

Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) – stakeholder consultation table
16 November – 15 December 2004

National Institute for Clinical Excellence

Type	Stakeholder	No	ection number	Comments	Developer's response
SH	Action Against Allergy	1		Overall, we feel that the proposed scope of the guideline will cover the subject effectively. However, we have some concern about how the guidelines will be achieved. CFS/ME, although now recognised as a genuine illness (which for many years it was not), still does not appear to attract the expertise of the professionals. There are only a handful (literally) of consultants who identify CFS as their primary interest or one of them. It will therefore be interesting to learn where (from whom) the guidelines will come.	Noted with thanks.
SH	Action Against Allergy	2		Is there some reference somewhere to existing practices and centres (if any) where CFS/ME is treated in any kind of specialised manner? If so, will they be represented among your guideline developers?	The Guideline Development Group (GDG) will be selected from nominees from professional and patient organisations based on the remit for GDG members.
SH	Action Against Allergy	3		Your draft refers to the research strategy being set up in 2002 by the Medical Research Council. How far has this progressed and with what result? This could surely have a bearing on the considerations for drawing up the guidelines.	Please refer to the Medical Research Council (MRC) website for more information. All good-quality published research will be considered.
SH	Action Against Allergy	4		While the objective is to provide guidelines for use at the Primary Care level, how is it envisaged these will be communicated? The scope draft does not cover training, but perhaps it should. Possibly there should be recommendation for including the subject in medical schools and providing relevant short courses for both doctors and other health professionals.	Please refer to the NICE website for more information on dissemination. Recommendations will be decided by the GDG and will be subject to consultation. The implementation team at NICE will consider educational aspects.
SH	Action Against Allergy	5		As this illness appears to require specialised and longterm treatment, is it proposed to consider through which health care facilities the treatment should take place, taking	The guideline will not address service provision.

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				account of what may currently be available, or perhaps recommend that special health centres are required?	
SH	Action for ME	1	Overall	Overall we welcome the programme of work and the prospect of producing guidelines that will improve the diagnosis and treatment of people with CFS/ME, and we welcome the draft Scope.	Thank you for your comments.
SH	Action for ME	2	4.1.1 / 4.1.2	<p>The Scope refers to people who are given a diagnosis of CFS/ME.</p> <p>Both diagnostic labels have proved controversial, and to our knowledge both because of this and because of the triggering event, doctors have given people with recognisable CFS/ME many other diagnostic labels¹. In the majority of cases these labels have not been amended over time.</p> <p>Thus we are aware from our membership that a high proportion has been given other diagnostic labels, the most significant alternative being PVFS.</p> <p>It would be helpful to clarify that people with CFS/ME, but who may have been given other diagnostic labels do not fall outside the Scope.</p> <p>We noted the discussion at the Stakeholders meeting regarding whether the guideline should cover a wide or narrow definition of people with CFS/ME, and the overwhelming show of hands for the wider definition.</p> <p>We would support this, but whilst recognising the limitations of current evidence, we would emphasise the importance of being aware of the heterogeneity of the</p>	We will refer the terms to the Information Scientist and your comments to the group.

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				<p>condition. We would emphasise both the importance from research evidence and clinical experience to identify sub-groups, and the risks of applying “one size fits all” treatment approaches to a heterogeneous condition.</p> <p>We would urge that in drawing up any statements within the Scope or elsewhere that NICE acknowledges these issues.</p> <p>1. Gallacher et al. Incidence of fatigue symptoms and diagnoses presenting in UK primary care from 1990 to 2001. <i>J R Soc Med</i> 2004;97:571-575</p>	
SH	Action for ME	3	4.2. b)	We support the comments made at the Stakeholder meeting that specialist care provided within tertiary centres should not be excluded from consideration	This has been clarified
SH	Action for ME	4	4.2. c)	<p>We also support the comments made at the Stakeholder meeting that there are many factors relevant to the management and recovery from CFS/ME including financial, employment and education issues, and with which health practitioners commonly interact.</p> <p>We would seek clarification that the important role played by health practitioners should not be ignored in the guidelines</p>	The remit of the guideline is NHS practitioners, however, it will cover the advice given by these practitioners with regard to many of the issues you mention.
SH	Action for ME	5	4.2. c)	Whilst the guideline cannot cover the practice of those working in the voluntary sector, we would seek confirmation that the contribution of the voluntary sector to the management of people with CFS/ME will be recognised where considered appropriate e.g. through the provision of information.	This has been the practice in other guidelines but it will be the decision of the GDG what recommendations are made.

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SH	Action for ME	6	4.3. c)	<p>The strategy of Pacing is one for which there is strong evidence, but that has been under-researched within the field of CFS/ME until now. We would ask whether "rehabilitation strategies" covers Pacing, and if not, where else it is included.</p> <p>If it is omitted we would make wish to make strong representations. We therefore seek urgent clarification on this point.</p>	Pacing will be considered.
SH	Action for ME	7	4.3. c)	<p>Counselling is an approach referred to in the Working Group's Report to the CMO, and has been more available (and is less costly) to people with CFS/ME than graded activity and CBT.</p> <p>We are aware that there is little research evidence, but one published study found no difference in outcome when comparing counselling with CBT, and clinical and patient experience is we believe relatively rich. Our own organisation has included counselling as a part of our services for people with CFS/ME for many years.</p> <p>We are therefore surprised by the omission of Counselling and suggest this be included within the Scope</p>	Psychological interventions will be considered.
SH	Action for ME	8	4.3. c)	<p>In support of the comment made at the Stakeholder meeting, we would seek confirmation that the role the Expert Patient Programmes would fall within the Scope</p>	We will be searching for evidence regarding information and support.
SH	Action for ME	9	4.3. c)	<p>We are concerned by the possible interpretations of the qualifying phrase that recommendations will be based on a range of interventions "where good evidence is available".</p> <p>Both the Systematic Review commissioned by the Chief</p>	Please refer to the NICE technical manual at http://www.nice.org.uk/page.aspx?o=201982

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				<p>Medical Officer's Working Group, and the Medical Research Council's Strategy Group identified major deficits in published peer reviewed research.</p> <p>We are concerned that the Scope should acknowledge that the evidence on which the Guidelines will be based will include other sources.</p>	
SH	Action for ME	10	e)	<p>We understand why service provision is excluded. However in the case for example of the severely affected, it is somewhat artificial to address management of the condition in isolation from the provision of services, and we would seek clarification regarding where "management stops" and "service provision begins".</p> <p>By way of illustration we are aware from our surveys of members that 25% see their doctor less than once a year, and the severely affected have been particularly isolated. We would consider it vital that regular monitoring and assessment of their patients and that outreach services be provided.</p> <p>It would be helpful to confirm that this would fall within the Scope.</p>	The remit of the guideline does not cover the configuration of services or how the services are provided. However, recommendations regarding the frequency of monitoring and assessment have been included in previous clinical guidelines and could be considered in this guideline.
SH	Action for ME	11	General	<p>A member with experience in drawing up guidelines in other fields has proposed that the Guidelines when produced should include recommendations on data collection, providing the capacity for audit projects.</p> <p>It does seem sensible that the NICE Guidelines should be integrated with other programmes of work such as those led by the Clinical Network Co-ordinating Centres and the Medical Research Council.</p>	NICE guidelines always contain audit criteria. There is now an implementation directorate at NICE and your advice, I am sure, will be extremely helpful to them.

