may or may not be helpful. They clearly need straightforward and sensible advice that covers a wide area of dietary management, along with advice on the vitamins, minerals and supplements that are extensively used and recommended to	Thank you. Further advice has been added to the guideline.

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						people with ME/CFS.	
SH	British Dietetic Association	10	NICE	1.35		There is a lack of information about the reasons why some people (especially those with self-imposed dietary restrictions) with ME/CFS could be at increased risk of developing osteoporosis and how diet may be relevant here e.g. There is no mention of the value of complex carbohydrates in helping to stabilise blood sugar levels or of the importance of a good fluid intake which is especially important in relation to those who have postural hypotension or orthostatic intolerance. There is no mention of simple self-help approaches that can help in	Thank you. General advice has been added on self-management approaches, but detailed pharmaceutical management of nausea is beyond the scope of the guideline.

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						the management of nausea (eg use of ginger) or the use of drugs such as ondansetron if more severe? There is no discussion on the use of EPA supplements which are probably the most popular supplement currently being used by people with ME/CFS. It is unhelpful to simply state that 'Exclusion diets are not Generally recommended for the management of CFS/ME' when irritable bowel symptomatology is quite common in this illness and there is good evidence to	

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						show that exclusion diets can be helpful in identifying food intolerances where these occur in IBS. We suggest that this section should also include advice about not going on a gluten-free diet before a screening test for coeliac disease has been carried out.	
SH	British Infection Society	2	NICE	16	1.2.2.3	2nd line tests should include autoimmune serology	We have listed those considered appropriate, but as always clinical judgement should be used.
SH	British Infection Society	3	NICE	32	1.3.4.9	There should not be inappropriate use of antibiotics as well as antiviral agents	Noted. Clearly there should not be inappropriate use of any medication. The most common drugs that may be used to treat this condition are listed.
SH	British Infection Society	4	NICE	16	1.2.2.3	Laboratory tests should be conducted at recognised accredited laboratories	This is true of all laboratory tests and not confined solely to the management of CFS/ME.
SH	British Paediatric Mental Health	6	NICE	1.31		We agree that the child has	We agree and have added a brief

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	Group of the Royal College of Paediatrics and Child Health					the right to refuse treatment if they are old enough to understand. However, if the medical practitioner feels that the child and family no longer have trust in them, then a second opinion should be sought as working closely together with the family is of great importance. If any practitioner has concerns about child protection issues, as with any child, this should be taken forward by the usual route (Working Together: 2006)	paragraph on this in Chapter 7.
SH	Cambridgeshire Neurological Alliance	26	NICE	26	All	"Clinical care pathways" It clearly states "Management for children who are severally affected should follow the same	The Guideline Development Group recognises the devastating symptoms of children and adults who are severely affected. The guideline promotes an individualised approach. It is promoting care in the home when patients are

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						principles as for those are mildly/moderately affected" ➢ According to the NICEdefinition of CFS/ME Mild/moderate/severe. You will see the symptoms and ability to function varies widely. Therefore, much consideration has to be afforded those affected severally and very severally. NICEappears to understand the wide gap between "mild CFS/ME" and Severe, yet	unable to travel to hospital.

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						promotes a harsh "programme" of "CBT" and "GET" for children with severe/very severe CFS/ME with its stance on "the individually tailored programme may be delivered at home (and/or by telephone if appropriate). ➢ NICEcannot and does understand the profound exhaustion (forget "Fatigue") that this group of CFS/ME people experience. ➢ To hold a telephone at all for these severally affected CFS/ME children	

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						will be impossible, due to physical exhaustions and muscles and joint pain, not to mention, feeling very unwell. ➢ It is noted NICE wish to "adopt" the same principles of "treatment" for the severally affected as for the moderate and mild cases.	
SH	Cambridgeshire Neurological Alliance	27	NICE	28	All	"Are current intervention strategies that have been shown to be effective in mild to moderately affected adults effective in a) children b) those who are	This recommendation has been substantially revised based on feedback in the consultation. This is the shortened version of the guideline; the evidence is in the longer

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						severally affected (adults and children). ➢ NICEshould consider revising this paragraph as appears to "skate" over the real issues surrounding "evidence" and "effectiveness". ➢ It is noted "Patient experience suggests that some "of these interventions may be harmful and/or not effective". ➢ "GET/CBT/ET" according to much research, are collectively, ranked as one of the very	one. The GDG recognises that there is a great deal of confusion about terminology. The term GET has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity

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						treatments that we can protest about, as they have caused harm.	activity, which may be sitting-up in bed or gentle stretches.
SH	Cambridgeshire Neurological Alliance	35	NICE			"Spatial disorientation" is a key symptom of CFS/M.E. along with difficulty with judging distance and cannot be rules out, as NICE appears to have done so. Anther common symptom affected the eyesight can be blurred-double vision.	Without a page number is it difficult to know to what you refer. We accept that a person with CFS/ME may experience a wide variety of symptoms. The Guideline does not attempt to list all of these but only those that would help to distinguish the condition from others.
SH	Cambridgeshire Neurological Alliance	36	NICE			"Sleep apnoea": Again, this cannot be ruled out by NICEas being "separate" from CFS/M.E. Sleep disturbance and reverse sleep pattern is another hallmark of CFS/M.E., due to neurotransmitter	See comment above. The section on red flags has been reworded to make clear that this is not about ruling out CFS but not ignoring symptoms that may indicate another acutely life-threatening condition.

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						disruption. However, we agree that this should be investigated, so any treatment can be accessed.	
SH	Cambridgeshire Neurological Alliance	37	NICE			"History and Exanimation"	Noted with thanks.
SH	Cambridgeshire Neurological Alliance	38	NICE			We agree with the view of the GDG in that "the individual doing the examination should have competencies in the recognition of CFS/ME". However, the truth of the matter is that many of those who do diagnose "CF/ME" are not "competent" in this diagnosis. Years later on seeing a Specialist, the diagnosis can be changed Lupus, a tick borne illness, to name a few. Others, insist "CFS/ME" does not exist, or the person is	The publication and implementation of a national guideline on CFS/ME with the accompanying document 'Understanding NICE guidance' will raise awareness of the condition and give both patients and healthcare professionals access to information on recognising and managing CFS/ME. Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.

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						"clinically depressed", severally mentally ill, which comes with the increased risk of being Sectioned under the Mental Health Act.	
SH	Cambridgeshire Neurological Alliance	39	NICE			We were not surprised to read "no evidence was found regarding referral to specialist care", as this is rarely carried out and in the cases that are, often wait many months and then, to find out they need to travel several hundred miles to access such.	Noted.
SH	Cambridgeshire Neurological Alliance	40	NICE	11	4	11 4. "Treatment is provided by the NHS in the context of availability of adequate numbers of competent, appropriately trained health care professionals" There are	The publication and implementation of a national guideline on CFS/ME with the accompanying document 'Understanding NICE guidance' will raise awareness of the condition and give both patients and healthcare professionals access to information on recognising and managing

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						very few "competent, appropriately trained health care professionals" which is why CFS/ME continues to be seen as a mental health issue, or just simply overlooked and misdiagnosed.	CFS/ME. Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.
SH	Cambridgeshire Neurological Alliance	41	NICE			People with M.E. like other patients, have a right to see a Specialist in the field of F/ME. And not left, as they currently are, in thousands of case, where even 20 years into the illness they have yet to have received a referral to a CFS/ME Specialist – this does not happen in any other neurological condition. All patients with moderate,	The publication and implementation of a national guideline on CFS/ME with the accompanying document 'Understanding NICE guidance' will raise awareness of the condition and give both patients and healthcare professionals access to information on recognising and managing CFS/ME. Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.

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						in particularly the severe and very severe CFS/ME cases should have seen a Specialist and received an agreed follow-up consultation/s. This should be in relation to children, young people and adults with suspected, or already diagnoses of CFS/ME.	
SH	Cambridgeshire Neurological Alliance	42	NICE			“5.4.6 Deriving Recommendations”. Although the DG “found no research evidence on criteria for or timing of referral to specialist CFS/ME care,” we would insist that such is carried out. This will highlight the horrendous gap in services, service provision, service commissioning and other	The publication and implementation of a national guideline on CFS/ME with the accompanying document ‘Understanding NICE guidance’ will raise awareness of the condition and give both patients and healthcare professionals access to information on recognising and managing CFS/ME. Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.

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						areas where CFS/ME has been a "Cinderella Syndrome" for far too long and is still very much so, in many PCT and NHS health authorities. Children must also be seen by competent, trained professional and not just "General paediatricians as this risks a misunderstanding of CFS/ME and an inappropriate diagnosis, treatment, education plan, and outcome for the child/young person and parents.	
SH	Cambridgeshire Neurological Alliance	43	NICE			We note from page 133 to 136 that only "CFS" is referred to. This must be reviewed and "CFS/ME" stated where appropriate.	Noted with thanks and corrected.
SH	Cambridgeshire Neurological Alliance	44	NICE			In areas of "management"	The guideline states that professionals

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						in CFS/ME it is crucial that the service involve actually understand CFS/ME and its impact on the person and family. Otherwise, inappropriate advice, management, information recorded, benefits etc risk becoming skewed and the CFS/ME patient being mismanaged.	should understand the condition and work with the family.
SH	Cambridgeshire Neurological Alliance	45	NICE			We agree with the GSG in that the "patients should take the lead on any behavioural approaches to manage their CF/ME" and not feel they are being "pushed" into any treatment plan other than what they feel is appropriate to their needs and should feel confident to say "no" without feeling risk to their	Noted with thanks.

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						benefits or health services accessed or provisions.	
SH	Cambridgeshire Neurological Alliance	46	NICE			"Brisk walks" are fine for healthy people and those who need to "get into gear". However, CFS/ME DOES NOT fit into either category. CFS/ME patients must be able to feel they can say "no" and make an appropriate request and comment in terms of if they feel the "health team" are "not listening" to them, without fear of loss of benefits and health services. Service Providers must always be mindful that they may not always be right, or get it right and they must listen to the person with	The detailed advice given in the guideline is to ensure that this is not the case.

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						CFS/ME and their families.	
SH	Cambridgeshire Neurological Alliance	47	NICE			If NICEis going to continue to support and promote GET/CBT/ET for CFS/ME then it risks not only a huge disservice to people affected by CFS/ME and their families. But, they also risks putting the "wrong power" into service providers hands, with the increased risk of "Litigation". NICEtherefore, must tread with caution, in areas it feels GET/CBT/ET is the answer to CFS/ME. Because, it is treading on thin ice already, in its approach that those therapies are a "cure" or even "treatment" – they are neither.	This section has been revised to make the advice clearer. In addition, it has been made clearer that patients may refuse treatment should they wish. The issues you raise are implementation issues and we will bring these to the attention of the implementation team.

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						Nor can NICEfeel that with the "promise" of additional millions of pounds into these "therapies" that they have found the answer. They have not, because where are all the appropriately trained service providers coming from and the trainers to train them, the time frames, waiting lists? NICEmust see that their "wish list" is light years away from reality in terms of appropriate CFS/ME services, provision, commissioning, implementation, or even their vision on this.	

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						NICEsimply cannot, or should not carry ahead and attempt this Draft CFS/ME Guideline to go further. It must go back to the Drawing Board and ensure it has the correct and appropriate information, research, evidence, patients and vested interests, before attempting the next Draft on this Guideline.	
SH	College of Occupational Therapists	84	NICE	3	Definitions	Same comments as for full.	Noted.
SH	College of Occupational Therapists	85	NICE	3	GET	Does the term "self-management" imply it does not need to be facilitated? Especially as the definition goes on the state mutually negotiated meaningful goals.	This section has been substantially revised based on feedback in the consultation.
SH	College of Occupational Therapists	86	NICE	4–5	Severity	These definitions were originally defined by Cox	Noted and added.

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						and Findley. The correct reference is; Cox DL, Findley L (1998) Management of chronic fatigue syndrome in an inpatient setting: presentation of an approach and perceived outcome *British Journal of Occupational Therapy 61:* 405-409. As cited in the 2002 report to the CMO pg. 27 (also published in a single authored paper in April 1998 in British Journal of Therapy & Rehabilitation).	
SH	College of Occupational Therapists	87	NICE	4		The majority will still be working, should also include "/studying".	Noted with thanks.
SH	College of Occupational Therapists	88	NICE	5		Should it be "maybe"	These definitions are based on those

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						wheelchair dependent, as not all are.	used in Chief Medical Officer's report – see guideline for details.
SH	College of Occupational Therapists	89	NICE	6	Order of priorities	Same comments as for FULL.	Noted.
SH	College of Occupational Therapists	90	NICE	6	First para	This paragraph needs clarification. It is not clear that there is not evidence for severe & very severe at present for CBT & GET.	This wording did not clearly reflect what was intended and has been changed to make it clearer.
SH	College of Occupational Therapists	91	NICE	6 18	Third para 1.3.1.6	In some people the initial objective may be to reduce activity levels, as commonly people are pushing too hard on their better days, then look to sustain and increase capacity.	This wording did not clearly reflect what was intended and has been changed to make it clearer.
SH	College of Occupational Therapists	92	NICE	12	Last sentence	Should that be "occupational activities" such as work and school, rather than these being seen as social activities?	Wording has been changed to reflect this comment.

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SH	College of Occupational Therapists	93	NICE	13	1.2.2.1	Not sure the sentence and fourth bullet point make sense–*and characterised by post exertional malaise and/ or fatigue.*	Noted and changed.
SH	College of Occupational Therapists	94	NICE	13		Same comments on diagnosis as for FULL.	Noted.
SH	College of Occupational Therapists	95	NICE	14	1.2.1.7	Who are we defining as a specialist? Many GPs will interpret this as a doctor, whilst there are many AHPs leading in this field. How will a GP be able to locate specialists?	Definitions are given in the glossary. This section has been clarified to make it clear that this recommendation is not about a referral for the management of CFS/ME but regarding concern about symptoms. In this case the advice will be sought from the specialist with the relevant knowledge for the area of concern.
SH	College of Occupational Therapists	96	NICE	18	1.3.1.3.	Is this paragraph clear enough that there is no evidence for severe & very severe at present for CBT & GET?	This has been clarified.
SH	College of Occupational Therapists	97	NICE	19	1.3.1.10	Seems to misrepresent energy envelope approach.	The wording has been revised in response your comment.

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						It is not about reducing or doing less but balancing activity and rest. The current PACE trial is not evaluating doing less but Adapted Pacing Therapy (activity management) which is not the same as the energy envelope theory.	
SH	College of Occupational Therapists	98	NICE		Presentation of therapies	Same comments as for the full in relation to recommending common core elements of therapy.	Noted.
SH	Department of Health, Peninsula Medical School	58	NICE	Overall		This is Generally a fair summary of the full Guideline. In some places, it is in fact clearer.	Noted with thanks.
SH	Department of Health, Peninsula Medical School	59	NICE	Overall		Substantive changes following comments on the full above would need to be reflected in the NICE, of course.	All changes will be made to both documents.

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SH	Department of Health, Peninsula Medical School	60	NICE	3		The glossary does not include all the definitions. These are all needed, including therapy approaches and severity levels.	These have been added.
SH	Department of Health, Peninsula Medical School	61	NICE	4		Severity. These definitions were published by Cox and Findley, who should be credited as the authors, as shown in the Report to CMO.	Noted with thanks.
SH	Department of Health, Peninsula Medical School	62	NICE	6	First bullet point	As above (FULL p21), these need to take their place in the normal order among treatments. Shared decision-making is the best starter, and sets a good tone.	Agreed and changed.
SH	Department of Health, Peninsula Medical School	63	NICE	14	1.2.1.4.	These red flags are not detailed as clearly in the full guideline. Whilst they are clearer and mainly	These have been revised.

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						understood, one neurological sign is commonly positive in CFS/ME, which is a positive Romberg test (often with some nystagmus). I wonder if the phrase should be slightly qualified?	
SH	Department of Health, Peninsula Medical School	64	NICE	16	1.2.2.2	Creatine Kinase. Adults too – see above (Full p95, etc).	Noted and added.
SH	Department of Health, Peninsula Medical School	65	NICE	17	1.2.4.2.	This implies that all such patients should be referred, see detail above. I would recommend adding eg "If diagnosis and/or management plan are unclear or not achieving expected outcomes, specialist referral should be considered."	The view of the Guideline Development Group was that referral should be *offered* to a patient.
SH	Department of Health, Peninsula Medical School	66	NICE	19	1.3.1.10.	See comments above about Envelope Theory	Noted.

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						(full, pp183-4).	
SH	Department of Health, Peninsula Medical School	67	NICE	31	1.3.4.4	High TSH and low thyroxine? See above (full pp 210-2, etc)	Acknowledged. The recommendation has been changed accordingly.
SH	Department of Health, Peninsula Medical School	68	NICE	31	1.3.4.8	"Tricyclic 'antidepressants', such as amitriptyline". Many other agents may be better for individual patients. Also important to convey that it is not their antidepressant role but their effect on sleep that is being used. And, as above, no need to add the phrase about being on SSRIs, as they can be used together, and this may be helpful as SSRIs don't have a direct effect on sleep.	The recommendation states that it may be considered' to indicate that it may be helpful for some patients. It is made clear that it is for sleep and pain. The Guideline Development Group considered that caution is needed when using tricyclics and SSRIs together as there is potential for significant adverse interactions. Whilst low-dose tricyclics are sometimes used with SSRIs, higher doses may cause real problems. Therefore, as a recommendation in a national guideline, the Guideline Development Group were being cautious.
SH	Department of Health, Peninsula Medical School	69	NICE	32	1.3.4.9	Antiviral treatment, unless active infection. See above (222 & 230).	The recommendation makes it clear that this is for the 'management of CFS', not other conditions.
SH	Local ME	2	NICE	Genera		All people with ME/CFS	The guideline recommends regular

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				l		should receive regular check-ups and monitoring by the GPs, with blood tests etc carried out annually–monitoring and collating the findings to assist with biomedical research.	review. Recommending a database of findings is beyond the scope of the guideline.
SH	Local ME	3	NICE	General		ME/CFS should be a notifiable illness–if all GPs had a register of patients, the local services would be able to plan their services, and government departments would know how much help is needed. Research participants could also be selected via GP registers.	NICE guidelines provide advice to NHS healthcare professionals. This is beyond the scope.
SH	Local ME	4	NICE	Cover, 260,and 266	10 Line 32	As many of M.E. Groups do not recognise the term "myalgic encephalopathy", which is not listed by the	The title was agreed at time of the initial scoping phase of the guideline.

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						World Health Organisation, we therefore suggest that the phrase "(or encephalopathy)" be removed from the guideline's title.	
SH	Local ME	5	NICE	1	1 Line 15	It's not clear what is meant by 'relatively common'– although it does seem to set the scene for the all-inclusive broad brush diagnostic criteria that follows. "CFS/ME like other chronic illnesses with no certain disease process…" Clearly, CFS/ME must have a 'certain disease process' but, at present, it is just not fully understood. It would be helpful to insert	The wording has been changed to reflect these comments.

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						into this first sentence the word "physical" or "organic", to read: "CFS/ME is a relatively common *physical/organic* illness …." There is sufficient worldwide evidence indicating a raft of physical abnormalities – it's time to, once and for all, clarify the key issue of physical illness or mental health issue.	
SH	Local ME	6	NICE	1	16	The phrase "… poses 'real problems', seems perhaps deliberately ambiguous and should be substituted by the word 'serious'.	This has been revised
SH	Local ME	7	NICE	2	1	We do not agree that the draft guideline offers best advice for PWME (CFS ICD-10)	Noted.

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SH	Local ME	8	NICE	2	3	Such an approach is commendable; problem is the only two approaches recommended in these guidelines are CBT and GET. GPs will look no further, unaware of the possible harm to his/her patient. Such a situation will not and cannot constitute 'informed decisions'. "Where patients do not have the capacity to make decisions…" Who will decide that a patient does not have the capacity to make a decision about his/her treatment?	The guideline contains many recommendations about approaches other than GET and CBT. Please refer to the document mentioned. This is standard text in all NICE guidelines. The guideline makes clear that patients are involved in care and decision-making.

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						Will a refusal to accept CBT and GET be regarded, as has happened too frequently in the past, as indicating such a lack of capacity even when the patient has made an 'informed decision' concerning his 'individual needs and preferences'? It is only one instance of a worrying tendency to adopt 'catch all' recommendations so that the patient can always be considered to be in the wrong or suffering from a mental, behavioural problem.	
SH	Local ME	9	NICE	2	14–15	It would seem that the term 'evidence based' translates to: "the treatment / intervention' that has	Please refer to the 'NICE Technical Manual' for information on how evidence is searched and graded.

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						received most funding, therefore the treatment/intervention with the most research studies. This is wholly unscientific. It is equal to a shop deciding bananas are the most popular fruit that they sell when they very rarely stock any other fruit It is important to ensure that international medical opinion about the dangers of exercise is included.	
SH	Local ME	10	NICE	3		Definitions used in this guideline: The rationale behind the use of CBT for PWME (ICD CFS) needs to be explained. NICEstate: “It is used in many health	Issue 1. CBT: The wording has been revised to make this clearer.

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						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 approach has already been attempted in the UK by the Collaborating Centre	

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						for the Institute of Psychiatry when ME /CFS was deliberately misclassified 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 NICEknow of no other way to treat PWME it is obviously too early to publish guidelines. Where will the necessary money come from to finance the required legions of CBT therapists with appropriate "expertise" in ME/CFS?	Issue 2. Funding: This will be part of the implementation strategy.
SH	Local ME	11	NICE	3	6	CBT is an evidence based	NICE guidelines are predicated on

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			NICE	3	15	treatment for CFS/ME. "This may be true for chronic fatigue but not for ME (ICD CFS). No research on GET has been undertaken with strictly defined ME (CFS ICD 10) participants. Convincing evidence exists to show that people with ME (ICD CFS) respond abnormally to exercise. We are not aware of any other serious, chronic physical illness in which CBT and GET are recommended as "the therapies of first choice…" By omitting the serious danger warnings in relation	research evidence where available. There is good research evidence for the improvement following GET programmes in people with CFS/ME.

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						to exercise and ME (ICD CFS) NICEand all other establishments that do the same are leaving themselves open to litigation. Doctors and healthcare professionals must prescribe exercise with exactly the same degree of care as with a prescription drug. In a survey of GPs conducted in 2004 by Shropshire & Wrekin ME Support Group, of 47 GPs who replied to the question "What management approach do you advocate for your ME/CFS patients?" 2 replied "Exercise on prescription"! It is necessary to let GP's	

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						know there is substantial evidence showing GET is harmful to Patients with ME (ICD CFS) i) AfME Survey: 'Severely Neglected – ME in the UK', March 2001, ii) Report on Survey of Members of Local ME Groups, Dr Lesley Cooper, AfME & ME Assoc., November, 2000. Both surveys clearly showed that GET harmed the majority of individuals. A 'treatment' with such an egregious record would not be recommended for any other illness and it is wholly unacceptable for sufferers	

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						of ME. "This [GET] is followed by an increase in intensity when able…" Alarmingly, there is no acknowledgement that GET may not be appropriate for some subsumed under the banner of CFS/ME. In addition there is no suggestion whatsoever about the course to be followed in the cases when GET is not effective or when it causes the patient's condition to deteriorate. It is clearly unsound, but implicit in the document, to assume that GET, or any psychological intervention,	

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						will be unfailingly efficacious. CBT and GET will not alleviate and, in some instances, will undoubtedly exacerbate mitochondrial dysfunction, as acknowledged in international research, (with its concomitant inability of the body to produce sufficient energy), post exertional malaise, delayed onset fatigue, postural hypotension, low cardiac output, orthostatic intolerance, loss of thermal stability, headaches, hypersensitivity to foods, chemical (e.g. cleaning products and cosmetics) and medicines, or any other of the many, severe	

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						symptoms experienced by people with ME. In the UK, CBT for PWME is a psychological intervention which aims to alter the ways patients view or cope with their illness and as advised in The Scottish Executive’s NICELife Working Group Report on CFS/ME: “It is not a technique that could or should be recommended to every patient…. Cognitive Behavioural Therapy may be helpful as an	

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						approach where the patients’ beliefs and concerns are central.” Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis (CFS/ME) Outline for Development of Services for CFS/ME in Scotland: Report of the Scottish NICELife Working Group. Scottish Executive Health Department 2002, page 15.	
SH	Local ME	12	NICE	5	4	The description of severe ME/CFS should include many of the more severe neurological symptoms frequently experienced–ie blackouts, atypical convulsions, loss of speech and swallowing necessitating tube feeding.	These are based on those of the Chief Medical Officer’s report

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Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
SH	Local ME	13	NICE	5	1	The phrase usually STOPPED work is totally inappropriate. It suggests there was a choice. For the vast majority, of people, this was certainly not the case. With many being dismissed by their employers on the grounds of medical incapability or had to give up work. Many have tried to return, but major relapses have meant they reluctantly ended their careers. Being forced out of employment does not involve any element of preference.	These are based on those of the Chief Medical Officer's report.
SH	Local ME	14	NICE	5		Four degrees of severity are commonly recognised: "mild", "moderate", "severe" and "very severe": the definition of "severe" fails to	We have used the definition 'severe' throughout.

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						identify, for example, those who are mostly housebound *but* not always "wheelchair dependent for mobility". It is most inappropriate to combine two of them into one (mild & moderate) as has been done in this document. While the divisions are undoubtedly artificial, the illness covering a continuous spectrum of severity, the four categories were defined for good reasons and they should always be treated separately, especially in, as the Guidelines say, “A person centred and collaborative approach to	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						managing symptoms."	
SH	Local ME	15	NICE	6	1 Line 3 Line 8 Line 11 Line 17 Line 24	'WHEN the adults main goal is to return to normal activities …'–What other goal would there be?! This is entirely unacceptable and should be removed, wherever it appears in the document. Nobody chooses to have ME and nobody has any desire to remain very seriously ill. As already pointed out, the evidence for CBT and GET being beneficial is extraordinarily weak. No unbiased reading of all the relevant literature would come to any other conclusion. "…acknowledge the reality	Issue 1. Wording: This wording did not clearly reflect what was intended and has been changed to make it clearer. Recommendations have also been revised.

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						and impact of the condition”– this seems to indicate that the patient needs to be reassured that people believe their condition is real. We would like to see the words "reality and" removed from this phrase. “..provide information about the range of therapies and management strategies as detailed in this guideline.” Given that ”..the therapies of first choice should be CBT or GET…” and as by far the largest section of the Guidelines is devoted to those two strategies, it seems highly likely, probably inevitable, that the only information provided	

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						will be about them with no alternatives being offered. Such a situation would not actually constitute "Shared decision-making between an adult or child and healthcare professionals…" We would welcome healthcare professionals offering information about access to ME/CFS self-help groups. The objectives of the programme are to:–sustain or gradually extend, if possible, the person's physical, emotional, cognitive capacity…" It is not clear what the course of action should be if the	

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						objectives are not possible?	
SH	Local ME	16	NICE	7	9	“excessive fatigue” – needs defining–it’s not clear if this is mental or physical. M.E. has many more symptoms which require managing than simply ‘excessive fatigue’.	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.
SH	Local ME	17	NICE	7	11	“Risk of prolonged bed rest …” In acute phase of the illness especially, this may be absolutely necessary and unavoidable. A gradual return to normal life may be impossible. What should the clinician do in those cases? Empirical research has shown that there is very little, if any, deterioration in muscle function as a	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						consequence of rest.	
SH	Local ME	18	NICE	8	1	“Healthcare professionals should be proactive in advising about fitness for work and education, and recommend adjustments or adaptations to work or studies to enable rehabilitation of adults and children with CFS/ME.” Now that healthcare professionals are being financially rewarded for each patient who returns to work, there is a grave risk to the patients’ well-being in advocating that doctors should be “..proactive in advising about fitness for work…” We do not agree that the	The guideline stresses the involvement and decision-making of the patients Wording has been changed.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						priority for M.E. patients is "rehabilitation", which implies a return to work or studies despite being ill. The words "rehabilitation of" should be replaced with *realistic coping and management strategies for*.	
SH	Local ME	19	NICE	9	Line 2 Line 18	The full contains several references to the fragility of evidence for ME/CFS treatment. It would be helpful here to refer to just HOW FRAGILE this so-called ‘best available evidence’ actually is here. We’re not convinced that they could provide an	Line 2: This is standard NICE wording. Readers are referred to the full guideline in this document. Both will be available on the NICE website. Line 18: Agreed and changed. Line 20: This is recognised and more detail is given later in the document.

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					Line 20–21	aetiological explanation especially as the guidelines suggest that aetiology isn’t properly understood! Whilst in theory it may be helpful for health professionals to be actively involved in advising about fitness for work or education and liasing with employers, schools, etc, this rather depends upon on whether they have sufficient understanding of the illness, are taking close account of the patient’s views and abilities and are remaining in negotiation and agreement with the patient throughout. There is a danger with health professionals who do not	

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						fully understand the nature of ME/CFS and the disability it confers that the patient will be pushed too hard to engage in work/education with resulting failure to improve or even relapse. This danger is very clear from reading the recently published appalling NHS Plus CFS/ME guidelines for occupational health which were published at the same time as the NICEdraft guidance. In some professions, where the nature of the work is such that it is very difficult or even impossible to maintain work with the illness and early retirement	

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						may be a valid option in order to be able to consider other less demanding part-time work.	
SH	Local ME	20	NICE	10	1	The Expert Patient Programme may help a small number of PWME. However, the programme' currently being piloted is too wide and General and unsuitable for people with Severe M.E., and very few PW moderate M.E.–many also report negative experiences and having to drop out. Programmes need to be specifically geared to participants – length of sessions to be shorter, frequency to be fortnightly instead of weekly, and advice to be appropriate. The U.S.	We note these comments but have provided sources of information that some people have found useful.

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						based CFIDS/Fibromyalgia self help course may provide a better model. http://www.cfidsselfhelp.org/course.htm	
SH	Local ME	21	NICE	10	1.1.1.2 Line 7 1.1.3.2	Unfortunately, professionals with appropriate skills and expertise in M.E. are very few in numbers and there is a grave risk that others will try to provide care, to the detriment of their patients. The established pattern in such circumstances is to apply CBT and GET and then to blame the patient either for making no progress or for regressing. A clear warning to healthcare professionals who do not have the necessary expertise would	Following publication of the guideline, detailed work should be undertaken by local commissioners and by the professional organisations to ensure the skills and expertise of healthcare professionals based on the guideline.

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						be greatly appreciated. “Healthcare professionals should provide validated, accurate information …” it is hoped that such information will also include the degree of harm caused by CBT and GET.	
SH	Local ME	22	NICE	11	1.1.3.6	As highlighted above (P8) - words "rehabilitation of" should be replaced with *realistic coping and management strategies for*.	Wording as been changed to reflect this comment.
SH	Local ME	23	NICE	12	1.1.4.3	“Healthcare professionals should aim to establish a supportive and collaborative relationship…” But perhaps the inadvisability of imposing any particular therapy	1.1.4.3 This is made clear in the guideline. 1.1.4.4 The wording as been changed to reflect

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					1.1.1.4	should be pointed out, as well as the patients' right to reject it. We do not consider that either work or education fall under the category of "social activities". we would like to see the words "including work and education" removed here, and the addition to the list of examples of support of the phrase "- assistance with work or education, where appropriate".	this comment.
SH	Local ME	24	NICE	13	1.2.1.2	Diagnostic criteria have been broadened here. Contrast these with "Canadian Consensus Document", (to which there appears to be no reference	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						in "NICE" version)? & Dr Melvin Ramsay's definition of ME: "Muscle phenomena & fatigability: Even following minor degree of physical exercise, 3 or more days may elapse before full muscle power is restored. This feature is unique and is the "sheet anchor" of diagnosis. In moderate cases there may be normal muscle power in remission. Muscle spasm and twitching. In severe cases there may be swollen and very tender bands of muscle including minute foci of exquisite tenderness in trapezii and gastrocnemii (the muscle groups most commonly involved).	

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						Variability of both symptoms and clinical findings during the day Tendency to become chronic. Estimate at least 25%. Also missing here from Ramsay's definition are: • Cold extremities • Hypersensitivity to climactic change. • Ashen grey facial pallor, 20 to 30 minutes before patient complains of being ill • Frequency of micturition • Hyperacusis • Episodic sweating	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						- Orthostatic tachycardia Crucially in the NICEdraft definition there is no reference to "New Onset", abnormalities of the neuroendocrine system, new sensitivities to food/medications/chemicals –all of which are detailed in the Canadian Guidelines.	
SH	Local ME	25	NICE	13	1.2.1.1 Line 1	'CFS/ME is recognised on clinical grounds alone.' There is good evidence to suggest that ME/CFS CAN be recognised from a characteristic constellation of abnormal lab data – IF the correct tests are carried out. (Ref Jacob Teitelbaum's work on lab	The Guideline Development Group did not find evidence that CFS/ME could be diagnosed by a series of tests. This is not a complete list of symptoms but ones that may lead to a suspicion of CFS/ME. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this

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						testing). It appears the GDG haven't been referred to the important neurological, neuroendocrine and neuroimmunological research findings that resulted in the WHO classifying M.E. as a neurological disorder, or read the page 2 of the Canadian Criteria covering the symptoms of the illness. The list is so poor they appear to have left out neurological and endocrine symptoms in the guidelines, e.g. perceptual and sensory disturbances; spatial disorientation and	clearer.

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						visual disturbances; photophobia and hypersensitivity to noise; autonomic symptoms; e.g. urinary frequency and bladder dysfunction which affect so many of us.	
SH	Local ME	26	NICE	13	19	'lymph nodes painful not enlarged'–as EBV may cause enlarged lymph nodes–so are we then to conclude that EBV is excluded as a causative factor of ME/CFS? (See comment below P16)	Wording has been clarified.
SH	Local ME	27	NICE	14	1.2.1.4	Alzheimer's disease should also be added to the list of 'red flags'–we're aware of one case locally where an individual was misdiagnosed with CFS/ME	This is not a comprehensive list of alternative diagnoses. We have clarified this section, which is included to ensure that patients in need of urgent medical treatment receive it.
SH	Local ME	28	NICE	14	1.2.1.8	We're not convinced it would be possible for	Any implementation issues regarding recommendations will be raised with the

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						ME/CFS patients to receive a mental health assessment within the 4 months that a diagnosis should be made in. These services already seem to be hard-pressed, with long waiting lists.	NICE implementation team.
SH	Local ME	29	NICE	14	3 1.2.1.4	This suggests that ME/CFS is not a serious disease! In severe cases, M.E. DOES produce 'abnormal neurological signs'. There may be significant overlap with all of the following and in addition to those listed, investigations and screening should also be carried out to exclude:	This was not the intention. 1.2.1.4 This has been re-worded so as not to imply that CFS/ME is not serious. This was not the intention; our intention was to ensure that urgent life-threatening symptoms were not ignored. 1.2.1.5 This recommendation is guidance prior to diagnosis based on the assumption that most people will have temporary illnesses from which they will recover. The intention is to ensure that symptoms are not ignored indefinitely and that action is taken.

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					1.2.1.5 1.2.1.7	Addison's Disease; Hypothyroidism; Multiple Sclerosis; Lyme Disease/ Borreliosis; Fybromyalgia; Sarcoidosis; Lupus; Hughes Syndrome and Parvovirus infection. ",,,assessment in an adult or child in whom symptoms do not resolve as expected."	1.2.1.7 Once again, this recommendation is guidance prior to diagnosis regarding seeking advice on unusual symptoms. Discussion with a specialist should be considered – This is an implementation issue that will be passed on to the NICE implementation team.