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				Confirmation that such co-ordination will fall within the Scope will be welcome.	
SH	Association of NHS Occupational Physicians	1	General and 2a	Although the guideline has been commissioned specifically for use in the NHS, it is likely to be used more widely – for example by employers and Disability Assessors.	The guidelines will be available on the NICE website for anyone who wishes to read and use them. It is also hoped that stakeholders will promote the guidance to those who may find it of interest.
SH	Association of NHS Occupational Physicians	2	4.2 c	It is not entirely clear from the scope document whether the guidelines are intended to cover aspects of fitness for work. I have understood from the discussion at the stakeholders meeting on 22 nd November that it is not your intention to cover aspects of delivery or provision of occupational health services for patients with CFS/ME. Indeed I agree that it would be difficult to do so, because occupational health services do not generally come under the umbrella of the NHS. However, return to work is a crucially important part of rehabilitation both for the patients themselves and for society (in view of the associated economic burden of chronic work loss). I feel very strongly that the scope must cover the occupational advice that should be given to CFS/ME patients, even if it does not include the mechanism by which the advice is provided. In reality, General Practitioners provide this advice in most cases, since Occupational Health services are only available to around 30% of the working population. As the scope of the document clearly does include care provided by health care workers in primary care (4.2 a) and b), it seems to be a contradiction that occupational health advice is not explicitly covered. I note the terms of the Referral from the Department of Health and the Welsh Assembly Government (Appendix),	This is now included in the scope. Please see section 4.2.

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				and in particular the remit. "guidance on theuse of rehabilitation strategies geared towards optimising function and achieving greater independence for adults" . I feel strongly that return to work is perhaps the most important marker of independent function in adults of working age and really should be included.	
SH	Association of NHS Occupational Physicians	3	4.3 c	It is important that the exploration of the evidence base for interventions should include the provision of graded return to work programmes. This fits under a number of the headings in this section including graded activity, rehabilitation strategies and psychological therapies. All of these aspects would be covered by a well-planned workplace rehabilitation programme. There is a real danger that, if work return to work is NOT included, graded activity will be prescribed in a manner that favours increasing physical and other activities at home at the expense of any return to work. I see many patients who feel that they cannot consider ANY return to work until they have built up activity outside the workplace to normal levels. My observation is that these patients do badly with respect to economic recovery. Conversely the patients who keep the grading of home and work activity in proportion (increasing both in parallel, and maintaining an appropriate balance between the two) achieve a better outcome overall and are better able to maintain their economic status. For this reason I feel it is extremely important to include return to work outcome in the literature review as an important facet of recovery from CFS/ME.	Return to work as an outcome measure in reviewing the evidence and return to work programmes will be included in the review.
SH	Association of NHS Occupational Physicians	4	4.3 d	In addition to the information needs of healthcare professionals, patients and carers, I feel the scope should include the information needs of employers. Informing	The appropriate information that a health professional should provide will be considered by the group.

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				employers about the need for adjustments at work will help to remove an important barrier to recovery in these patients.	
SH	Association of the British Pharmaceutical Industry (ABPI)	1	General	The ABPI welcomes the fact that NICE will be developing a clinical guideline on Chronic Fatigue Syndrome/Myalgic Encephalomyelitis. This is a poorly understood condition and therefore guidance is timely.	Noted with thanks.
SH	Association of Young People with ME	1	General	We would just like to note that we are disappointed that you have decided to use Encephalomyelitis as Encephalopathy is now the preferred terminology and is used in the new paediatric guidelines. Myelitis refers to inflammation of the spine of which there is no evidence in CFS/ME. By using the term opathy it gets around the problem whilst still recognising the brain dysfunction, which is a hallmark for the illness.	The title of the guideline has been changed to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (or encephalopathy).
SH	Association of Young People with ME	2	General	The specific needs of the severely affected require special consideration and attention in this document.	This is noted in the scope in section 4.1.1.
SH	Blackwater Valley & Hart Primary Care Trust	1	4.2b	I support this element, but would want to be clear that the GDG will need to ensure that there is a significant membership from individuals with day to day experience in primary and local secondary care services – rather than input from tertiary care.	The GDG will be comprised of health professionals from primary, secondary and tertiary care.
SH	Blackwater Valley & Hart Primary Care Trust	2	4.2c	This needs to be re-phrased to indicate the areas in which clinicians will be able to give advise to these other agencies and the sort of advice that they should be giving. i.e. <i>recommendations</i> about home tuition.	This is now included in section 4.3.e.
SH	Blackwater Valley & Hart Primary Care Trust	3	4.3b	This is very important, but we need to ensure that this is clear but not totally exclusive.	Noted.
SH	Blackwater Valley & Hart Primary Care	4	General	Not mentioned in the Scoping document, but noted at the stakeholder meeting is the issue of pharmacological	This is standard NICE procedure.

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	Trust			interventions. This will need to include off license use of licensed medication, where there is adequate evidence of benefit and safety.	
SH	Blackwater Valley & Hart Primary Care Trust	5	General	The development will benefit from having access to the RCPCH guideline on CFS/ME, but should note the conclusion of that document about the dearth of really good evidence based information. The GDG may need to identify a compromise between the appropriate desire for a strong evidence base and having a document which says very little, due to the lack of such evidence.	The GDG will have access to the RCPCH guideline. The GDG will use formal consensus methodology to agree recommendations in areas where there is a lack of evidence.
SH	Blackwater Valley & Hart Primary Care Trust	6	General	There may be a need to decide at an early stage how the separate needs of children and young people should be handled. There is a risk of confusion if there is no division within the guidelines. I would wish to see strong input from Community Paediatricians and School Nursing services in this area. In addition I wonder whether the GDG should include someone from Education – it may well be that such an individual will be able to bring evidence from Education literature that might not normally be accessed by health professionals.	It is agreed that the guideline will need to address children and young people separately where appropriate. The Centre has prepared the guideline on Epilepsy with a similar remit and you may want to look at that to see how we approached it. Please see the NICE website. There will be community paediatricians in the group. The guideline will not advise on practice outside the NHS although, if needed, someone from education could be consulted. The difficulty is that many professionals are involved in the management of this condition and the group needs to be kept to a size that facilitates good discussion.
SH	BRAME Blue Ribbon Awareness for ME	1	4.2 c	Although you are not covering the practice of these groups, will guidance/information be given regarding the impact that these services' decisions and their ME have on the lives/life quality of those affected by ME, in order to aid them in making the appropriate assessment.	The remit of the guideline is advice to the NHS. Unfortunately, we cannot address the practice of other agencies. Advice the health care professional should give is now included under section 4.3.e.
SH	BRAME Blue Ribbon Awareness	2	4.3 c Graded activity	Pacing or pacing/graded activity, would be a more acceptable terminology to the ME community, as graded	This has been changed.

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	for ME			activity is too linked to Graded Exercise in their minds.	
SH	BRAME Blue Ribbon Awareness for ME	3	4.3 c Rehabilitation strategies	Does this refer to the OT style of appropriate management/pacing?	Searches for evidence of all rehabilitation strategies will be considered.
SH	BRAME Blue Ribbon Awareness for ME	4	4.3 c Psychological therapies	Would suggest in its place 'coping strategies' as therapies suggests a psychological illness rather than coping strategies for an organic illness, just as is done with other chronic illnesses.	Coping has been added.
SH	BRAME Blue Ribbon Awareness for ME	5	4.3 d Bullet 1	Feel that symptom management should be number one on the intervention list, as this is usually the one thing that doctor's can provide, alongside understanding and support.	This has been changed.
SH	BRAME Blue Ribbon Awareness for ME	6	4.3 d Bullet 2	Severity should be included and put before age/ethnic/cultural groups – the diversity of severity and the reactions/effectiveness for the different levels is of primary importance when creating a strategy, also the severity of the illness often determines the success or detrimental impact the treatment has on a patient.	Under section 4.1.1 a & b it states that the guideline will address mild, moderate and severe illness. This means that all aspects of the guideline will be considered for the differences in severity.
SH	BRAME Blue Ribbon Awareness for ME	7	4.3 d Bullet 4	Service provision – how will NICE recommend changes/shortfalls of suitable referral/care systems, specialist and treatment clinics if not covering service provision?	It is the remit of the guideline to provide clinical guidance. The Department of Health (DH) and local service providers will then develop strategies for its implementation within the local health community.
SH	BRAME Blue Ribbon Awareness for ME	8	4.3 d Bullet 4	Models of Care – surely recommendations for the management of patients is suggestions of models of care.	In this context this means the model of how care is configured, which is beyond the scope of the guideline.
SH	BRAME Blue Ribbon Awareness for ME	9	General	Patient evidence and experience must be at the forefront when making decisions, with patient experience varying so differently from 'research findings'. This is especially important for the severely affected and children as most research does not include these groups – therefore the only relevant evidence is that of the patients eg. for the	All stakeholders will be invited to submit evidence which will be considered.

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				CMO report the main charities presented the results of a survey of approximately 4,000 patients of which 66% were harmed or not helped by GET and 93% were harmed or not helped by CBT – therefore you can see that patient evidence is highly relevant to these guidelines.	
SH	BRAME Blue Ribbon Awareness for ME	10	General	Some mention should be made about education of health professionals about how to relate to/treat patients with ME. So many are still sceptical and dismissive about this illness, that before treatment recommendations can be made, education must be the first port of call, as without a GP understanding the illness ME, you cannot proceed any further, with either management or referral.	The information needs of health professionals is included in the scope under section 4.3.e. The production of the guideline will in itself serve to educate health professionals and raise awareness.
SH	BRAME Blue Ribbon Awareness for ME	11	General	We sincerely hope that the remit of the group will enable them to study all areas of research and not just the psychiatric therapies, especially eg. with so much research now being revealed about the altered gene expression in ME patients – which could lead to a test for ME and hopefully in time a successful treatment.	The developers will search for all evidence related to diagnosis and management as defined in the scope. The causes of the condition are not, however, within the scope and will not be reviewed. While this is an important topic, the scope of the guideline is already very broad.
SH	British Association for Counselling and Psychotherapy (BACP)	1	General	BACP welcomes the development of this Guideline for wider understanding and service improvement, and also as further demonstration of the relatively recent acknowledgement of its status as a chronic and debilitating illness.	Thank you.
SH	British Association for Counselling and Psychotherapy (BACP)	2	4.3 (d): p4	Regarding the second bullet point outlining recommendations to be included: 'criteria for referral to secondary and tertiary care for children, young people and adults.' This contradicts 4.2 (b) which states: 'The guideline will address care in primary and secondary centres, but will not address the delivery of tertiary procedures.' We would suggest that recommendations for referral to primary care services are essential. For example, primary	We agree. We have changed this to say specialist care.

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				care trusts now commission a wide range of services that are not necessarily related to secondary or tertiary care, and may be appropriate for milder cases of CFS/ME. For example, exercise therapy, self-help groups, counselling and psychotherapy and some complementary therapies.	
SH	British Dietetic Association	-	No comment	Thank you for giving the British Dietetic Association the opportunity to comment. We do not have any comments on the scope.	Thank you.
SH	British Nuclear Medicine Society	1	General	No specific role for Nuclear Medicine in this context except in cases where it is necessary to exclude other disease.	Noted.
SH	British Psychological Society	1	4.1.1 a	It would be helpful to have some definitions of "profound" and "fatigue"!! Working definitions of >50% disabled >50% of the time are the best we've got but it would be useful to have more robust definitions!	Noted.
SH	British Psychological Society	2	4.1.1 b	Management for individuals at-risk of developing CFS (i.e. presenting with post-viral fatigue, glandular fever) in a primary care setting should be within the remit of prevention interventions.	While this is an important topic, the scope of the guideline is already very broad and unfortunately cannot include prevention.
SH	British Psychological Society	3	4.1.1	Guidelines should cover management of patients who have had persistent fatigue for a period of 3 months in the primary care setting.	Diagnostic criteria will be included in the guideline.
SH	British Psychological Society	4	4.1.1	Separate guidelines are required for very young children (5-8) and pre-pubescent (11-13) children.	It is extremely rare in young children and there is likely to be very little evidence. The considered opinion was that the management of younger children is likely to be similar to that of older children.
SH	British Psychological Society	5	4.2 b	It is imperative that guidelines cover provision of tertiary care services – model and approach is similar through primary-secondary-tertiary service delivery. Consistency of management is key in this clinical work.	This has been defined more clearly.
SH	British	6	4.2 c	Reference to the role of other organisation and helpful	The remit of the guideline is advice to the NHS.

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	Psychological Society			advice to be used in consultancy with other organisations such as education; occupational health, employers etc would be extremely helpful.	Unfortunately, we cannot address the practice of other agencies. Advice the health care professional should give is now included under section 4.3.
SH	British Psychological Society	7	4.2 c	Completed guidelines should be distributed throughout the healthcare setting but also to stakeholders in other fields such as education and employment. (ie. educational psychologists; occupational health organisations).	Noted. Guidelines are available on line and it is hoped that stakeholders will circulate them as appropriate.
SH	British Psychological Society	8	4.3a	Guidelines should cover assessment for psychological therapies, exclusion criteria for psychological approaches and issues regarding engagement and appropriateness for psychological treatment.	Referral criteria for specialist services will be included in the guideline.
SH	British Psychological Society	9	4.3 c	Psychological therapies guidelines should explicitly address symptoms attribution, non-pathological aetiology of symptoms as well as strategies for symptom management.	While aetiology is an important topic, the scope of the guideline is already very broad and unfortunately this cannot be included. Psychological therapies will be included, however.
SH	British Psychological Society	10	4.3 c	Successful psychological work involves using a broad range of treatment modalities in both formulation and intervention level. NICE guidelines should reflect the depth of these approaches and make reference to systemic, narrative, solution-focussed, motivational-interviewing practices in addition to CBT.	The literature will be searched for evidence in these areas.
SH	British Psychological Society	11	4.3 c	Guidelines should reflect therapeutic processes used to validate patient experiences and difficulties in their relationships to help that may result from issues of stigma and complex journeys to services experienced by CFS patients.	Noted.
SH	BUPA	1	General	Occupational health staff would find it particularly useful if long term prognosis could be included in the scope of this piece of work. Clinicians often consider prognosis over 4-5 years, but an evaluation of what is known about prognosis	If the evidence is available the guideline will comment on this.