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						This presupposes that the healthcare professional believes that symptoms *should* resolve, whereas the evidence of countless thousands of M.E. patients is that symptoms *DO NOT* resolve. By adopting and adhering to Carruthers et al, (Canadian criteria) physicians will have all the advice needed about diagnosis and prognosis. It should be noted that Carruthers et al states: cardinal symptoms are no longer optional and that patients must have neurological, immune and/or neuroendocrine	

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						manifestations. Discussion with a specialist should be considered …" This would be a useful diagnostic aid, however there are insufficient specialists throughout the UK to meet the need. Even in areas where there are specialists, they are not funded to spend sufficient time on ME/CFS and many doctors and healthcare practitioners do not understand the complexities of ME/CFS–as detailed in the Canadian Guidelines.	
SH	Local ME	30	NICE	15	1.2.1.9	It is vital that, when waiting for a definite diagnosis, patients are advised to rest, particularly avoiding	The guideline is not about compelling anyone.

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						strenuous physical exertion, which will exacerbate the illness and make recovery less likely. Children should not be urged or compelled to resume full-time education.	
SH	Local ME	31	NICE	15	1.2.1.9	Whatever the precipitating factor, patients require much more than advice about 'self management' which has only limited value.	The recommendation refers to symptom management.
SH	Local ME	32	NICE	16	1.2.2.3	It seems very odd to suggest that EBV should not be routinely tested for when this is widely acknowledged to be one of the precipitating causes of CFS/ME? A patient may have been an asymptomatic carrier for	Testing is only not recommended when there is no indication that the individual previously had an infection as without an indicative history this is extremely unlikely, according to statistics. Therefore patients who have had symptoms of an infection will be appropriately tested.

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						many years. There is also documented evidence that EBV can initiate neurological damage. Viral tests should also be carried out for Coxsackie B, & RNase L for which there is good evidence that these might also help to validate the diagnosis, confirm an organic origin, and may help discriminate ME/CFS from other illnesses.	
SH	Local ME	33	NICE	18	3 1.3.1.3	'WHEN the adults goal …' See comment for page 6. This is offensive & should be removed.	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	Local ME	34	NICE	18	1.3.14 1.3.16	This is contradictory; if CBT and GET are not appropriate, then their individual components will not be appropriate.	This section has been revised.

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						Patients require much more than activity management, sleep management and relaxation, which will do nothing to alleviate most of the symptoms. There are many examples like this in the document. There is no acknowledgement of the possibility that the suggested course will not be successful or of what to do in such an eventuality. Advice must be provided for dealing with lack of improvement and for relapses, especially when they are caused by the suggested 'treatment'. We have been given many	

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						incidences of sufferers left to sort themselves out after such situations.	
SH	Local ME	35	NICE	19	1.3.1.10 Line 13	We profoundly disagree that there is "no evidence" to support the so-called "envelope theory". It is not simply anecdotal evidence that supports this approach – but EVERY patient centred survey that has ever been carried out; Patient evidence included in the CMOs report (2002) suggested 89% found pacing helpful; 70% of respondents found pacing helpful in the 25% M.E. Groups 2004 Analysis Report. We would expect that 'considerable patient	While there is patient support, there are very differing views. In addition there is no research evidence. The recommendation does not disparage but reflects this position. It again illustrates differing understanding of terminology. The terms 'pacing', 'envelope theory' and 'activity management' may be used interchangeably or have separate meanings. The guideline has been revised to include more on pacing and rest.

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						support' would be taken as a sign of benefit and something to inform treatment, rather than something to be disparaged. It is remarkable to note how completely the experiences of patients have been ignored! This clause completely ignores the phases of the illness and the serious risk of relapse. One of the defining characteristics of ME/CFS is the relapsing-remitting nature of the illness. Coping strategies need to be VERY DIFFERENT in remission rather than when experiencing a relapse. Patients should NOT be	

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						encouraged to push themselves harder than they feel able to do without suffering unacceptable payback. FIRST DO NO HARM If patients who report that an approach is beneficial are not to be believed, then how is the effectiveness of any therapy to be evaluated? We would have thought that the reason for treating a patient is to bring about an improvement–not to impose a treatment regime which may cause distress and actually make matters worse. It should of course be remembered there is no evidence to suggest that	

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						those who benefit from GET or CBT actually suffer from ME (ICD-10 CFS). It is more than possible that all positive results in the research cited were due to the participants suffering with something other than ME/ (ICD-10 CFS)	
SH	Local ME	36	NICE	20	1.3.1.12 Line 6	A change in behaviour will no more cure ME than MS, motor neurone disease or typhoid. It is insulting to suggest otherwise.	NICE guidelines are predicated on research evidence where available; there is good research evidence for the improvement following CBT programmes in people with CFS/ME.
SH	Local ME	37	NICE NICE	20 20 cont.	1.3.1.13 Lines 24 and 25	This section appears to blame the patient for being ill! Will the recommended "therapies" alleviate low cardiac output, food/chemical/medicine intolerance, IBS, post-exertional malaise, alcohol intolerance, heat/cold	There is research evidence for the benefit of CBT for people with this condition as with many other chronic conditions. These are accepted components of any CBT programme regardless of condition, but the examples of how this may be applied have been revised.

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						intolerance, light/sound intolerance etc etc? 'Fear of activity & perfectionists beliefs': We're not aware of any evidence or data to support this. This appears to be wild, speculative (and offensive) hypothesis that has no place in an "evidence based" guideline and it should be removed. As highlighted previously this also contradicts the full (pages 202/3) where it states that CBT is NOT directed at illness beliefs or at the underlying disease process and is not regarded as curative. There may also be ethical	The Guideline Development Group have recommended that the preference and needs of the individual should be taken into account.

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						issues here about “challenging cognition of fear of activity” in patients whose core symptom is post-exertional malaise, and who have usually adapted sensibly to cope with their illness, by carefully managing their activity levels?	
SH	Local ME	38	NICE	21	1.3.1.13 Lines 4 and 5	For NICEto talk about ‘symptom over-vigilance’ and “checking behaviours” is offensive and should be removed. It wouldn’t be included in the NICEGuidelines for M.S. why should it appear here? However, it gives the reader a good indication of the reasoning behind the therapies and the guidelines.	The wording has been changed as a result of the consultation.

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SH	Local ME	39	NICE	21	Line 4	‘Decreasing somatic attributions’ and address symptom over vigilance …’ This is offensive and based upon misguided opinion rather than evidence.	The wording has been changed as a result of the consultation.
SH	Local ME	40	NICE	21	1.3.1.14	It is wrong to try and prescribe for mild & “moderately” affected in the same way. Combining two degrees of severity for the purposes of suggesting treatments is an unforgivable error. There may be a world of difference. Also, as mentioned previously, many people that were once mild/moderate have become severely affected due to the prescribing of	The emphasis is on an individual programme based on the person’s situation and symptoms. There is a great deal of detail on other recommendations on the development of the programme. The evidence supports the use of GET. We have stressed throughout the need for appropriate monitoring and review.

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						GET. Empirical research has demonstrated that people with ME cannot tolerate exercise; their muscles fatigue more quickly and take longer to recover than healthy controls; and lasting damage to the patient's health is a significant possibility.	
SH	Local ME	41	NICE	22	1.3.1.15 Line 5	"How (&who) would explain the symptoms and "benefits of exercise in a physiological context "? The physiological aspects of ME (ICD-10 CFS) are not sufficiently researched and understood and of course some proponents of GET/CBT support the unacceptable, unsupported	As with all treatments a full explanation should be offered by the healthcare professional with experience of CFS/ME.

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						de-conditioning theory which is not borne out by the evidence. See extract below from King's College CFS Unit, found at: http://www.kcl.ac.uk/projects/cfs/patients/physiology.html "Over time, reduced or irregular activity and increased periods of rest cause physical changes in the body. These changes cause unpleasant sensations and symptoms that can be very distressing. It is important to point out that these changes are reversible with physical rehabilitation and/or exercise."	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						Please note one resrach outcome: Bazelmans (2005) Found that: "physical de-conditioning does not seem a perpetuating factor in CFS." Psychol Med. 2001 Jan;31(1):107-14.	
SH	Local ME	42	NICE	22	1.3.1.16 Lines 12 and 13	Whilst we realise that this may be 'ultimate goal': Many will find advocating a "daily brisk walk" … and CYCLING for "moderately affected", an utterly absurd thing to suggest, and potentially very dangerous. This is the sort of poor quality advice that has made people severely affected, who were not so	The recommendations have been revised and expanded to reflect this and other concerns.

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						previously.	
SH	Local ME	43	NICE	23	5 1.3.1.18	The final words "if necessary" should be deleted: if any activity results in prolonged exacerbation of symptoms, it should be reduced *immediately*. If the suggested activity level must be 'reviewed and reduced if necessary', then what should happen next? There appears here to be a sweeping assumption that there will be an inevitable improvement in the patient. There is no mention of who will 'pick up the pieces' or what will happen if the symptoms actually	This recommendation has been revised to reflect concerns. Please refer to the definition of exercise in the glossary.

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						increase, perhaps to a severe degree or if they cause long term relapse? It may be negligent and misguided in the extreme to recommend aerobic exercise for them. Those with bona fide M.E. do NOT experience normal stiffness/fatigue – this is one of the defining characteristics of the illness as described by Dr Melvin Ramsay. Many previously fit & active people with this illness know exactly what it is like to experience normal muscle fatigue response to exercise and IT IS NOT THE SAME. [A. Melvin Ramsay. Myalgic Encephalomyelitis and	

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						Postviral Fatigue States: The Sage of Royal Free disease. 2nd edition. Gower Medical Publishing, London 1988. See http://www.cfs-news.org/me.htm]	
SH	Local ME	44	NICE	23	1.3.1.19 1.3.1.20	This section through to p25 with the emphasis on and the repeated use of the word "exercise", gives the reader the distinct impression that in this illness patients actually wish to succumb to disability, rest too much and are not sufficiently motivated to improve. It is also based on the premise that improvement will not only inevitably take place, but that the rate of improvement will increase.	Issue 1. We have stressed throughout that programmes are tailored to the individual and the need for appropriate monitoring and review.

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						There is no mention about what should happen if ‘agreed GET goals’ CANNOT be met? Suggesting that exercise can be increased ‘if the patient would like to’ implies that some patients would not like to improve their state of health– preposterous. ‘IF the patient would like to progress!’ What other goal would there be! See comment for page 6. (Line 1) This should be removed. It is offensive.	Issue 2: – this refers to the patient progressing *further.* Different individuals will have different activity goals all may not want to progress their activity beyond their GET goals. Issue 3. The approach will be individualised.

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						During a setback, exercise or activity should be *decreased*, not maintained.	
SH	Local ME	45	NICE	24	1.3.1.22	What happens to those who live alone and who are obliged to exceed their 'baseline' of manageable activity simply in the process of eating, washing, dressing, etc? It is not easy to see how one could choose to relinquish any such 'activities' for the 'establishment of 'baseline'	Throughout the guideline we stress that programmes should be tailored to the individual's circumstances.
SH	Local ME	46	NICE	25	1.3.1.23	Given the advice, made elsewhere, that patients	The advice on diary keeping has been clarified and is an optional strategy that

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					1.3.1.24	should not focus on symptoms, we find the advice to keep a diary/schedule to be contradictory. We also consider that such mental and physical exertion is counterproductive for someone trying to optimise their fitness and capabilities within the confines of being ill. (The aim should be to *cutout* any unnecessary stresses in life.) We question the sense in the use of the words "unless absolutely necessary" here: M.E. patients do not *choose* to rest when symptoms increase – they are *compelled* to. We would	may be helpful for some people. The phrase 'unless absolutely necessary' has been reworded.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						like to see this entire paragraph removed.	
SH	Local ME	47	NICE	26	17	Sleep Management– “Excessive sleep doesn’t Generally improve physical or mental functioning in patients with CFS/ME”. We do not agree with this statement, particularly in the early stages when the body needs to convalesce. Dr Charles Shepherd in “CFS/ME A Guide to Research, Diagnosis and Management” states– “During the early post-infectious state of CFS/ME, many people have excessive sleep requirements (hypersomnia) and this should not be interfered	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						with." ,Many M.E. patients do not, for the most part, *choose* when they need to sleep. There is little mention of the very central and disabling nature of the sleep disturbances experienced, and negligible mention of other ways to help with sleep. Many PWME report, that insomnia or sleep quality is worse when they have not included rest periods during the day. Also ref: Dr Darrel Ho Yen (Better Recovery from Viral Illness).	
SH	Local ME	48	NICE	26	1.3.2.	PWME are entitled to, and require, more than a 'self-management strategy'.	Agreed – this is only one section of the guideline.
SH	Local ME	49	NICE	26	1.3.2.1	As mentioned previously	This section has been simplified this

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
				26	1.3.2.1 1.3.2.2	above, during the acute phase of the illness "excessive sleep" may be precisely what is required! For most PWME 'establishing a normal sleep-wake pattern' would be impossible and would probably lead to deterioration. Whilst 'excessive sleep' may not always produce benefits–it may well prevent further deterioration. While we acknowledge the benefit of advice concerning relaxation and avoidance of stimulants before sleep, we recognise that this is commonsense advice for *everyone, whether ill or healthy*, and	section and made specific to CFS/ME rather than general sleep management advice.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						is not specifically or exclusively relevant to M.E patients. We are, however, alarmed at advice which entails sleep deprivation, e.g. "limiting (or reducing to 30 minutes) daytime naps": M.E. patients are *compelled* to sleep at times during the day (they do not do so through choice) and in our view deliberate sleep deprivation could be construed as deliberate self-harm.	
SH	Local ME	50	NICE	27	1.3.2.2 Line 17	For NICEto mention ‘Excessive alcohol’ in the context of ME/CFS sets alarm bells ringing that that they may not actually be talking about the same illness here? (See	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						comments above on heterogeneity.) Many PWME cannot tolerate alcohol AT ALL. Ref: Woolley, Allen & Wessely (2003) and with doctors with a good knowledge of M.E. it often helps confirm a diagnosis.	
SH	Local ME	51	NICE	28	1.3.3.2	PWME experience relapses as a part of the cyclical nature of the illness; they cannot always be attributed to or precipitated by infection, 'other illness' or activity. It is alarming to think that GET may be considered to be an appropriate response to a relapse.	This section has been revised to reflect concerns.
SH	Local ME	52	NICE	29–30	1.3.3.3	This section is simplistic and overly prescriptive– much greater flexibility and	This section has been substantially revised based on feedback in the consultation.

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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						sensitivity is required. Clinicians must be made aware that some activities may have to be reduced or even eliminated permanently to prevent causing harm. They must listen to the patient; when the patient says he has reached the limit of possible activity that must be accepted, to avoid the risk of further deterioration.	
SH	Local ME	53	NICE	30	1.3.3.4	'Appropriately trained professionals' in ME/CFS are rare and we wonder who decides that they are 'suitably trained'. Certainly if they subscribe to the psychosocial model of ME/CFS, they are likely to	Training competencies are beyond the scope of the guideline.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						cause more harm than good and should not be allowed to treat PWME.	
SH	Local ME	54	NICE	30	27 1.3.3.5	'A GET programme should be delivered by an appropriately trained professional with experience of GET with CFS/ME'– As above there must be very few potential GET instructors who have experienced ME.. As yet, nobody has 'trained' any 'professionals' in the application of GET to ME. What sort of professionals would they be? With no recognised or appropriate 'training programme' one wonders how one will be devised	This comment will be referred to the NICE implementation team.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						and who will be responsible. Unless the experiences of patients with M.E. are taken into account, the effect on patients will be disastrous.	
SH	Local ME	55	NICE	31	1.3.4.2	The warning about lower tolerances and more adverse affects from medication certainly concurs with patient experience and is both welcome and important.	Issue 1. Tolerance: The GDG was concerned about sub-optimal doses being prescribed that would not benefit the patient. As an in-depth search of the literature yielded no evidence for greater intolerance, this recommendation has been redrafted as part of an individual management strategy. Issue 2 .Thyroid: This may be part of an individual management strategy. The Guideline Development Group has recommended that investigations and diagnosis are regularly reviewed in CFS/ME, and that investigations are

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
					1.3.4.4	Whilst thyroid hormone may appear normal on laboratory tests, the patient may actually be clinically hypothyroid due to tissue insensitivity. It must be recognised that the thyroid test has required updating numerous times although at each stage it was thought to be as accurate as it would ever be.	repeated if there is no improvement, particularly in the severely affected. Issue 3. Melatonin: Revised with thanks.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
					1.3.4.7	The NICEGDG seem to acknowledge the voice of the wider group on melatonin, but there is inconsistency between FULL and NICEs. The full tentatively suggests trial of melatonin (presumably for children or adults) but the NICEspecifies this for children.	
SH	Local ME	56	NICE	32	1.3.5	Nutrition/dietary support	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						As mentioned previously, with so many people with ME/CFS experiencing food intolerances/allergies/digestive problems, often acute it is hard to credit that this is all NICEare going to say about diet/nutrition. Whilst the effort required to buy food and prepare nutritious meals can mean that PWME find it difficult to maintain a healthy diet– many have found an exclusion diet to be an important part of their treatment protocol. Also no mention of appropriate symptom control for nausea, treating IBS, or helping to stabilise	Managing food intolerances was beyond the scope of the guideline. The guideline now cross-refers to the NICE IBS guideline, which has more in-depth guidance on this matter. General dietary advice and advice for nausea is now given.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						blood sugar levels, or highlighting the importance of good fluid intake?	
SH	Local ME	57	NICE	33	1.3.6 1.3.7	NICEare unacceptably dismissive of complementary therapies. There appears to be plenty of evidence that they may help with` treating symptoms of ME/CFS. However, because of the necessary individual nature of treatment, it may never be possible to carry out "gold standard" RCTs to properly test this, in a way that would be acceptable to NICE- even if necessary funding were forthcoming. A number of PWME are reporting improvements on EPA/Omega-3	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS. The Guideline Development Group found insufficient evidence to recommend nutritional supplements routinely. It is acknowledged, however, that some individuals may find these approaches helpful. Regular check-ups: noted. This would be part of an individual plan.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						supplements. There is also some evidence to suggest that B12 & magnesium may also have a role to play in some patients. At present the new Local Multi-Disciplinary Teams are seeing newly	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						diagnosed patients, and after following the local care pathway patients will be referred back to their GPs—we believe all people with ME/CFS should receive regular check-ups with their GPs.	
SH	Local ME	58	NICE	34	1.4 .1.1	Severely affected need special interventions suited to the severity of their condition, if necessary providing appropriate therapies in their homes. A ‘one size fits all’ approach is unsound and inadvisable.	The intention of Recommendation 1.4.1.1 is to make it clear that those who are severely affected should have treatment regardless of whether they can get to hospital or clinic. The wording has been revised to make this clear.
SH	Local ME	59	NICE	34	1.4.1.3	We do not believe, or accept, that “GET is appropriate and it is simply ludicrous to even suggest for the severely affected.	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term ‘GET’ has been applied to a variety of programmes. As indicated in the patient evidence, some of these have

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
							unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches informed by the principles of GET.
SH	Local ME	60	NICE	35	1.4.1.8	Clinicians should be urged to be cautious about hospital admissions. A stay in hospital can be a	This is the intent of this recommendation.

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						traumatic and damaging experience for both the severely and moderately affected not least due to noise, bright lights and chemical sensitivity. There may also be situations where a PWMEs home circumstances are unsupportive and they cannot improve without residential care. Consideration must be given to the provision when necessary of residential or hospital care giving due regard to environmental factors mentioned above.	
SH	Local ME	61	NICE	37	4.1	Research Recommendations Why are the main	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope

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						research recommendations limited to current intervention strategies? Especially as mentioned previously, when currently potentially ground-breaking research is going on in several other fields such as gene expression, which seems likely to provide new intervention strategies and further understanding. If there is no evidence to suggest that GET/CBT is effective in severely affected adults & children then why are they being advocated by NICE? Given that there may be up to 240,000 people with ME/CFS, surely biomedical	of the guideline.

The comments made by registered stakeholders during consultation, and responses from the guideline development group (GDG), are now available in the following tables. The comments received from stakeholders are not endorsed by the GDG or the Institute and appear here only as record of the comments that the GDG received. (Please note that where a particular comment has not been responded to directly by GDG, this should not be taken to mean that the GDG agrees with that comment.)
A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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						research to establish the pathophysiology of ME/CFS should be considered an urgent priority?	
SH	Local ME	62	NICE	38 38	4.4 4.4 cont.	NICEstate: 'It is not known how much improvement is important for patients with CFS/ME.' So the message is that there are known knowns– there are things that we know that we know. There are known unknowns–that is to say, there are things that we now know we don't know. But there are also unknown unknowns–there are things we do not know we don't know. And each year we discover a few more of those unknown	This is intended to convey that different people will have different goals based on their current individual circumstances. Some may set as an objective maintaining their current level and avoiding deterioration for the time being. This question could be asked of most serious chronic illnesses. In studies on hip replacement, there are disputes about whether the better outcome is being able to walk again without pain or that the x-ray shows a good placement of the device. In looking at the CFS/ME research, there were a wide variety of outcomes with little indication of their relative benefits.

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						unknowns? This in an incredible (and perhaps very telling) statement to make–it suggests that we do not know the best way of measuring outcomes in research studies, yet CBT & GET are being put forward with a degree of certainty that we do not have. This question could not conceivably be asked in relation to any other serious, chronic illness such as cancer, diabetes, M.S. The answer is obvious: PWME wish to return good health and have the opportunity to return to full-time work or	

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						education and enjoy a normal life! The MAIN question is: What patients and WHAT disorder are we discussing here?	
SH	Local ME	63	NICE	40	6	The psychosocial bias which is evident throughout the NICEdraft is exposed yet again. The only two (relatively rare) symptoms deemed worthy of further "related" guidance are anxiety and depression.	The guideline refers to other relevant NICE guidelines.
SH	Maidstone and Tunbridge Wells NHS Trust	1	NICE	31	1.3.4.2	The warning about lower tolerances and more adverse affects from medication certainly concurs with patient experience and is both welcome and important.	The Guideline Development Group was concerned about sub-optimal doses being prescribed that would not benefit the patient. As an in depth search of the literature which yielded no evidence for greater intolerance, this recommendation has been redrafted as part of an individual

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
					1.3.4.4	Whilst thyroid hormone may appear normal on laboratory tests, the patient may actually be clinically hypothyroid due to tissue insensitivity. It must be	management strategy. Issue 2. Thyroid: This may be part of an individual management strategy. The Guideline Development Group has recommended that investigations and diagnosis are regularly reviewed in CFS/ME, and that investigations are repeated if there is no improvement, particularly in the severely affected. Issue 3. Melatonin: We have recommended this only for children as there are other options for adults.

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						recognised that the thyroid test has required updating numerous times although at each stage it was thought to be as accurate as it would ever be.	
					1.3.4.7	The NICE GDG seem to acknowledge the voice of the wider group on melatonin, but there is inconsistency between full and NICEs. The full	

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						tentatively suggests trial of melatonin (presumably for children or adults) but the NICE specifies this for children.	
SH	Manchester Mental Health & Social Care Trust	1	NICE	32	1.3.5	Nutrition/dietary support As mentioned previously, with so many people with ME/CFS experiencing food intolerances/allergies/digestive problems, often acute it is hard to credit that this is all NICE are going to say about diet/nutrition. Whilst the effort required to buy food and prepare nutritious meals can mean that PWME find it difficult to maintain a healthy diet– many have found an exclusion diet to be an	Managing food intolerances was beyond the scope of the guideline. The guideline now cross-refers to the NICE IBS guideline, which has more in depth guidance on this matter. General dietary advice and advice for nausea is now given.

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						important part of their treatment protocol. Also no mention of appropriate symptom control for nausea, treating IBS, or helping to stabilise blood sugar levels, or highlighting the importance of good fluid intake?	
SH	ME Research UK (formerly MERGE)	2	NICE	1		SPECIFIC COMMENTS ON THE DRAFT ...like other chronic illnesses with no certain disease process.... This leaves open the possibility that there might not be a disease process at all, when there are thousands of people with a physical illness:	Wording has been changed to reflect this comment.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						REPLACE WITH "like other chronic illnesses whose causes have yet to be discovered and disease processes elucidated......"	
SH	ME Research UK (formerly MERGE)	3	NICE	2	14	... Communication should be supported by the provision of evidence-based information..... Given the particular problems with the meaning and relevance of the RCT evidence in ME/CFS, evidence-based information should have a wider scope. REPLACE WITH "Communication should be supported by the provision of evidence-based biomedical and scientific information from the	This is standard text in all NICE guidelines.

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						international literature, as well as evidence-based suggestions for coping with symptoms...	
SH	ME Research UK (formerly MERGE)	4	NICE FULL	3 138	23	... CBT is an evidence based treatment for CFS/ME.... It is not. The evidence base consists of only 5 trials which have a validity score >10, one of which is negative for the intervention (vide Chambers 2006). Again, “treatment” is too strong a word for the relatively modest (and probably non-specific) effects seen in these trials. As proponents of the biopsychosocial model of ME/CFS (CMO report 2002, page 24)	NICE guidelines are predicated on research evidence where available and there is good research evidence for the improvement following CBT programmes in people with CFS/ME. However, we have recommended that the preference and needs of the individual should be taken into account. O’Dowd has been added to the evidence base. This statement refers to cost effectiveness.

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						themselves make clear: it is “not a cure” (Deale 2001); it is "modestly effective" and not “remotely curative" and "not the answer to CFS” (Wessely 2001); and “...it should be kept in mind that evidence from randomized trials bears no guarantee for treatment success in routine practice. In fact, many CFS patients, in specialized treatment centres and the wider world, do not benefit from these interventions. When it comes to the management and treatment of CFS patients, there is still a lot to be learned.” (Huibers and Wessely 2006). We note that the most recently published	We revised this recommendation.

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						RCT on CBT (O’Dowd 2006) states, "...there was, however, no evidence that the treatment restored normal levels of function for the majority of patients." Furthermore, the methodological problems with these trials have been well-described by Carruthers et al (2003): "The complexity of CBT studies, their varied inclusion and exclusion criteria, the very limited portions that can be properly blinded, and the subjective means used for most evaluations, puts in question the validity of their results. In addition, the numerous variables	

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						between the CBT studies, the CBTs and control programs, the different comparison therapies, and the varied frequency and duration of therapy, make it very challenging to determine which parts are responsible for any perceived improvement. Are any effects due to the shift in cognitive beliefs, the exercise involved, the amount and quality of the attention and counseling, the discontinuance of other medical therapies during the test period, etc.? Thus the Powell et al [2001] study found GET alone to be as effective as CBT, and the Ridsdale et al [2001] study found CBT to be no	

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						more effective than counseling." REPLACE WITH: .... While cognitive behavioural therapy most likely has some role in helping patients with all illnesses, including cancer and MS, to better cope with their symptoms until a cure is found, this role is limited and essentially non-curative...	
SH	ME Research UK (formerly MERGE)	5	NICE FULL	3 138	 25	... 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	The wording has been revised in light of your comments. NICE guidelines are predicated on research evidence where available and there is good research evidence for the improvement following CBT programmes in people with CFS/ME.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						mood disorders such as anxiety and depression.... This is a disingenuous paragraph. The British Association for Behavioural and Cognitive Psychotherapies website (http://www.babcp.org.uk/) states that "CBT is an approach to help people experiencing a wide range of mental health difficulties. The basis of CBT is that what people think affects how they feel emotionally and also alters what they do....CBT practitioners... aim to work jointly with the person to help them begin to identify and then change their extreme thinking and unhelpful behaviour...."	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						CBT is universally recognised to be a form of psychotherapy used to treat a variety of psychological impairments, but also used as a therapeutic adjunct for symptom management and coping in illnesses such as cardiac, cancer, diabetes and chronic pain. Indeed, we note that when references to CBT appear in the document, "Multiple Sclerosis: National Clinical Guideline for Diagnosis and Management in Primary and Secondary Care" (2004), it is in the context that that psychological management strategies be employed IF the patient is depressed or anxious, but	The wording has been revised in light of your comments.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						not otherwise. Interestingly, the rationale for using CBT in ME/CFS is that inaccurate beliefs/ineffective coping maintain and perpetuate the illness, but it has never been proven that these illness beliefs have caused or maintain the illness, and correlations (where they exist) might just as well have arisen from the valid belief that illness does have a physical cause, and that activity avoidance is the correct course of action. The GDG guidelines could follow the NICE Guidelines for Multiple Sclerosis, and reinforce the adjunctive,	

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						supportive role of CBT in ME/CFS by stating the below: REPLACE WITH: .... CBT or psychological approaches to CFS/ME do not imply that symptoms are psychological, 'made up' or in the patient's head. Rather, they can be thought of as essentially adjunctive management and coping strategies which might be useful for some people some of the time.....	
SH	ME Research UK (formerly MERGE)	6	NICE FULL	3 139	 2	... GET is an evidence-based self-management approach to CFS/ME.... It is not. The evidence base consists of only 3 RCTs	NICE guidelines are predicated on research evidence where available and there is good research evidence for the improvement following GET programmes in people with CFS/ME.

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						with a validity score >10, one of which concludes, "...graded exercise produces small but clinically significant improvements in case level fatigue and functional work capacity in CFS patients...." (Wearden 1998). Given that all three trials recruited patients on the basis of the Oxford criteria which selects an over-broad groups of patients including those with idiopathic chronic fatigue; that there is a strong likelihood of significant non-specific effects given the design of the studies; and the likelihood that self-pacing or good quality clinical care would produce similar small	

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						effects much more cheaply (free, in fact), this management approach cannot be called properly evidence-based or cost-effective in ME/CFS at present. THIS SHOULD BE DELETED	
SH	ME Research UK (formerly MERGE)	7	NICE	4 5		...Severity...These definitions were agreed by the GDG and have been derived from definitions in the Royal College of Paediatrics and Child Health Guidelines and the CMO report.... These three severity levels are not evidence-based. Levels should be based on clinical observation of	Noted.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						clusters of symptoms, each scored according to severity, to allow accurate ascription of a patient to a category of severity. The simple but effective "Symptom Severity Chart" of the Canadian Consensus Document (Carruthers 2003) – which allows for scoring – would be a good starting point. REPLACE WITH: .... Severity...These definitions are ad hoc and essentially based on mobility, and efforts are underway to derive a symptom-based scale.	
SH	ME Research UK (formerly MERGE)	8	NICE	5	1	...they have usually stopped work....	These are based on those of the Chief Medical Officer's report.

National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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						REPLACE WITH: ...they have usually been forced by illness to stop working...	
SH	ME Research UK (formerly MERGE)	9	NICE FULL FULL	6 21 161	 20 6.3.6.3	... When the adult or child's main goal is to return to normal activities... There is a suspicion that this would not be written of patients with other illnesses, and that it is included to suggest that some people with ME/CFS could be malingerers. THIS CLAUSE SHOULD BE DELETED	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	ME Research UK (formerly MERGE)	10	NICE FULL	6 21	 23	... then the therapies of first choice should be CBT or GET because there is good evidence of benefit for this condition in mild to moderately affected adults	This wording did not clearly reflect what was intended. It has been changed to make it clearer.

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						and some evidence in mild to moderately affected children. This is not true for adults (as discussed above). As regards children, the updated systematic review which informs the GDG (Chambers 2006) says: “The recommendations for children and young people were largely developed by consensus because of a lack of specific evidence for this age group. GET and CBT were recommended for consideration based on extrapolation from studies in adults. The effectiveness of CBT for adolescents is supported by a recent high-quality RCT [Stulemeijer	

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						2005] although this had only 69 participants" (It is also the only positive RCT on children with a validity score >10.) And the GDG's draft guidelines subsequently say, in section 4.1, "There is no evidence for the use or effectiveness of these strategies in these two patient groups [young people and the severely affected]". THIS RECOMMENDATION SHOULD BE DELETED	
SH	ME Research UK (formerly MERGE)	11	NICE FULL FULL	7 23 106	 10	... When an acute infection is followed by excessive fatigue, the adult or child should receive advice on how to promote recovery....	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						REPLACE WITH: ... When an acute infection has characteristic sequelae of ME/CFS, then the adult or child should receive advice on how to receive treatment and promote recovery.......	
SH	ME Research UK (formerly MERGE)	12	NICE FULL	8 and 11 83	22	... Healthcare professionals should be proactive in advising about fitness for work and education... This is not a standard phrase used in NICE Guidelines for other chronic conditions. The GDG should show why it is necessary to use this phrase here since there is a suspicion that this phrase would not be written of patients with other	This was considered to be an appropriate recommendation.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						illnesses. What evidence is there – to inform evidence-based guidelines – that people with ME/CFS need unusual prompting from healthcare professionals to return to their pre-illness lives and jobs? THIS SHOULD BE DELETED	
SH	ME Research UK (formerly MERGE)	13	NICE FULL	12 86	 7	... A documented, individualised management plan should be developed with the adult or child with CFS/ME, and the carer, where appropriate to include......education or employment plans... As above, this seems to imply that people with ME/CFS need a healthcare	This is a checklist for healthcare professionals. Support for returning to work or education would be part of a management plan if appropriate. Refer to the section on advice on support.

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						professional to prompt them into education or employment. THIS SHOULD BE AMENDED	
SH	ME Research UK (formerly MERGE)	14	NICE FULL	13 104	 1	... CFS/ME is recognised on clinical grounds alone.... The reasons for this, and its implications for the validity of any guidelines produced by NICE, have been discussed in the long preamble to these specific comments. However, the clinical-basedness of the rubric ME/CFS does not mean that widening it further (as proposed by the GDG – see below) is sensible. Nor does it mean that other supportive	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						evidence of illness need be absent. For example: a) The paper by Devanur and Kerr (2006) expresses the biomedical evidence well – and there is a range of reviews in a similar vein: "Studies of pathogenesis have revealed immune system abnormalities and chronic immune activation, dysfunction of the hypothalamic-pituitary-adrenal (HPA) axis, brain abnormalities, evidence of emotional stress (comprising host aspects) and evidence of exogenous insults, for example, various microbial infections (Epstein-Barr virus, enteroviruses, parvovirus	

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						B19, Coxiella burnetii and Chlamydia pneumoniae), vaccinations and exposure to organophosphate chemicals and other toxins (comprising environmental aspects)." b) The Canadian Consensus Document (Carruthers 2003) is a diagnostic guideline distilled from the panel's collective extensive clinical experience of diagnosing and/or treating more than twenty thousand ME/CFS patients. The clinical definition derived "encompasses the broad cluster of symptoms and signs that give ME/CFS its distinctive character.	