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				to normal retirement age – which can be 20 or 30 years hence – would improve the evidence base for occupational health practice.	
SH	BUPA	2	General	Concerning people recovering from CFS/ME: might this guidance assess the evidence base for the assertion that it is preferable for such people to work Tues/Weds/Thurs (with breaks) rather than Mon/Weds/Fri, please? Again, a critical appraisal of this would be useful to occupational health staff.	Strategies for return to work will be covered if evidence is available (see section 4.3).
SH	CFS/ME Clinical Network Coordinating Centre	1		4.2b: The Scope excludes tertiary procedures - I am not clear what is meant by this. I think that, in view of the often bizarre therapies used in CFS that some cognisance is paid to them in the final guideline.	This has been clarified.
SH	CFS/ME Clinical Network Coordinating Centre	2		4.3c: Nutrition needs to be addressed in view of unscientific diets given to patient.	There is a dietician on the GDG and this will be addressed.
SH	CFS/ME Clinical Network Coordinating Centre	3		4.3b: The Guideline needs to review the use of laboratory tests, following on from the Colleges' report. In particular the Guideline needs to address tests of NO diagnostic value, particularly those used by alternative practitioners	The guideline will advise on the process of assessment leading to a diagnosis, including diagnostic tests, and this has been clarified.
SH	CFS/ME Clinical Network Coordinating Centre	4		4.3d The Guideline must define those therapies for which there is no scientific evidence.	This will be part of the guideline methodology. Please refer to the methods section of the NICE website.
SH	Chartered Society of Physiotherapy	1	1. Guideline title	Should this include the newer definition of ME as Myalgic Encephalomyelopathy, as it is not really an "itis"?	The title of the guideline has been changed to Chronic Fatigue Syndrome/Myalgic encephalomyelitis (or encephalopathy).
SH	Chartered Society of Physiotherapy	2	3a	"and often triggered by" might be more accurately phrased "which can be" . Use of the word "often" suggests "more often than not" , when in fact different people with CFS/ME will report a wide range of responses	Changed, with thanks.

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				to "minimal" activity, depending upon a range of factors including the severity of the illness. We suggest the wording is changed.	
SH	Chartered Society of Physiotherapy	3	4.1.1 a	The scope is huge and we suggest that it is divided into paediatric/adolescent and adult groups as although some of the issues will be similar some will be very different requiring knowledge from the specialist teams in each.	The aim is to have an integrated guideline. There will be individuals with expertise in the care of both adults and children in the group, and where appropriate topics will be addressed separately.
SH	Chartered Society of Physiotherapy	4	4.1.1 a and b	We suggest adding ' very severely affected ' to the list	Those very severely affected will be addressed within 'severely affected'. If the management is substantially different they will be addressed separately in the guideline.
SH	Chartered Society of Physiotherapy	5	4.1.2 a	What is the definition being used for CFS? There needs to be a very clear definition of CFS including the source of this definition. It also needs to be clear if ' post viral fatigues ' are included or excluded.	We will use the definitions given in the Chief Medical Officer's report as working definitions.
SH	Chartered Society of Physiotherapy	6	4.2 b	Shouldn't these guidelines apply to all people working with patients with CFS/ME, not just primary and secondary centres? Tertiary institutions should also be included in the document since that is where a lot of the delivery of care is and having guidelines to work by is integral to standardisation of excellent care. If tertiary institutions are to be excluded – the reasons for the exclusion need to be given.	This has been clarified.
SH	Chartered Society of Physiotherapy	7	4.3 c	' Graded Exercise Therapy ' should be included as an intervention. There are four published RCT's addressing Graded Exercise Therapy. There are no similar trials examining the role of Graded Activity. Whilst it is reasonable to assume that Graded Activity is helpful, the evidence base currently explores exercise. limitations of the evidence. Reference should be made to the limited evidence for more severely affected people, and the	Thank you for this. We will use these as search terms to ensure that we find the evidence. We have added 'Lifestyle management' as a separate category.

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				potential for setbacks caused by over-exercise. It is possible that Graded Exercise and Graded Activity are complementary and overlapping, but they are not identical. A suitable title for this section could be: " graded activity and graded exercise " Are "rehabilitation strategies" different from Graded Exercise and Activity? Should Lifestyle Management be included within these headings? Should ' Cognitive Behavioural Therapy ' (CBT) be included? Rather than 'psychological therapies'. There are aspects of chronic disease management and rehabilitation which are embedded in CBT. Most CBT includes a change in behaviour of the person, which could be interpreted as rehabilitation. ' Adaptive Pacing Therapy ' should be included as an intervention. ' Graded Return to Work ' should also be included as an intervention.	
SH	Chartered Society of Physiotherapy	8	4.3d	Take out the " on " before symptom management, [typographical error]. There should also be reference to any pharmacological treatments available.	Thank you. This has now been made explicit
SH	Chartered Society of Physiotherapy	9	Appendix	The wording ' management of adjustment and coping ' is not worded very positively. The sentence needs to be reworded to convey the possibility of improvement in the condition rather than just 'coping'.	The appendix is the commission given to NICE by the DH and is not subject to re-wording.
SH	College of Occupational Therapists	1	1. Guideline title	What definition of CFS will be used for this guideline?	We will use the definition in the Chief Medical Officer's report as our working definition.
SH	College of Occupational Therapists	2	3. Clinical need for guideline	It needs to be acknowledged that this condition has a controversial and misunderstood history. This is important to the service users and a good reason to justify the need for clinical guidelines due to the impact that this has had on the often poor relationship with healthcare professionals.	Noted.

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Type	Stakeholder	No	Section number	Comments	Developer's response
SH	College of Occupational Therapists	3	3 c	CFS/ME is not similar to other chronic illnesses because it is not necessarily permanent and has a very unusual pattern e.g. relapses and rebound effects mean it is not always in evidence. Also, no diagnostic test for the condition.	Noted.
SH	College of Occupational Therapists	4	3 c	Impact of the illness goes beyond the individual and their family to the health service, society etc.	Noted.
SH	College of Occupational Therapists	5	4.1 Population	Why do we need to say " <i>mildly, moderately or severely</i> " affected? Is it not relevant to all people affected by the illness? Or define the terms above if they are to be used.	Definitions will be considered by the group. These terms were included to make clear that consideration will be given to severe illness as well as mild and moderate.
SH	College of Occupational Therapists	6	4.1	We need to ensure that the guideline covers severe and very severe presentations as most trials are carried out with people in the mild to moderate range due to the need to attend regularly for outpatient treatment. Sub divisions need to be defined clearly and considered.	Noted.
SH	College of Occupational Therapists	7	4.2 Healthcare setting b	The guideline should cover primary, secondary and tertiary aspects of the NHS if CFS is to become considered a 'mainstream' condition. Most research to date has been carried out in secondary and tertiary so is likely to be a bulk of the evidence considered.	Evidence from tertiary care will be considered but the guideline will not advise on management in tertiary care.
SH	College of Occupational Therapists	8	4.2	State that the guideline is directly relevant to lots of other areas e.g. work, social services etc but, that this is beyond the remit of the NICE powers.	This is what we have tried to do.
SH	College of Occupational Therapists	9	4.2 c	What does " <i>relevant</i> " encompass? The Guideline needs to state clearly its importance to other work practices. The often negative impact on patients who try to access support and services from these areas greatly adds to the suffering of patients and families.	NICE's remit does not cover these groups. They are free to access guidance. As with other guidelines, it is hoped that stakeholders will promote the guidance to these groups.
SH	College of Occupational	10	4.3 c Clinical management	This section needs a lot of work to encompass and accurately name the interventions it will cover. For	The scope provides a general template and does not go into detail on every intervention.

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Type	Stakeholder	No	Section number	Comments	Developer's response
	Therapists			example, it should cover GET, and graded activity separately as very different approaches as opposed to pacing etc. Also, needs to use terms like health promotion and self-management techniques, which covers a lot of the lifestyle management and expert patient issues. This section at this stage either needs to just state rehabilitation/ psychological strategies or list all the approaches in current practice; cognitive behaviour therapy, graded exercise therapy, pacing, lifestyle management, occupational therapy, physiotherapy & complementary therapies.	The evidence will be searched and assessed for any intervention. The terms you listed will be used as search terms.
SH	College of Occupational Therapists	11	4.3 c	What does “good evidence” mean? This needs to be clarified. For instance, does this include patient validation as well as RCTs etc.	The NICE criteria on levels of evidence and quality assessment of studies will be used. Please refer to the NICE manual.
SH	College of Occupational Therapists	12	4.3 c	For many therapists, graded activity is a rehabilitation strategy. To avoid confusion these terms need to be very clear and acceptable to healthcare professionals and patients.	Noted.
SH	College of Occupational Therapists	13	4.3 d	Talks about different approaches for age, ethnic and cultural groups but doesn't mention gender (important given the different prevalence for women).	If evidence exists for differences in management between men and women, this will be considered.
SH	College of Occupational Therapists	14	4.3 d	Given the future directions of NHS services, could prevention/public health recommendations be also considered here?	While this is an important topic, the scope of the guideline is already very broad and unfortunately cannot include prevention.
SH	College of Occupational Therapists	15	4.3	There is no specific mention of nutrition. Per se. No doubt it will be encompassed in the wider sense throughout the whole guideline. But should it also be identified as a topic in this section?	Noted and changed.
SH	Community Practitioners' and Health Visitors'	1	General	<ul style="list-style-type: none"> We welcome the scope and its excellent attempt to deal with a very challenging area. It would seem that post viral syndrome, commonly 	<ul style="list-style-type: none"> While a very worthwhile topic, it would be very difficult in the time to address prevention as well as diagnosis and

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Type	Stakeholder	No	Section number	Comments	Developer's response
	Association			<p>resulting from glandular fever in children leads to chronic fatigue and if this persists ME is diagnosed. It would be helpful if the guideline could explore whether there are any effective preventative interventions which could stop this progression at the post viral stage and hence should be instigated in all cases of GF. The social, emotional and educational consequences of ME for children and young people can be so distressing that the NHS should be exploring early interventions. Currently such is ignorance of the disease in general practice that the diagnosis tends to be late when the consequences are already significant.</p> <ul style="list-style-type: none"> • This condition needs to always be looked at holistically. The physical symptoms have a significant impact on the individual's social and emotional wellbeing and in turn on their ability to achieve in education or the workplace • Could a link to SCIE be helpful to explore the social management of the condition for the most severely affected, eg the role of OTs? • Carers often support patients with this condition with very little understanding of it. Some exploration of support for carers in terms of specific information would be helpful. Also in relation to the secondary impact the condition can have on a family and preventative interventions to lessen this impact. • Should there be some mention of competencies for primary care staff? There is no doubt that there is a need for better professional training and 	<p>management.</p> <ul style="list-style-type: none"> • This is noted, and is not unique to this condition. • While extremely worthwhile, it would be difficult for the guideline to extend beyond advice to the NHS because of both NICE's remit and the workload. • Support in general will be addressed in the guideline. • One of the aims of the guideline will be to improve knowledge about this condition.

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Type	Stakeholder	No	Section number	Comments	Developer's response
				understanding of this condition.	
SH	Community Practitioners' and Health Visitors' Association	2	4.1.1	It would be helpful to separate teenagers from younger children and each group has different needs	The term young people in transition to adulthood has been used in section 4.1.1.a
SH	Community Practitioners' and Health Visitors' Association	3	4.2.a	Whilst at the moment school nurses may not have a significant role in working with children and families where a child has ME, their role in the future could be very helpful as workforce numbers increase. Health visitors also may support families where one parent has ME but do not have specific training to do so.	Noted, and we will welcome your comments on the draft guideline.
SH	Community Practitioners' and Health Visitors' Association	4	4.2.b	It seems counterproductive not to include some review of tertiary services as these could have the most significant impact on individual sufferers if they are accessible to them.	This has now been clarified.
SH	Community Practitioners' and Health Visitors' Association	5	4.3a	Should this include post viral syndrome (see above) eg what are the risk factors for the development of ME?	Risk factors will be covered in the general background in the full guideline but, as explained above, prevention is not in the scope.
SH	Community Practitioners' and Health Visitors' Association	6	4.3.c	Anti-depressants can be the only treatment offered by the GP. Their value as a primary or secondary intervention should be investigated.	Noted. Pharmacological interventions are now mentioned explicitly
SH	Community Practitioners' and Health Visitors' Association	7	4.3.d	Information also needs to be available for the patient to share with their school or work place if necessary. This can relieve a great deal of external pressure on the patient.	NICE will produce information for the public on the guideline. Voluntary organisations may then use the guideline as a basis for further information.
SH	Faculty of Occupational Medicine	1		My comments regard the scope of the guideline work. I understand that currently NICE is responsible for the NHS and therefore the guidelines will not cover occupational health services. As most occupational health is conducted	Thank you.

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				<p>outside the NHS, I understand and accept this point subject to my subsequent comments, although I hope that the guidelines will inform good occupational health practice as well.</p>	
SH	Faculty of Occupational Medicine	2	4.3	<p>Clinical management – I believe there needs to be explicit guidance developed with regard to the clinical advice as to whether a working patient should or should not withdraw from work. There also needs to be acknowledged the requirement that advice on rehabilitation is not focused entirely on clinical aspects, but has a strong vocational element to it.</p> <p>I say this, as the data from DWP is clear and unequivocal that the longer the person stays away from work the worse the chances of returning to work in the future, whatever the diagnosis. This disease is rarely, if ever, fatal, but does affect economically active people and so, I would suggest ability to continue working should be one of the most important outcome measures for the disease.</p> <p>In this condition, the experience of most occupational physicians is that this group do particularly badly due to delays in diagnosis and delays in accessing treatment (should any be available). These delays will place considerable strain on any employment relationship. This can then be compounded by a relative lack of appreciation of the nature of the employment contract amongst clinicians and the lack of a strong vocational element to maintaining people in work or rehabilitating them back to work.</p>	<p>Noted.</p> <p>We will include this as an outcome measure on which to judge evidence.</p> <p>Noted.</p>