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						Diagnosis is based on these characteristic symptom patterns, which reflect specific areas of pathogenesis". This is a superb 108-page document which should inform the deliberations of the GDG. c) There is clinical evidence, and some research evidence, that frank signs can be found if clinicians look for them. For example, of the qualdricepts muscle, "To our surprise, the patients with CFS were physically weaker than both the depressed patients and sedentary subjects" (Fulcher & White 2002), and more Generally, "In all	

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						three groups, a majority of patients exhibited muscle weakness in the lower limbs, and significant numbers of patients had absent or abnormal reflexes." (Kennedy et al 2004). NICE has a great opportunity to look beyond the significantly rudimentary and skewed RCT evidence-base towards a fresh assessment of the biomedical evidence in ME/CFS, and the revision of the symptoms and signs in people with the illness. A full examination of the Canadian Consensus Document (2003) would be	

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						a good starting point.	
SH	ME Research UK (formerly MERGE)	15	NICE FULL	13 104	 4	...CFS/ME should be considered if an adult or child has fatigue that is all of the following:... This section introduces a novel – and entirely unvalidated – method of "diagnosing" CFS clinically. The criticism of the most widely used "research" definition – the CDC (Fukuda) 1994 – is that it is impossibly broad, being based on "fatigue" plus 4/8 concurrent "minor criteria" symptoms, thereby lacking specificity since it does not, in practice, completely exclude patients with other biomedical conditions or, indeed, those with a	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						primary psychiatric basis for their fatigue. This attempt by the GDG in section 1.2.1.2 to define a clinical definition – on a basis other than systematised clinical experience – makes the situation far worse. It introduces a diagnosis based on "fatigue" plus ONE or more of 9 vague, ill-defined symptoms shared with many other illnesses. To be clear, if (as many believe on the basis of evidence) the current CDC-1994 research definition is an "umbrella term" covering diverse groups of patients, then NICE is proposing to	

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						replace it with a marquis similar to a circus tent. The widened diagnosis would include many thousands of patients currently diagnosed with idiopathic fatigue (most of whom could report at least one of nine common concurrent symptoms); it would lead to significantly increased heterogeneity within the diagnostic category (which could contain a still-working person with a sore throat alongside a bed-bound person with all 9 symptoms to a severe degree; yes, they might have the same illness at a different stage of development, but NICE has no evidence of that); and it would not be taken	

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						seriously since it flies in the face of other expert opinion. For example, even the CFS Working Group at the CDC has recommended that symptom severity be taken into consideration, and standardised outcome measures be used to improve its specificity (Reeves 2005). Furthermore, the experts devising the Canadian Consensus Document (Carruthers 2003) derived a diagnostic rubric based on characteristic symptom patterns, which reflect specific areas of pathogenesis. The central issue has been	

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						put very nicely by Dr Charles Shepherd of the ME Association in a letter to the BMJ (December 2004; 329: 1405): "The medical profession has only itself to blame for the awful mess that currently surrounds ME/CFS. It has created an illness that covers a wide variety of fatigue state clinical presentations, with or without psychiatric co-morbidity, and almost certainly an equally diverse range of possible pathological and physiological explanations. Doctors who deal with patients suffering from unexplained abdominal pain, arthralgia or	

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						headaches do not work on the basis that they all have the same pathoaetiology and will therefore respond to the same form of treatment. So why apply this form of flawed logic to ME/CFS?" The "clinical" revision proposed by the GDG in these guidelines can only make worse the pre-existing mess awful mess. THE ATTEMPT TO ARRIVE AT A CLINICAL DEFINITION SHOULD BE POSTPONED UNTIL INTERNATIONAL EXPERTS ON ME/CFS HAVE BEEN CONSULTED AND EXISTING CLINICAL	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						EVIDENCE EVALUATED	
SH	ME Research UK (formerly MERGE)	16	NICE FULL	13 104	Recommendations	"...physical or mental exertion making symptoms worse..." This "symptom" is almost synonymous with "characterised by post-exertion malaise and/or fatigue" of the major fatigue criteria. Is this an indication that the novel revision of the clinical criteria by the GDG needs revising? THE ATTEMPT TO ARRIVE AT A CLINICAL DEFINITION SHOULD BE POSTPONED UNTIL INTERNATIONAL EXPERTS IN ME/CFS HAVE BEEN CONSULTED AND EXISTING CLINICAL	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer. We welcome further research evidence, which will be incorporated into updates.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						EVIDENCE EVALUATED•	
SH	ME Research UK (formerly MERGE)	17	NICE FULL	14 105	 6	...Some serious underlying diseases might present with similar symptoms and signs as CFS/ME. The following should be regarded as 'red flags', indicating a higher index of suspicion of serious underlying pathology. • Abnormal neurological signs. • Features of cardiovascular problems. • Weight loss. • Features of sleep apnoea. • Features of anxiety and depression.... Most patients currently diagnosed with ME/CFS – including the 20,000	Thank you for this. We have clarified this section, which is included to ensure that patients in need of urgent medical treatment receive this.

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						members of ME/CFS self-help groups – have arrived there after some minor clinical investigations by their GPs that have had negative results. They remain ill, however, and – in the absence of investigations for clinical signs, or in the face of disbelief – lose faith in clinical services. However, the umbrella diagnosis certainly contains seriously people who could benefit from full and comprehensive clinical examinations, and in whom alternative diagnoses (e.g. Lyme disease; frank sleep apnoea; Addison's disease – just some of the re-diagnoses that have come	

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						to our attention) could be found if healthcare professionals and researchers were motivated to find them.	
SH	ME Research UK (formerly MERGE)	18	NICE FULL	16 107	 3	...the following tests should not be done routinely....The head-up tilt test... ...Serology testing for chronic bacterial infections (for example, borelliosis) in the absence of any indicative history. .. Serology for chronic virus infections: HIV, hepatitis B and C, in the absence of any indicative history. .. ..Serology for General viruses (for example, heterophile antibody tests	The Guideline Development Group did not regard the evidence as sufficient to recommend these tests. Serology is recommended where there is evidence of infection.

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						for infectious mononucleosis) in the absence of any indicative history. ...Serology testing for latent infections: toxoplasma, EBV (Epstein Barr virus), CMV (cytomegalovirus) in the absence of any indicative history. These recommendations are in direct contrast to those forming the basis of the Canadian Consensus Document (Carruthers 2003) which have been distilled from the panel's collective extensive clinical experience diagnosing and/or treating more than twenty thousand ME/CFS	

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						patients. Examples of their recommendations include the below: Autonomic Manifestations ...Orthostatic intolerance is commonly seen in ME/CFS patients and Includes neurally mediated hypotension (NMH); postural orthostatic tachycardia syndrome (POTS); and delayed postural hypotension... Laboratory and Investigative Protocol ...a) Further Laboratory Testing: diurnal cortisol levels, 24 hour urine free cortisol; hormones including free testosterone,	

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						B 12 and folate levels, DHEA sulphate, 5-HIAA screen, abdominal ultrasound, stool for ova and parasites, NK cell activity, flow cytometry for lymphocyte activity, Western blot test for Lyme disease, hepatitis B and C, chest x-ray, TB skin test and HIV testing. Do the 37-kDa 2-5A RNase L immunoassay when it becomes available. b) Differential Brain Function and Static Testing: MRI: those with significant neurological finding should be considered for a MRI to rule out multiple sclerosis (MS), and cervical stenosis. Quantitative EEG, SPECT and PET Scans and	

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						Spectography: qEEG analysis of brain waves, SPECT estimation of dynamic brain blood flow and PET analysis of brain metabolism show diagnostic promise and will become more important as these techniques are refined and research confirms their diagnostic value. c) Tilt Table Test d). Sleep Study; e) 24-Hour Holter Monitoring: if a significant arrhythmia is suspected. f) Neuropsychological Testing: can be utilized to identify cognitive dysfunction and/or confirm diagnosis. If done, it should focus on the abnormalities known to differentiate	

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						ME/CFS from other causes of organic brain dysfunctions etc....... There is a clear mismatch between the truncated recommendations of the GDG, and the routine examinations recommended by ME/CFS clinicians across the world. THIS RECOMMENDATION SHOULD BE REVISED AND RE-EXAMINED IN LIGHT OF BEST PRACTICE AND CURRENT RESEARCH.	
SH	ME Research UK (formerly MERGE)	19	NICE FULL	16 124	1.2.3.3 7	... When a diagnosis is made, a prognosis of cautious optimism should be conveyed. With appropriate management,	This has been reworded based on your comment.

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						most children and adults, but not all, will have some improvement and some will recover fully.... This is not true (and again the problem involves "what" diagnosis and using which definition). Two separate recent reviews have concluded that, "…patients exhibit severe, long-term functional impairment. Substantial improvement is uncommon and is less than 6%" (Andersen 2004); and, "full recovery... is rare" (Cairns and Hotopf 2005). REPLACE WITH: .... When a precise diagnosis is made, a prognosis of	

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						cautious optimism should be conveyed. With appropriate management, most children and some adults can improve or even recover fully, though the patient must be left in no doubt that long-tern morbidity can be high....	
SH	ME Research UK (formerly MERGE)	20	NICE FULL	17 181	1.3.1.1 9	....When the adult or child’s main goal is to return to normal activities... There is a suspicion that this phrase would not be written of patients with other illnesses, and that it is included to suggest that some people with ME/CFS could be malingerers. THIS SHOULD BE DELETED	This wording did not clearly reflect what was intended and has been changed to make it clearer.

The comments made by registered stakeholders during consultation, and responses from the guideline development group (GDG), are now available in the following tables. The comments received from stakeholders are not endorsed by the GDG or the Institute and appear here only as record of the comments that the GDG received. (Please note that where a particular comment has not been responded to directly by GDG, this should not be taken to mean that the GDG agrees with that comment.)
A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process.”
Where text has been removed, this is indicated by ‘[…]’. Summarised comments are in *italic type* inside square brackets.

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SH	ME Research UK (formerly MERGE)	21	NICE FULL	17–24 138 onwards	1.3 Management	General Global Comments This section consists of recommendations for management that include: Cognitive behavioural therapy Graded exercise therapy Neither cognitive behavioural therapy (a form of psychotherapy designed to manage dysfunctional illness beliefs) nor graded exercise therapy (which is used as part of a biopsychosocial programme predicated on a model of physical deconditioning) are evidence-based to a level that would allow NICE to recommend that these	Good research evidence was found that CBT and GET programmes result in improvements in functioning.

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						management strategies be rolled out to the 120,000–240,000 people with ME/CFS in the UK. In addition, in the few good quality RCTs which exist, the effect is modest and non-curative, and there is more than a strong suspicion that much of the apparent treatment outcome relates to the non-specific effects, i.e., that good quality usual clinical care (in the case of CBT) and self-pacing (in the case of GET) would produce similar results. Also, the evidence from formal RCTs is opposed by evidence from patient surveys which	

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						overwhelmingly find against the usefulness of these strategies. As the full guideline (56/269, line 2) states "Graded exercise was felt to be the treatment that made more people worse than any other. 39% were made worse by this whereas, in contrast, only 2% were made worse by diet. Graded exercise was also considered to be the least helpful treatment or management schedule; only 13% said that it helped a lot and 26% said that it helped a little [n=347]". Again, as regards cognitive behavioural therapy, the full guideline (pages, 56 and 58, Table) states that only "7% reported to be helped	

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						by CBT whereas 67% were unaffected and 26% made worse." Accordingly, the emphasis on these strategies in the NICE guideline draft is misplaced, as described in the preamble to these comments by ME research UK. THE ENTIRE SECTION 1.3 (PAGES 17–24) SHOULD BE REMOVED, OR TRUNCATED TO A PASSAGE SUCH AS THE BELOW: ...Cognitive behavioural therapy (CBT) and graded exercise therapy (GET) are comparatively expensive	

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						symptom management strategies which some patients might want to try until the cause(s) of ME/CFS are unravelled and a cure identified....	
SH	ME Research UK (formerly MERGE)	22	NICE FULL	19–21 185	1.3.1.11 9	…Cognitive behaviour therapy (CBT) …A programme of CBT should include: …explanation of the CBT model for CFS/ME… There is no CBT model for ME/CFS per se. Rather there is CBT, a form of psychotherapy, which can be applied to all illnesses though the supposed biopsychosocial model. Even though CBT has its critics – such as Holmes (2002), "...the foundations	This section has been revised.

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						on which [CBT] rests are not as secure as some of its proponents would have us believe."– there is some evidence that it can be used as a tool to help some patients cope with some symptoms. Its application for people with ME/CFS would therefore be as a management tool, and not as an overarching model for the pathophysiology of illness. REPLACE WITH: ……Cognitive behaviour therapy (CBT) …A programme of CBT should include: …explanation of how CBT, a form of psychotherapy, might be a	

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						useful as part of a management strategy for coping with symptoms.	
SH	ME Research UK (formerly MERGE)	23	NICE FULL	19–21 186	1.3.1.11 11	…discussion of the patient's attitudes and expectations… …developing awareness of thoughts or expectations, or beliefs and defining fatigue-related cognitions and behaviour… …challenging cognitions which may adversely affect rehabilitation and/or symptom management, for example, fear of activity and perfectionist beliefs… …decreasing somatic attributions and addressing symptom overvigilance... …problem solving using	NICE guidelines are predicated on research evidence where available and there is good research evidence for the improvement following CBT programmes in people with CFS/ME.

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						activity management and homework tasks to test out alternative thoughts or beliefs… Such sentences, characteristic of proponents of the pure Generalist biopsychosocial model, have been given undue prominence by the GDG. There is a suspicion that they would not be so prominently displayed in NICE guidelines for other illnesses; indeed, we note that they do not appear in the document, "Multiple Sclerosis: National Clinical Guideline for Diagnosis and Management in Primary and Secondary Care" (2004) − despite the fact	

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						that fatigue is one of the dominant symptoms of most people with MS – which recommends (on the basis of three positive trials of CBT for MS) that psychological management strategies be employed IF the patient is depressed or anxious, but not otherwise. A quote from the Canadian Consensus Document (Carruthers 2003) expresses well how many ME/CFS patients and charities feel when they see such statement so prominently displayed: "…there is much that is objectionable in the very value-laden…hypothesis, with its implied primary	

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						causal role of cognitive, behavioural and emotional processes in the genesis of ME/CFS. This hypothesis is far from being confirmed, either on the basis of research findings or from its empirical results. Nevertheless, the assumption of its truth by some has been used to influence attitudes and decisions within the medical community and the General cultural and social milieu of ME/CFS. To ignore the demonstrated biological pathology of this illness, to disregard the patient's autonomy and experience and tell them to ignore their symptoms, all too often leads to blaming	

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						patients for their illness and withholding medical support and treatment…Crucially, there is a serious question mark over whether a program of formal CBT or GET program adds anything to what is available in the ordinary medical setting". THE GUIDELINE SHOULD REMOVE THESE AND SUGGEST THAT – LIKE THE NICE GUIDELINES FOR MULTIPLE SCLEROSIS – PSYCHOLOGICAL STRATEGIES MIGHT BE USEFUL FOR ANXIETY AND DEPRESSION.	
SH	ME Research UK (formerly MERGE)	24	NICE	19–21 184	1.3.1.10	...Health professionals should be aware that there	The guideline has been revised to include more on pacing and rest.

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			FULL		Recommendations	is no evidence for the following strategies: ....those which encourage complete rest (cognitive, physical and emotional) during significant increases in symptoms... There is well-founded support from patient surveys and from established ME/CFS clinicians that during periods of stabilisation of illness (as well as in the very early post-infectious phases) periods of rest are very important (vide Shepherd and Chaudhuri 2001).	
SH	ME Research UK (formerly MERGE)	25	NICE	21–23 188	6.3.6.15	..Adults with mild or moderate CFS/ME should	The recommendations have been revised and expanded to reflect these and other

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			FULL			be offered a programme that includes planned increases in duration of physical activity/exercise followed by increases in intensity leading to aerobic exercise (that is, exercise which increases the pulse rate) such as GET.... Much of the current thinking about ME/CFS is driven by models of deconditioning, predicated on the belief that deconditioning is a factor in the perpetuation of the illness. However, there is good evidence that deconditioning is not a significant factor (Brazelmans 2001; Van der Werf 2000) and that it	concern, but the evidence supports the effectiveness of GET in improving functioning. The section has been revised to make clear the tailored approach. The ultimate goal may be aerobic exercise in some cases, but it is clear that this is not the starting point. We have stressed throughout the need for appropriate monitoring and review.

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						cannot account for delayed post-exertional symptoms or the documented changes in muscle metabolism (Lane 1998 and 2000). Historically, Myalgic Encephalomyelitis is characterised by a delay in muscle recovery after exercise (with pain and fatigue 24 or 48 hours after exertion), a phenomenon which few have studied and which the deconditioning hypothesis does not address. In modern ME/CFS patients, there is both clinical and anecdotal evidence that exercise can exacerbate symptoms and cause relapse, particularly	

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						the some 50% of the patient group whose illness had a post-infectious onset. One study, however, has confirmed patient’s experience by demonstrating that CFS patients fail to recover properly from a fatiguing exercise protocol and that the failure was more pronounced after 24 hours (Paul 1999). Further, the new “CFS Toolkit for Health Care Professionals: Managing Activity” (2006) produced by the CDC in Atlanta (vide http://www.cdc.gov/cfs/toolkit.htm) is clear that “Advising patients who have chronic fatigue syndrome to engage in	

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						aerobic exercise... can be detrimental. Most CFS patients cannot tolerate traditional exercise routines aimed at optimizing aerobic capacity. Instead of helping patients, such vigorous exercise can cause postexertional malaise, a hallmark of CFS that is defined as exacerbation of fatigue and other symptoms following physical or mental exertion. Even worse, this kind of exercise can precipitate a full-scale relapse that lasts for days or weeks. A different way of defining exercise and managing activity is needed for CFS patients and their health care team." And a similar	

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						view is expressed in the Canadian Consensus Document (Carruthers 2003) "Exercise programmes must be entered cautiously as clinical studies have indicated that symptoms worsened in approximately half of the ME/CFS patients". And again, Dr Charles Lapp re-emphasised at the American Association for Chronic Fatigue Syndrome (AACFS) 6th International Conference in 2003, "....although may clinicians have heard that graded exercise can be helpful, patients should not embark on an exercise regime which increases the	

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						severity of illness, a phenomenon occurs, as many experienced clinicians recognise, when patients push themselves too much”. Finally, people with ME/CFS themselves consistently report the phenomenon of post-exercise worsening of symptoms: in one report of 1,214 patients graded exercise therapy was reported to make 50% of patients worse (CMO report 2002) − the greatest number of ‘worse’ reports of any therapy; and the survey of the severely affected (25% M.E. Group, 2004) found 82% of ME patients reporting that exercise therapy worsened	

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						their condition, with only 5% finding it useful. There may be sound physiological reasons for the specific post-exercise malaise encountered. First, post-viral fatigue (which is not related to the muscle disuse and deconditioning that can result from the initial period of illness; Lane 2003) might result in a long-term smouldering infection involving glutathione depletion (Pierce and Pierce 2006), and be exacerbated by exercise; or there might be an exercise-induced physiologically-significant delivery of free radicals, not because of disuse of	

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						muscle and deconditioning, but because there is something organically wrong with muscle metabolism and/or vascular endothelial function. Whatever the reason, it is important to remember that the current evidence for deconditioning from the psychosocial literature is not based on scientific investigations of muscle but on suppositions about patients with "fatigue". Thus, issues regarding the role of rest and exercise (whether in the form of GET or not) for people with ME/CFS is not as clear-cut as the GDG suggests. And, as Shepherd (2001) has	

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						pointed out, physicians must take as much care in prescribing appropriate exercise as in prescribing medications to ME/CFS patients. And physicians should only approve of exercise programs in which the patient’s autonomy is respected, appropriate pacing is encouraged, fluctuations in severity of symptoms are taken into account, and adequate rest periods are incorporated (Carruthers 2003). THE GDG SHOULD TAKE ACCOUNT OF THESE POINTS IN SUBSEQUENT REVISIONS TO ITS DRAFT	
SH	ME Research UK (formerly MERGE)	27	NICE	34	1	1.4 Key principles of care	Most of the recommendations in the whole

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			FULL	256	1	for people with severe CFS/ME.... It is Generally agreed that severely affected people could make up 25% of the total number of ME/CFS patients, though some estimates put the figure higher; the late Dr Melvin Ramsay, the doyen of ME patients in the UK, stated that one third of patients experience "a severe and debilitating downhill course", and one Members Survey of November 2000 reported some 34% classifying themselves as severely affected. It is surprising then that the care and management of people with severe illness	guideline relate to people who are severely affected. These are additional recommendations

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						takes up only 1.5 pages in the guideline draft produced by the GDG. For the benefit of the Guideline Development Group, the article by Crowhurst (2005) is an excellent starting point for the development of meaningful and patient-specific principles of care; indeed the tabled section, "impact and service response" would do credit to NICE guidelines, and we hope NICE will consider their incorporation in its final document.	
SH	ME Research UK (formerly MERGE)	28	NICE	34	1.4.1.3/4	....GET may be an appropriate addition to help patients to develop their physical capacity and functioning.... ,,,Activity management	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. As indicated in the patient evidence, some of these have

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						should be the core therapeutic strategy but elements of CBT may be suitable for some adults and children.... This is disingenuous. As regards activity, a survey by The 25% Severe ME Group (2004), 82 per cent of patients with severe ME/CFS stated that their condition was exacerbated by graded exercise therapy, of which activity management is a satellite in this context (as stated in section 1.3.1.4 on the NICE Guideline draft). Also, the statement that follows this section (NICE Guideline draft Section 4.1) states: "There is no evidence for	unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches, informed by the principles of GET.

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						the use or effectiveness of these strategies in these two patient groups [children and the severely affected].... Patient experience suggests that some of these interventions may be harmful and/or not effective.....” The support for the statement of the possible usefulness of CBT for the most severely ill patients is a single report in the scientific literature (Powell et al, 1999) which describes two wheelchair-bound patients who had dramatic improvements in health following a the “pragmatic rehabilitation regimen”. Two other	

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						seemingly relevant reports in the scientific literature are, in fact, small pilot studies that refer to inpatient treatments within psychiatric wards (vide Chalder et al 1996 and Essame et al 1998).	
SH	ME Research UK (formerly MERGE)	29	NICE	30	1.3.4	...Pharmacological interventions... There is now much clinical experience to inform this section – which comprises only 1.5 pages in the NICE guideline. For example, recent reviews (Carruthers 2003; Shepherd and Chaudhuri 2001; and Spotilla 2005) have much to say.	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. Please refer to the 'NICE Technical Manual' available on their website for the methods used in assessing evidence.
SH	ME Research UK (formerly MERGE)	30	NICE FULL	37 Genera	Research recommen	General Comment	The GDG identified these areas as the most important in informing updates of the

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				l 258	dations	The research recommendations consist of refining existing biopsychosocial coping strategies, assessing their cost-effectiveness, looking at rates of prevalence, and tinkering with outcome measures. Crucially no research recommendations are given for strategies to uncover the cause(s) of the illness or find a cure. While the GDG were asked to produce a guideline on "Diagnosis and Management", the very remit begs the questions: Diagnose what, and manage what? ME/CFS is a diagnosis of exclusion – albeit one that the NICE	guideline. Aetiology is beyond the scope of the guideline.

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						guideline draft would widen impossibly (see above) – containing patients who apparently do not fit squarely into any other category. The human beings inside it are a heterogeneous group who might all have the same illness at varying degrees of severity, but might not– the GDG doesn't know where the truth lies, but fills the gap with General non-specific management and coping strategies which might help some in a modest way but solve nothing for most. A programme of research is urgently required, but to boost and extend	

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						physiological and biochemical abnormalities found in groups of patients meeting the broad criteria for ME/CFS. Examples of anomalies that can be found include: Oxidative stress (e.g. Kennedy 2005); Dysregulation of anti-viral pathways (e.g., De Meirleir 2000); Endothelial dysregulation (e.g., Khan 2004); Altered brain perfusion (e.g., Tirelli et al., 1998); Orthostatic hypotension (e.g., Spence and Stewart 2004); Brain metabolic abnormalities (e.g., Chaudhuri et al., 2003); and Cardiac anomalies (e.g., Lerner	

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						2004); Altered muscle metabolism (e.g., fulle et al., 2003); Abnormal response to exercise ((e.g., McCully et al., 2004); Enteroviral sequences in muscle (e.g., Lane et al., 2003) ....and so on........ THESE RESEARCH RECOMMENDATIONS SHOULD BE REMOVED FOR RENOVATION	
SH	Mid Staffordshire General Hospitals NHS Trust	1	NICE	34	1.4.1.3	We do not believe, or accept, that “GET is appropriate and it is simply ludicrous to even suggest for the severely affected.	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term ‘GET’ has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects on patients. There is, however, evidence that very gradual programmes of increases in activity,

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							where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches, informed by the principles of GET.
SH	Mid Staffordshire General Hospitals NHS Trust	2	NICE	35	1.4.1.8	Clinicians should be urged to be cautious about hospital admissions. A stay in hospital can be a traumatic and damaging experience for both the severely and moderately affected not least due to	Noted. This is the intention of this recommendation.

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						noise, bright lights and chemical sensitivity. There may also be situations where a PWMEs home circumstances are unsupportive and they cannot improve without residential care. Consideration must be given to the provision when necessary of residential or hospital care giving due regard to environmental factors mentioned above.	
SH	Mid Staffordshire General Hospitals NHS Trust	3	NICE	37	4.1	Research Recommendations Why are the main research recommendations limited to current intervention strategies? Especially as mentioned previously, when currently	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope of the guideline but the GDG did recognise the need for research into aetiology.

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						potentially ground-breaking research is going on in several other fields such as gene expression, which seems likely to provide new intervention strategies and further understanding. If there is no evidence to suggest that GET/CBT is effective in severely affected adults & children then why are they being advocated by NICE? Given that there may be up to 240,000 people with ME/CFS, surely biomedical research to establish the pathophysiology of ME/CFS should be considered an urgent priority?	

National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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SH	Mid Staffordshire General Hospitals NHS Trust	4	NICE	38 38	4.4 4.4 cont.	NICE state: 'It is not known how much improvement is important for patients with CFS/ME.' So the message is that there are known knowns– there are things that we know that we know. There are known unknowns–that is to say, there are things that we now know we don't know. But there are also unknown unknowns–there are things we do not know we don't know. And each year we discover a few more of those unknown unknowns? This in an incredible (and perhaps very telling) statement to make–it	This is intended to convey that different people will have different goals based on their current individual circumstances. Some may set as an objective maintaining their current level and avoiding deterioration for the time being. This question could be asked of most serious chronic illnesses. In studies on hip replacement, there are disputes about whether the better outcome is being able to walk again without pain or that the x-ray shows a good placement of the device. In looking at the CFS/ME research, there were a wide variety of outcomes with little indication of their relative benefits.

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						suggests that we do not know the best way of measuring outcomes in research studies, yet CBT & GET are being put forward with a degree of certainty that we do not have. This question could not conceivably be asked in relation to any other serious, chronic illness such as cancer, diabetes, M.S. The answer is obvious: PWME wish to return good health and have the opportunity to return to full-time work or education and enjoy a normal life! The MAIN question is: What patients and WHAT	

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						disorder are we discussing here?	
SH	Mid Staffordshire General Hospitals NHS Trust	5	NICE	40	6	The psychosocial bias which is evident throughout the NICE draft is exposed yet again. The only two (relatively rare) symptoms deemed worthy of further "related" guidance are anxiety and depression.	The guideline refers to other relevant NICE guidelines.
SH	National CFS/ME Observatory	1	NICE version	General		The National ME Observatory The National ME Observatory is a research collaboration, sponsored by Action for ME and funded by the Big Lottery Fund, comprising the London School of Hygiene and Tropical Medicine, the University of East Anglia, and the Hull-York Medical	Noted with thanks. This research will be considered in the update.

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						School. It was established earlier this year in order to address the serious problem about what we considered to be a totally inadequate corpus of scientific knowledge about CFS/ME. The Observatory has a programme of research which, over the next three years, should enable a start to be made, in a systematic way, to filling some of the gaps in our knowledge, in particular in the areas of epidemiology and qualitative social research.	
SH	National CFS/ME Observatory	2	NICE version	General		Adequacy of the Evidence Base We appreciate that the role	The choice of topics and their timing is made by the Department of Health. Please see the NICE Technical Manual and Chpater 2 of the guideline with regard

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						of NICE is to review the evidence base regarding specific clinical conditions, and to develop evidence-based guidelines for their management, to be applied throughout the NHS in England. Given our misgivings about the inadequacy of the evidence base pertaining to CFS/ME, we are concerned that the current draft, while it contains some helpful points, is premature. The belief that evidence-based guidelines can be constructed on such an inadequate evidence base is, in our opinion, misguided. Indeed, many of the recommendations in the draft guidelines appear	to how recommendations were developed in the absence of evidence.

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						not to be evidence-based at all.	
SH	National CFS/ME Observatory	3	NICE version	General		Impact of Guidelines on Practice The scientific study of CFS/ME is a rapidly developing field where little is known at present, but in which a great deal is likely to be learned in the next few years. The current draft guidelines largely reflect what limited research was carried out in the 1990s and before. If promulgated, even if subject to subsequent review, the guidelines are likely to be in force for at least five years, during which time people with ME receiving NHS	See above. The guideline will be reviewed after 2 years. Should significant new research have been published which may change a recommendation this will be considered at that time.

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						care will be unable to benefit from whatever scientific advances may be made.	
SH	National CFS/ME Observatory	4	NICE version	General		Subsequent sections of this commentary review some of the specific recommendations contained in the draft guidance.	Noted
SH	National CFS/ME Observatory	5				Key Priorities for Implementation	
SH	National CFS/ME Observatory	6	NICE version	6	2-5	The draft states:- "When the adult or child's main goal is to return to normal activities then the therapies of first choice should be	This wording did not clearly reflect what was intended and has been changed to make it clearer. Recommendations have also been revised

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						CBT or GET 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." This is very misleading. It implies that there is a group of people with CFS/ME who may not have as their main goal a return to normal activities. We have never encountered this. It also implies that, of a range of possible therapeutic approaches, CBT and GET are the two which emerge as being the most effective,	

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						whereas the reality is that there has been very little clinical trial activity involving other treatments or management approaches, and there is therefore no basis for comparison of CBT and GET with other possible approaches. The statement is also misleading because it does not consider at all the extent to which the outcomes of trials of CBT and GET, all of which have been conducted in groups of subjects which in their various ways do not appear representative of the population with CFS/ME as a whole, are generalisable, and applicable to that whole population.	

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SH	National CFS/ME Observatory	7	NICE version	6	6-23	The section on shared decision-making is helpful, though outlining principles of largely general application rather than pertaining specifically to CFS/ME. The first point, that "… the healthcare professional should acknowledge the reality and impact of the condition and the symptoms", is valuable, because recent research has demonstrated that some fifty per cent of all GPs, for example, still do not accept CFS/ME as a genuine clinical entity.	Noted with thanks
SH	National CFS/ME Observatory	8	NICE version	6	28	Among the objectives of a management programme is "to manage the physical	Many of these points are addressed on other recommendations such as returning to education or work and accessing

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						and emotional impact of [the] symptoms." This does not go far enough, as there needs also to be awareness of the social consequences of the illness, including for example the effects on families and carers, on employment and education, and on the likelihood of social exclusion.	community care.
SH	National CFS/ME Observatory	9	NICE version	7	1-2	It is stated that a diagnosis of CFS/ME can be made after persistence of symptoms for four months. From a management point of view, this is more satisfactory than the six months stated in most clinical research case definitions, but the	This is made clear in recommdation in the recommendation 1.2.3.1 on page 17. Not everything can be covered in the key priorities.

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						recommendation should also be noted that "advice and symptom management should not be delayed until a diagnosis is made."	
SH	National CFS/ME Observatory	10				General Principles of Care (paragraph 1.1)	
SH	National CFS/ME Observatory	11	NICE version	7 8	12-29 1-5	Paragraph 1.1.1.1 repeats the section on shared decision making in Key Priorities for Implementation, and is helpful.	Noted with thanks
SH	National CFS/ME Observatory	12	NICE version	8	6-8	The statement in paragraph 1.1.1.2 is also useful, viz. that:- "Healthcare professionals who are responsible for	Technical competencies are beyond the scope of the clinical guideline. This is an issue for the iimplementation team who will work with the appropriate professional and education organisations.

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						the care of an adult or child with CFS/ME should have the appropriate skills and expertise in the condition.” What the document does not state is what skills and expertise are appropriate, nor how they are to be acquired. Given that CFS/ME is a relatively common condition, and that a wide range of healthcare professionals, particularly in primary care, are likely to be involved in the care of people with CFS/ME, this has considerable implications for education and training, at both	

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						undergraduate and postgraduate levels. These in turn have substantial organisational and resource implications which will have to be addressed.	
SH	National CFS/ME Observatory	13	NICE version	12	26	The emphasis in paragraph 1.1 on accurate and complete information is welcome, as is the statement at paragraph 1.1.4.4 that there should be "… availability of care regardless of ability to travel to services." This if important, because there is evidence, albeit largely anecdotal, that people with severe ME who are housebound or bedbound may receive inadequate care because of problems	Noted with thanks. Resource implications will be addressed by the NICE Imprlementation Team.

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						of accessibility of services. Again, there are resource implications, because for this to be achieved there would need to be a considerable expansion of community-based outreach facilities.	
SH	National CFS/ME Observatory	14				Making a Diagnosis of CFS/ME (Paragraph 1.2)	
SH	National CFS/ME Observatory	15	NICE version	13	7-28	The diagnostic criteria detailed in paragraph 1.2.1.2 do not conform to any existing clinical case definition for CFS/ME, and appear to be based on poor evidence.	Please refer to the full guideline which addresses the GDG views on current diagnostic criteria.
SH	National CFS/ME Observatory	16	NICE versi	17	6-15	Paragraph 1.2.4.2 makes recommendations	The view of the GDG was that referral should be *offered* to a patient.

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			on			regarding referral of patients with CFS/ME to specialised care. It recommends that all such patients, both adults and children, irrespective of severity, should be referred to specialist care, with severity determining the speed of referral, the maximum permissible delay being six months for adults in whom the condition is mild. This advice appears somewhat arbitrary and dogmatic, as there is no reason why many people, particularly with mild CFS/ME, cannot be treated in the primary care sector, albeit with back-up from community-based multi-disciplinary	

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						teams. However, if this recommendation were to be implemented, it would require a very considerable expansion of the existing network of secondary and tertiary referral facilities to ensure that all parts of the country were adequately covered.	
SH	National CFS/ME Observatory	17				Management (paragraph 1.3)	
SH	National CFS/ME Observatory	18	NICE version	18	3-7	The statement in Key Priorities for Implementation that:- "When the adult or child's main goal is to return to normal activities then the therapies of first	This wording did not clearly reflect what was intended and has been changed to make it clearer.

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						choice should be CBT or GET 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." is repeated in paragraph 1.3.1.3, and is as questionable as before, both because we are unaware of the existence of a group of people with CFS/ME who may not have as their main goal a return to normal activities, and because we do not consider that CBT and GET	

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						have been evaluated sufficiently for this blanket claim as to their effectiveness to be justified (see paragraph 2.1). This recommendation should be revised, because:- • Patients want to get better, if not completely free of symptoms, and to live full lives. This is obviously their and their physicians' primary goal. It is hard to recognize a	

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						situation when patients do not want to return to normal. So, the first part of this sentence contributes nothing and should be deleted. • There is no doubt people with any chronic condition are entitled to be fully supported and this should not be different in CFS/ME. CBT and GET and other	

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						psychological therapies are useful strategies to support people with a wide variety of chronic conditions and aid rehabilitation of people who have been made unfit or emotionally affected as a consequence of their illnesses. These could therefore be recommended as	

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						rehabilitation strategies, in selected cases only. However, they should not be regarded as the first choice of treatment, or as providing a cure. To put rehabilitation before secondary prevention or early intervention is not a good idea, and falls short of the truly patient centred approach which the draft	

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						guidelines claim to be advocating. • At present the evidence for benefit of CBT and GET is small, particularly as a first option of treatment rather than as an approach to help the rehabilitation of some complicated cases of CFS/ME. The studies on these interventions	

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						have mostly addressed complicated cases at tertiary centres and most have considerable methodological flaws. Moreover the positive results, when shown, are quite modest and one needs to carefully balance these against the possible complications of these forms of management.	

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						Very importantly, the slightly larger volume of local publications on one or two interventions should not bias the guidelines towards these, especially considering the above. We therefore propose that this sentence, if it is to be retained at all, be changed, for example, to: ' CBT and GET should be offered as a rehabilitation approach to people with complications of CFS/ME that may benefit from such approaches'.	

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						Greater emphasis should be placed on medical interventions (and research into medical interventions due to the lack of evidence), including symptom control, activity management, and improved access by patients to services and appropriate information and resources.	
SH	National CFS/ME Observatory	19	NICE version	19 and 33	13 10	In paragraph 1.3.1.10 it is stated:- "… there is no evidence for the following strategies …",	The recommendations have been revised to reflect where the GDG recommending that a test or strategy should NOT be used (e.g. 'going to the gym') vrs those where there was in sufficient evidence to recommend them as a treatment for CFS/ME. Please refer to the full guideline for background information. .

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						and, again, in paragraph 1.3.6.3:- "There is no evidence on the use of supplements for adults and children with CFS/ME …". However, in stating that there is "no evidence", the draft guidelines fail to distinguish between interventions and management strategies the outcomes of which have been studied, but with negative or equivocal results, and those which have not been studied at all. Thus we have the familiar confusion between	

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						lack of evidence and evidence of lack of effect. NICE should indicate clearly which interventions come into which category.	
SH	National CFS/ME Observatory	20				Key Principles of Care for People with Severe CFS/ME (paragraph 1.4)	
SH	National CFS/ME Observatory	21	NICE version	34	14-16	The statement at paragraph 1.4.1.1 that:- "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	Please see response above.

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						appropriate” is very welcome, but, as previously stated, this has considerable resource implications, and implications also for the ways in which services are organised so as to make them accessible to people who may be housebound or bedbound.	
SH	National CFS/ME Observatory	22	NICE version	34	21-25	Subsequent sections of paragraph 1.4 promoting the use of CBT and GET in severely affected people are extremely dubious, since there is a dearth of evidence supporting the use of these approaches to management in such patients, and plenty of	This has been revised

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						anecdotal evidence, as well as evidence from surveys conducted by patient organisations, of these methods being at best of limited and at worse damaging to people with severe ME.	
SH	National CFS/ME Observatory	23				Research Recommendations (section 4)	
SH	National CFS/ME Observatory	24	NICE version	General		The identification of areas where research is needed is very useful, but it serves also to underline our misgivings about the document as a whole, by spotlighting the extent to which the research evidence base, upon which the guidelines are	The aim is to improve the research base for subsequent updates.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						supposed to be based is deficient.	
SH	National CFS/ME Observatory	25	NICE version	37	19-24	Paragraph 4.1, for example, in answer to the question:- “Are current intervention strategies that have been shown to be effective in mild to moderately affected adults [i.e. CBT and GET] effective in a) children and b) those who are severely affected (adults and children)? states that:-	The aim is to improve the research base for subsequent updates.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						"There is no evidence for the use or effectiveness of these strategies in these two patient groups." and yet the guideline recommends that they may be used in such cases.	
SH	National CFS/ME Observatory	26	NICE version	38	10-12 and 19-22	In paragraph 4.3, the question is put:- "What is the prevalence and incidence of CFS/ME in different populations? What is the natural	The aim is to improve the research base for subsequent updates.

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						course of the illness?" The document goes on to state:- "We need reliable information on prevalence and incidence of this condition to plan services. This will require well constructed epidemiological studies across different populations to collect longitudinal data needed to predict outcome, and to calculate the economic impact	

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						due to loss of work/education.” This of course is correct, yet the draft guidelines have made a number of recommendations, which, to be implemented, will require the planning and implementation of services on a large scale across the country. This therefore reinforces our conclusion that, in addition to the deficiencies in the evidence base on which the guidance regarding management is said to be based, there are further deficiencies in the corpus of evidence necessary for the effective implementation of many of	

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						the recommendations. The Observatory has already identified lack of epidemiological information as a major gap in knowledge of CFS/ME, and has a funded programme, including piloting a disease register, and descriptive and epidemiological research, to address this gap.	
SH	National CFS/ME Observatory	27	NICE version	38	23-24	Paragraph 4.4 asks: "What is the best way of measuring outcome in research studies?" This is very important, as agreement on this could	Noted with thanks

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						facilitate, for example, meta-analysis in years to come.	
SH	National CFS/ME Observatory	28	NICE version	General		It is surprising that, among research recommendations, there is no indication of a need for intervention studies, despite the fact that few interventions except for CBT and GET have been subject to any form of evaluation whatsoever. This suggests a somewhat uncritical attitude to the research evidence base and its deficiencies. In particular, the lack of any such recommendation could mean that the current window of opportunity to conduct a comparative	The research recommendations are not intended to be a comprehensive lsit, but are limited the research recommendations to those areas which would most inform the updates of the guideline. The number and guideline can make is retricted – see NICE Technical Manual

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						evaluation of the various approaches to service developments currently being established under the Department of Health's programme, may be lost. This would be a great pity, as this constitutes a natural experiment which is unlikely ever to recur.	
SH	National CFS/ME Observatory	29				Conclusions	
SH	National CFS/ME Observatory	30	NICE version	General		The draft, as it stands, has obvious defects, which make it unsuitable for general application throughout the NHS. It is difficult to read, demonstrates lack of understanding of CFS/ME, and often misses the point.	The full guideline is intended as a background document. Please refer to the *Quick Reference Guide* and the *Understanding NICE Guidance* both on the NICE website which present the information in a more accessible format. Please see above about referral of topic at this time.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						In our view, it is premature, as the evidence base is inadequate to support the conclusions and recommendations made, and is also inadequate to support the service developments to which those recommendations would inevitably lead.	
SH	National CFS/ME Observatory	31	NICE version	General		The review claims to be evidence-based, but is in fact mostly based on expert opinion, rather than on evidence. This needs to be made very clear throughout the document. However, there is no indication that the document reflects a balanced view of expert opinion on CFS/ME. In many instances there are	As with all NICE guidelines, this guideline is based on the *available* evidence. Please refer to the full guideline where the evidence review is presented as a complete document in the appendix of the full guideline. The full guideline also documents the consensus methods used.

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						clear differences of opinion which are not reflected in what in many ways is a highly tendentious document.	
SH	National CFS/ME Observatory	32	NICE version	General		The report places too much and perhaps premature emphasis on the contribution of CBT and GET in the primary treatment of and rehabilitation from CFS/ME, before this has been properly researched. The report gives the erroneous impression that the role of these management options have been satisfactorily-evidenced and widely agreed by professional and lay groups involved in this field.	As stated above, the guideline is based on available evidence for CBT and GET which was discussed at length by the GDG. Once again, please refer to the full guideline for how recommendations were developed.

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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SH	National CFS/ME Observatory	33	NICE version	General		The draft guidelines, as they stand, are premature, because the evidence base is inadequate to support a development of this nature. Some of the recommendations are wrong in principle. Guidance which ensures equitable and effective care for all people with CFS/ME, irrespective of who or where they are, would be a major advance, but this draft does not constitute such guidance. Instead, it creates a serious risk of being set in tablets of stone, so that for some years the treatment of people with ME in the NHS will be based upon it,	The choice of topics and their timing is made by the Department of Health. Please see the NICE Technical Manual and Chpater 2 of the guideline with regard to how recommendations were developed in the absence of evidence.

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						thereby denying them the opportunity to benefit from therapeutic developments that are likely to occur over the next few years.	
SH	National CFS/ME Observatory	34	NICE version	General		The research recommendations are helpful, but contain serious omissions, especially as regards intervention studies, and serve only to underline the extent to which the existing evidence base is inadequate.	The research recommendations are not intended to be a comprehensive lsit, but are limited the research recommendations to those areas which would most inform the updates of the guideline. The number and guideline can make is retricted – see NICE Technical Manual
SH	National CFS/ME Observatory	35	NICE version	General		We therefore strongly recommend that the draft be rewritten in order to reflect more accurately the current state of scientific knowledge, and also the views of stakeholders,	The draft has been substantially rewritten based on stakeholder comments. It follows the NICE methodology with regard to consideration of the evidence by the GDG and makes clear where recommendations were developed by consensus.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						including patient organisations, which do not appear to have been taken very much into account in developing the present draft. NICE guidance is of such importance in the NHS, and has huge repercussions on patterns of treatment and care. It therefore needs to be accurate, to reflect the evidence base as it stands. Where there are differences of opinion among experts, as often as not because of the shortcomings of the evidence base, such differences should be reflected in the document.	
SH	Newport Pharmaceuticals Ltd		NICE	13		**Diagnostic**	Wording as been changed to reflect this

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						Recommendations This is a curious paragraph in a number of respects: ME is a neurological illness (ref. to WHO classification) – so why would patients with neurological signs be excluded from diagnosis? Cardiovascular abnormalities have been found in patients with ME (ref. 'Human Tragedy and the Heart of the Matter', vascular research by ME Research UK). Surely anxiety and depression indicate anxiety and depression – rather than acting as markers for some 'serious underlying	comment.

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						pathology'. Of course anxiety and depression should be treated in their own right if present. More Generally, the implication is that a diagnosis of ME/ICD CFS does not in itself indicate a likelihood of 'serious underlying pathology'. Even if 'serious' is intended to be read as 'life threatening', this does not always hold true: fatalities, although rare, do occur (ref. Carruthers et al, 2003, p34, and the documented deaths of [X, X, andX]).	
SH	North Staffordshire Combined Healthcare NHS Trust	4	NICE	General		**SUMMARY** The consensus of opinion of LocalME respondents is that we cannot support the	Any physical illness has a psycho-social aspect to its management. The Guideline Development Group did not promulgate a psychosocial theory for the causes.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						current NICE Draft Guideline whilst it: - promulgates a psychosocial theory of ME/CFS - fails to subgroup those under the umbrella diagnosis of CFS/ME - fails to heed international research and opinion that GET–and CBT aimed at encouraging patients to exercise–can cause serious, possibly irreversible harm to patients with strictly defined ME (CFS ICD-10). Without major changes to the current draft guideline	The evidence does not allow distinctions between sub-groups. The evidence supports the use of CBT and GET. However, we have recommended that the preferences and needs of the individual should be taken into account. While there is some good evidence-based advice in the Caruthers guidance, which is included in this guideline, much of it is consensus-based rather than evidence-based.

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						the international reputation of NICE is in danger of being seriously damaged by allowing its name to be attached to dangerously flawed guidance that may result in iatrogenic damage to patients with strictly defined ME aka CFS (ICD-10 G93.3) whilst hindering physiological progress in this field. The major failure is to conflate the needs of patients with the neurological illness ME (ICD-10) with those of patients experiencing chronic fatigue states without a medical basis (ICD10- F48.0). By adopting the NICE Guidelines, whilst failing to	

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						take cognisance of the Caruthers B*. et al.guidance (refer to above)* the UK is putting itself in a somewhat precarious legal and ethical position as current definitions and practice, alongside lack of recognition, acceptance and due consideration of the physiological characteristics of ME or strictly defined CFS may result in avoidable, possibly irreversible harm to some patients currently subsumed under an unnecessarily broad diagnostic label. The draft guideline is clearly aimed at	

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						unexplained chronic fatigue and the overriding message to healthcare professionals is that all patients need to do to get well is to change their beliefs and activity patterns. LocalME therefore rejects these guidelines as highly inappropriate to the needs of people with ME (CFS ICD-10) and is deeply concerned about the possibility of iatrogenic harm to PWME if these guidelines are applied. Consequently, we deem the content of the current draft guideline as not being conducive to the well-being and interests of ME	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						sufferers. We feel it is unlikely the Draft NICE Guideline will reassure anyone that M.E/CFS (ICD-10 G93.3) is being taken seriously–in fact the current NICE guidelines will leave PWME no other option than to seek help and support in the private sector. When contrasted to the "Canadian Clinical Case Definition and Guidelines for Medical Practitioners" NICE guidelines fair very badly indeed and in actual fact do not relate to the same disorder.	
SH	North Staffordshire Combined Healthcare NHS Trust	5	NICE	7, 13,16		Many experts use the Oxford diagnostic criteria which are more rigorous in	Noted.

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						terms of time, but are broader. Extending the time interval by 2 further months could allow for natural improvement, particularly when the aetiology is post-viral.	
SH	North Staffordshire Combined Healthcare NHS Trust	6	NICE	7	8	Primary care needs education and support in order to assess, diagnose and treat early cases.	Noted.
SH	North Staffordshire Combined Healthcare NHS Trust	10	NICE	17	2, 3 1.2.4	Specialist services are not available within many areas. PCTs would need to commission services.	This is an implementation issue that will be taken up by local health communities.
SH	North Staffordshire Combined Healthcare NHS Trust	11	NICE	18+		Useful description of therapeutic options including advise about what is not useful.	Noted with thanks.
SH	North Staffordshire Combined Healthcare NHS Trust	12	NICE	31	1.3.4.8	The evidence for the use of low dose tricyclics is flawed. These tend to induce anticholinergic side-	None of the anti-depressants is licensed for use in pain. All of the anti-depressants have side effects and amitriptyline is not worse that the others, in fact a low dose

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						effects. If used for pain the evidence would suggest that all broad-spectrum antidepressants are useful and the more modern, such as mirtazapine, venlafaxine, duloxetine have fewer side-effects.	may be less so. The Guideline Development Group was of the view that low-dose amitriptyline is a perfectly reasonable choice for pain control.
SH	North Staffordshire Combined Healthcare NHS Trust	13	NICE	33	1.3.6.3	In desperation many patients turn to alternative therapies. There are individuals, particularly on the internet, who exploit this and patients may be seriously financially disadvantaged by these people.	This guidance provides advice for the NHS on those treatments that have been found to be effective and those for which there is no evidence. It will be accompanied by a version for the public ‘Understanding NICE Guidance’, which will explain this to patients. It is beyond the scope to the guideline to advise on what patients should or should not spend their own money on.
SH	North Staffordshire Combined Healthcare NHS Trust	14	NICE	35	1.4.1.8	Hospital facilities are largely unavailable – appropriate services should be commissioned.	Noted with thanks. This will be referred to the NICE implementation team.
SH	Royal College of General	6	NICE	29	Bottom	Add bullet point:	There is a now a section on re-evaluation.

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	Practitioners Wales					- Review basis for diagnosis. See page 36-7 full	
SH	Royal College of Nursing	3	NICE	5	9/10	Not all severe patients are noise and light sensitive, but will be housebound/bedridden, therefore, this sentence is mixing symptoms with the level of disability and is therefore confusing.	These are based on those of the Chief Medical Officer's report
SH	Royal College of Nursing	4	NICE	6 and 7		These key priorities need to be put in order of importance e.g. starting with page 7 line 17. The current order seems to imply that CBT and GET are the most important factors and this could be a source of upset with service users.	Noted.
SH	Royal College of Nursing	5	NICE	13	14	Diagnosis to be considered	The intention is to raise awareness that

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				16	24	if fatigue plus one additional symptom – It does not clarify the symptom presentation later when making the diagnosis – what sort of impact will this have on the number of patients being referred to the CFS/ME services?	the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.
SH	Royal College of Nursing	6	NICE	17	5	This reads as a negative statement when people do recover and improve with the correct advice.	This has been reworded.
SH	Royal College of Nursing	7	NICE	19	19	This sentence is confusing and can suggests that going to the gym or taking more exercise is harmful – we assume that what the sentence is trying to say is that unstructured exercise – boom/bust pattern is harmful.	We have clarified the wording in response to your comments.
SH	Royal College of Nursing	8	NICE	30	26	Many health professionals	This comment will be referred to the NICE

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						working within the CSF/ME services are using components of CBT although may not be CBT therapists – how will this be affected?	implementation team.
SH	Royal College of Nursing	9	NICE	32	19	Needs re-wording – statement does not appear to make sense	This section has been substantially revised.
SH	Royal College of Nursing	10	NICE	35	5	GET needs to be graded appropriately to the patient's severity	Noted.
SH	Royal College of Nursing	11	NICE	35	28	Some patients with severe CFS/ME do require hospital admission specifically for management of their CFS/ME. This period of in-patient treatment can last from 2-6 months. There are currently only 2 specific units for in-patient treatment for CFS/ME	Noted.

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						without specific recommendation for this, the development of further in-patient units and negotiation with commissioners will be very difficult	
SH	Royal College of Nursing	12	NICE	35	1.4.1.8	In conjunction with earlier comments, we support that young people should wherever possible be managed within the community. In the experience of one service (Nottingham Children and Young Peoples' Rheumatology Service) however, a significant proportion of young people with complex needs and circumstances require in-patient	Noted. This is the intention of this recommendation. Thank you for submitting your criteria for admission. The view of the Guideline Development Group is that hospital admission should be avoided if possible.

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						admission. As one of the centres with the resources and expertise, the centre is being referred patients nationally. Of these national referrals some have come via the Department of Health and others via Association of Young People with ME. In patient admission is only considered when all other avenues have been explored and the resources available are recognised as insufficient to meet the complexity and intensity of those young people. The service applies strict criteria to this process and have clearly defined outcome measures, re-integrating	

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						back into the community as soon as possible with appropriate support. Criteria for admission to the Nottingham CFS / ME inpatient management programme: • Where young people have failed to progress with an out patient programme. • Where local community services are unable to meet the specialist needs of the young person. • Where the physical challenges of attending out	

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						patient appointments leads to an increase in the severity of symptoms. • Where young people are unable to tolerate the travel involved in attending out patient consultations. • Where young people are not accessing school or whose mobility and function are severely limited. • Where lengthy chronic illness has lead to social isolation such as the young person's	

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						social and emotional development is significantly impaired. • Where co-morbid conditions are presenting additional challenges to a community based programme. Consideration needs to be given to this very specific group of young people requiring in-patient care, as currently families have to travel significant distances to access more intensive management. One of the concerns is that if services such as this is not	

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						recognised, young people will not be able to access the care they need and PCTs will potentially, use the guidance to negate their support for in-patient programmes. Management strategy Young people are managed with a consistent and coordinated approach to address their needs holistically. This is currently provided by education, physiotherapy, occupational therapy, liaison psychiatry, youth worker, complementary therapy nurse specialist, play specialists and the pain team. The	

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						rehabilitation programme works on an educational model, running term time only. The appointment of a CFS/ME Coordinator enabled other professionals to concentrate on their acute clinical work by undertaking the liaison and coordination of services. In addition to the above, for out of area referrals, the following are provided: • Initial home assessment – for those unable to attend an out-patient appointment	

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						• Liaison with local professionals • Diagnosis/ confirmation of diagnosis and assessment of co-morbid conditions • Multi-disciplinary assessment as an inpatient – tailored to the individuals level of functioning • Assessment for appropriateness for programme • Inpatient management • Discharge planning • Post discharge follow up and liaison • Negotiation of funding with GP	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						and PCT’s Whilst the above may appear time consuming and costly, for the young people concerned and their families, this service is often cited as their last option and is vital to their care.	
SH	Royal College of Paediatrics and Child Health	13	NICE	6	12	It says practitioners are advised to provide information on the aetiology of CFS/ME – but where is the information to assist them in doing this?	Noted – see also the Introduction. It should also be noted that aetiology was outside the scope of the guideline, and that the evidence on this was not reviewed in detail.
SH	Royal College of Paediatrics and Child Health	14	NICE	6	18	There is a referral to the NHS Expert patient programme, yet the CFS/ME Service Investment Programme Report 2004 – 2006. found this not suitable for all	We have revised the explanation for this recommendation.

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						patients (See Page 25– 2.4.1 Expert Patient Programme of this report.)	
SH	Royal College of Paediatrics and Child Health	15	NICE	6	24	It is important that this paragraph reflects the need to initially set a base line of activity that is sustainable and avoids boom and bust. Sometimes to do this people have had to initially reduce activity. This is in the full guidelines, but not everyone will read the full guidelines which is why it is important to include it here.	These are the key priorities more information is given later in the guideline.
SH	Royal College of Paediatrics and Child Health	16	NICE	7	3	We are pleased the recommendation is that the diagnosis should be made by a paediatrician although it is not clear why it needs to be a 'General' paediatrician. The	Noted. We have recommended that any healthcare professional involved in the diagnosis or management should have experience in CFS/ME.

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						important thing is that the paediatrician who makes the diagnosis has expertise in the management of CFS/ME. Some General paediatricians might not. This description comes up throughout the document.	
SH	Royal College of Paediatrics and Child Health	17	NICE	8 11	10 and 23	Connexions for school is only relevant for children 13-19, and does not exist in Scotland or Wales. With the restructuring that is taking place across England in 2007, as part of the Every Child Matters initiative it is likely that some local authorities will integrate Connexions for School within other structures. Hence it might be safer to say schools and	Noted and changed.

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						local authorities, rather than Connexions for school.	
SH	Royal College of Paediatrics and Child Health	18	NICE FULL	10 79	11 1	We are disappointed that transition of care got such little attention and such woolly recommendations. The recommendations do not make it clear that they are talking about adolescent transition (if indeed it is) and we found that it is one of the areas when things can go really wrong. This is a prime opportunity to try to improve things. At a minimum could we have a reference here to the NSF exemplar for CFS/ME which includes the transitions process as well	Added with thanks.

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						as the recently published NSF report -‘Transition: getting it right for young people’ here?	
SH	Royal College of Paediatrics and Child Health	19	NICE	14	17	The recommendation refers to seeking a second opinion if a child fails to recover as expected – but how do they know what is expected?	This recommendation is guidance prior to diagnosis based on the assumption that most children will have temporary illnesses from which they will recover.
SH	Royal College of Paediatrics and Child Health	20	NICE	14	28	NICE recommends assessment of mental health is carried out before a diagnosis is made. This does not appear to be evidence based and could appear as threatening in some situations. In the RCPCH guideline we emphasised the importance of an assessment of ‘pshychological well being’ as part of the diagnostic	This has been revised.

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						process and tried to emphasise how important the family were in this process.	
SH	Royal College of Paediatrics and Child Health	21	NICE	16	16	NICE do not recommend serology testing for EBV in the absence of any indicative history. The the RCPCH guideline we recommended that this was the only one worth testing as when we appraised the evidence we considered it to be 2+ evidence that recovery in EBV associated CFS/ME may be quicker than other forms and it may help patients and their families to know this.	Noted with thanks.
SH	Royal College of Paediatrics and Child Health	22	NICE	16	28	'…most children and adults, but not all, will have some improvement and some will recover fully.'	This has been reworded based on your comment.

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						The experience of managing children is that significantly more will recover and improve and this statement is too negative for paediatric care. There should be acknowledgement that the outcome for children is often better than for adults, but with limited evidence.	
SH	Royal College of Paediatrics and Child Health	23	NICE	17	8	All children with CFS/ME should be managed by staff with expertise, or the support of someone with expertise in the management of CFS/ME. The care of young people with CFS/ME is within the curriculum of the paediatrician and they should be supported by	This is the view of the Guideline Development Group and is why the recommendation regarding referral was made.

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						someone with more expertise if they haven’t the skills.	
SH	Royal College of Paediatrics and Child Health	24	NICE Section 1.3	17–28		It would seem to make sense to change the order of these sections so activity, sleep and relaxation come first followed by the CBT and GET, with an explanation that CBT and GET incorporate these but also include additional components.	The structure has been changed and reflects this comment.
SH	Royal College of Paediatrics and Child Health	25	NICE	18	1	We agree that the child has the right to refuse treatment if they are old enough to understand. However, if the medical practitioner feels that the child and family no longer have trust in them, then a second opinion should be sought as	This is general guidance with all conditions.

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						working closely together with the family is of great importance. If any practitioner has concerns about child protection issues, as with any child, this should be taken forward by the usual route (Working Together: 2006)	
SH	Royal College of Paediatrics and Child Health	26	NICE	18	3	‘…when the adult of child’s main goal is to return to normal activities’. Several people reviewing this document have found this statement offensive and insulting. Are there any circumstances where this isn’t the case?	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	Royal College of Paediatrics and Child Health	27	NICE	18	8	This recommendation was found to be confusing. The document states quite clearly that activity	Noted. These recommendations have been revised.

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						management strategies, sleep management and relaxation techniques are components of CBT and GET. These are also strategies that could (and should) be implemented in the very early stages of the condition, prior to diagnosis, which cannot by definition happen until the patient has been unwell for some months. If people are offered CBT or GET it is likely to be some months into their illness. Could these two paragraphs be reworded to reflect this? Patients with the symptoms of CFS/ME should be given	

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						information and advise to assist them in managing their condition early on, well before symptoms have persisted long enough for a diagnosis to be confirmed. This information and advice includes: • Activity management strategies (see recommendations below) • Sleep management (see recommendations below) • Relaxation techniques (see recommendations below)	
SH	Royal College of Paediatrics and Child Health	28	NICE	19	1	The majority of children with moderate symptoms of	We have noted the need for appropriate use and monitoring of equipment.

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						CFS/ME with an integrated multi-agency management plan will have improved to a level of not requiring equipment and adaptations within a six month period. The provision of equipment such as stair lifts assumes a poorer recovery process than most of us experience within a process of early diagnosis, intervention and multi-agency management. There needs to be research on whether the speed of recovery from moderate to severe depends upon the balance of a optimistic rehabilatitive management plan, versus provision of equipment with the anticipation of long-term disability.	

National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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SH	Royal College of Paediatrics and Child Health	29	NICE	21	24	1.3.1.1 and 1.3.1.2 state that individual programme should be offered which should be the patient's choice. Then under 1.3.1.14 it is stated that adults should be offered a GET programme but there do not appear to be any recommendations for children around GET implying that GET is not suitable for children. When developing the RCPCH guideline we found evidence that children should be considered for GET or activity programmes.	The guideline recommendation has been clarified (now refers to people – i.e. adults and children).
SH	Royal College of Paediatrics and Child Health	30	NICE	28	12	I think this would benefit from adding that setbacks do happen and at times no one really ever finds the	This section has been revised to reflect concerns including that it may not always be possible to identify the cause.

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						cause. It is at these times that patients are likely to disengage with the management plan, so care must be taken that the professioanls is perceived as supportive, understanding and encouraging rather than critical.	
SH	Royal College of Paediatrics and Child Health	31	NICE	31	3	What evidence is there that children with CFS/ME experience greater intolerance and more severe adverse events / side effects from drug treatment than other patient groups? This should not be stated as fact without universal professional support that this is the case.	The Guideline Development Group was concerned about sub-optimal doses being prescribed that would not benefit the patient. As an in-depth search of the literature yielded no evidence for greater intolerance, this recommendation has been redrafted as part of an individual management strategy.

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						We could find not any discussion or evidence for this provided in the main guideline about how this recommendation was developed and it does not appear to have been through the formal consensus method. I am assuming it was a good practice point developed by the group, but with NICE having removed the grading from their recommendations, it is impossible to tell.	
SH	Royal College of Paediatrics and Child Health	32	NICE	31	32	In addition to our General comments regarding the way this recommendation was developed NICE does not cover dosages of such pharmaceuticals or by whom they should be	We do not generally include dosages or reproduce information available in the British National Formulary (BNF) or summary of product characteristics. We do make it clear that drug treatment for children should be under the

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						prescribed. During the development of the RCPCH guideline the GDG was concerned that the message given was that it was OK for anyone to prescribe these for children which we fear might be interpreted from the NICE recommendation. The experts on our guideline development group felt that it should be prescribed at a much lower dosage that may be used for prescribing for depression, for example.	supervision of a paediatrician.
SH	Royal College of Paediatrics and Child Health	33	NICE	33	6	In accessing complementary therapies for children, it is important that the therapist is registered appropriately and has the skills and	This is beyond the scope of the guideline.

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						training to be working with children (enhanced CRB check etc.)	
SH	Royal College of Paediatrics and Child Health	34	NICE	34	19	Children with severe CFS/ME should be having their educational, social, emotional and physical needs met. The management will involve the young person and their family and telephone delivery is inappropriate.	This recommendation has been revised to make the meaning clearer. Telephone is used as one example.
SH	Royal College of Paediatrics and Child Health	35	NICE	34	21	Where the patient is bed ridden, it is helpful to ensure muscles and joints are kept in working order to try and preventing complications occurring as a result of the patients inactivity. We suggest a sentence is added to this effect	Noted with thanks. The risks to bedridden patients are now given in a recommendation.
SH	Royal College of Paediatrics and	36	NICE	34	24	Why is it that CBT may be	The guideline makes clear that all people

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	Child Health					suitable for some children with severe CFS/ME as opposed to the expectation in mild to moderate. All children with severe CFS/ME require their needs to be met as per "Every Child Matters" and multi-agency assessment as a Child in Need needs to be initiated to ensure a multi-agency plan can be initiated. Referral to the child and adolescent mental health services should be considered.	with severe CFS/ME should have their needs met.
SH	Royal College of Paediatrics and Child Health	37	NICE	35	12	The statutory requirements to ensure that children's needs are met means that admission to hospital needs to be considered if community care is not able to achieve the meeting of	This is general to all children with complex medical conditions and beyond the scope of this guideline.

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						their needs. A complex, multi-agency, multi-disciplinary rehabilitation programme is not always achievable within a community based setting. Where indication, it is important that inpatients stays are planned so that the hospital can meet the patients more complex needs.	
SH	Royal College of Physicians of London	3	NICE	13	From 1.2.1.2	We do not believe that an acceptable definition of CFS/ME has been adhered to. For instance, the commonly accepted definition for research and diagnosis is that of Fukuda et al 1994. The consensus group here have presented their own definition, which really describes fatigue for	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						four months in the adult, with one, of a limited number, of other symptoms. This opens up the diagnosis from CFS/ME into a wider remit of fatigue disorders and not what is Generally accepted in medical practice as the heterogeneous group of fatigue conditions known as CFS. If the consensus group are confident in this new classification, then this should be emphasised and stated that the remit of these guidelines extend to "virtually any intrusive prolonged fatigue state".	
SH	Royal College of Physicians of London	4	NICE	17	1.2.4.2	On the subject of referral, the guideline suggests the timing of referral to specialist care should be	The view of the Guideline Development Group was that referral should be *offered* to a patient.

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						dependent on severity of symptoms, eg adults and children with mild CFS should be referred at six months, and adults and children with severe CFS should be referred immediately. Firstly, we are not aware of a case of CFS which could be identified as such from onset with severe symptoms. This also runs against the recommendations of the CMO's Report of 2002, which states that CFS should be recognised, and for the majority, managed at primary care level.	
SH	Royal College of Physicians of London	5	NICE	18	1.3.1.3.	The implication is that CBT and GET is based on good evidence in mild to	Please refer to the full guideline.

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						moderately affected adults, and some evidence in mild to moderately affected children. The guidelines do state that the evidence supporting CBT and GET are limited to certain groups of patients with CFS/ME. It also states the therapies of first choice should be CBT or GET. We feel that these are not either/or therapies, but quite different in their total effects and would be additive. The major studies on GET have only been used in ambulant patients who are able to travel, and never in isolation but always with a General management package, including recommendations	

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						for lifestyle changes etc. Clinical evidence and patient experience suggests strongly that some patients may be worsened with GET and more emphasis should be stated that it should be used in individuals who are able to sustain regular day to day activities and that appropriate supervision would be required.	
SH	Royal College of Physicians of London	6	NICE	23	1.3.1.20	This is managing setbacks: We think this is a potentially dangerous statement, that with increase in CFS/ME symptoms, exercise or physical activity should be maintained if possible to avoid the negative effects of deconditioning. We are	This recommendation has been revised to reflect concerns. However, the Guideline Development Group wished to reflect the general risks and deleterious effects of bedrest such as DVTs, chest infections, muscle wastage, etc., which should be avoided if possible.

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						not aware of any clinician who would make this recommendation, except in a very mildly affected patient. There are many reasons for setbacks in CFS, including excess physical activity or stress. If this is the case, and activity levels remain unchanged, the patient is at risk of having a more major or serious relapse. This needs to be emphasised.	
SH	Royal College of Physicians of London	8	NICE	28	1.3.3.3	Overall in the sections concerning setbacks, there seems to be some confusion. For instance, with mild to moderate setbacks it states "maintain usual activity levels or implement a gentle reduction in activity or	This section has been revised to reflect concerns.

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						exercise". Then it further states that rest periods should be increased, or frequency of rests should be increased. We believe clarification is required in the whole section of how to deal with a setback.	
SH	Royal College of Physicians of London	9	NICE	30	1.3.3.4	Competencies: This seems reasonable, however, CBT is being recommended by all. Current estimates state a minimum of 250,000 with CFS at any one time. Current DHSS usage of CBT has suggested as much as 15,000 more therapists will be required for current indications. Current waiting lists for CBT average between six months and one year. The Implementation Group	This comment will be referred to the NICE implementation team.

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						expressed concern that although guidelines are to set best standards of practice, the wholesale recommendation of CBT would not be practical in any "reasonable timescale" and without huge funding. This requires comment in the Guidelines.	
SH	Royal College of Physicians of London	10	NICE	30/32	1.3.4.1–1.3.4.8	Generally sensible comments except 1.3.4.1. which states "there is no pharmacological treatment or cure for CFS/ME". This is ostensibly true, but misses the point that few patients present with "pure" CFS. Most have additional symptoms which are not the cause but often become the perpetuators of the fatigue state, eg sleep	Noted with thanks.

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						disturbance, pain, anxiety, mood changes, new onset headache, bowel symptoms, allergies, vertigo etc, etc. Without the management of these symptoms the individual is unlikely to improve easily. Most of these symptoms will respond to conventional pharmacological measures if properly applied and most are evidence based. A statement is required, to say that CFS is a heterogeneous group of conditions with many symptoms. These may be manageable in the normal holistic manner to allow better functioning and almost certainly earlier recovery. The statement	

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						"there is no pharmacological treatment or cure for CFS/ME" should be rewritten as "the pharmacological management of CFS/ME is complex but should follow conventional evidence based practice. As with most medical conditions, single pharmacological agents are not able to induce a "cure".	
SH	Royal College of Physicians of London	11	NICE	32 –33	1.3.5.1–1.3.5.3	Nutritional and dietary support. Sensible comments from an experienced nutritionist.	Noted with thanks.
SH	Royal College of Physicians of London	12	NICE	34 –35	1.4 1.4.1.3	Severe CFS/ME. It is stated that GET may be an appropriate addition to help patients develop their physical capacity and functioning. GET in its	This is made clear in the recommendation. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a

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						traditional form is not applicable and not possible in the very severe dependent patients. It has little place in those that are severely affected but not dependent. Early rehabilitation in these cases is difficult and requires careful controlled activity of daily living management, and expert goal setting.	sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches, informed by the principles of GET.
SH	Royal College of Physicians of London	13	NICE	35	1.4.1.8	This statement needs to be endorsed and emphasised, in that there may be circumstances where hospital admissions may be necessary in adults and children may require hospitalisation for assessment diagnosis and management. The reason	This is the intention of this recommendation.