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Type	Stakeholder	No	Section number	Comments	Developer's response
				<p>You will perhaps appreciate that we have only a few hundred specialists in occupational medicine in the UK for 28m workers, approximately one for every 43,000. This means that many workers will have little or no access to occupational health support. Without advocacy and negotiation with their employer, the chance of return to work after even a few months away on sick leave will be poor. Again, the DWP statistics show that there is an 80% chance of not working again in the next five years if a person is off work for six months, whatever the diagnosis.</p> <p>It is for these reasons that I believe a strong occupational health element to the potential guidelines is important, as GPs and other professionals will frequently be making important clinical decisions that affect the economic wellbeing of their patients, and the country as a whole.</p>	Noted. There is an occupational physician on the guideline development group.
SH	Health Protection Agency	1		Please can we make sure that the rational use of microbiology laboratories is covered in the diagnosis and/or exclusion of CFS/ME?	Advice will be given on investigations needed to diagnose the condition.
SH	Human Givens Institute	1	General	HGI has no comments to make on the draft scope. We will focus on the psychological interventions and recommendations to secondary and tertiary care.	Noted.
SH	ME Association	1	4.2.c Healthcare setting	<p>The MEA is concerned that the guidelines will not properly address crucial management issues relating to:</p> <p>Work (return to work on a part-time or flexible basis; early retirement from work where appropriate)</p> <p>Education (of crucial importance to children and adolescents)</p>	<p>Thank you for your comments.</p> <ul style="list-style-type: none"> • Work and education are now included more specifically in sections 4.3. c & d. • Support is a topic, and the voluntary sector will be covered there. • While an important issue, the guideline's remit is the NHS. While it can provide advice to health care professionals on sickness and disability, it cannot advise

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				<p>Voluntary sector (vital role played by self-help support groups)</p> <p>Department of Work and Pensions (refusal of state sickness and disability benefits is a major issue for many people with ME/CFS)</p>	the DWP.
SH	ME Association	2	4.3.a Clinical management	We believe the guidelines will have to cover a range of possible diagnostic terms which may be used to describe different stages of the illness (eg post-viral fatigue syndrome when symptoms become suggestive of ME/CFS but it is too early to make a definite diagnosis of ME/CFS).	Relevant terms will be searched. If you have any specific terms to include, please send them to us.
SH	ME Association	3	4.3.e Clinical management	<p>We are concerned that service provision has been excluded from the scope because the guidelines will need to make some sort of recommendation as to which patients should be basically managed in primary care and which should be referred to secondary or tertiary care. The fact that there are no secondary care facilities in some parts of the UK (especially Wales) will also need to be addressed.</p> <p>We believe that all pharmacological interventions which are currently being used to manage symptoms, or possibly affect the underlying disease process, must be included in the guidelines. Clinicians currently make use of a number of unlicensed medicines for symptomatic relief (eg low doses of amitriptyline for pain and/or sleep disturbance). There are also a growing number of new and experimental drugs that are being assessed (eg low doses of hydrocortisone; modafinil/Provigil). We believe that NICE will need to comment on these drugs even</p>	<p>Criteria for referral to specialist care are included in the guideline.</p> <p>Service configuration is beyond the remit of this clinical guideline.</p> <p>Pharmacological interventions are now included more specifically.</p>

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				though evidence from RCTs may well be unavailable.	
SH	National ME Centre	1	4.3 Clinical management	<p>There is little about the management of severe grades of chronic fatigue syndrome – probably representing up to 10 or 20% of the total population. Limited papers on the effect of graded exercises and cognitive behavioural therapy apply to relatively mild to moderately affected patients only.</p> <p>It has to be recognised, that patients with severe forms of chronic fatigue syndrome/ME invariably have complex constellation of symptoms, and require an individualised management programme, best provided from unit or team with experience in managing severe chronic fatigue syndrome (eg Essex Neurosciences Centre). The policy of managing severe chronic fatigue syndrome/ME must be based on the best evidence available if, as yet, it cannot be truly evidence based within NHS definitions.</p>	<p>As indicated in section 4.1, advice on the diagnosis and clinical management of patients with severe illness will be included in the guideline.</p> <p>All registered stakeholders will be asked to submit evidence. We encourage you to submit the evidence from the Essex Neurosciences Centre for consideration. Where evidence is not available the GDG will formulate recommendations through formal consensus methods.</p>
SH	North Bristol Trust	1	4.2b	Unclear what is meant by 'tertiary' procedures	This has now been clarified.
SH	North Bristol Trust	2	General	More specific about severe cases	The guideline itself will seek to be specific in its advice about severe cases.
SH	North Bristol Trust	3	General	Should explicitly consider the management of comorbidity (both physical and mental)	The scope of this guideline is very broad. While co-morbidities is an important area, it will be difficult for the guideline to address a range of co-morbidities.
SH	North Staffordshire Combined Healthcare	1	General	The guideline, as described in the scoping document, is only intended for use in primary and secondary care. Most CFS services are in the tertiary care sector and it would therefore be important to include those services, particularly now that new tertiary services are in the process of being created.	Thank you. This has now been clarified.
SH	North Staffordshire Combined	2	General	Clinicians with direct experience should be involved. These are usually psychiatrists, psychologists,	Health professionals with direct experience from all of these backgrounds will be on the GDG.

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Type	Stakeholder	No	Section number	Comments	Developer's response
	Healthcare			physiotherapists and OTs.	
SH	North Staffordshire Combined Healthcare	3	General	It is important to be clear with respect to diagnosis. The Oxford Criteria are most commonly used.	Noted with thanks.
SH	North Staffordshire Combined Healthcare	4	General	They should consider taking a broader view of the diagnosis and possibly to include conditions such as fibromyalgia.	While this is an important topic, the scope of the guideline is already very broad and unfortunately this cannot be included.
SH	Pain Concern	1	General	Overall, we are happy with this scope	Noted with thanks.
SH	Qualipharm UK Ltd	1	General	I can appreciate that these conditions are complex and that fatigue can be a subjective symptom although I think the scope should include the thorough diagnosis of anaemia, to exclude it if nothing else. The most common causes of anaemia and hence fatigue, once haematinics such as B12 and folate are ruled out, are iron deficiency and reduced erythropoiesis. There is one recent study in this population looking at the evidence for anaemia. It found that the erythropoietin levels were within normal range. However, Erythropoietin levels are measured logarithmically and any reduction in haemoglobin should result in significant increases in erythropoietin production. In patients with Anaemia of Chronic Disease (ACD) pro-inflammatory cytokines inhibit the production and effectiveness of endogenous erythropoietin although increased stimulation of the marrow can overcome this inhibition. Additionally, in ACD the mobilisation of iron is decreased which could also reduce the natural response to anaemia. Ensuring sufficient iron is available is important for effective erythroiesis. Traditional iron salts are poorly tolerated and not well absorbed during situations where ferritins are elevated. Also although newer IV irons exists with improved safety the administration of such products is costly.	Noted with thanks.