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						this needs emphasis is, this is a problem today as many PCTs will not accept that some complex and severe patients do require admission to secondary and tertiary centres. The reason for admission should be expanded and may include severity of symptoms which preclude frequent visits to hospital, because of difficulties with travel, diagnostic dilemmas, situations where environmental factors may be perpetuating symptomatology, situations where local services are not developed sufficiently to provide the necessary community support etc, etc.	
SH	Royal College of Physicians of	14	NICE	35	2	Notes on the scope of the	The scope was agreed and signed off at

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	London			36		guidance. The guideline does not cover the management of co-morbidities. Whilst some would consider that this is acceptable, the management of moderately severe, severe and very severe CFS/ME is precisely the management of co-morbidities, which become the "driving perpetuators" of CFS. These have already been listed in some of the above comments, but would include diverse psychological states, pain, sleep disturbances, allergies, balance disturbances, headache etc.	the beginning of development and is included here for information.
SH	Royal Liverpool Children's NHS Trust	1	NICE	3	6	CBT–perhaps add that it is a treatment to be offered to	Changed.

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						both adults and children.	
SH	Royal Liverpool Children's NHS Trust	2	NICE	4	8	GDG–needs written in full first time mentioned.	Revised.
SH	Royal Liverpool Children's NHS Trust	3	NICE	6	10	When discussing providing information, perhaps add something about how this could be achieved (written, audio, visual etc.).	Revised.
SH	Royal Liverpool Children's NHS Trust	4	NICE	10	11	The transition process is a huge issue and is not explored in enough detail here. We need to have points added such as having link members in both child and adult services to aid transition, cross-over / overlapping services to aid transition etc.	The guideline stresses continuity of care. Local health communities will implement the guideline as is best for their population.
SH	Royal Liverpool Children's NHS Trust	5	NICE	11	13	Liaison with hospital schools / home tutors needs acknowledged. Extremely important within	This is general guidance for all children in hospital rather than specific to CFS/ME.

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						the child population.	
SH	Royal Liverpool Children's NHS Trust	6	NICE	13	29	‘common self-limiting conditions’–needs clarity.	Wording has been clarified.
SH	Royal Liverpool Children's NHS Trust	7	NICE	17	6	mild-moderate-severe CFS/ME. Are there going to be any guidelines which will help improve clarity to what constitute these groupings? Otherwise this is a subjective matter and may lead to major differences in categorisation.	Guidance is given in the glossary. There is, however, insufficient evidence to give definitive diagnosis criteria.
SH	Royal Liverpool Children's NHS Trust	8	NICE	18	16	The choice of components of strategies. Perhaps a mention of support networks which help children and adults to implement the strategies they have learned.	These are mentioned elsewhere.
SH	Royal Liverpool Children's NHS Trust	9	NICE	21	23	GET–no mention that this is useful for children. I know you have mentioned in the full draft (p.140 line	The guideline recommendation has been clarified (now refers to people – i.e. adults and children).

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						17 that this has not been researched in children– perhaps a brief mention of this can be added to the NICE guideline, to help the reader?).	
SH	Royal Liverpool Children's NHS Trust	10	NICE	General		I found this a cohesive, well written summary. It should be a valuable resource for families and professionals alike.s	Noted with thanks.
SH	Sheffield South West Primary Care Trust	12	NICE	12	1.1.4.4	Re availability of care regardless of ability to travel, this has resource implications as specialist teams so small are unable to undertake regular home visits	Noted.
SH	Sheffield South West Primary Care Trust	13	NICE	19	1.3.1.8	Do not think it is helpful to mention stair lifts as would not recommend these for children because it implies a permanent disability.	The view of the Guideline Development Group is that equipment can help to maintain independence.

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SH	Sheffield South West Primary Care Trust	14	NICE	General		CBT and GET are mentioned several times and I appreciate there is reasonable evidence for these approaches. However, there may be other approaches which are more helpful in response to certain clinical situations, e.g. motivational interviewing or solution focussed therapy. Lack of evidence does not necessarily mean lack of effectiveness for these approaches. The narrow focus of the NICE Guidelines may lead to helpful approaches or creativity being undermined and patient preference/clinical judgement being	Your point is noted. However, there was no evidence for these interventions and they cannot be recommended in preference to those for which there was evidence. We have, however, endorsed an individual approach and these may be helpful in individual cases.

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						undervalued.	
SH	Sheffield South West Primary Care Trust	15	NICE	4	P. 4 of 48-page version	Query re. definition of mildly affected – would substitute 'most leisure and social' for 'all…'. Would state 'many will rest at the weekend to cope with the rest of the week's activity' instead of the current wording in the last line of the mildly affected description.	These are based on those of the Chief Medical Officer's report.
SH	Sheffield South West Primary Care Trust	16	NICE	5		Query – would 'often sensitive to noise' be better than 'often unable to tolerate any noise'	These are based on those of the Chief Medical Officer's report.
SH	Sheffield South West Primary Care Trust	17	NICE	12	1.1.4.1	Section on support Think it is unrealistic and too forceful to say that 'the management plan should be reviewed and documented at each contact' would suggest	The view of the Guideline Development Group was that this should be done at each contact. 'Regularly' is too vague.

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						stating 'regularly' rather than at each contact.	
SH	Sheffield South West Primary Care Trust	18	NICE	13	1.2.1.3	Query re wording 'self limiting conditions' – have not come across this before and feel it is ambiguous and possibly has connotations of blaming the patient – could it just be 'other conditions' or 'other similar conditions'	The wording has been clarified.
SH	Sheffield South West Primary Care Trust	19	NICE	20	1.3.1.12	All clinicians do not subscribe to 'the CBT model of CFS/ME' and this does not seem to be well received by many ME Support Groups either. Instead could it be 'explanation of the CBT model and therapy rationale'. Explaining a specific controversial application of this model	The evidence supports the use of CBT. However, the GDG have recommended that the preference and needs of the individual should be taken into account.

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						would hugely jeopardise engagement and feels too forceful and 'expert position' for me to be comfortable with.	
SH	Sheffield South West Primary Care Trust	20	NICE	27	1.3.2.3	I disagree that sleep management should never include encouragement of day time sleeping. This works well for some people (siesta style!) and under certain circumstance can be a helpful management tool.	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.
SH	St Bartholomew's Hospital Chronic Fatigue Services	32	FULL	35–36	General	This section is extremely well written and based on the best available evidence. We particularly commend this.	Noted with thanks.
SH	St Bartholomew's Hospital Chronic Fatigue Services	97	NICE	General		We understand this is a summary version of the main document, so will not repeat all our comments	Noted.

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						and suggestions given above, apart from providing some comments for emphasis.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	98	NICE	4	Severity	We think it illogical to mix symptoms and disability. For instance sleep disturbance can occur in the large majority of patients, not just those with "moderate" illness. We do not think the evidence supports separating severe from very severe.	Noted. We have used 'severe' throughout.
SH	St Bartholomew's Hospital Chronic Fatigue Services	99	NICE	6	First Key recommendation	We emphasise that CBT and GET can also help those small number of patients who do not wish to return to normal health. CBT and GET are helpful for severely disabled patients on the basis of	This wording did not clearly reflect what was intended and has been changed to make it clearer.

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						several open studies.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	100	NICE	13	Diagnosis	There are too many symptoms included, which will encourage practitioners to attribute symptoms, such as palpitations, to CFS/ME when their cause is another or comorbid condition.	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.
SH	St Bartholomew's Hospital Chronic Fatigue Services	101	NICE	15	Investigations	The guideline emphasises the importance of investigations, with little if any guidance about the importance of examining the patient. Examination should include an appropriate physical examination as well as a proper mental state examination (since mood and other psychiatric disorders are common alternative and comorbid disorders).	Noted and revised.

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						In a similar way the guideline could usefully provide guidance about the most relevant parts of the history, such as exacerbating and alleviating factors, sleep disturbance, mood state, intercurrent stressors, and illness insight and beliefs.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	102	NICE	13–15	Diagnosis	Since patients diagnosed with CFS/ME commit suicide, the guideline should explicitly explain how to screen for suicidal thoughts and actions, and what to do for the patient, if found. We would be happy to help NICE in this matter with a screen developed for this purpose for the PACE trial, by [X].	Noted with thanks.

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SH	St Bartholomew's Hospital Chronic Fatigue Services	103	NICE	18	1.3.1.6	The emphasis here would be appropriate for someone suffering from an incurable chronic disease, which CFS/ME is most often not. The aim of an individualised programme should be to help the patient recover, or, if this is not possible, to help the patient improve their quality of life and minimise disability. The expectation of both the patient and the practitioner is vitally important in determining outcome, and these current aims are too conservative, and inconsistent with the best available evidence.	The Guideline Development Group had to balance a positive outlook with the recognition that some people will not recover.
SH	St Bartholomew's Hospital Chronic Fatigue Services	104	NICE	19	1.3.1.8	Equipment and aids may hinder recovery as much as help it, and their	The view of the Guideline Development Group is that equipment can help to maintain independence and this is

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						prescription needs to consider both outcomes. We believe disability aids can help a patient towards recovery if their use encourages a widening and increase in their own activities, on a temporary basis, as a means of supporting a rehabilitation programme. They should rarely if ever be used for patients with only moderate disabilities.	stressed in the section heading and in the recommendation.
SH	St Bartholomew's Hospital Chronic Fatigue Services	105	NICE	19	1.3.1.11	There is more substantial evidence for the efficacy and effectiveness of individual delivered compared with group delivered CBT. The guideline advice should reflect this.	This has been revised to reflect this comment.
SH	St Bartholomew's Hospital Chronic	107	NICE	24	Activity	The guideline should	The evidence base is detailed in the full

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	Fatigue Services				management	acknowledge the absence of RCTs testing this approach, while emphasising the common sense and consensual nature of this advice.	guideline.
SH	St Bartholomew's Hospital Chronic Fatigue Services	108	NICE	26	Sleep	This is very well written.	Note with thanks.
SH	St Bartholomew's Hospital Chronic Fatigue Services	109	NICE	29	Severe setbacks	We are aware of no evidence that would support division of set-back advice depending on severity.	This section has been substantially revised based on feedback in the consultation.
SH	St Bartholomew's Hospital Chronic Fatigue Services	110	NICE	30	Competencies	The levels of professional competencies and governance arrangements of both CBT and GET therapists should be similar.	This comment will be referred to the NICE implementation team.
SH	St Bartholomew's Hospital Chronic Fatigue Services	111	NICE	31	Drugs	The advice regarding drug treatment should be better grounded in evidence, and consistent with treatment of	This section has been revised to reflect comments from stakeholders.

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						the relevant comorbid conditions, without implying comorbid conditions, such as neuropathic pain and IBS are part of CFS/ME.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	112	NICE	32	1.3.5.2	Severe weight loss is a "red flag" event, as you suggest earlier, and such patients should be properly assessed not only by a dietician, but more importantly by the relevant specialist, such as a gastro-enterologist or psychiatrist. Weight loss is not a part of CFS/ME at any age.	The view of the Guideline Development Group is that some children may lose weight and require nutritional support.
SH	SWAME (South West Alliance for ME)	4	NICE NICE	23 25	1.3.1.20 bullet 5 also 1.3.1.24, bullet 1	Concepts of Exercise and Rest Following on from the above, the emphasis on and recurrent use of the word "exercise", combined	Issue 1: Please refer to the glossary definition of 'exercise'. Issue 2. The section on setbacks has been revised to reflect concerns.

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			NICE NICE NICE NICE FULL	20 19 19 19 15 7 192		with recurring references to potential risks of rest, and exhortation even at times of "setback" to maintain normal activities, gives the reader the distinct impression that in this illness patients are all too keen to succumb to disability, rest too much and are not sufficiently motivated to improve. Whereas in the vast majority of cases the opposite is the case. Having had much involvement with the setting up of new specialist services in our local area and both attended presentations made by clinical champions and discussed with health	

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					1.3.1.13, bullet 5	professionals involved in our local service, it is clear that the majority of their time with patients is spent helping patients to do less, to find manageable activity baselines, to not feel guilty for not being able to meet all their family, social or work commitments, to build suitable rest breaks into their day. However, in the proposed NICE guideline the opposite guidance is given. The document is dominated by exhortations for patients to maintain and increase exercise/activity and avoid rest, be informed about the dangers of rest, challenged about fear of activity, and there is but one mention of this very	Issue 3. Recommendation 1.3.1.10: While there is patient support there are very differing views. In addition there is no research evidence. The recommendation does not disparage but reflects this position. It again illustrates differing understanding of terminology. The terms 'pacing', 'envelope theory' and 'activity management' may be used interchangeably or have separate meanings.

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					1.3.1.10 1.3.1.10 1.3.1.10 1.2.1.10 lines 11–12 6.3.6.20	important work to support patients and help them reduce activity, and only as a "may include", "addressing complex adjustment …" On the issue of exercise/rest the balance and emphasis in the document is completely wrong and will give health professionals learning for the first time about CFS/ME completely the wrong impression, thus rendering them less able to help patients. This paragraph is unhelpful and displays a disingenuous way of using one statement to point to	 The guideline has been revised to include more on pacing and rest.

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						another. It makes a point that there is "no evidence for" the strategies, which is likely to be interpreted by health professionals as "these strategies are to be discouraged". What is not mentioned is the fragile nature of any evidence for any strategies at all, including those recommended, nor that neither is there any evidence against the strategies mentioned. As it says in the draft guidance that research is currently being undertaken to evaluate the evidence for the approach of maintaining activity levels at substantially less than	Issue 4. Bed rest and deconditioning. There are general risks and deleterious

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						full capacity, does this refer to the PACE trial? Is this supposed to be a description of Pacing? And does "substantially less than full capacity" refer to full capacity pre-illness or full capacity within the limits of the illness? If the latter is the case, this is not what most patients would understand by 'pacing'. Most patients use pacing and switching to do as much as they can within the limits of the illness (ie NOT "substantially less than full capacity"), but use it to avoid transgressing a manageable baseline level of activity above which they are likely to experience further symptoms or	effects of bedrest, such as DVTs, chest infections, muscle wastage, etc., which should be avoided if possible.

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						relapse. Concerning complete rest, it would be useful for the guideline to acknowledge that sometimes, particularly in the early acute phase of illness or when symptoms are particularly severe, or at a time of significant relapse (please use the correct word, not 'set-back'), complete rest can be very helpful. By it's very nature, complete rest is self-limiting because as soon as it is no longer necessary, dictated by severe symptom levels, the individual will naturally want to be doing things again and will build up activity. The challenge is not to	

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						build up activity too quickly or suddenly. Warning against risks of prolonged bed rest must be set in context. It may be that the individual needs some prolonged rest and will become worried by being advised of risks into becoming too active too soon. It would seem that the NICE draft guidance is underpinned by the deconditioning theory for perpetuation of CFS-type illness; ie that someone starts with say viral illness, is very ill and rests, becomes deconditioned because of too much rest	

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						and can't get better. This theory is disproved in CFS/ME by those with, eg, gradual onset ME, moderately affected, who have for sometime not been aware of the illness and continued working, or have received advice to just do as much as they can and have never rested completely nor had opportunity to become deconditioned, yet still have CFS/ME symptoms. There is also considerable difference of opinion on deconditioning, with those of us in the South West having attended talks by our clinical champion in which it has been stated that deconditioning is not a	

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						risk in CFS/ME. This does not seem to have been considered by NICE. It is essential that this issue of deconditioning and exercise/rest is resolved since the advice given to maintain exercise even when there is an increase in symptoms is potentially harmful and dangerous. It is this sort of advice that can lead to the harm described in the section on GET above. The supposed negative effects of deconditioning would be negligible in comparison and it is very clear that on balance the guidelines should err on the side of safety and caution.	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						The balance of advice on activity and rest and the use at all of the word "exercise" must be reconsidered. References: Is physical deconditioning a perpetuating factor in chronic fatigue syndrome? A controlled study on maximal exercise performance and relations with fatigue, impairment and physical activity. Bazelmans E, Bleijenberg G, Van Der Meer JW, Folgering H. Psychol Med. 2001 Jan;31(1):107-14.	

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						RESULTS: There were no statistically significant differences in physical fitness between CFS patients and their controls. CONCLUSIONS: Physical deconditioning does not seem a perpetuating factor in CFS. Snell CF, Vanness JM, Strayer DR, Stevens SR. Exercise capacity and immune function in male and female patients with chronic fatigue syndrome (CFS). In Vivo 19(2):387-90, Mar-Apr. 2005 ABSTRACT: …..These results implicate abnormal immune activity in the pathology of exercise	

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						intolerance in CFS and are consistent with a channelopathy involving oxidative stress and nitric oxide-related toxicity. J Psychosom Res. 2005 Apr;58(4):375-81. A longitudinal study of physical activity and body mass index among persons with unexplained chronic fatigue. Schmaling KB, Fiedelak JI, Bader J, Buchwald D. RESULTS: … Increasing energy expenditure was associated with increasing vitality and decreasing CF symptom severity over	

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						time, and decreasing perceived exertion was associated with increasing physical functioning. However, increasing perceived exertion was also associated with increasing CF symptoms. CONCLUSIONS: These data do not support models that posit associations between CF and deconditioning.	
SH	SWAME (South West Alliance for ME)	6	NICE NICE FULL NICE NICE NICE	13 –16 20 35 1 14 15	1.3.1.13, bullet 4 21–22 para 3 1.2.1.4 bullet 1 1.2.2.2 bullet 6	Diagnosis We welcome the inclusion of post-exertional malaise as a core descriptor of the type of fatigue experienced but believe that clinical guidelines need to go much further in describing the	The Canadian guideline is a consensus document and does not provide an evidence-base for their guidance. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						range of accompanying symptoms, as do the Canadian Clinical Guidelines. This is particularly important since recent research has shown that nearly half of GPs are not confident about making a diagnosis of CFS/ME. Therefore guidance on diagnosis should be as full and helpful as at all possible. We would like to include here an account written by a member of one of our constituent groups about that group's experiences with the Canadian diagnostic protocols: "I knew nothing at all about ME/CFS when in 2003 my	

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						GP tentatively diagnosed it. I then started reading both books and internet to find out what I might have and how to deal with it. Onset had been gradual, so not an easy diagnosis; the GP concerned, thankfully, was very experienced. I came across the Canadian guidance, printed it out and showed it to my GP. My own reaction was like the pieces of a jigsaw suddenly came together, suddenly all my various experiences and symptoms made sense and it brought a strong feeling of relief that things were now explained. The way symptoms are grouped in the Canadian diagnostic guidelines adds much	

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						clarity. Both I and my GP then found it easy to feel considerably more confident about the tentative diagnosis he had so helpfully made within 4 months of my consulting him. I believe my finding and reading the Canadian guidance has been the single most beneficial and helpful thing in my journey through this illness, which has been a positive one. I would not in any sense be able to say the same about the current draft of the NICE guidance." "When I subsequently joined the local ME support group, I showed others this Canadian guidance, and	

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						later on the internet communicated about it with other patients and patient group reps. I have consistently found others to have had similar experiences to mine. I have yet to come across a seriously bad word said about the Canadian guidance, which is rare in ME-circles. We have used it in our local group to help people wondering whether they had CFS/ME and found it most helpful. We have also had positive feed-back locally from health professionals to whom we have distributed copies." We hear that in East Anglia	

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						the Canadian guidance has been endorsed by Clinical Champions and distributed to primary care professionals by specialist CFS/ME services. We request that NICE make this initiative national by incorporating much more of the very useful Canadian diagnostic guidance into the new NICE guidance. Unless this happens, the NICE consultation will have been a meaningless paper exercise. Making particular note of how the GDG have found the post-exertional nature of CFS/ME fatigue sufficiently key to include in the core fatigue description,	Issue: 'And, is it right to "challenge cognition of fear of activity"': this wording has been changed. The GDG considered the wording for thyroxine to be appropriate.

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						which has not been the case in previous fatigue descriptions in both Oxford and Fukuda definitions, and, bearing in mind our above comments about GET, will the GDG please give serious consideration to the question of the validity of the evidence supporting GET in so far as the subjects in these studies were patients at psychiatric clinics whose fatigue was not necessarily defined as post-exertional and probably constitutes a different patient population to those with ME/CFS to whom this guideline now refers. Please see the paper appended below (Appendix B), Does graded	

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						exercise therapy improve post-exertional malaise in CFS? Susanna Agardy, 31.3.05, Source: http://listserv.nodak.edu/cgi-bin/wa.exe?A2=ind0503e&L=co-cure&T=0&P=1616 accessed 24.11.06 And, is it right to "challenge cognition of fear of activity" in patients whose core symptom is post-exertional malaise, and who probably have adapted sensibly to cope with this illness for which there is no cure by wisely, knowledgeably and carefully managing their activity levels??	

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						Listening to people contacting support groups, who have had problems obtaining a diagnosis, it is clear that an area GPs have difficulty with is differentiating between CFS/ME and depression. There is a very useful checklist on page 95 of Dr Anne McIntyre's book, ME/CFS A Practical Guide. Also, Dr Eleanor Stein has written as a psychiatrist and expert on this theme, see www.fm-cfs.ca/Psychiatry-overview.pdf. Given that the GDG, thankfully, recognise that the clinical need for the guideline stems from current uncertainties about	

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						diagnosis and management amongst health professionals, causing their inability to prevent or minimise the profound illness and its impact on patients and their families, it would be as well for the guideline to provide specific guidance, such as mentioned here and included in the Canadian clinical guidance, to remedy these current uncertainties. Abnormal neurological signs are not uncommon as symptoms of ME/CFS itself. This is not made clear, in fact the inclusion of this here suggests that abnormal neurological	

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						signs would not be common. However a Romberg test is recommended by many experts in the field as a diagnostic aid and ME is classified by WHO as a neurological illness, G93.3. Thyroid function tests needs to specify TSH, T3 and T4, because the latter are not Generally available. We have had reports from patients of normal TSH tests but who went on to get private T3 and T4 tests which were low and their condition subsequently improved substantially after treatment with thyroxine and terotroxin.	
SH	SWAME (South West Alliance for ME)	8	NICE	26 –27	9–11	Sleep	This section has been simplified this

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			FULL/NICE	233 31	1.3.4.7	There is overemphasis on sleep 'management', with scant mention of the very central and disabling nature of the sleep disturbances experienced, and negligible mention of other ways to help with sleep. Many patients work hard with sleep management self help guidelines to little avail – it feels like there is a chemical switch inside that is simply out of reach. Health professionals need to be aware of this so that they can help and encourage them when sleep is an uphill struggle. Many patients report, as also documented by Dr Darrel Ho Yen (Better	section and made specific to CFS/ME rather than general sleep management advice.

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						Recovery from Viral Illness, Dodona Books), that insomnia or sleep quality is worse when they have mismanaged activity during the day and done too much or not included rest periods. These aspects are included in the Canadian Guideline and the NICE guideline could also helpfully inform of this effect. Patients who manage to obtain melatonin often report positive effects. Although mention of melatonin actually constitutes a rare occasion where the GDG acknowledges the voice of the wider group and shows that advice does not have to be limited to data from	

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						randomised controlled studies, there is inconsistency between full and NICEs. The full tentatively suggests melatonin (presumably for children or adults) but the NICE specifies this only for children.	
SH	SWAME (South West Alliance for ME)	10	NICE	33	1.3.6.1	Complementary Therapies By their very nature such therapies may not lend themselves to evidence gathering such as considered acceptable by NICE, however again, there is consensus amongst patients and many clinicians about the helpfulness of many complementary therapies. The rigidity of the language	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS. The language is the convention for NICE guidance in these circumstances. It is acknowledged, however, that some individuals may find these approaches helpful.

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						used (eg no … not recommended) is most unhelpful and has the effect of the first sentence completely negating the more helpful second sentence, "However …". A statement such as "Whilst it is noted that there is as yet no gold-standard evidence for … people may choose to access… " would be more beneficial.	
SH	SWAME (South West Alliance for ME)	12	NICE	37–38		Research Recommendations The NICE states that the GDG's full set of recommendations is detailed in the full guideline (see section 5). However, Section 5 is titled Making a Diagnosis and we see no	Please see the addition to this section where the GDG recognise the need for research into aetiology

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						mention there of research recommendations, nor anywhere else in the full guideline. Therefore this comment is based on the NICE. It is most disappointing that the GDG limits research recommendations to current intervention strategies, especially when currently interesting research is going on in several other fields and seems likely in the future to provide new intervention strategies and further understanding. (ME Research UK, Dr Gow, Dr Kerr, Professor Puri). These should be mentioned as opportunities	The GDG identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope of the guideline.

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						for future development in diagnosis and treatment.	
SH	SWAME (South West Alliance for ME)	13	NICE	13	1.2.1.2	Treatment of Symptoms Although in the section "making a diagnosis" a list of other possible symptoms is given, this list would not convey to health professionals the full variety of symptoms experienced by people with ME, especially at the severe end of the spectrum. There is also no acknowledgment that symptoms other than fatigue, particularly pain, can for many sufferers be the most prominent or more disabling aspect of the illness. GPs need much more guidance as to the	This is not a complete list of symptoms but ones that may lead to a suspicion of CFS/ME. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						best ways to help CFS/ME patients cope with pain, and access to pain clinics may need to be available. This echoes other comments about treatment for pain (Generally) made by Dr Archand for RCGP http://news.bbc.co.uk/1/hi/health/6065754.stm "The government needs to prioritise pain control. There is very little in the way of guidelines to help GPs to control pain properly. It's much more complicated than simply giving painkillers."	
SH	SWAME (South West Alliance for ME)	13.1	NICE	31	1.3.4	The single page on pharmacological interventions gives insufficient guidance on treatment of other	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly

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						symptoms, particularly pain.	related to CFS/ME. Where the management of symptoms is the same as that of people who do not have CFS/ME it is not addressed. The Guideline Development Group did not have the time or remit to write a guideline on each symptom.
SH	SWAME (South West Alliance for ME)	13.2	NICE	18	1.3.1.7	Another area without sufficient mention is orthostatic problems, blood pressure tests that provide helpful indicators and so forth. We will not go into detail here as this is all fully documented in the Canadian Guidelines Overview, to which we request the GDG give detailed consideration in order to include further useful guidance in the final NICE document.	This comment does not relate to the recommendation.

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SH	SWAME (South West Alliance for ME)	13.3	NICE	31	1.3.4	In its current draft, NICE guidance is inferior to Canadian and also inconsistent in so far as the GDG on page 18 of NICE recommends components of a programme include "treatment of deterioration of symptoms", and yet provides scant guidance for health professionals precisely how to treat deteriorating symptoms, or which medications to prescribe for help with the wide range of possible symptoms.	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. Where the management of symptoms is the same as that of people who do not have CFS/ME it is not addressed. The Guideline Development Group did not have the time or remit to write a guideline on each symptom.
SH	SWAME (South West Alliance for ME)	13.4	NICE	31	1.3.4.2	Whilst discussing medication however, the warning about lower tolerances and more adverse affects from	The Guideline Development Group was concerned about doses being prescribed that would not benefit the patient. As an in-depth search of the literature yielded no evidence for greater intolerance, this

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						medication is most welcome and important.	recommendation has been redrafted as part of an individual management strategy.
SH	SWAME (South West Alliance for ME)	14	NICE NICE	14 17	1.2.1.7 1.2.4.2	Implementation Discussion with a specialist would be a useful diagnostic aid, however there are insufficient specialists throughout the UK to meet the need. Even in areas where there are specialists, they are not funded to spend sufficient time on CFS/ME. This aspect of the guidance is currently impossible to implement as many areas are without specialist CFS/ME services. Where there are services they are hopelessly under-	As you say, these are implementation issues and will be raised with the NICE implementation team.

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						resourced to meet demand, with waiting lists as high as 9-12 months in some cases. So a GP may wait the recommended length of time before referring, but then the waiting time before the patient actually sees a specialist completely eclipses that and the appropriate point for specialist help with the newly diagnosed is lost. Services currently provided manage a few domiciliary visits to the severely affected, one-to-one CBT-based programmes only for some people not well enough to get to group programmes, and CBT-based self-help group	

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						programmes for the rest. Patients have long waits to access even this rudimentary treatment. Services simply do not exist that could implement the treatment recommended as first choice by NICE. Furthermore it is not clear that even were this level of funding suddenly provided, that it would be best spent on individual CBT/GET programmes for all mildly and moderately affected patients. To implement guidelines on services for CFS/ME, many more health professionals will need to be appointed and trained. However, as	

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						yet there is little evidence of consistently successful training programmes in place, with much depending on the individuals involved. The situation is such that in some areas, as for example the South West, there are meaningful and productive partnerships with patient groups and patients have good levels of confidence in the service provided, whereas in other areas patient support groups find themselves dealing with problems created by the new specialist health professionals and there is much dissatisfaction with the specialist CFS/ME	

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						provision. These situations need to be resolved and an acceptable training model found before further expansion of specialist services takes place.	
SH	SWAME (South West Alliance for ME)	16	NICE	1 1	1 para 3	It would be helpful to insert into this first sentence the word "physical" or "organic", to read: "CFS/ME is a relatively common physical illness …." This would seem like an excellent opportunity to clarify some of the uncertainties that have existed in the past about CFS/ME and impacted badly on patients and their families. With the level of research across the globe now evidencing a raft of physical abnormalities it	The wording as been changed to reflect this comment.

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						must finally be time to once and for all clarify on the key issue of physical illness or mental health issue. It is interesting to note that just in the last few days this should be mentioned in the American Medical News, journal of the AMA, in conjunction with the CDC's public awareness campaign: "Thousands of research studies provide abundant evidence that CFS is a physiological illness, not a form of depression or hypochondriasis, according to the agency (the CDC)". www.ama-assn.org/amednews/2006/11/27/hlsb1127.htm	

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SH	SWAME (South West Alliance for ME)	17	NICE	2		Informed decisions: If patients are to be in a position to make informed decisions about their care and treatment, it will be necessary to provide them with more/better information than is contained with these NICE draft guidelines.	This is standard text in all NICE guidelines.
SH	SWAME (South West Alliance for ME)	18	NICE	3		Definition of CBT. This does not go far enough in clarifying the basis upon which CBT is used, as discussed above. It is difficult to see what is added by the final sentence of this definition	This recommendation has been substantially revised based on feedback in the consultation.
SH	SWAME (South West Alliance for ME)	19	NICE	3		Definition of Specialised Care. The emphasis on the multidisciplinary nature of such care is very helpful.	Noted with thanks.

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SH	SWAME (South West Alliance for ME)	20	NICE	6	1	The phrasing of this first-listed key priority for implementation, "When the adult or child's main goal is to return to normal activities…" is difficult to interpret and offensive to patients.	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	SWAME (South West Alliance for ME)	21	NICE	6	7–24	Shared decision-making bullet point, with details. This is all very helpful and welcome.	Noted with thanks.
SH	SWAME (South West Alliance for ME)	22	NICE	8 11	All 1.1.3.6	We agree that it can be helpful for health professionals to be actively involved in advising about fitness for work or education and liaising with employers, schools, etc, as long as the health professionals involved have sufficient understanding of the illness, are taking close	We have noted that all healthcare professionals working with people with CFS/ME should have appropriate training and experience.

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						account of the patient's views and abilities and are remaining in negotiation and agreement with the patient throughout. It must be mentioned that there is a danger with health professionals who do not fully understand the nature of the condition and the disability it confers that the patient will be pushed too hard to engage in work/education with resulting failure to improve or even relapse. This danger is very clear from reading the dreadful NHS Plus CFS/ME guidelines for occupational health, which were published at the same time as the NICE draft guidance, but without	

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						consultation and with negligible patient representation. It must also be noted that there are some professions, eg teaching, where the nature of the work is such that it is very difficult or even impossible to maintain work with the illness and early retirement may be a valid option in order to be able to consider other less demanding part-time work. Another problem with work, for example again for teachers, is that teachers who try first to reduce hours and struggle on with the illness may ultimately	

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						be forced to retire anyway but will find that their pension is seriously affected because of the way that it is calculated based on their last 3 years of work. Ways must be found whereby in such occupations workers can experiment realistically with rehabilitation without adversely affecting pension rights.	
SH	SWAME (South West Alliance for ME)	23	NICE	9	2	The full contains several references to the fragility of evidence for CFS/ME treatment. It would be helpful here to refer to just how fragile this ‘best available evidence’ is.	This is standard NICE wording. Readers are referred to the full guideline in this document. Both will be available on the NICE website.
SH	SWAME (South West Alliance for ME)	24	NICE	9–12	1.1	The General principles of care overall are helpful and welcome, with the proviso	Noted with thanks.

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						mentioned above re 1.1.3.6. Particularly welcome are support measures detailed in 1.1.4 such as an individualised management plan, assistance negotiating the healthcare, benefits and social services systems, and availability of care regardless of ability to travel to services.	
SH	SWAME (South West Alliance for ME)	25	NICE	14	1.2.1.5	Would be better as: “Primary healthcare professionals should listen carefully to patients’, parents’ and/or carers’ concerns …”	Noted and changed.
SH	SWAME (South West Alliance for ME)	26	NICE	17–19	1.3.1.1 to 1.3.1.9	Paragraphs 1.3.1.1,2,5,6 and 7 are all helpful. Unfortunately, they are totally eclipsed by the inappropriateness of	1.3.1.1 has as been reworded.

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						1.3.1.3 since a full CBT/GET programme is not seen as first choice for all mildly and moderately affected patients. Paragraph 1.3.1.3 also eclipses paragraph 1.3.1.4 since activity management, sleep management and relaxation techniques actually do seem to be useful for a majority of patients. This whole section would be helpful and welcome without 1.3.1.3. Points 1.3.1.8 and 9 are particularly welcome and most helpful. Point 1.3.1.10 is	Noted. Thank you. Noted with thanks. Noted.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						considered elsewhere above.	
SH	SWAME (South West Alliance for ME)	27	NICE	26–27	25, 24	In stating in 1.3.2.3 that daytime sleeping should not be encouraged, it may be considered to contradict the guidance on page 26 that daytime naps of 30 minutes or less are acceptable. It should also indicate that daytime naps can usefully be replaced by periods of total relaxation. Incorporating periods of rest and relaxation into the day actually helps sleep at night, as mentioned above under 'sleep'.	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.
SH	SWAME (South West Alliance for ME)	28	NICE	34 –35		Although it is helpful to mention rights of access to services for the severely affected, the guidance does not come near to	Symptoms: as symptoms are so varied and individual, they are difficult to list without misleading clinicians that a given symptom is or is not part of CFS/ME. The concern of the Guideline Development

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						sufficiently describing the symptoms and needs of the severely affected such that health professionals using the guidelines will be adequately prepared to help their patients.	Group was that symptoms of life threatening co-morbid conditions may be dismissed as symptoms of CFS and not treated if these were part of a comprehensive list.
SH	SWAME (South West Alliance for ME)	29	NICE	35	1.4.1.7	This point was well-received when discussed in our support group and additionally, that some moderately affected patients had sufficient cognitive difficulties to appreciate this too. Please make available to moderate as well as severe.	Noted, but the Guideline Development Group did not think that it would be generally necessary for all mild/moderate patients.
SH	SWAME (South West Alliance for ME)	30	NICE	35	1.4.1.8	There may also be situations where a person's home circumstances are so unsupportive that he/she cannot improve without residential care.	This is the intention of this recommendation.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						Consideration must be given to the provision when necessary of residential or hospital care giving due regard to such things as noise, light and chemical sensitivity.	
SH	The British Psychological Society	5	NICE	1	First para	CFS/ME is not an illness. There is no evidence that it's an entity. It's the name given for a collection of symptoms. The description of the 'illness' resembles that for neurasthenia, a psychiatric disorder. In light of the case histories, research showing extremely low MOS-SF scores for physical functioning (Komaroff et al 1996) and extremely high scores for illness intrusiveness, Goudsmit et	Sections have been reworded.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						al 2006), we should consider describing the syndrome as comprising symptoms such as exhaustion or profound fatigue, rather than ‘fatigue’. One can then clarify that the fatigue is not like everyday tiredness etc. Please also consider the section on fatigue in the latest revision of the CDC guidelines (Reeves et al 2003).	
SH	The British Psychological Society	6	NICE	1		The prevalence figures are not realistic. The .4 comes from Jason et al in the US. However, most estimates have been higher (e.g. Wessely et al 1997). Only the prevalence for post-viral fatigue is lower (e.g. 0.1%, Ho-Yen and	The values are consistent with other reports – see the Chief Medical Officer’s report.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						McNamara 1991). Consider amending the estimates e.g. from .1 to 2%.	
SH	The British Psychological Society	7	NICE	2		Good to see early emphasis on patient centred care and this continues throughout with talk of collaboration, respect etc	Noted with thanks.
SH	The British Psychological Society	8	NICE	4		This section should include pacing, as promoted by the two national organisations before APT (adaptive pacing therapy). It is this version which was adopted around the world during the nineties and which was reported as helpful in several surveys (information about APT and the more structured versions were not in the public domain when most	Pacing has been added.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						of the surveys were carried out). Pacing, as originally conceived by a member of this organisation, does not require or promote gradual increases in activity (Goudsmit 2005). The basic advice is that patients should remain as active as possible, within the limits imposed by their illness. Everyone with this condition learns fairly quickly what they can do without worsening their symptoms. Individuals should be encouraged to keep active but to avoid overexertion. Mild fatigue can be ignored. However, significant muscle weakness and symptoms such as nausea cannot.	

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						Those who cannot follow this General advice should be offered more structured versions, using diaries to note activities and symptoms in order to determine tolerance levels (e.g. Jason et al 1999). In contrast to APT, the original version of pacing is not based on the envelope theory but on the research on ME, 50 years of clinical experience and on feedback from patients (e.g. Paul et al 1990, Goudsmit 2005). It was devised on the basis that some patients cannot increase activity levels beyond a certain point (see reference to ‘plateau’	

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						below, and Black and McCully 2005). Neither Jason nor Goudsmit regard pacing as a form of therapy. The basic version can be explained to the patient by a GP or practice nurse, who can assess progress and if required, recommend the use of diaries etc. Gradual increases in activities may identify upper limits, but given conditions like ME fluctuate, these are liable to change from day to day. This version of pacing takes this into account. There are no mutually agreed, pre-determined schedules which cannot be sustained	

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						and may lead to a sense of failure. Pacing avoids overexertion and therefore limits the number of relapses. It’s also helpful in preventing deconditioning. The boom/bust cycle referred to in the draft is an indication that patients are not pacing their activities and have not worked out what their limits are. Psychologists such as Jason and Goudsmit recommend that pacing should be a component of a programme, also including medical care, counselling or CBT as required, dietary advice etc.	

The comments made by registered stakeholders during consultation, and responses from the guideline development group (GDG), are now available in the following tables. The comments received from stakeholders are not endorsed by the GDG or the Institute and appear here only as record of the comments that the GDG received. (Please note that where a particular comment has not been responded to directly by GDG, this should not be taken to mean that the GDG agrees with that comment.)
A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
Where text has been removed, this is indicated by '[…]'. Summarised comments are in *italic type* inside square brackets.

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SH	The British Psychological Society	9	NICE	8		Could also mention Disability Discrimination Act	Noted. This would be general information offered.
SH	The British Psychological Society	10	NICE	16	1.2.3	We should consider subgroups. See above.	The Guideline Development Group did not find clear evidence of sub-groups.
SH	The British Psychological Society	11	NICE	16	1.2.3.1	The 4 month minimum would exclude epidemic cases. If there is a cluster of cases and one is able to recognise the illness at an early stage, which diagnosis should be made? Post-viral fatigue syndrome?	This is guidance. Clearly healthcare professionals will use their clinical judgement.
SH	The British Psychological Society	12	NICE	17	1.3.1	This section should include counselling. Supportive (Rogerian) counselling is as useful as CBT, and cheaper (see full for the references and discussion).	No good research evidence was found for counselling with CFS/ME.
SH	The British Psychological Society	13	NICE	18	1.3.1.4	This section should include pacing (original version, which does not include goals and targets, mutually	The guideline has been restructured and pacing is included in general management.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						agreed plans etc).	
SH	The British Psychological Society	14	NICE	18	5	Given the controversy around CBT and ME/CFS, we wonder whether it would be a good idea to make note of the evidence cited in the full that two surveys of patients have shown significant numbers of people being made worse by CBT e.g. Action for ME (2001) that 7% found it helpful vs 26% found it made the condition worse. We say this in awareness that these surveys do not meet the usual RCT criteria used by NICE. The findings may reflect the way the CBT is practised, as the full guidance suggests, however, we are aware that	The information on the studies is given in the full guideline. The limitation of the patient surveys is that it is unclear what the programme was. This is detailed on the full guideline.

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						a number of people have felt that CBT at the specialist clinic at Kings has made them worse.	
SH	The British Psychological Society	15	NICE	18	General	Good to see emphasis of patient choice and involvement.	Noted with thanks.
SH	The British Psychological Society	16	NICE	19	1.3.1.10	While there is no evidence for the use of pacing based on the envelope theory (APT), and indeed, there is some evidence against (Wright et al 2005), this is no reason not to include the original concept of pacing with the emphasis on avoiding overexertion (Goudsmit 1996, see CRD review, Wallman et al 2004 and others).	The wording has been revised in response your comment.
SH	The British Psychological Society	17	NICE	19	24	It would be useful to differentiate between complete bed rest and	The section on rest has been extended.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						appropriate rest (not doing activity when too tired)	
SH	The British Psychological Society	18	NICE	21	1.3.1.13	Re decreasing somatic attributions. As Wessely has noted, the aetiology of CFS is unclear and discounting an underlying disease process may be premature. It may also be a waste of energy. Changing attributions does not appear to be linked with good outcome per se (e.g. Bonner et al, Lawrie et al).	There is research evidence for the benefit of CBT for people with this condition.
SH	The British Psychological Society	19	NICE	21	1.3.1.14	This should not be offered to everyone with CFS (NB Black and McCully 2006). There is no evidence that it helps patients with neurological symptoms such as muscle weakness, balance problems, let alone severe cognitive	The guideline supports an individual approach.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						dysfunction. This universal prescription ignores growing evidence, e.g. that GET is not superior to CBT (Ridsdale et al 2004), that it does not increase activity levels if measured objectively etc (see below).	
SH	The British Psychological Society	21	NICE	23	26	Query the way this is worded ie: maintain exercise at times of set back – worry that people might see this as continuing at all costs which the guidance is not saying. Some research e.g. CBT in Australia, suggests a day of rest after a set back and then to continue	This recommendation has been revised to reflect concerns.
SH	The British Psychological Society	22	NICE	24	1.3.1.22	This is an untested approach for which there is no supportive evidence e.g. from the CRD. It seems	This is the intention.

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						anecdotal. The activity programme described here may be suitable for those who find simple pacing too difficult, or who refuse to pace their activities and therefore end up in a 'boom/bust' cycle. If the recommendations are to include strategies which have not been previously assessed in detail, then this section could also mention Multi Convergent Therapy, a tailor-made programme (Thomas et al, Cardiff University, one published report) and SMIs, as used in the management of diseases like asthma, diabetes, (e.g. Barlow et al, Coventry University, two	

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						published reports). See also Surawy et al above.	
SH	The British Psychological Society	23	NICE	25	25 (last)	Good to see advice to not rigidly adhere to fixed schedule	Noted with thanks.
SH	The British Psychological Society	24	NICE	28	1.3.2.6 Line 2	Progressive muscle relaxation should not be offered to patients with muscle pain and the symptoms of ME. Indeed, there is no evidence that it's helpful for CFS in General, so it's surprising this has been included.	This section has been simplified this section and made specific to CFS/ME rather than general relaxation advice.
SH	The British Psychological Society	25	NICE	32	1.3.5.3	Exclusion diets may not be helpful in CFS but they are the gold standard as far as identifying food sensitivities are concerned. Food sensitivities are extremely common in this population. The diets need to be supervised by properly	The guideline did not review the evidence for food intolerances generally, but no evidence was found specifically pertaining to people with CFS/ME. The guideline does recommend referral to a dietitian. The guideline now cross-refers to the NICE IBS guideline, which has more in-depth guidance on this matter.

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						qualified dieticians. Without this option, some may consult 'alternative' practitioners who advocate extreme diets, leading to malnutrition.	
SH	The Chartered Society of Physiotherapy	19	NICE	26	2 1.3.2.1	Who is likely to take responsibility for explanation and discussion about sleep management?	This is beyond the scope of the guideline.
SH	The Chartered Society of Physiotherapy	20	NICE	21	1.3.1.14	The role of the physiotherapist needs to be strengthened in relation to exercise therapy for this client group.	There is an emphasis on trained healthcare professionals.
SH	The Chartered Society of Physiotherapy	22	NICE	37 6	7 4.1 para 2, point 6	Reports of adverse reactions to exercise may have come from articles by Charles Shepherd, Medical Director ME Association (see e.g. a commentary in Physiotherapy (2001) Aug; 87(8): 395-6, describing a	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope of the guideline.

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						questionnaire survey of the members of 3 CFS/ME support groups) In this he reports that 50% of the respondents from **one** of the groups (ME Association?) felt graded exercise made their condition worse. *[This stakeholder commented that access to self-help groups is to be encouraged, but stated that it has been reported that membership of one such group is a poor predictor of treatment outcome.]*	
SH	The Chartered Society of Physiotherapy	23	NICE	Overall		The CSP is impressed by this draft guideline as they allow for some flexibility of response. e.g. in our experience patients with	Noted with thanks.

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						moderate to severe illness can be reluctant to expend their meagre energy levels on graded exercise when they are unable to fulfil all their daily responsibilities. Congratulations to the Committee	
SH	The Chartered Society of Physiotherapy	24	NICE	22	1.3.1.17	Advice to undertake baseline activity for 5 out of 7 days is far too prescriptive and does not take individual reaction times into account. The frequency must be done on an individual patient basis	We have stressed throughout the need for appropriate monitoring and review.
SH	The Chartered Society of Physiotherapy	25	NICE	23	1.3.1.19	In progression strategies duration should be followed by increase in frequency before increases in intensity	This recommendation has been revised.
SH	The Chartered Society of Physiotherapy	26	NICE	24	1.3.1.22	Activity management **MUST** be the first line of	The establishment of a baseline has now been made clear.

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						management before any form of GET or pacing is attempted. Without this baseline there is a high risk of exacerbating patient's symptoms and losing their trust in the health care professional.	
SH	The ME Association		NICE	16–17		**PROGNOSIS** The very nice sections on prognosis (1.2.3.3 and 1.2.4.3) are inadequate and fail to provide an accurate overall picture of current research evidence on prognosis. While we accept that an approach of cautious optimism, especially early on, should be adopted, the overall impression being given of a Generally good prognosis	This has been reworded based on your comment.

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						is not consistent with published evidence. We suggest that the Guideline Development Group refer to the information on prognosis that is provided in section 1.4.3 of the CMO report.	
SH	The ME Association	1	NICE	General		The MEA fully supports the view that a guideline on assessment and management of ME/CFS should be prepared by NICE and made available to all health professionals in the UK.	Noted.
SH	The ME Association	2	NICE	General		A key feature of any such guideline is that it must reflect the wide variety of clinical presentations and pathophysiological mechanisms that come under the ME/CFS	We have aimed to do this.

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						umbrella.	
SH	The ME Association	3	NICE	General		Equally, it must be acceptable to people who have this illness.	We have aimed to do this.
SH	The ME Association	4	NICE	General		Overall, we feel that the current (i.e. September 2006) version of the guideline that has been prepared by NICE is unfit for purpose and we would not be willing to endorse it.	We have revised the guideline to address many of the points made in consultation.
SH	The ME Association	5	NICE	General		We have five major disagreements. First involves the unbalanced coverage of CBT and GET.	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term ‘GET’ has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects to patients. There is however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been

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							described in detail in the guideline, with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity.
SH	The ME Association	6	NICE	General		Second is the failure to provide any meaningful advice on management during the acute and very early stages of the illness before a firm diagnosis of ME/CFS has been made.	The guideline has been revised to address this more clearly.
SH	The ME Association	7	NICE	General		Third is the failure to provide any meaningful advice on symptomatic management as the illness enters a more chronic stage.	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. No evidence was found for this intervention that related directly to patients with CFS/ME.
SH	The ME Association	8	NICE	General		Fourth is the way in which it deals with issues affecting the severely affected.	Noted.

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SH	The ME Association	9	NICE	General		Fifth is the failure to acknowledge the WHO classification of ME/CFS (and PVFS) as being neurological disorders (in section G93.3 of ICD 10) – a position that the Department of Health also accepts – and instead the NICE draft produces a new and much wider clinical definition of ME/CFS that includes almost anyone with chronic unexpected fatigue	The guideline has been revised to address this more clearly.
SH	The ME Association	10	NICE	General		We will start by commenting on these five objections in more detail.	Noted.
SH	The ME Association	11	NICE	17–25		1. A VERY UNBALANCED ACCOUNT OF THE BENEFITS OF COGNATIVE BEHAVIOUR THERAPY (CBT) AND	This has been revised

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						GRADED EXERCISE THERAPY (GET) in section 1.3.1	
SH	The ME Association	12	NICE	General		Our principal disagreement involves the way in which almost all of the management section is devoted to a manual-like approach that sets out how the authors believe that cognitive behaviour therapy (CBT) and graded exercise therapy (GET) should be used as an automatic first line treatment for almost everyone who has mild to moderate ME/CFS.	The evidence supports the use of CBT and GET. However, we have recommended that the preferences and needs of the individual should be taken into account.
SH	The ME Association	13	NICE	General		The sections on CBT and GET contain numerous recommendations on how to deal with specific management problems – most of which are based on	The evidence supports the use of CBT and GET. However, we have recommended that the preferences and needs of the individual should be taken into account. As is the case in many guidelines, there is not definitive research

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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						opinion rather than the type of evidence based medicine that normally dominates a NICE guideline.	on how to deliver a multi-faceted programme. The specific advice is generally based on the protocols of research trials and/or manuals for practitioners.
SH	The ME Association	14	NICE	General		Some of the advice on non-pharmacological management contains sensible and common sense suggestions. The ME Association already recommends some of these coping strategies in our own self-help literature. But there is no reason why this type of advice has to be given by specially trained behaviour therapists in hospital. Where the advice is sensible, and not based purely on the psychosocial model of abnormal illness	We have revised this to reflect your suggestions.

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						beliefs and behaviour, it should form part of a self-help or Expert Patient management programme. This sort of advice could easily be given out in a primary care setting – where most people with ME/CFS are, and will continue to be, managed.	
SH	The ME Association	15	NICE	General		However, much of the coverage here is seriously flawed because the opinions or those who are obviously very enthusiastic about the overall value of hospital-based CBT and GET are given undue emphasis whereas any form of critical opinion from people who have been treated with these approaches is simply	Noted. A NICE guideline has a different status than a report from the Chief Medical Officer.

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						ignored. The Chief Medical Officer's report adopted a trident approach to deal with this difficult issue whereby it took note of opinion from clinicians and patients, as well as the results from published research studies, when it came to dealing with CBT and GET.	
SH	The ME Association	16	NICE	General		This point is crucial because patient opinion submitted to the CMO report indicated that the results of CBT were not at all impressive with around 65% saying that this approach had not been helpful. And around 50% of people who had been placed on a graded exercise regime reported	The research evidence supports the use of CBT and GET. The Guideline Development Group recognised that these were areas where there was the most misunderstanding. They have therefore endeavoured to be clear exactly what is meant by these terms.

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						that this had made their condition 'worse'.	
SH	The ME Association	17	NICE	General		NICE has clearly not grasped the fact that the treatment trials being quoted to support the use of CBT and GET have only used relatively small numbers of carefully selected patients, having Generally been carried out in tertiary care centres that support the psychosocial model of ME/CFS causation, and in some cases have had quite high drop-out rates (e.g. 37% in the Manchester GET trial. Ref: Randomised, double-blind, placebo controlled treatment trial of fluoxetine and graded exercise for chronic fatigue syndrome.	The evidence does support the use of CBT or GET as part of the overall management plan. Dropout rates, and reasons if available, as reported in all trials are included in the evidence review and were assessed as part of both the validity scores (follow-up and intention-to-treat) and the grading assigned.

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						British Journal of Psychiatry 1998; 172:485-490). Our feedback in relation to GET dropouts is that some of these people have gone on to relapse as a result of the exercise programme – but this is never made clear in published results.	
SH	The ME Association	18	NICE	General		Whilst preparing this response we have received feedback from someone who has recently been treated at an internationally recognised centre where this type of behavioural research is carried out. This person has stated that:	Responses to individual points below.
SH	The ME Association	19	NICE	General		*When you cannot build up the exercises in the speed that xxx want you to, xxx*	Noted with thanks.

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						tell you that you are not motivated enough to follow the programme. You get a last chance, but even then when you can't follow the programme they tell you to stop because of lack of motivation. Even when you do your best to keep up with longer walks and less rest, when you cannot do it, you are out.	
SH	The ME Association	20	NICE	General		*The psychologist really believes that when you are motivated enough you can keep up with the programme. They push you to do the activities, sometimes forcing it by manipulating the parents or school as well.*	Noted with thanks.
SH	The ME Association	21	NICE	General		*Last year people were told that when they have*	Noted with thanks.

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						contact with other patients, they get the wrong signals and adopt a sick role. So they insist that there should be no contact with patient groups, most patients follow this advice and so we don't have any contact with them. Patients who do stay in contact often drop out before ending the programme.	
SH	The ME Association	22	NICE	General		We would be willing to forward the complete response to NICE is requested.	Noted with thanks.
SH	The ME Association	23	NICE	17–21		**CBT** With regard to CBT (sections 1.3.1.11-13), we believe it is completely unacceptable to imply that everyone with mild to	It is made clear in the introductory recommendations to this section and throughout the guideline that patients will be involved in decisions about treatment based on their own goals. The guideline is not therefore advising that everyone have CBT. The clinical trials of CBT have

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						moderate ME/CFS needs to take part in a hospital-based CBT programme that includes an underlying assumption that sympt9ms are maintained by factors such as abnormal illness beliefs and behaviour. While a minority of people who come under the diagnostic umbrella of CFS do fit the psychosocial model of illness perpetuation, and would benefit from such an approach, the majority do not, have no significant psychiatric co-morbidity, are well motivated, and are doing everything they can to try to get better. They would, quite rightly object to such an approach being	shown improvement in people with CFS/ME and therefore the Guideline Development Group recommended it as a therapy.

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						taken to their management.	
SH	The ME Association	24	NICE	17–21		The Guideline Development Group (GDG) should also take note of the most recent research study on CBT. This found that CBT did not offer any significant overall benefit when compared to education and support and standard medical care reference: Cognitive behaviour therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme. Health Technology Assessment. 2006 Oct; 10: number 37 – available on line at http://www.hta.ac.uk/fullmono/mon1037.pdf).	This was related to group CBT and some outcomes did show improvements.
SH	The ME Association	25	NICE	17–21		Neither does NICE appear	There is no research evidence for the

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						to appreciate that counselling may well be just as effective, and cost effective, as CBT in some instances. Two relevant references there are:	effectiveness of counselling with CFS/ME.
SH	The ME Association	26	NICE	17–21		Chronic fatigue in General practice; economic evaluation of counselling versus cognitive behaviour therapy. British Journal of General Practice 2001; 51: 15-18.	This trial was not conducted in a population of people with CFS but people with CF, some of whom (less than 30%) had CFS.
SH	The ME Association	27	NICE	17–21		Chronic fatigue in General practice: is counselling as good as good as cognitive behaviour therapy? A UK randomised trial. British Journal of General Practice 2001; 51: 19-24.	This trial was not conducted in a population of people with CFS but people with CF, some of whom (less than 30%) had CFS.
SH	The ME Association	28	NICE	21–25		**GET** We have a number of	The recommendations have been revised and expanded to reflect concerns.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						major concerns about the information being given on GET (sections 1.3.1.14 – 18)	
SH	The ME Association	29	NICE	17–21		Our first concern relates to the word 'exercise' and the fact that most people – doctors, patients, the General public – take this to mean some form of NICE lived and fairly intense physical activity.	This section has been re-written to make it clearer. The term 'exercise' is clearly defined in the glossary and does not mean vigorous activity.
SH	The ME Association	30	NICE	17–21		Exercise is a completely misleading term for energy management in the severely affected group. It is also inappropriate for most people in the moderately affected group. It may or may not be appropriate in mild cases. Furthermore, the guideline	Please see definition of 'exercise', which encompasses activities including activities of daily living and other activity.

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						fails to put over the fact that energy management affects not only physical functioning in ME/CFS, and that inappropriate advice on energy management will also have an adverse effect on cognitive performance.	
SH	The ME Association	31	NICE	17–21		The unqualified and frequent use of the term 'exercise' clearly implies that exercise is the key to recovery and that rest/relaxation is Generally harmful.	Please see definition of 'exercise', which encompasses activity including activities of daily living.
SH	The ME Association	32	NICE	17–21		NICE only have to look at the press coverage of the York systematic review in the Journal of the Royal Society of Medicine to see that this is how the media is already interpreting this type of advice. Exactly the	Please see definition of 'exercise', which encompasses activity including activities of daily living.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						same sort of over-simplistic interpretation of the term 'exercise' will be made by most doctors who have no special interest in ME/CFS.	
SH	The ME Association	33	NICE	17–21		What is required is a name and a practical approach that advises people with ME/CFS on how to achieve a sensible and flexible balance between activity or energy management (not purely exercise) and rest. This will depend on the stage, severity and variability of their condition – as we point out in some detail in our own information literature. Some people may need to increase their activity levels whereas others may actually need to reduce	The Guideline Development Group was of the view that the terms such as GET are already in use and it would cause greater confusion to invent new terms. The guideline has adopted a flexible individual approach.

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						them, especially in the early weeks and months following an acute onset – this is not what graded exercise implies.	
SH	The ME Association	34	NICE	17–21		Our second concern relates to the way in which the guideline appears to have dealt with energy/activity management during the very early stages of this illness (i.e. the first few weeks and months) before a firm diagnosis of ME/CFS has been made. At this stage we believe that a period of appropriate rest and convalescence is essential (we are not advocating that people go to bed and stay there) and that inappropriate exercise could well produce a further	This recommendation has been removed.

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						deterioration. Is NICE really advocating graded exercise during the very early stages of ME/CFS? This appears to be the case in section 1.2.1.10	
SH	The ME Association	35	NICE	17–21		Our third concern relates to what is commonly referred to as the 'glass ceiling' effect whereby people with ME/CFS often make a degree of improvement over the prolonged course of time, but then reach a point at which they are unable to increase their physical activity – despite high levels of motivation. The guideline does not even acknowledge that this situation exists – presumably on the assumption that graded	The guideline adopts a very slow and measured approach. It sets individual goals, which may even be to sit up in bed, and then says to recognise that it can take weeks, months, or even years to achieve goals and ensure that this rate of progress

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						exercise will eventually return almost everyone to normal health.	
SH	The ME Association	36	NICE	17–21		On this point we suggest that the Guideline Development Group reads the important study by Black et al (Increased daily physical activity and fatigue symptoms in chronic fatigue syndrome. Dynamic Medicine 2005; 4: 3 Electronic version available at http://www.dynamic-med.com/content/4/1/3) that concluded:	Noted with thanks. This study was of very short duration and on very small numbers of subjects.
SH	The ME Association	37	NICE	17–21		*'CFS patients were able to increase their daily activity for a period of four weeks. In contract to previous studies fatigue, muscle pain, and overall mood did*	Not sure what this refers to.

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						not improve with increased activity. Increased activity was not presented as a treatment which may account for the differential findings between this and previous studies. The results suggest that a daily “activity limit” may exist in this population. Future studies on the impact of physical activity on the symptoms of CFS patients as needed’.	
SH	The ME Association	38	NICE	17–21		And in a further study (Time course of exercise induced alterations in daily activity in chronic fatigue syndrome. Dynamic Medicine 2005; 4: 10. Electronic version available at: http://www.dynamic-med.com/content/4/1/10)	Please see comments above about timescales and rate of change. The Guideline Development Group agrees that there would not be a sudden increase in activity over a few days.

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						Black and McCully concluded: Daily activity assessed via an accelerator worn at the hip was divided into sleep, active, and walking periods. Over the first 4-10 days of walking the subjects with CFS were able to reach the prescribed goals each day. After this time, walking and total activity counts decreased. Sedentary controls subjects were able to maintain their daily walking and total activity goals throughout the four weeks. Unlike our previous interpretations of this data, we feel this new analysis suggests that CF patients may develop exercise	See comments above. The setback section has been substantially revised.

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						intolerance as demonstrated by reduced total activity after 4 – 10 days. The inability to sustain target activity levels, associated with pronounced worsening of symptomatology, suggests the subjects with CFS had reached their activity limit. Our fourth concern relates to the advice that activity levels should largely be maintained during a period of relapse or setback (section 1.3.1.20) we believe this advice is over simplistic and potentially dangerous, and is once again based on opinion rather than any sound evidence. We do not	

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						believe that spending a few days resting in bed during a significant relapse of symptoms, certainly one caused by an infection, is going to be harmful or result in deconditioning. This is the way in which many people with ME/CFS successfully cope with a relapse and we believe it would be irresponsible to ignore the views of patients yet again.	
SH	The ME Association	39	NICE	17–21		In relation to this we quote from what is very typical feedback on this particular aspect.	Noted with thanks.
SH	The ME Association	40	NICE	17–21		"After reading the MEA summary of the October meeting on the draft NICE guidelines I am very concerned about the	Please note that no one will be forced to do exercise or to be pushed too far. See comments above.

The comments made by registered stakeholders during consultation, and responses from the guideline development group (GDG), are now available in the following tables. The comments received from stakeholders are not endorsed by the GDG or the Institute and appear here only as record of the comments that the GDG received. (Please note that where a particular comment has not been responded to directly by GDG, this should not be taken to mean that the GDG agrees with that comment.)
A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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						emphasis on graded exercise. *I have had bouts of ME since 1991, when a run of flu-like illnesses was made worse by trying to carry on through them and indeed by trying to take exercise to throw it off.* *During the last two years, when my problems have recurred, it has been necessary to dramatically scale back the previous routine of yoga and gentle swimming that was keeping me fit during the nine years or so of relative health that I enjoyed between xxxx and xxxx. In fact, Professor xxxx, who I am now seeing at xxxx*	

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						Hospital, advised me that the muscle pains and recurrent fever which I was suffering last winter were probably not being helped by my constant attempts to tackle exercise and regain strength. *Very soon after stopping exercise I found the muscle pains and weakness had lessened.* *This leads me to conclude that forcing people to do exercise when they are actually, or pushing them too far when they are in recover, could be really counter-productive. It will also, I expect, make patients feel disempowered and controlled by medics, which is extremely bad for*	

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						self-respect and the self-confidence you need to cope with when recovering from such a challenging condition".	
SH	The ME Association	41	NICE	17–21		Our fifth concern relates to the way in which NICE does not appear to have taken any notice of published evidence that contradicts the commonly held view that deconditioning is a major factor in the perpetuation of symptoms. Key references here include:	The Guideline Development Group were stressing the general risks and deleterious effects of deconditioning and inactivity, such as DVTs, muscle wastage, etc.
SH	The ME Association	42	NICE	17–21		1. A longitudinal study of physical activity and body mass index among persons with unexplained chronic fatigue. Journal f Psychosomatic Research 2005; 58: 375 – 381:	See response above.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						Conclusion: These data do not support models that posit associations between CFS and deconditioning.	
SH	The ME Association	43	NICE	17–21		2. Is physical deconditioning a perpetuating factor in chronic fatigue syndrome? A controlled study on maximal exercise performance and relations with fatigue, impairment and physical activity. Psychological Medicine 2001; 31: 107 – 114. Conclusion: Physical deconditioning does not seem a perpetuating factor in CFS.	See response above.
SH	The ME Association	44	NICE	17–21		Our sixth concern is that important evidence indicating that inappropriate exercise can be harmful	There is a recommendation about not advising vigorous or unstructured exercise.

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						also appears to have been ignored. For example, the Lapp exercise study (reference; Exercise limits in chronic fatigue syndrome. American Journal of Medicine 1997; 103: 83 – 84) found that:	
SH	The ME Association	45	NICE	17–21		*"In particular, 23 (74%) experienced worsening fatigue and 8 (26%) stayed about the same after maximum exercise. None improved. The average relapse lasted 8.82 days, although 12 subjects (22%) were still in relapse when the study ended at 12 days. Interestingly, we found similar changes in exercise in lymph pain, depression, abdominal pain, sleep quality, joint and muscle*	See response above.

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						pain, headache, and sore throat. *The data would suggest that when PWC's (people with cfs) are pushed to maximal exertion, they frequently relapse for long periods of time."*	
SH	The ME Association	46	NICE	17–25		CBT AND GET The sections on CBT and GET are unbalanced, not properly researched, and contain advice that is potentially harmful for a significant proportion of people who come under the ME/CFS umbrella. We cannot therefore endorse them.	The strongest research evidence was found for cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The Guideline Development Group was concerned that both therapies may be misunderstood and not used correctly. Therefore detailed guidance was given.
SH	The ME Association	47	NICE	17–25		Instead, we would like to see a guideline that advocates the type of	The guideline has been restructured to make this clearer.

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						common sense, self-help strategies (i.e. pacing a person's activities according to stage and severity of their illness) that have been repeatedly endorsed by people with ME/CFS. This is an approach that could be incorporated into primary care management and/or an Expert Patient programme. And we find it strange that the Expert Patient Programme in relation to ME/CFS is not even mentioned in the shortened version, which will presumably form the basis for what s sent out to health professionals.	
SH	The ME Association	48	NICE	17–25		We also wonder whether NICE is living in the real	Any implementation issues regarding recommendations will be raised with the

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						world. The clear implication being given in this guideline (key priorities section on p6/48) is that if people with mild to moderate ME/CFS want to improve then they need to be referred by their GP to a multidisciplinary hospital-based ME/CFS service that has expertise in CBT and GET. We agree with NICE that these services cannot be delivered by General practitioners. A relevant reference here is: Long-term efficacy of cognitive behavioural therapy by General practitioners for fatigue. A	NICE implementation team.

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						four year follow-up study. Journal of Psychosomatic Research 2006; 61: 601 – 607. Conclusion: CBT delivered by GPs is not effective in the long term.	
SH	The ME Association	49	NICE	17–25		But where is the money going to come from to assess and treat around 180,000 people with ME/CFS in the mild to moderate category? If an assessment and course of CBT and/or GET costs around £1,000, the total cost to the NHS would be around £180 million. Since NICE have not produced a cost-benefit analysis to support the CBT and GET recommendations, it must	A cost–impact analysis will accompany the guideline.

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						be assumed that no costing evaluation has taken place. Without this vital information the draft lacks an economic strategy. The Department of Health will surely want to know why.	
SH	The ME Association	50	NICE	17–25		And where are all the cognitive behaviour therapists going to come from? CBT services are already in a position where they cannot cope with a rapidly increasing referral rate for common psychiatric conditions such as anxiety and depression – a steadily worsening situation that NICE has been well aware of for some time.	Any implementation issues regarding recommendations will be raised with the NICE implementation team.
SH	The ME Association	51	NICE	15		2. A FAILURE TO PROVIDE INFORMATION ON THE VERY EARLY	The guideline has been restructured to make this clearer.

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						STAGES OF THE ILLNESS.	
SH	The ME Association	52	NICE	15		Our second major disagreement concerns the way in which the guideline has almost completely ignored (apart from section 1.2.1.10) what happens in the first four months before a diagnosis of ME/CFS is confirmed. Whilst we agree that a period of time needs to elapse before the diagnostic label of ME/CFS is used, there are a number of crucial points that need to be discussed in relation to how these patients should be managed during the very early stages (i.e. the first few weeks and months).	The guideline has been restructured to make this clearer.
SH	The ME Association	53	NICE	15		On the question of	This is a guideline about CFS/ME and

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						labelling, the 2005 ME Alliance report into early diagnosis suggested that there are appropriate names that could be used while the diagnosis of ME/CFS is being considered – on example being a post-viral fatigue syndrome.	diagnosing another condition is beyond the scope. In addition, many people who present have not had a virus.
SH	The ME Association	54	NICE	15		But what is far more important is the fact hat advice on aspects such as sleep disturbance and energy management is likely to differ quite significantly from that offered once the illness enters a more chronic stage. In regard to sleep, excessive sleep (hypersomnia) is very common at this stage and	The view of the Guideline Development Group is that there are risks to establishing an abnormal sleep pattern resulting from daytime sleeping for long periods of time. The wording has been changed to reflect that in the short-term extra sleep may be required.

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						may well form a crucial part of a natural recovery process. We know of no evidence to suggest that people who need to sleep for a long period of time at night following an acute infection should be coerced into adopting a more normal pattern of sleeping (as appears to be recommended in 1.3.2.1).	
SH	The ME Association	55	NICE	15		Anecdotal evidence is overwhelmingly in favour of a period of carefully monitored rest during the very early stages, something that may include a period of bed rest, followed by convalescence. Exercise in the normal sense of the word usually has little or no role to play	There is advice on rest as differentiated from sleep.

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						during this very early stage. In fact, an inappropriate exercise programme is very likely to make the illness worse if introduced too early on.	
SH	The ME Association	56	NICE	30–32		3. A FAILURE TO PROVIDE AN ADEQUATE DESCRIPTION OF MANY IMPORTANT ASPECTS OF MANAGEMENT (mainly section 1.3.4)	Response to individual points below.
SH	The ME Association	57	NICE	30–32		Our third major disagreement is that having spent most of the guideline recommending CBT and GET, the remainder contains a totally inadequate review of all the other aspects of management – many of which are extremely important to patients, and	The structure of the guideline has been substantially revised based on feedback in the consultation to reflect the interventions in primary care. However, the Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. This programme has been described in detail in the guideline

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						are likely to be dealt with in primary care rather than hospital-based services.	with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity..
SH	The ME Association	58	NICE	30–32		In particular, the almost non-existent coverage of pain, which for some people is the most disabling aspect of their illness, is extremely poor – especially when this is compared to the vast amount of space given to sleep disturbance.	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. However, the option of referral to a pain management clinical has been added.
SH	The ME Association	59	NICE	30–32		In other words, there is very little of practical value in this guideline for General practitioners and members of the primary healthcare team – who are likely to remain the main source of information, advice and support for people with	The structure of the guideline has been substantially revised based on feedback in the consultation to reflect the interventions in primary care.

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						ME/CFS.	
SH	The ME Association	60	NICE	34–35		4. ISSUES AFFECTING THE SEVERELY AFFECTED (mainly section 1.4)	
SH	The ME Association	61	NICE	34–35		Although the guideline acknowledges that its recommendations regarding CBT and GET do not apply to the severely affected, we feel that the information that has been supplied does not take account of the enormous difficulties currently being experienced by many people in this group when it comes to accessing either hospital-based or domiciliary-delivered medical care, obtaining practical support, and being refused one or more	This section has been revised to reflect your comments and to make it clear that if patients are unable to travel care should be in the home. The implementation issues will be raised with the implementation team.