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SH	RCGP	1	General	The scope is well written and clear. All my specific comments are therefore minor.	Noted with thanks.
SH	RCGP	2	4.2b	The difficulty with excluding tertiary care is that the line between secondary care and tertiary care is quite blurred in this subject. In that respect it is quite different for a subject like (say) neurosurgery. Patients in secondary and tertiary care may in practice be seen in the same clinic, by the same staff, and receive the same treatment. Furthermore much of the research has been conducted in tertiary care, so by excluding this setting from the scope, you are reducing the research's appropriateness.	Research from tertiary care will be included. Advice on highly specialised procedures will not.
SH	RCGP	3	4.2c	This was raised at the stakeholders meeting on 22.11.04. The one category on this list that would be worth considering is OT. Some NHS centres offer this, though some is outwith the NHS. The other categories are appropriately excluded.	The evidence for occupational therapy will be assessed.
SH	RCGP	4	4.3	We may have a terminology problem. Although CFS/ME is the label used by most with fatigue syndromes, we must ensure post-viral fatigue syndrome is not omitted.	Post-viral fatigue syndrome will be used as a search term, among others.
SH	RCGP	5	3	The scope acknowledges that CFS is a relatively common illness that is medically unexplained. Medically unexplained symptoms have been estimated to account for up to 30% of general practice and 50% of hospital outpatient presentations. The decision to produce NICE guideline on CFS is a bold step from the concept of a single disease towards the greyer notion of illness and sickness as defined by the WHO. The recognition of the wider impact of CFS on a sufferer's family, work and healthcare provision increases the complexity of the task. This is a substantial challenge for guideline production but it is also an exciting opportunity to examine the levels of evidence and types of evidence suitable for producing a	Noted with thanks.

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Type	Stakeholder	No	Section number	Comments	Developer's response
				guideline for the diagnosis and management of 'non disease', illness and sickness. The guideline for CFS will need to be a holistic guideline.	
SH	RCGP	6	4.1 (b) 4.1.2 (a)	A patient with CFS is most likely to present to a GP in general practice for a diagnosis. The presenting symptoms of CFS could overlap with other disease process eg systemic lupus erythematosus or another 'non-disease' process e g fibromyalgia. The CFS guideline will be required to aid the formulation of a differential diagnosis and a definitive diagnosis for GPs and other physicians. Read codes for CFS for clinical governance purposes will be required.	The guideline will cover diagnosis as you describe. Read codes are beyond the remit of the guideline.
SH	RCGP	7	4.2 9(b) (c) 4.3 (e)	The division of health services into primary, secondary and tertiary is outdated and fails to acknowledge the changing landscape of healthcare provision. Working across organisational and professional boundaries, professional role reconfiguration, quality team development, a primary care led NHS, private/ public partnerships, provider competition, quality outcome frameworks, electronic referrals and the patients journey etc are the language of the new NHS. The CFS guideline must take into account the real world of healthcare provision today and anticipate the future. The NHS as a service for health should consider other stakeholders e g occupational health/social services. As the patient with CFS is at the centre of this guideline, organisations involved in the patients journey should not be excluded as indicated by the draft scope paper.	This has now been clarified.
SH	RCGP	8	4.3 (c)	Producing guidelines for CFS will be challenging. Evidence that is suitable for drug interventions and current evidence- based medicine might not be available or appropriate for CFS guideline production. Also, outcome	Noted with thanks.

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				<p>measures suitable for CFS might require a different approach to that presently used for disease- based quality outcome frameworks.</p> <p>Details about complementary therapies in the NHS are contained in the document:-</p> <p><i>Clinical Governance for Complementary and Alternative Medicine in Primary Care: Final Report to the Department of Health and King's Fund: October 2004. University of Westminster. Jane Wilkinson, Professor David Peters, Julie Donaldson.</i></p>	
SH	RCGP Wales	1	1	Please use term CFS and stop perpetuating 'ME'	We have used the terminology given to us by the DH.
SH	RCGP Wales	2	3(a)	Fluctuating intensity of symptoms is a striking feature that is worth mentioning in the document at this stage.	Included.
SH	RCGP Wales	3	4.1.2	People with major co-morbidity are also excluded.	Now included.
SH	RCGP Wales	4	4.3(d)	Substitute patient management for symptom management.	I assume that you wish there to be a more holistic view. However, I think the term 'patient management' would not be acceptable.
SH	RCGP Wales	5	Clinical questions	(1) Lyme Disease is rightly or wrongly beginning to be promoted as an important diagnosis to exclude in the differential diagnosis of CFS. Yet the diagnosis of cerebral Lyme is controversial and the diagnostic tests equivocal in terms of QA and interpretation. It would help clinicians if expert guidance can be agreed in this area and then be part of the final guideline.	Noted.
SH	RCGP Wales	6		(2) CFS is always diagnosed against a back-drop of strongly held health/illness beliefs. Under these circumstances clinicians need written care plans that have	The guideline will address information needs, including sharing information between health professionals and with patients.

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				been agreed with patient & family in the light of their health beliefs. The plans need periodic formal review. Why is it that so many clinicians fail to follow this simple yet workable policy?	
SH	RCGP Wales	7		(3) The conceptualisation of CFS as a set of physiological dysfunctions/ dysrhythmias rather than as a disease process is gaining currency in clinical circles. Please can these developments be properly discussed in the guideline?	Noted.
SH	Royal College of Nursing	1	4.1.1 a)	'aged 5 years and upwards' – suggest that this is changed to '10 years and upwards' in that our experience of working with children and young people is that CFS/ME is extremely rare in the under 10s, and that the guideline will not be able to cover this.	It was agreed that it is rare in young children and there is likely to be very little evidence. The considered opinion was that the management of younger children is likely to be similar to that of older children.
SH	Royal College of Nursing	2	4.2 b)	It would be useful to include tertiary services here.	The distinctions have now been clarified.
SH	Royal College of Nursing	3	4.2 c	Excellent that the guideline will be relevant to the work of professionals working in the wider world, education being particularly relevant where children and young people are concerned.	Thank you.
SH	Royal College of Nursing	4	Section 4.3	Given that there are a number of diagnostic systems e.g. Oxford and 'Centre for disease control', should the guideline form an opinion as to which one should be routinely used?	This issue will be addressed as part of diagnosis.
SH	Royal College of Nursing	5	Section 4.3	Would it be helpful if patients were defined in terms of being relatively active and relatively under-active, as this would aid accurate therapy if a behavioural approach were being considered?	Noted. At this point the scope has used the more conventional categorisations. However, a redefinition of categories may be considered by the GDG.
SH	Royal College of Nursing	6	Section 4.3	Could the guideline recommend validated questionnaires to aid assessment?	The guideline will search and review all evidence under assessment. If there is good evidence for validated questionnaires, the GDG will consider it.