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						component of the disability living allowance because both lay and medically qualified assessors have received misinformation about the cause of potential severity of this illness.	
SH	The ME Association	62	NICE	34–35		The description of severe ME/CFS (pp 4 – 5 of the NICE) needs to include they type of more severe neurological symptoms – i.e. blackouts, atypical convulsions, loss of speech and swallowing necessitating tube feeding – that are prominently referred to in section 4.2.1.2 of the CMO report.	Symptoms: as symptoms are so varied and individual, they are difficult to list without misleading clinicians that a given symptom is or is not part of CFS/ME. The concern of the Guideline Development Group was that symptoms of life threatening co-morbid conditions may be dismissed as symptoms of CFS and not treated if these were part of a comprehensive list. Hospital admission: the view of the Guideline Development Group was that in most cases patients preferred to remain in their home and have access to services there. We have reflected this.

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						Of particular concern is the fact that during the preparation of our own response we have been told that PCTs are already using quotations from the draft guideline to prevent the hospitalisation of severely affected patients. We assume this probably refers to the following statement in 1.4.1.8:	

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						The majority of adults and children with (severe) ME/CFS will not need hospital admission.	
SH	The ME Association	63	NICE	13–17		5. DIAGNOSTIC CRITERIA FOR ME/CFS (section 1.2)	Response below
SH	The ME Association	64	NICE	13–17		We are very concerned at the way in which the guideline has modified the current Fukuda research criteria for CFS (section 1.2.1.2) to produce a new clinical criteria that extends the boundaries of what currently constitutes ME/CFS (i.e. chronic unexplained fatigue + one other symptom). Many clinicians and researchers believe that the existing research criteria are already far too wide and as	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						a result CFS has become a dustbin diagnosis for anyone with unexplained chronic fatigue. The diagnostic criteria proposed by NICE means that almost anyone with unexplained chronic fatigue, or feeling 'tired all the time' will now be diagnosed as having ME/CFS.	
SH	The ME Association	65	NICE	13–17		The practical result is that hospital-based services, which are still virtually non-existent in some parts of the UK, or are struggling to cope with their existing workload in others – will be flooded with referrals for people with unexplained chronic fatigue.	The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.
SH	The ME Association	66	NICE	13–17		It makes no sense whatsoever to advocate	While it is widely accepted that CFS/ME is a very heterogeneous condition, no

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						what is basically a 'one treatment fits all' approach to the extremely heterogeneous range of illness presentations that comes under the existing ME/CFS umbrella. To Try and do this to everyone with unexplained chronic fatigue indicates a very serious lack of judgement.	research evidence was found for defined sub-groups or different management strategies. The guideline takes an individualised approach based on the patients' symptoms and circumstances to accommodate differences.
SH	The ME Association	67	NICE	13–17		And while we appreciate that the aetiology and pathogenesis of ME/CFS falls outside the NICE guideline remit, the situation regarding ME/CFS is unique in that a significant proportion of doctors still do not even accept that this illness exists as a distinct clinical entity (reference: Primary	The publication of the guideline will raise awareness of the illness as a distinct clinical entity.

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						healthcare provision and Chronic Fatigue Syndrome: a survey of patients’ and General Practitioners’ beliefs. BMC Family Practice 2005; 6: 49; epublication: http://www.biomedcentral.com/content/6/1/49). So there must be reference to some of the important neuroradiological, neuroendocrine and neuroimmunological research findings that support the World Health Organisation classification of ME/CFS as a neurological disorder.	
SH	The ME Association	68	NICE	13–17		There should also be some reference to the important new research into gene expression that is being	This has been mentioned in the text of the full guideline but it is too early to put into a recommendation.

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						carried out in both the UK and the USA. Preliminary results have already identified abnormalities in gene expression that may be characteristic of ME/CFS – a finding that could, of course, lead to a diagnostic test and specific forms of treatment.	
SH	The ME Association	69	NICE	13–17		We are also very disappointed to find that the Guideline Development Group (GDG) appear to have totally rejected the way in which the Canadian Guidelines have, quite sensibly, moved towards a much tighter clinical definition that clearly recognises the importance of sub-grouping under the ME/CFS umbrella, and	The view of the Guideline Development Group was that there was no one diagnostic criterion that was better validated. We accept that investigations to inform management, tailored to the individual’s symptoms, should be carried out. This is in a later section.

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						recommends that individual differences in symptoms and signs should play an important role in how an individual patient should be managed.	
SH	The ME Association	70	NICE	13–17		If NICE fails to take note of these crucial points relating to causation and subgrouping in formulating a new clinical criteria, ME/CFS will continue to be revialised as a dustbin diagnosis with patients being incorrectly labelled as having some sort of psychosomatic or somatoform disorder.	The causes of CFS/ME were beyond the scope of this guideline. The Guideline Development Group did not find evidence of sub-groups.
SH	The ME Association	71	NICE	13–17		As a result, people with ME/CFS will not receive the individual approach to management that they deserve and this will add	The Guideline Development Group stresses an individual approach to management based on symptoms.

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						to, rather than alleviate, the cost of health and social service provision.	
SH	The ME Association	72	NICE	13–17		We now move on to comment on some of the other conclusions and recommendations:	Responses to individual points below.
SH	The ME Association	73	NICE	9–12		GENERAL PRINCIPLES OF CARE (section 1.1) This is the one and only area where we find the content to be Generally balanced, helpful and sensible – as it sets out the common sense protocols that should govern the management of any chronic disabling illness. We are particularly pleased to see that information regarding the issue of informed consent has been included here.	Noted with thanks.

National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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SH	The ME Association	74	NICE	9–12		However, the value of the advice in this section is obviously going to be dependent on the quality of the advice that is contained elsewhere in the guideline.	Noted.
SH	The ME Association	75	NICE	13–16		CLINICAL ASSESSMENT (section 1.2)	
SH	The ME Association	76	NICE	13–16		The failure to include a comprehensive list of illnesses that ought to be considered before the diagnosis is confirmed is a serious omission – as is the failure to point out that there are important clinical and research findings that differentiate ME/CFS from depression.	The Guideline Development Group's view was that there were a very large number of illnesses that could be considered. As the guideline cannot be a medical textbook, there was a concern about mentioning only a handful.
SH	The ME Association	77	NICE	13–16		Where symptoms are being discussed in relation to disease severity (e.g. on page 5 of the shortened	We have based these definitions on those of the Chief Medical Officer's report.

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						version) it should be pointed out, as was done in section 4.2.1.2 of the CMO report, that some people with more severe ME/CFS may have neurological symptoms and signs such as those already referred to.	
SH	The ME Association	78	NICE	13–16		With regard to the investigation of people with a possible diagnosis of ME/CFS:	Response below.
SH	The ME Association	79	NICE	13–16		Some of the recommendations regarding the investigation of people with a possible diagnosis of ME/CFS in section 1.2.2 suggest that the authors are not in touch with the sort of information and queries that patients are taking to their doctors	No research evidence was found on these tests which met the agreed inclusion criteria.

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						regarding more speculative diagnostic tests. For example, having funded research into the value of investigations involving RNaseL (for antiviral activity) and chronic fatigue syndrome urinary markers (CSFUMs), The ME Association is surprised to find no mention of these tests.	
SH	The ME Association	80	NICE	13–16		We are also concerned at the lack of emphasis regarding the need to further investigate people who, while they fit the diagnosis of ME/CFS, still have a symptom or symptoms, which is/are more prominent than is normally found in this illness. For example, the	The Guideline Development Group's view was that there were a very large number of illnesses that could be considered. As the guideline cannot be a medical textbook, there was a concern about mentioning only a handful.

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						need to exclude sarcoidosis or tuberculosis in someone who also has respiratory symptoms. Or systemic lupus and parvovirus infection in someone with joint pains. Or multiple sclerosis where neurological symptoms and signs are difficult to differentiate between the two – as does sometimes happen. Or an assessment for possible sleep apnoea, with an Epworth sleepiness score, where daytime sleepiness is excessive or comes on suddenly.	
SH	The ME Association	81	NICE	13–16		There also needs to be far more information on where extended investigation is required from points that are gathered during the	This is a guideline about CFS/ME. Unfortunately, the time and the scope preclude starting the diagnostic process with each presenting symptom. We had the same difficulty with the 'Referral for

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						routine history taking. For example, a positive response to a past history of blood transfusion prior to 1991 indicates the need to check hepatitis C status. Or a history with symptoms suggestive of more significant or widespread autonomic dysfunction would need to be assessed in hospital.	Suspected Cancer Guideline'. We could not start with for example the presenting symptom of 'weight loss' and what that could signify as that is a guideline in itself.
SH	The ME Association	82	NICE	13–16		And why is the estimation of creatine kinase (section 1.2.2.2) only recommended in children when it may be a marker of a muscle disease in adults?	Added for adults.
SH	The ME Association	83	NICE	13–16		With regard to the physical examination of patients:	Response below.
SH	The ME Association	84	NICE	13–16		We are perplexed as to why there is no mention of clinical examination in the	A physical examination has been added. Please refer to previous comments about ruling out other conditions.

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						diagnostic assessment – in particular the assessment of problems such as disequilibrium where a Romberg test or Fukuda test (for vestibular function) may demonstrate abnormal findings. Equally, people with symptoms suggesting postural hypotension should have their blood pressure checked lying and standing, and may in some circumstances require hospital based investigations. The various fibromyalgia trigger points need to be checked in those patients who have a fibromyalgic component.	
SH	The ME Association	86	NICE	23 and 29–30		The term setback is a completely inappropriate way of describing the sort	The guideline is aimed at healthcare professionals and the Guideline Development Group did not think that

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process.”
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						of relapses that quite frequently occur in ME/CFS. Although some relapses are relatively minor and NICE-lived, other people experience far more significant and long lasting relapses as a result of the sort of events that often trigger the illness to start with. We therefore believe that a red line should be placed through ‘setback’ and the term ‘relapse’ used instead.	what was being described fell within the clinical definition of a ‘relapse’.
SH	The ME Association	87	NICE	23 and 29–30		The section covering relapse is curious in that while it provides advice on how to cope with a relapse/setback it fails to include a list of very common causes of a relapse (e.g. infections;	Changed with thanks for pointing this out.

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						over-exertion; temperature extremes; trauma; surgery and General anaesthetics; some types of vaccination – especially for hepatitis B). This is important information that doctors need to be aware of and informing their patients accordingly.	
SH	The ME Association	88	NICE	23 and 29–30		In particular, we are concerned about the lack of appreciation amongst many dentists and anaesthetists regarding the way in which both local anaesthetics and General anaesthetics can cause a relapse in symptoms. Advice such as using an adrenaline-free dental anaesthetic where appropriate, and the possible use of a shorter-	This is beyond the scope of the guideline.

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						acting General anaesthetic, ought to be included.	
SH	The ME Association	89	NICE	30–32		SYMPTOMATIC RELIEF AND PHARMACOLOGICAL TREATMENT (section 1.3.4) This section is hopelessly inadequate because, for many people with ME/CFS, providing effective management for one or more of their symptoms can be far more important than the contribution of lifestyle management.	The guideline does not address the management of individual symptoms. Please refer to the scope and methodology chapter. The evidence search was confined to that directly related to CFS/ME. Where the management of symptoms is the same as that of people who do not have CFS/ME it is not addressed. The Guideline Development Group did not have the time or remit to write a guideline on each symptom.
SH	The ME Association	90	NICE	30–32		People with ME/CFS have a number of symptoms – pain, sleep disturbance, gastric symptoms – where a combination of self-help strategies and medication	See comment above.

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						can often be very helpful. We do not understand why the guideline cannot provide more detailed information on the sort of approaches that can and should be given to patients. We have already referred to pain control, which for some is the most disabling aspect of having ME/CFS, but there are numerous other symptoms where symptomatic relief plays an important role in any management programme.	
SH	The ME Association	91	NICE	30–32		We will forward by post some examples of MEA self-help literature on pain relief and our ABC of symptomatic management to illustrate what can actually be done here.	Noted with thanks.

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SH	The ME Association	92	NICE	32		DIET AND NUTRITION (section 1.3.5)Again, this is hopelessly inadequate – especially in view of the fact that people with ME/CFS are very interested in dietary approaches and are going to ask questions about what may or may not be helpful. They clearly need straightforward and sensible advice that covers a wide area of dietary management, along with advice on the vitamins, minerals and supplements that are extensively used and recommended to people with ME/CFS.	The remit of NICE is to develop evidence-based guidelines for healthcare professionals. No trial evidence was found which supported the use of supplements in the management of this condition.
SH	The ME Association	93	NICE	32		Why, for example is there no information about the reasons why some people	Issue 1. General dietary advice: The Guideline Development Group recognises that these approaches may be useful for

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						(especially those with self-imposed dietary restrictions) with ME/CFS could be at increased risk of developing osteoporosis and how diet may be relevant here. Why is there no mention about the value of complex carbohydrates in helping to stabilise blood sugar	people with CFS/ME but this is general dietary advice rather than specifically relevant to this condition. To make this clearer there is now a general recommendation added about this. Issue 2. The use of drugs for the treatment of nausea: The guideline did not review the literature for the general management of each symptom but searched for evidence directly relevant to patients with CFS/ME. No evidence was found for the management of nausea. The guidelines advise that symptoms would generally be managed in the same way as other patients with that symptom. Issue 3. EPA: The Guideline Development Group found insufficient evidence to recommend nutritional supplements routinely. Please refer to full guideline. It is acknowledged, however, that some individuals may find them helpful.

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						levels? Why is there no mention of the importance of a good fluid intake? This is especially important in relation to those who have postural hypotension or orthostatic intolerance. Why is there no mention of simple self-help approaches that can help in the management of nausea (e.g. use of ginger) or the use of drugs such as ondansetron if this is more severe?	

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						Why is there no discussion on the use of EPA supplements? These are probably the most popular supplement currently being used by people with ME/CFS, and while we accept that there have been no randomised controlled trials to support the use of EPA, it is untrue to say that there is 'no evidence' in relation to this supplement (reference: The use of eicosapentaenoic acid in the treatment of chronic fatigue syndrome.	

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						Prostaglandins, Leukotrines and Essential Fatty Acids 2004; 70: 399 – 401).	
SH	The ME Association	94	NICE	32		It is also unhelpful to simply state that 'Exclusion diets are not Generally recommended for the management of CFS/ME' when irritable bowel symptomatology is quite common in this illness and there is good evidence to show that exclusion diets can be helpful in identifying food intolerances – where these occur in IBS. This section should also include advice about not going on a gluten-free diet before a screening test for celiac disease has been carried out. We could go on.	The guideline now cross-refers to the NICE Irritable Bowel Syndrome (IBS) guideline, which has more in-depth guidance on this matter.

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SH	The ME Association	95	NICE	33		ALTERNATIVE AND COMPLEMENTARY APPROACHES (section 1.3.6) Again, this section is hopelessly inadequate. It also appears from the first sentence – i.e. 'There are no complementary therapies that treat CFS/ME for adults and children and their use is not recommended' – to be very dismissive about any aspect of alternative medicine.	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS. It is acknowledged, however, that some individuals may find these approaches helpful.
SH	The ME Association	96	NICE			With the lack of recognition, or limited management input from many NHS practitioners, people with ME/CFS have been spending large amounts of	Our remit is to develop guidance for the NHS healthcare professionals. There was no research evidence found in the searches for these therapies and the guideline does not recommend them to be available on the NHS.

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						time and money in the alternative health sector. So the pros and cons of the popular alternative treatments – e.g. anticandida regimes; dubious allergy tests and treatments; magnetic therapy; Reverse therapy – commonly aimed at people with ME/CFS must be properly reviewed, and where necessary criticised or discredited. Approaches such as acupuncture for pain relief, which can be supported by some degree of clinical evidence, need to be included in a fair and balanced discussion.	

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SH	The ME Association	97	NICE	General		**SERIOUS OMISSIONS** As the CMP report acknowledged, the management of ME/CFS crosses many boundaries. It is not just dealing with a wide range of symptoms. The NICE guideline, while acknowledging that other management issues exist, almost completely ignores what could and should be done in these areas.	Please see response to individual points below.
SH	The ME Association	98	NICE	General		State sickness and disability benefits, for example, are a major source of anxiety for people with ME/CFS with many currently having to go to appeal in order to obtain benefits to which they should be entitled. (NB: In a House of Commons	NICE guidelines provide advice to NHS healthcare professionals. State benefits are beyond the scope. The guideline, however, advises healthcare professionals to discuss this with patients.

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						written answer dated 9 October 2006, the Minister of State at the Department of Constitutional Affairs, confirmed that 800 people with CFS successfully appealed against disqualification of their disability living allowance award in 2005). Any guideline on management must, therefore, contain a section on state benefits, and make it clear that where ME/CFS is concerned people should be entitled to Incapacity Benefit and Disability Living Allowance where there is a genuine need.	
SH	The ME Association	99	NICE	General		The guideline also needs to point out that ME/CFS has been recognised as a	NICE guidelines provide advice to NHS healthcare professionals. This is beyond the scope.

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						disease that can be covered by the Disability Discrimination Act, and that this can be very useful in relation to employment and education. A useful reference here is the case of O'Neill v Symm and Company, details of 3hich can be found at: www.outertemple.co.uk/cms/uploads/Disability%20Discrinmination.pdf.	
SH	The ME Association	100	NICE	21–25		**LEGAL ISSUES** The medical defence organisations have repeatedly warned doctors that prescriptions for exercise must be given with exactly the same care as with a prescription drug. Failure to do so is likely to	The emphasis is on an individualised programme. We have stressed throughout the need for appropriate monitoring and review.

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						result in litigation if harm occurs as a result of inappropriate advice. The MEA continues to receive reports from people with ME/CFS whose condition has relapsed following inappropriate advice about exercise and we quote from one such response that was received during this consultation process:	
SH	The ME Association	101	NICE	21–25		“*I have been told by several doctors who don’t have a clue about exercise. I went to see one while in a relapse, and hence was struggling to do even normal daily living stuff, without trying to add any more into my day. When I replied back to the doctor that I was working part time, doing*	One aim of the guideline is to give clear and consistent guidance to all healthcare professionals. Please refer to the definition of ‘exercise’.

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						gardening, doing too much and this exercise was making me worse, he told me this wasn't counted as exercise and that I need to do something like aerobics…"	
SH	The ME Association	102	NICE	21–25		As a result of the very disturbing accounts we continue to receive about completely inappropriate advice on exercise and activity management, we believe that the guideline must include a proper warning if it continues to use the term 'exercise' – even when what is being referred to is activity or energy management. Otherwise, we have no doubt that someone will take a claim for negligent	Please refer to the definition of 'exercise'.

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						advice about exercise management to the courts.	
SH	The ME Association	103	NICE	18		UNHELPFUL OR INAPPROPRIATE LANGUAGE Section 1.3.1.3 'Where the adult or child's main goal is to return to normal activities …' Many people will find this offensive as it implies that there are a substantial proportion of people who do not want to return to normal activities. This statement reinforces prejudices about sick role behaviour held by some health professionals.	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	The ME Association	104	NICE	38		Section 4.4 'It is not known how much improvement is important for patients with	This is intended to convey that different people will have different goals based on their current individual circumstances.

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						CFS/ME'. Again, many people will find this offensive as it implies that some may not want to get better.	Some may set as an objective maintaining their current level and avoiding deterioration for the time being.
SH	The ME Association	105	NICE	18		**TWO FINAL POINTS** 1. We welcome the inclusion of information about informed consent but feel that the guidance needs to make it clear, as did the CMO report in section 4.4.2, that benefit provision must not be made conditional on agreeing to participate in a particular form of treatment.	Benefit provision is beyond the scope of the guideline, which is for the NHS.
SH	The ME Association	106	NICE	General		2. The guidance, certainly in the shortened version repeats itself at times to no added effect. We feel that	We have revised this to reflect your suggestions.

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						this will cause frustration to health professionals who are hard pressed for time and will consequently tend to skip read through this type of information.	
SH	The ME Association	107	NICE	General		**CONCLUDING REMARKS** In sending in this response as a stakeholder in the guideline development process, The MEA has consulted widely with its members and reflected their very strong views on the composition of the current draft.	Noted. Thank you for your effort.
SH	The ME Association	108	NICE	General		We find it hard to imagine another situation where a group of people, many of whom have little or no direct experience in the clinical care of an illness they are advising one, have	The clinical members of the Guideline Development Group were nominated by professional organisations for their experience in the area. Every member has a great deal of experience with this condition.

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						produced such a poor quality guideline.	
SH	The ME Association	109	NICE	General		We cannot understand why the views of people with ME/CFS and their charity representatives are not being listened to by NICE.	A great many of the recommendations have been derived based directly on input from the patient representatives and the wider survey.
SH	The ME Association	110	NICE	General		Unless NICE takes on board what the stakeholders representing patient opinion have to say, they will have failed the stakeholder principle – something that government continually tells us is at the heart of the consulting and listening process.	Noted.
SH	The ME Association	111	NICE	General		If this draft guidance becomes definitive guidance for health professionals in April 2007, it will be a very sad day for people with ME/CFS.	Noted.

National Institute for Health and Clinical Excellence
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis Consultation Table
29 September – 24 November 2006
Comments on NICE version

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SH	The Royal Society of Medicine	1	NICE	5–6		Definition of severity levels is important and appropriate	Noted.
SH	The Royal Society of Medicine	2	NICE	7, 16	1.2.3	Making the diagnosis in children on the basis of a 3-month history seems appropriate to help avoid prolonged untreated impairment. However it is important to establish whether this reduction from 6 to 3 months results in practice in an increase in CFS diagnoses in children with other explanatory medical or psychiatric disorders (see Taylor S, Garralda E, Martinez-Alier N, Tudor-Williams G (2003) An organic cause of neuropsychiatric illness in adolescence. Lancet, 361, 572)	Noted. The Guideline Development Group considered the time frame to be appropriate.

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SH	The Royal Society of Medicine	3	NICE	9+	1	Excellent	Noted with thanks.
SH	The Royal Society of Medicine	4	NICE	17	1.3	Management in children needs to include work with parents and family, and the techniques advocated may be delivered in a group (child/parents or child/family) context. CFS in children is associated with marked parental involvement and family burden (more so than for other chronic disabling disorders such as juvenile arthritis: see Rangel L, Garralda ME, Jeffs J, Rose G. (2005) Family health and characteristics in chronic fatigue syndrome, juvenile rheumatoid arthritis and emotional disorders of childhood. Journal of the American Academy of	This is recognised by the Guideline Development Group.

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						Child and Adolescent Psychiatry, 44, 150-158)	
SH	The Royal Society of Medicine	5	NICE	37	1.4.1.8	Treatment in hospitals with specialised units can be effective for severely affected children (see Sankey et al, (2006) A follow-up study of CFS in children and adolescents: symptom persistence and school absenteeism. Clinical Child Psychology and Psychiatry, 11, 126-138	This recommendation does not say that hospital admission is always inadvisable. In fact it addresses when it would be.
SH	The Young ME Sufferers Trust	1	NICE	General		OVERALL VIEW OF THE NICE GUIDELINE The Trust believes that the present draft of the NICE guideline on CFS/ME is unacceptable, and not fit for purpose for patients suffering from ME.	While it is recognised that it is heterogeneous, the evidence does not allow distinctions between sub-groups. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						ANALYSIS OF THE PROBLEM The problem NICE faces is that it has attempted to put together guidance on a medical condition that has been artificially constructed. CFS is not a discrete disease, it is an arbitrary grouping of symptoms, now with the profile even further widened by NICE. By the very nature of the process by which 'CFS' was created, different pathologies must be trapped within its remit; descriptions of CFS always refer to it as a 'heterogeneous condition' eg the Report of the Chief	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects to patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity

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						Medical Officer's Working Group on CFS/ME published by the DOH in 2002. Those who coined the term CFS were divided as to the symptom profile they would research, rather than researching a specific and recognisable disease. Government, physicians and patients are all having to deal with the fall-out of this process. In the Trust's opinion, this guideline as it stands would lead to an unprecedented degree of iatrogenic injury to people with genuine ME, particularly children, those in the early stages of ME,	activity, which may be sitting-up in bed or gentle stretches. Please refer to the definition of 'exercise' in the glossary.

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						and the severely ill. Those who are not yet severely ill risk being made so, both by the treatments recommended, and by the fact of relapses being trivialised by the term ‘setbacks’ and patients being urged to continue with programmes despite these setbacks. This is demonstrated in the many accounts we have been given over the years, together with numerous patient surveys such as that by the 25% Group. If a key symptom of a disease is post-exertional malaise, it is illogical and inappropriate to prescribe exercise as a treatment and the damage done by	

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						such an approach is evident in patient histories. Before CFS was born (originally for research purposes only) ‘ME’ was the name for a well-defined, virally triggered, potentially severe and chronic neurological disease. Incorporating it into a collection of symptoms in which ‘chronic fatigue’ is the main symptom masks its true nature. The fact that the CFS construct has been taken into clinical use compounds the problem. This has put NICE in the position of issuing guidance on an unscientific basis, for a hopelessly mixed group	

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						of patients. Consequently, if this guideline were published, physicians face the stark choice of ignoring NICE when dealing with patients who have ME rather than CFS, or risking actively causing harm to this group of patients. They would also have no guidance on how to distinguish this group. Having seen and experienced what comes of trying to put together guidance for 'CFS/ME', the Trust now believes that ME and CFS should be the subject of separate guidelines. Despite the step	

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						forward that the (recently updated) Canadian Criteria for CFS/ME represented - criteria which the Trust was the first to recommend in the UK–we believe that ME should now be removed from the CFS bracket and steps taken to issue guidance to doctors as to its true nature, using information from appropriate ME specialists, who will not be those at present advising the government on CFS. They should be drawn from those who have the necessary knowledge, expertise and experience of examining and investigating ME patients and who can point to the	

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						infectious origin of ME, its known epidemiology, history of epidemics, known biomedical research profile, testable pathological changes, post mortem findings and other robust scientific evidence. We respectfully submit as evidence selected quotes from the Nightingale Definition of ME by The Nightingale Research Foundation, Ottawa, Canada, with which our Executive Director Jane Colby was invited to assist. The Nightingale Definition will shortly be available in full. The expertise and	

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						knowledge that NICE needs on ME is available. The Trust is dismayed that NICE has allowed such a narrow perspective to inform such vital work and requests that it reconsider the whole guideline in the light of our submission, our new evidence, and that of other patient organisations. QUOTES FROM THE NIGHTINGALE DEFINITION OF ME : ME is a clearly defined disease process. CFS by definition has always been a syndrome. At one of the meetings held to determine the 1994 CDC definition of CFS […] Dr. K Fukuda stated that numerous ME	

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						epidemics–he cited the Los Angeles County Hospital epidemic of 1934, the Akureyri outbreak of 1947-48 and the 1955-58 Royal Free Hospitals epidemics–were definitely not CFS epidemics. Dr. Fukuda was correct. […] Primary ME is an acute onset biphasic infectious disease process, where there is always a measurable and persistent diffuse vascular injury of the CNS in both the acute and chronic phases. Primary ME is associated with immune and other pathologies. […] Primary ME is a chronic	

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						disabling, acute onset biphasic infectious disease process affecting both children and adults. There are both central and peripheral aspects to this illness. […] Primary Infection Phase: The first phase is an epidemic or endemic infectious disease Generally with an incubation period of 3 to 7 days; in most, but not all cases, an infection or infectious process is evident. (See Clinical and Scientific Basis of M.E./CFS, Hyde B, pps.124-126) Secondary Chronic Phase:	

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						The second and chronic phase follows closely on the first phase, usually within two to seven days; it is characterized by a measurable diffuse change in the function of the Central Nervous System. This second phase is the persisting disease that most characterizes ME […] Extent of Injury Type 1: One side of the cortex is involved. Those patients labeled as 1A have the best chance of recovery. Type 2: Both sides of the cortex are involved. These patients have the least chance of spontaneous recovery.	

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						Type 3: Both sides of the cortex, and either one or all of the following: posterior chamber organs (the pons and cerebellum), limbic system, the sub-cortical and brainstem structures are involved. Type 3B are the most severely affected patients and the most likely to be progressive or demonstrate little or no improvement with time. Degree of injury Type A: Anatomical integrity is largely maintained in the Brain SPECT scan. Type B: Anatomical integrity is not visible in the CNS SPECT scan. Type 3B are some of the most	

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						severely and chronically injured patients. […] What is new and different about the Nightingale ME Definition is the following: A Testable Definition: The definition is set out in both a clinical diagnostic and scientifically testable fashion. This will allow the physician both an early diagnostic bedside or office understanding of the illness and a scientific and technological method to investigate and confirm the diagnosis. […] END QUOTES The Nightingale Definition lists the following:	

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						Testable Neuropsychological Changes Testable Major Sleep Dysfunction Testable Muscle Dysfunction Testable Vascular Dysfunction. POTS; Cardiac Irregularity; Raynaud's Disease; Circulating Blood Volume Decrease; Bowel Dysfunction; Ehlers-Danlos Syndromes Group; Persantine Effect in ME Patients; ME Associated Clotting Defects	

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						Testable Endocrine Dysfunction: This feature is common and tends to be a late appearance. It is most obvious in: Pituitary-Thyroid Axis; Pituitary-Adrenal Axis Changes; Pituitary-Ovarian Axis Changes; Bladder Dysfunction Changes In the Nightingale Definition of ME, more than 30 physicians are listed who have to varying degrees also noted the historical and the more recent investigational findings. We recommend this definition to NICE.	
SH	The Young ME Sufferers Trust	2	NICE	General		FURTHER COMMENT The Trust has been	Noted with thanks.

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						working co-operatively with the ME Association regarding children with ME at their invitation. We endorse the critique of the NICE guideline by the ME Association in its submission.	
SH	The Young ME Sufferers Trust	3	NICE	General		The Trust agrees with the stance taken by the 25% Group on this draft.	Noted with thanks.
SH	The Young ME Sufferers Trust	4	NICE	General		The Trust agrees with the view of the Edinburgh MESH group and others that patient evidence has not been accorded sufficient weight or respect. This is entirely at variance with the government’s own Expert Patient scheme and its aim to involve the Patient Voice.	Please refer to the ‘NICE Technical Manual’ available on their website for the methods used in developing this guideline.
SH	The Young ME Sufferers Trust	5	NICE	Genera		The Trust is in sympathy	Noted.

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				l		with virtually all comments that we have read from ME Support Groups and group consortia around the UK. Some responses have included a plethora of detail with research references. We would emphasise that when virtually every patient group and support organisation in the country explains in a respectful and well-defined way that these guidelines are not fit for purpose, NICE would be well advised to take full cognisance of these views.	
SH	The Young ME Sufferers Trust	6	NICE	General		In the Trust's opinion there is a lack of information about children's needs in the guideline and in some ways they are very badly served by it; see our points	At first the Guideline Development Group envisioned that there would be two separate pieces of guidance, but as development progressed the view was that the care of children is in general similar to adults.

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						below, which should be taken to refer to children and young people with ME rather than the broader chronic fatigue.	
SH	The Young ME Sufferers Trust	7	NICE	4		NICE appears to suggest that young people aged 16-19 may choose to remain under the care of a paediatrician rather than transfer to adult services. It is unclear if NICE is suggesting an increase in paediatricians' caseloads and a change in the usual system of transfer at 16.	We have revised the age definitions for clarity.
SH	The Young ME Sufferers Trust	8	NICE	General		NICE has used the RGPCH guideline to inform this guideline and so has perpetuated some of its mistakes rather than re-considering the issues afresh with new advisers.	The Guideline Development Group did an independent search and did not rely on the RCPCH guidelines as its primary source of information.

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SH	The Young ME Sufferers Trust	9	NICE	34	1.4 1.3	On the severely affected, it is suggested that Graded Exercise Therapy may be appropriate 'to help develop their physical capacity and functioning'. This perception of exercise as being able to 'do the recovery' to the person, is at variance with patient experience, and the clinical experience of other physicians not asked to advise NICE, who maintain that supporting the body's natural recovery process, so that it is able to do more when healing occurs (the same principle as applying a plaster to broken bone) is safer and more effective than trying to force the pace of healing. Capacity	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects to patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or

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						extends naturally as healing takes place. In the Trust's opinion, GET should only be considered as an option when a person is sufficiently well into the recovery phase and is much stronger and able to start increasing activity without making themselves worse. Severely affected children are commonly pressurised to increase activity inappropriately and we have seen terrible relapses as a result, with memory loss, paralysis, return to the stage of tube feeding due to inability to swallow. Such relapses can be very long term. One young person of [x]	gentle stretches, informed by the principles of GET.

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						reported still being unable to walk [x] years after receiving such treatment in his teens. Referring to those advocating GET, he wrote to us: 'They must be stopped'. In more than one instance physicians have openly admitted that GET has caused harm and apologised to the family. We do not wish to see further examples of such treatment being meted out to severely affected children.	
SH	The Young ME Sufferers Trust	10	NICE	General		We can see no specific warning such as that set out in Chapter 5 of the CMO's Working Group Report against mistakenly attributing cases of ME to Munchausen's Syndrome	This is beyond the scope of the guideline.

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						by Proxy or FII (Fabricated Induced Illness). This is necessary due to the still persistent mislabelling of families as either neglecting or abusing their children. It seems particularly prevalent in our home county of Essex and our 2005 report ‘Our Needs Our Lives’ showed an increase rather than a decrease in such problems. We have submitted evidence at the invitation of the parliamentary group that is calling for the withdrawal of the guidelines on MSBP and FII issued in 2002 by the Department of Health under the title ‘Safeguarding Children in	

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						Whom Illness is Fabricated or Induced'. These same 2002 guidelines are incorporated without amendment at Section 6.6 of the 2006 DfES initiative 'Working Together – A Guide to Interagency Working'. In Chapter 5 of the CMO's Working Group Report, it states: a) In cases of CFS/ME, evidence clearly suggestive of harm should be obtained before convening child protection conferences or initiating care proceedings in a	

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						family court b) Neither the fact of a child or young person having unexplained symptoms nor the exercising of selective choice about treatment or education constitutes evidence of abuse. It is frequently Local Education Authorities and Social Services who report the family because the child cannot get to school in the normal way. Rather than providing them with their legal entitlement to suitable education and abiding by Disability	

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						Discrimination legislation, they institute inappropriate proceedings which could be stopped and resolved by well informed physicians. NICE should assist them in this. For further such evidence we refer you to NMEC (National ME Centre, Harold Wood, Essex).	
SH	The Young ME Sufferers Trust	11	NICE	General		We would refer NICE to the NICE summary document 'Children and Young People: The Key Points', located at www.tymestrust.org/pdfs/keypoints.pdf which lists statements from the CMO's Working Group Report that we consider particularly relevant for professionals working with children.	Noted with thanks. These will be referred to the NICE editors for consideration for inclusion in the 'Understanding NICE Guidance' document.

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						Points such as these need to be clearly incorporated into the NICE guideline.	
SH	The Young ME Sufferers Trust	12	NICE	10	1.1.1.3	HELPFUL STATEMENTS There are some helpful statement in the NICE guideline which we wish to recognise. One is that healthcare professionals for both adults and children should have the appropriate skills and expertise – but who is training them? If the training simply perpetuates the same inappropriate psychologically based attitudes to ME, then this worthy aim will produce harm rather than good.	The guideline has provided some information on competencies but detailed work should be undertaken by local commissioners and by the professional organisations to ensure the skills and expertise of healthcare professionals based on the guideline.
SH	The Young ME Sufferers Trust	13	NICE	11	1.1.3.4	The statement that paediatricians should follow	Wording as been changed to reflect this comment.

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						advice from the Department for Education and Skills on education for sick children is helpful. However, the publication 'Access to Education for Children and Young People with Medical Needs' by the DfES contains ambiguities that have been the subject of personal discussion between Parliamentary Under-Secretary of State for Schools, Lord Adonis and the Young ME Sufferers Trust. Lord Adonis has, as a result, issued a clarification to state that a GP's support and advice eg for tuition in the home, is valid. A sick child must legally be offered education by other	

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						means after 15 days of being unable to attend school through illness. Almost no family will see a paediatrician within this timescale. This should be reflected by NICE by referring to the usefulness of supportive advice from GPs as well as consultants in its guidance. Many GPs do not feel able to give such support at the moment or are ignored when they do.	
SH	The Young ME Sufferers Trust	14	NICE	11	1.1.3.5/6	Sharing supportive information with schools and making recommendations for adaptations to education are both worthy aims but this is only helpful when such information takes full	Home tuition has been added.

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						account of the young person's needs, includes full recognition of the disabilities inherent in ME, and recognises that in the 21st century new forms of education are extremely useful to children with ME, such as interactive online education. The Trust works with Nisai Education to provide one such system, which is producing far better educational grades than conventional methods of education for children with ME. School is not a social club and it is perfectly possible to provide for social contact separately. The child has educational rights which are effectively contravened	

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						by physicians insisting on school attendance regardless of academic results. There is an increased tendency for medical studies to use attendance at school as a measure of recovery. School attendance is not a suitable measure of recovery in itself; studies should take account of whether or not the young person's academic achievement is on a par with that of their healthy peers as a result of going back into school.	
SH	The Young ME Sufferers Trust	15	NICE	11	1.1.3.6	The recommendation to liaise with Disability advisers is welcome.	Noted with thanks.
SH	The Young ME Sufferers Trust	16	NICE	11	1.3.1.8	The recommendation to consider the provision of	Noted with thanks.

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						equipment and aids such as wheelchairs, blue badges and stair lifts is particularly welcome as it is not only helpful in itself, it contradicts the view prevalent amongst many physicians that such provision will not facilitate recovery but will instead perpetuate disability.	
SH	The Young ME Sufferers Trust	17	NICE	General		OVERALL COMMENT The guideline uses compassionate language in many places and we do feel that overall the intention is to help patients rather than perpetuate and propagate dogma based on opinion rather than sound evidence. However, the selective use of 'evidence' does just that; it does	Noted with thanks. Please refer to the NICE Technical Manual available on their website for the methods used in developing this guideline. The use of available evidence was not selective, but very systematic.

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						perpetuate ill-informed opinion and dogma and takes far too much account of studies whose subjects plainly did not have ME at all. Compassionate language in itself is not enough. It is the message that is the most important thing, and the message of this guideline is that many people with ME do not prioritise getting better. This is not only untrue, it is a grave insult to those who are already doing their utmost to cope with one of the most disabling illness in existence. Our bottom line is that this	The Guideline Development Group was convened according to NICE methodology, which advises having two patient representatives. We in fact had

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						guidance should have emphasised helping patients towards autonomy and supported self-management. It does not fulfil this purpose and its sidelining of the specific needs of the young do them a great disservice. We recommend NICE to read Chapter 5 of the CMO’s Working Group Report in full. In the Trust’s opinion, this guideline needs a complete rewrite, involving a more balanced group of advisers including full patient representation. If it were published as it stands, the political fallout and the personal fallout for patients	three. In addition, this development piloted the wider questionnaire.

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						with ME would be huge.	
SH	West Midlands Consortium	2	NICE	General		The new Local Multi-Disciplinary Teams will be seeing newly diagnosed patients–we believe all people with CFS/ME should receive regular check-ups with their GPs. This could then involve regular monitoring by the GPs, with more blood tests carried out annually–monitoring and collating the findings to assist with biomedical research.	Please refer to guidance on follow-up.
SH	West Midlands Consortium	3	NICE	General		It is felt that this should be a notifiable illness–if all GPs had a register of CFS/ME patients, the local services would be able to plan their services, and the various government departments would know	This is beyond the scope of this guideline.

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						how much help is needed.	
SH	West Midlands Consortium	4	NICE	1	1 15	It's unclear what is meant by 'relatively common'– although it does seem to set the scene for the all-inclusive broad diagnostic criteria that follows. "CFS/ME, like other chronic illnesses with no certain disease process…" Clearly, CFS/ME must have a 'certain disease process' but, at present, it is not fully understood.	The prevalence is detailed in the next paragraph. The wording has been changed to reflect this comment.
SH	West Midlands Consortium	5	NICE	1	16	"… poses 'real problems', seems perhaps deliberately ambiguous and should be substituted by the word 'serious'.	The wording has been changed to reflect this comment.
SH	West Midlands Consortium	6	NICE	2	1	should start or conclude with 'to date' or 'at the time of publication'	This is implied.
SH	West Midlands Consortium	7	NICE	2	3	Such an approach is	The guideline contains many

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						commendable, but when patients have no knowledge of the illness or of possible treatments for it, their options will almost certainly be limited to the only two approaches recommended in these guidelines i.e. CBT and GET. GPs will look no further, regardless of any harm which the patient suffers. Such a situation will not and cannot constitute 'informed decisions'. "Where patients do not have the capacity to make decisions…" Who will decide that a patient does not have the capacity to make a decision about	recommendations about approaches other than GET and CBT. Please refer to the document mentioned. This is standard text in all NICE guidelines. The guideline makes clear that patients are involved in care and decision-making.

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						his/her treatment? Will a refusal to accept CBT and GET be regarded, as has happened too frequently in the past, as indicating such a lack of capacity even when the patient has made an 'informed decision' concerning his 'individual needs and preferences'? It is only one instance of a worrying tendency to adopt 'catch all' recommendations so that the patient can always be considered to be in the wrong.	
SH	West Midlands Consortium	8	NICE	2	14–15	'Communication should be supported by the provision of evidence-based information offered in a	Comment noted but no action is required.

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						form that is tailored to the needs of the individual patient.' It is important to just offer information on the current level of understanding of the condition at international level.	
SH	West Midlands Consortium	9	NICE	3	6	<u>Definitions used in this guideline:</u> As mentioned above the "evidence" for CBT is much weaker than is portrayed– counselling may be just as effective as an illness management tool. Where will the necessary money come from to finance the required legions of CBT therapists with appropriate "expertise" in CFS/ME?	Issue 1. Counselling: In the view of the Guideline Development Group the evidence was stronger for CBT than counselling. Issue 2. Funding: Please refer to the NICE website for information on implementation initiatives that accompany the publication of a guideline.
SH	West Midlands Consortium	10	NICE	3	15 Line 20	"GET is an evidence-based self-management	NICE guidelines are predicated on research evidence where available. There

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						approach…” As above–the “evidence” for GET is remarkably weak. There is strong evidence that people with CFS/ME respond abnormally to exercise. There is a very fine line between improving mobility and doing lasting damage. There is no other serious, chronic illness in which CBT and GET are recommended as “the therapies of first choice…” Will patients be able to sue for compensation should health professionals give inappropriate advice? Doctors and healthcare professionals must prescribe exercise with exactly the same degree of	is good research evidence for the improvement following GET programmes in people with CFS/ME.

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						care as with a prescription drug. In a survey of GPs conducted in 2004 by Shropshire & Wrekin ME Support Group, of 47 GPs who replied to the question "What management approach do you advocate for your CFS/ME patients?" 2 replied "Exercise on prescription"!! Much of the evidence concerning GET shows that it is harmful to Patients with ME: iii) AfME Survey*:* 'Severely Neglected – ME in the UK', March 2001, iv) Report on Survey of Members of Local ME Groups,	

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						Dr Lesley Cooper, AfME & ME Assoc., November, 2000. Both surveys clearly showed that GET harmed the majority of individuals. A 'treatment' with such an egregious record would not be recommended for any other illness and it is unacceptable to sufferers of ME. "This [GET] is followed by an increase in intensity when able…" Alarmingly, there is no suggestion about the course to be followed in the cases when GET is *not* effective or when it causes the patient's condition to deteriorate. It is	

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						clearly unsound, but implicit in the document, to assume that GET, or *any* intervention, will be unfailingly efficacious. CBT and GET will not alleviate and, in some instances, will undoubtedly exacerbate mitochondrial dysfunction (with its concomitant inability of the body to produce sufficient energy), post exertional malaise, delayed onset fatigue, postural hypotension, low cardiac output, orthostatic intolerance, loss of thermal stability, headaches, hypersensitivity to foods, chemical (e.g. cleaning products and cosmetics)	

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						and medicines, or any other of the many, severe symptoms experienced by people with ME. As "therapies of first choice", CBT and GET have very little to offer but strong reasons to be very cautious about their use.	
SH	West Midlands Consortium	11	NICE	5	4	The description of severe CFS/ME should include many of the more severe neurological symptoms frequently experienced–ie blackouts, atypical convulsions, loss of speech and swallowing necessitating tube feeding.	These are based on those of the Chief Medical Officer's report
SH	West Midlands Consortium	12	NICE	5	1	The phrase usually STOPPED work is totally inappropriate. It suggests there was a choice. For	These are based on those of the Chief Medical Officer's report.

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						the vast majority, of people, this was certainly not the case. With many being dismissed by their employers on the grounds of medical incapability or had to give up work. Many have tried to return, but major relapses have meant they reluctantly ended their careers. Being forced out of employment does not involve any element of preference.	
SH	West Midlands Consortium	13	NICE	5		Four degrees of severity are commonly recognised. It is most inappropriate to combine two of them into one as has been done in this document. While the divisions are undoubtedly artificial, the	We have used the definition 'severe' throughout.

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						illness covering a continuous spectrum of severity, the four categories were defined for good reasons and they should always be treated separately, especially in, as the Guidelines say, "A person centred and collaborative approach to managing symptoms."	
SH	West Midlands Consortium	14	NICE	6	1 Line 3 Line 11 Line 24	'WHEN the adults <u>main</u> goal is to return to normal activities …'–What other goal would there be?! This is entirely unacceptable and should be removed, wherever it appears in the document. Nobody chooses to have ME and nobody has any desire to remain very seriously ill.	Issue 1. Wording: This wording did not clearly reflect what was intended. It has been changed to make it clearer. Recommendations have also been revised.

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						As already pointed out, the evidence for CBT and GET being beneficial is extraordinarily weak. No unbiased reading of *all* the relevant literature would come to any other conclusion. “..provide information about the range of therapies and management strategies as detailed in this guideline.” Given that ”..the therapies of first choice should be CBT or GET…” and as by far the largest section of the Guidelines is devoted to those two strategies, it seems highly likely, probably inevitable, that the only information provided	

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						will be about them with no alternatives being offered. Such a situation would not constitute" Shared decision-making between an adult or child and healthcare professionals…" "The objectives of the programme are to:–sustain or gradually extend, if possible, the person's physical, emotional, cognitive capacity…" The course of action to be followed if the objectives are not possible has been omitted. What should it be?	
SH	West Midlands Consortium	15	NICE	6	8	"…acknowledge the reality and impact of the condition"– this seems to indicate that the patient	The Guideline Development Group wished to encourage a sympathetic approach to managing the condition.

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						needs to be reassured that people believe their condition is real.	
SH	West Midlands Consortium	16	NICE	7	9	"excessive fatigue" – needs defining–it's not clear if this is mental or physical. ME has many more symptoms than 'excessive fatigue', symptoms which require managing.	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.
SH	West Midlands Consortium	17	NICE	7	11	"Risk of prolonged bed rest …" In acute phase of the illness especially, this may be absolutely necessary and unavoidable. A gradual return to normal life may be impossible. What should the physician do in those cases? Empirical research has shown that there is very	This has been removed as it is beyond the scope of the guideline and it is not directly relevant to the diagnosis and management of CFS/ME.

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						little, if any, deterioration in muscle function as a consequence of rest.	
SH	West Midlands Consortium	18	NICE	8	1	"Healthcare professionals should be proactive in advising about fitness for work and education, and recommend adjustments or adaptations to work or studies to enable rehabilitation of adults and children with CFS/ME." Now that healthcare professionals are being financially rewarded for each patient who returns to work, there is a grave risk to the patients' well-being in advocating that doctors should be "..proactive in advising about fitness for work…"	The guideline stresses the involvement and decision-making of the patients.

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						It is also true that many children have been harmed by being forced back into schools while being too unwell to cope with the rigours of daily life. Caution should be strongly advised.	
SH	West Midlands Consortium	19	NICE	9	18 1.1.1.1	We're not convinced that they could provide an aetiological explanation especially as the guidelines suggest that aetiology isn't properly understood!	Agreed and changed.
SH	West Midlands Consortium	20	NICE	10	1	"Offer information about …, and also the NHS Expert Patient Programme." The Expert Patient Programme helps a small number of people with M.E. but many people report that their	We note these comments but have provided sources of information that some people have found useful.

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						experience was not good and they had to drop out. Programmes need to be specifically geared to the audience: The West Midlands Needs Assessment Survey results suggests that length of sessions needs to be shorter, frequency to be fortnightly instead of weekly, and advice to be appropriate. These programmes are not suitable for people with Severe M.E., and very few people with moderate M.E. are able to attend the full course.	
SH	West Midlands Consortium	21	NICE	10	7 1.1.1.2	Unfortunately, professionals with appropriate skills and	The guideline has provided some information on competencies but detailed work should be undertaken by local

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					1.1.3.2	expertise in ME are very few in numbers and there is a grave risk that others will try to provide care, to the detriment of their patients. The established pattern in such circumstances is to apply CBT and GET and then to blame the patient either for making no progress or for regressing. A clear warning to healthcare professionals who do not have the necessary expertise would be greatly appreciated. "Healthcare professionals should provide validated, accurate information …" it is hoped that such information will also include the degree of harm caused	commissioners and by the professional organisations to ensure the skills and expertise of healthcare professionals based on the guideline.

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						by CBT and GET.	
SH	West Midlands Consortium	22	NICE	12	1.1.4.1	An individualised management plan would be very warmly welcomed, though perhaps unlikely to materialise.	Noted with thanks.
SH	West Midlands Consortium	23	NICE	12	1.1.4.3	"Healthcare professionals should aim to establish a supportive and collaborative relationship…" Good, but perhaps the inadvisability of imposing any particular therapy should be pointed out, as well as the patients' right to reject it.	1.1.4.3 This is made clear in the guideline.
SH	West Midlands Consortium	24	NICE	13	1.2.1.2	Diagnostic criteria have been broadened here. Contrast these with "Canadian Consensus Document", (to which there	This is not a complete list of symptoms but ones that may lead to a suspicion of CFS/ME. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an early stage prior to a diagnosis. We have

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						appears to be no reference in "NICE" version)? & Dr Melvin Ramsay's definition of ME: "Muscle phenomena & fatigability: Even following minor degree of physical exercise, 3 or more days may elapse before full muscle power is restored. This feature is unique and is the "sheet anchor" of diagnosis. In moderate cases there may be normal muscle power in remission. Muscle spasm and twitching. In severe cases there may be swollen and very tender bands of muscle including minute foci of exquisite tenderness in trapezii and gastrocnemii	redrafted this section in order to make this clearer.

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						(the muscle groups most commonly involved). Variability of both symptoms and clinical findings during the day Tendency to become chronic. Estimate at least 25%. Also missing here from Ramsay's definition are: • Cold extremities • Hypersensitivity to climactic change. • Ashen grey facial pallor, 20 to 30 minutes before patient complains of being ill • Frequency of micturition	

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						• Hyperacuisis • Episodic sweating • Orthostatic tachycardia Crucially in the NICE draft definition there is no reference to "New Onset", abnormalities of the neuroendocrine system, new sensitivities to food/medications/chemicals –all of which are detailed in the Canadian Guidelines.	
SH	West Midlands Consortium	25	NICE	13	1.2.1.1 Line 1	'CFS/ME is recognised on clinical grounds alone.' There is good evidence to suggest that CFS/ME CAN be recognised from a characteristic constellation of abnormal lab data – IF the correct tests are carried	The Guideline Development Group did not find evidence that CFS/ME could be diagnosed by a series of tests. This is not a complete list of symptoms but ones that may lead to a suspicion of CFS/ME. The intention is to raise awareness that the individual *may* have CFS/ME and to manage symptoms at an

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						out. (Ref Jacob Teitelbaum’s work on lab testing). It appears the GDG haven't been referred to the important neurological, neuroendocrine and neuroimmunological research findings that resulted in the WHO classifying ME as a neurological disorder, or read the page 2 of the Canadian Criteria covering the symptoms of the illness. The list is so poor they appear to have left out neurological and endocrine symptoms in the guidelines, e.g. perceptual	early stage prior to a diagnosis. We have redrafted this section in order to make this clearer.

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						and sensory disturbances; spatial disorientation and visual disturbances; photophobia and hypersensitivity to noise; autonomic symptoms; e.g. urinary frequency and bladder dysfunction which affect so many of us.	
SH	West Midlands Consortium	26	NICE	13	19	'lymph nodes painful not enlarged'–as EBV may cause enlarged lymph nodes–so are we then to conclude that EBV is excluded as a causative factor of CFS/ME? (See comment below P16)	Wording has been clarified.
SH	West Midlands Consortium	27	NICE	14	1.2.1.4	Alzheimer's disease should also be added to the list of 'red flags'–we're aware of one case locally where an individual was misdiagnosed with CFS/ME	This is not a comprehensive list of alternative diagnoses.

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SH	West Midlands Consortium	28	NICE	14	1.2.1.8	We're not convinced it would be possible for CFS/ME patients to receive a mental health assessment within the 4 months that a diagnosis should be made in. These services already seem to be hard-pressed, with long waiting lists.	Any implementation issues regarding recommendations will be raised with the NICE implementation team.
SH	West Midlands Consortium	29	NICE	14	3 1.2.1.4	This suggests that CFS/ME is not a serious disease! In severe cases, CFS/ME DOES produce 'abnormal neurological signs'. There may be significant overlap with all of the following and in addition to those listed, investigations and screening should also be carried out to exclude:	This is not a comprehensive list of alternative diagnoses. The Guideline Development Group's view was that there were a very large number of illnesses that could be considered. As the guideline cannot be a medical textbook, there was a concern about mentioning only a handful. We have clarified this section, which is included to ensure that patients in need of urgent medical treatment receive it.

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						Addison's Disease; Hypothyroidism; Multiple Sclerosis; Lyme Disease/ Borreliosis; Fybromyalgia; Sarcoidosis; Lupus; Hughes Syndrome and Parvovirus infection.	
SH	West Midlands Consortium	30	NICE	15	1.2.1.9	It is vital that, when waiting for a definite diagnosis, patients are advised to rest, particularly avoiding strenuous physical exertion, which will exacerbate the illness and make recovery less likely. Children should *not* be urged or compelled to resume full-time education.	The guideline is not about compelling anyone.
SH	West Midlands Consortium	31	NICE	15	1.2.1.9	Whatever the precipitating factor, patients require much more than advice about 'self management'	The recommendation refers to symptom management.

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						which has only limited value.	
SH	West Midlands Consortium	32	NICE	16	1.2.2.3	It seems very odd to suggest that EBV should not be routinely tested for when this is widely acknowledged to be one of the precipitating causes of CFS/ME? A patient may have been an asymptomatic carrier for many years. There is also documented evidence that EBV can initiate neurological damage. Viral tests should also be carried out for Coxsackie B, & RNase L for which there is good evidence that these might also help to validate the diagnosis, confirm an organic origin, and may help discriminate CFS/ME	Testing is only not recommended when there is no indication that the individual previously had an infection, as without an indicative history this is extremely unlikely, according to statistics. Therefore patients who have had symptoms of an infection will be appropriately tested.

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						from other illnesses.	
SH	West Midlands Consortium	33	NICE	18	3 1.3.1.3	'WHEN the adults goal …' See comment for page 6. This is offensive & should be removed.	This wording did not clearly reflect what was intended. It has been changed to make it clearer.
SH	West Midlands Consortium	34	NICE	18	1.3.14 1.3.16	This is contradictory; if CBT and GET are not appropriate, then their individual components will not be appropriate. Patients require much more than activity management, sleep management and relaxation, which will do nothing to alleviate most of the symptoms. There are many examples like this in the document. There is no acknowledgement of the possibility that the	This section has been revised.

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						suggested course will not be successful or of what to do in such an eventuality. Advice *must* be provided for dealing with lack of improvement and for relapses, especially when they are caused by the suggested 'treatment'. We have been given many incidences of sufferers left to sort themselves out after such situations.	
SH	West Midlands Consortium	35	NICE	19	13 1.3.1.10	We profoundly disagree. It is not simply anecdotal evidence that supports this approach – but EVERY patient centred survey that has ever been carried out. It is amazing to note how completely the experiences of patients have been ignored. This clause	While there is patient support there are very differing views. In addition there is no research evidence. The recommendation does not disparage but reflects this position. It again illustrates differing understanding of terminology. The terms 'pacing', 'envelope theory' and 'activity management' may be used interchangeably or have separate meanings.

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						completely ignores the phases of the illness and the serious risk of relapse. One would expect that 'considerable patient support' (sic) would be taken as a sign of benefit and something to inform treatment, rather than something to be disparaged. If patients who report that an approach is beneficial are not to be believed, how is the effectiveness of any therapy to be gauged? The point of treating someone is to bring about an improvement, not to impose a treatment regime which causes distress. If	The guideline has been revised to include more on pacing and rest.

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						using less than the meagre, available energy is more beneficial to a patient than engaging in activity to the point of exhaustion, then surely that should be encouraged. One of the principle symptoms is the relapsing-remitting nature of the illness. Obviously, coping strategies are different when in remission than when experiencing a relapse. <u>First, do no harm.</u>	
SH	West Midlands Consortium	36	NICE	20	6 1.3.1.12	A change in behaviour will no more cure ME than MS, motor neurone disease or typhoid. It is insulting to suggest otherwise.	NICE guidelines are predicated on research evidence where available; there is good research evidence for the improvement following CBT programmes in people with CFS/ME.
SH	West Midlands Consortium	37	NICE	20	24 and 25 1.3.1.13	This section appears to blame the patient for being	NICE guidelines are predicated on research evidence where available; there

Status	SH organisation	Order no.	Document	Page no.	Line no.	Comments	Responses
						ill; Neither of the recommended therapies.." will alleviate low cardiac output, food/chemical/medicine intolerance, IBS, post-exertional malaise, etc 'Fear of activity & perfectionists beliefs': We're not aware of any evidence or data to support this. This appears to be wild, speculative hypothesis that has no place in an "evidence based" guideline and it should be removed.	is good research evidence for the improvement following CBT programmes in people with CFS/ME. These are accepted components of any CBT programme regardless of condition but the examples of how this may be applied have been revised. The Guideline Development Group have recommended that the preference and needs of the individual should be taken into account.
SH	West Midlands Consortium	38	NICE	21	4, 5 1.3.1.13	To talk about 'symptom over-vigilance' is offensive and should be removed. Does this appear in the M.S. NICE guidelines?	The wording has been changed as a result of the consultation.

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SH	West Midlands Consortium	39	NICE	21	4	‘decreasing somatic attributions’ and address symptom over vigilance …’ This is offensive and based upon misguided opinion rather than evidence.	The wording has been changed as a result of the consultation.
SH	West Midlands Consortium	40	NICE	21	1.3.1.14	It is wrong to try and prescribe for mild & “moderately” affected in the same way. Combining two degrees of severity for the purposes of suggesting treatments is an unforgivable error. There may be a world of difference. Also, as mentioned previously, how many people that were once mild/moderate have become severely affected due to inappropriate prescribing of GET?	The emphasis is on an individual programme based on the person’s situation and symptoms. There is a great deal of detail in other recommendations on the development of the programme. The evidence supports the use of GET. We have stressed throughout the need for appropriate monitoring and review.

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						Empirical research has demonstrated that people with ME cannot tolerate exercise; their muscles fatigue more quickly and take longer to recover than healthy controls.	
SH	West Midlands Consortium	41	NICE	22	5 1.3.1.15	"How (&who) would explain the symptoms and "benefits of exercise in a physiological context "? The illness is not sufficiently well understood! Sufferers do not need any explanation of the symptoms of exercise in a 'physiological context' or in any other way–they are experts in them; they know exactly what the symptoms are.	As with all treatments a full explanation should be offered by the healthcare professional.
SH	West Midlands Consortium	42	NICE	22	12, 13	Whilst we realise that this	The recommendations have been revised

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					1.3.1.16	*may* be 'ultimate goal': Many will find advocating a "daily brisk walk" … and CYCLING for "moderately affected", an utterly absurd thing to suggest, and potentially very dangerous. This is the sort of poor quality advice that has made people severely affected, who were not so previously.	and expanded to reflect this and other concerns.
SH	West Midlands Consortium	43	NICE	23	1.3.1.18	If the suggested activity level has to be 'reviewed and reduced if necessary', what should happen next? There appears to be an assumption that there will be an inevitable improvement in the patient. What will happen if the	We have stressed throughout that programmes are tailored to the individual and the need for appropriate monitoring and review. This recommendation has been revised to reflect concerns.

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A number of comments and responses relating to particular individuals have been removed from the table, or summarised, on legal advice. However we would like to reassure all stakeholders that all comments received during the consultation have been considered as part of the guidance production process."
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						symptoms increase to a severe degree and not 'mildly'? Who will 'pick up the pieces'? And what should be done if the symptoms persist for more than 'a few days' or if they cause a permanent relapse? Those with correctly diagnosed M.E. DO NOT experience normal stiffness/fatigue; it is one of the defining characteristics of the illness as described by Dr Melvin Ramsay. Many previously fit & active people with this illness know exactly what it is like to experience normal muscle fatigue response to exercise and IT IS NOT THE SAME.	

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SH	West Midlands Consortium	44	NICE	23	1.3.1.19 1.3.1.19	This section is based on the premise that improvement will not only inevitably take place, but that the rate of improvement will increase. What should happen if 'agreed GET goals' *cannot* be met? Again the document is silent about the possibility. Suggesting that exercise can be increased 'if the patient would like to' implies that some patients would not like to improve their state of health– preposterous. 'IF the patient would like to progress!' What other goal	It is made clear that progress may be very slow and there may be setbacks. GET is also one of a number of strategies, described in the guideline. This refers to the patient progressing *further.* Different individuals will have different activity goals, all may not want to progress their activity beyond their GET goals.

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						would there be! See comment for page 6. (Line 1) This should be removed. It is offensive.	
SH	West Midlands Consortium	45	NICE	24	1.3.1.22	What happens to those who live alone and who are obliged to exceed their 'baseline' of manageable activity simply in the process of eating, washing, dressing, etc? It is not easy to see how one could choose to relinquish any such 'activities' for the 'establishment of 'baseline'	Throughout the guideline we stress that programmes should be tailored to the individual's circumstances.
SH	West Midlands Consortium	46	NICE	26	17	Sleep Management– "Excessive sleep doesn't Generally improve physical or mental functioning in patients with CFS/ME".	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.

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						We totally disagree with this statement–particularly in the early stages when the body needs to convalesce. In "CFS/ME A Guide to Research, Diagnosis and Management" by Dr Charles Shepherd, it states–"During the early post-infectious state of CFS/ME, many people have excessive sleep requirements (hypersomnia) and this should not be interfered with."	
SH	West Midlands Consortium	47	NICE	26	1.3.2.	Patients are entitled to, and, especially in the early stages, require, far more than a 'self-management	Agreed – this is only one section of the guideline

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						strategy’.	
SH	West Midlands Consortium	48	NICE	26	1.3.2.1	As mentioned above, during the acute phase of the illness “excessive sleep” may be exactly what is required?!” For most people with ME ‘establishing a normal sleep-wake pattern’ would be impossible and would probably lead to deterioration. ‘Excessive sleep’ may not always produce benefits but it almost always prevents deterioration	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.
SH	West Midlands Consortium	49	NICE	27	17 1.3.2.2	‘Excessive alcohol’ -This gives real cause for concern that we might not actually be talking about the same illness here?! Most people with CFS/ME	This section has been simplified this section and made specific to CFS/ME rather than general sleep management advice.

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						cannot tolerate alcohol AT ALL. Ref paper by Woolley, Allen & Wessely (2003). It is considered a diagnostic symptom by doctors with a good knowledge of M.E.	
SH	West Midlands Consortium	50	NICE	28	1.3.3.2	Relapses are a part of the cyclical nature of the illness; they are not always precipitated by infection, 'other illness' or activity.	This section has been revised to reflect concerns.
SH	West Midlands Consortium	51	NICE	29–30	1.3.3.3	This section is simplistic and prescriptive–much more flexibility and sensitivity is needed. Clinicians should be aware that some activities may have to be reduced or even eliminated permanently to avoid causing harm.	This section has been substantially revised based on feedback in the consultation.

Status	**SH organisation**	**Order no.**	**Document**	**Page no.**	**Line no.**	**Comments**	**Responses**
						Clinicians must be advised to listen to the patient; when the patient says he has reached the limit of possible activity, that must be accepted, otherwise another relapse will certainly follow.	
SH	West Midlands Consortium	52	NICE	30	1.3.3.4	Such professionals are rare and one wonders who decides that they are 'suitably trained'. If they subscribe to the psychosocial model of ME, they will cause more harm than good and should not be allowed to treat PWME.	Training competencies are beyond the scope of the guideline.
SH	West Midlands Consortium	53	NICE	30	1.3.3.5 Line 27	'A GET programme should be delivered by an appropriately trained professional with experience of GET with CFS/ME'– As above there	Training competencies are beyond the scope of the guideline. This comment will be referred to the NICE implementation team.

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						must be very few potential GET instructors who have experienced ME.. As yet, nobody has 'trained' any 'professionals' in the application of GET to ME. What sort of professionals would they be? With no recognised or appropriate 'training programme' one wonders how one will be devised and who will be responsible. Unless the experiences of patients with ME are taken into account, the effect on patients will be disastrous.	
SH	West Midlands Consortium	54	NICE	31	1.3.4.4	Thyroid hormone may appear normal, thus	Thyroid: this may be part of an individual management strategy. The Guideline

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						causing the patient to appear earthyroid on lab data, when he/she is clinically hypothyroid due to tissue insensitivity.	Development Group has recommended that investigations and diagnosis are regularly reviewed in CFS/ME, and that investigations are repeated if there is no improvement, particularly in the severely affected.
SH	West Midlands Consortium	55	NICE	32	1.3.5	As mentioned previously, with so many people with CFS/ME experiencing food intolerances/allergies/digestive problems, sometimes acute, it is hard to believe that this is all these guidelines are going to say about diet/nutrition. Nutrition/dietary support– The effort required to buy food and prepare nutritious meals can mean that people with CFS/ME find it difficult to maintain a healthy diet–and yet, there	Managing food intolerances was beyond the scope of the guideline. The guideline now cross-refers to the NICE IBS guideline, which has more in-depth guidance on this matter. General dietary advice and advice for nausea is now given.

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						is no mention of how people can be supported. Many have found an exclusion diet to be an important part of their treatment protocol. There appears to be no mention of the importance of good fluid intake? Also no mention of appropriate symptom control for nausea, treating IBS, or helping to stabilise blood sugar levels.	
SH	West Midlands Consortium	56	NICE	33		We welcome the section on Ongoing Management and Review. At present the new Local Multi-Disciplinary Teams are seeing newly diagnosed patients, and after following the local	Noted with thanks.

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						care pathway patients will be referred back to their GPs. –we believe all people with CFS/ME should receive regular check-ups with their GPs.	
SH	West Midlands Consortium	57	NICE	33	1.3.6	The guidelines are unacceptably dismissive of complementary therapies. There appears to be plenty of evidence that they may help with treating symptoms of CFS/ME. (Because of the individual nature of treatment, it may never be possible to carry out RCTs to test this, in a way that would be acceptable to NICE, even if sufficient funding were forthcoming.)	This is guidance for healthcare practitioners in the NHS. The Guideline Development Group did not think that the evidence was sufficient to recommend alternative or complementary approaches routinely on the NHS. The Guideline Development Group found insufficient evidence to recommend nutritional supplements routinely. It is acknowledged, however, that some individuals may find these approaches helpful.

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						A number of people with CFS/ME are reporting improvements on EPA/Omega-3 supplements. There is also some evidence to suggest that B12 & magnesium may also have a role to play in some patients.	
SH	West Midlands Consortium	58	NICE	34	1.4 .1.1	It is not clear exactly how the severely affected will access "the same diagnostic and therapeutic options"- even if they wanted to! Frequently they cannot 'access' anything and in any case do not require 'the same diagnostic and therapeutic options', they need special interventions	The intention of Recommendation 1.4.1.1 is to make it clear that those who are severely affected should have treatment regardless of whether they can get to hospital or clinic. The wording has been revised to make this clear.

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						suited to the severity of their condition, if necessary providing appropriate therapies in their homes. A 'one size fits all' approach is unsound and inadvisable.	
SH	West Midlands Consortium	59	NICE	34	1.4.1.3	We do not believe, or accept, that "GET may be an appropriate addition …" for the severely affected.	The Guideline Development Group recognises that there is a great deal of confusion about terminology. The term 'GET' has been applied to a variety of programmes. As indicated in the patient evidence, some of these have unfortunately had deleterious not to say disastrous effects to patients. There is, however, evidence that very gradual programmes of increases in activity, where possible, can have beneficial results. This programme has been described in detail in the guideline with the aim of promoting understanding and avoiding patients being subjected to an ill-advised programme of exercise/activity

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							beyond their capacity. The guideline does not recommend that people with CFS/ME undertake vigorous exercise. It recommends starting with a sustainable baseline of low-intensity activity, which may be sitting-up in bed or gentle stretches, informed by the principles of GET.
SH	West Midlands Consortium	60	NICE	35	1.4.1.8	Clinicians should be urged to be cautious about hospital admissions. A stay in hospital can be a traumatic and damaging experience for both the severely and moderately affected often caused by the noise and the bright lights.	This is the intention of this recommendation.
SH	West Midlands Consortium	61	NICE	37	4.1	<u>Research Recommendations</u> If there is no evidence to	The Guideline Development Group identified these areas as the most important in informing updates of the guideline. Aetiology is beyond the scope

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						suggest that GET/CBT is effective in severely affected adults & children then why are they being so strenuously advocated in the Guidelines! It is admitted that "There is no evidence for the use or effectiveness of these strategies" in children and the severely affected. Why were they recommended so potently? The glaring omission is the absence of any recommendation that research should conducted to find the causes of ME as well as treatments and cures for it.	of the guideline.

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						With an illness affecting up to 250,000 people and costing the nation £6 billion p.a., surely biomedical research should be considered an urgent priority?	
SH	West Midlands Consortium	62	NICE	38	4.4	'It is not known how much improvement is important for patients with CFS/ME.' This in an incredible (and perhaps very telling) statement to make–it suggests that we do not know the best way of measuring outcomes in research studies, yet CBT & GET are put forward with a degree of certainty that we do not have. The answer is so obvious that the question is	This is intended to convey that different people will have different goals based on their current individual circumstances. Some may set as an objective maintaining their current level and avoiding deterioration for the time being. This question could be asked of most serious chronic illnesses. In studies on hip replacement, there are disputes about whether the better outcome is being able to walk again without pain or that the x-ray shows a good placement of the device. In looking at the CFS/ME research, there were a wide variety of outcomes with little indication of their relative benefits.

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						redundant; diminution of symptoms and a return to good health and a normal life. This question could not conceivably be asked in relation to any other serious, chronic illness such as cancer, diabetes, MS, etc.	
SH	West Midlands Consortium	63	NICE	40	6	The psychosocial bias which is evident throughout, is laid bare. The only two, relatively rare, symptoms deemed worthy of further guidance are anxiety and depression.	The guideline refers to other relevant NICE guidelines.