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SH	Royal College of Nursing	7	Section 4.3	Are there particular self help books or materials that the guideline would recommend to be used?	This will be considered by the GDG. However, NICE guidelines do not endorse particular voluntary organisations.
SH	Royal College of Nursing	8	Section 4.3	Will graded exercise be included under rehabilitation strategies?	Graded exercise will be considered.
SH	Royal College of Nursing	9	Section 4.3	If graded activity/exercise is to be recommended then specific information should be given as to intensity, duration, timing of the activity, and whether it should be aerobic or not.	If the evidence is available, specific recommendations will be made.
SH	Royal College of Nursing	10	Section 4.3 c	Suggest that 'graded activity' is changed to 'graded activity / exercise' or that 'graded activity' and 'graded exercise' are both included but as separate entities. Reason to include both would be that professionals use both terms, often interchangeably.	Both will be used in the search terms.
SH	Royal College of Nursing	11	General	Happy with the layout and contents of the draft Scope document.	Noted with thanks.
SH	Royal College of Nursing	12	General	Also would have liked something for tier 4 as in some areas, we see the complex end of such cases.	The management of very severely affected will be considered.
SH	Royal College of Paediatrics and Child Health	1	General	<p>The RCPCH welcomes this guideline, addressing as it does a topic that is common, important, and where effective collaboration with patients and their families is important.</p> <p>The RCPCH has just completed an evidence-based clinical guideline on this topic, underpinned by a rigorous literature search. Where evidence was lacking a Delphi consensus process was used to formulate recommendations. This clinical guideline should be of use to NICE both in assisting in identifying important questions and providing consensus statements in areas where evidence is lacking.</p>	Noted with thanks, and thank you for the copy of your guideline.
SH	Royal College of	2	1. Guideline	We note that the guideline title refers to myalgic	The title of the guideline has been changed to

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	Paediatrics and Child Health		title	encephalomyelitis rather than myalgic encephalopathy. Although this conforms to the classification under the ICD-10 codes (G93.3) and is preferred by many patient groups, other groups and most clinicians consider the use of the term encephalopathy to be more accurate as there is no physiological evidence of encephalomyelitis. The RCPCH guideline used the term myalgic encephalopathy. In the CMOs document there was no explicit definition of the term ME presumably to avoid the inevitable controversy.	Chronic Fatigue Syndrome/Myalgic encephalomyelitis (or encephalopathy).
SH	Royal College of Paediatrics and Child Health		4.2 Healthcare setting b	Although point b states that the guideline will not address the delivery of tertiary procedures this conflicts with 4.3 c where it states that the guideline will include recommendations on the criteria for referral to secondary and tertiary care.	The criteria for referral will be included, but advice on the procedures will not.
SH	Royal College of Pathologists	-	No comments	The Royal College of Pathologists have no comments to submit at this stage.	Noted with thanks.
SH	Royal College of Physicians	1	3 a	Replace last sentence with "The defining characteristic is fatigue or tiredness". There is no need to add the qualifications of fatigue as the qualification is anticipating the conclusions of the report.	The word defining has been removed.
SH	Royal College of Physicians	2	4.1.1	The guideline should address the diagnosis, treatment and management of patients who are bed bound.	Very severely ill patients will be included in the guideline.
SH Royal College of Physicians	Royal College of Physicians	3	4.1.2	No need to put this exclusion in. NICE should decide on the final application of any its conclusions. For instance, some of the conclusions may apply to patients with fibromyalgia and fatigue.	The scope defines what will be searched, reviewed and discussed. As we will not search for evidence for patients with other conditions, the guideline cannot advise on care for these conditions.
SH	Royal College of Physicians	4	4.2 b	The guideline should include 'tertiary procedures' such as inpatient management. In any case it is not possible to separate secondary and tertiary care, since several CFS	This has now been clarified.

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				centres provide both. In fact, it is likely that most of the best evidence for treatment comes from tertiary settings and the evidence base for the primary setting is thinner.	
SH	Royal College of Physicians	5	4.2.c	The guidelines should include advice relevant to occupational health services and educational services. Advice on the desirability of work and school attendance is a central challenge in the management of CFS. Advice should be given on liaison with occupational health services, and on how to manage a phased return to employment for patients who are recovering. Many clinicians would also welcome some guidance on if, when, and how to advise retirement on the grounds of ill health.	This is now more explicit in section 4.3.e.
SH	Royal College of Physicians	6	4.3 a	There is a wide overlap between CFS and other functional somatic symptoms, particularly chronic pain syndromes and fibromyalgia. The guideline should therefore be clear about treatment aims and objectives in relation to the core features of CFS.	Agreed.
SH	Royal College of Physicians	7	4.3.b	Clearly the assessment of patients with CFS should be included. However, it is not clear what the term "accurate diagnosis" means.	We will seek to minimise the number of false positive and false negative diagnoses of CFS/ME. We have this changed to <i>correct</i> diagnosis.
SH	Royal College of Physicians	8		Recommendations should be given for referral to specialties such as Pain Relief, Rheumatology, Neurology, Psychiatry and Clinical Psychology.	A patient pathway will be defined.
SH	Royal College of Physicians	9		The guideline should focus closely on treatment goals, aims and outcomes. To what extent should these be defined by the individual patient/client?	Noted.
SH	Royal College of Physicians	10		Advice should be given on whether evidence based treatments (graded exercise and cognitive behaviour therapy) should be offered to patients under conditions which did not apply in the original controlled trials. Should, for instance, these interventions be applied to a group	As with every guideline, this will be part of the work of the GDG. For this guideline, this will be done by formal consensus.

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				therapy setting, and/or be offered to children, adolescents, or the severely disabled?	
SH	Royal College of Physicians	11		The place of 'pacing' should be carefully defined. What are the roles of pacing in maintaining function, preventing relapse, and improving outcome?	Noted with thanks.
SH	Royal Pharmaceutical Society	1	No comment	Please note that the Royal Pharmaceutical Society will not be commenting on the above consultation.	Noted with thanks.
SH	Royal Society of Medicine (Paediatrics and Child Health)	1	General	Good overview and aims.	Noted with thanks.
SH	Royal Society of Medicine (Paediatrics and Child Health)	2	3b	Statistics for children *(preferably by age ranges) needed. If not possible "population prevalence in adults"	These will be in the final guideline.
SH	Royal Society of Medicine	3	General	Despite NICE's comment that "The guideline will also be relevant to the work, but will not cover the practice, of those working in: ...occupational health", returning to work is an essential component in the recovery of these patients. Work has been shown in peer-reviewed research to be of significant positive benefit to the mental health of individuals. This CFS/ME group benefit from a return to work in the longer term. A clinical guideline would be seriously deficient without recommendations on returning to work. All too often, guidelines do not address a full return to normal life, which includes a return to productive and satisfying employment. In this diagnosis, this is more important than many other clinical conditions	Note that this has been extended in section 4d.
SH	St Bartholomew's Hospital Chronic	1	4.2 b	Tertiary referral should be covered. Useful to clarify who to refer to secondary vs. tertiary centres. ie. complex	Criteria for referral will be addressed.

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	Fatigue Services			cases, strong co-morbid depression/anxiety, non-responders who aren't making progress in local services.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	2	4.2 b	Need clarification of delivery of tertiary procedures - what does this mean? Tertiary care and secondary overlap and may be false distinction in many instances. As CNCC we could be considered tertiary service providing second opinions, developing treatment models and models of devlivery of care, research etc.	This has now been clarified.
SH	St Bartholomew's Hospital Chronic Fatigue Services	3	4.1 Population	We suggest that the guidelines include secondary prevention of CFS/ME in patients with post-viral fatigue syndrome. There are at least two trials of interventions for patients recovering from viral infections that suggest that simple educational interventions can prevent abnormal fatigue six months after infection (Dalrymple, 1964; Candy et al, 2004).	While a very worthwhile topic, it would be very difficult in the time to address prevention as well as diagnosis and management
SH	St Bartholomew's Hospital Chronic Fatigue Services	4	4.2 b) Healthcare setting	We suggest that it is not possible to separate secondary and tertiary care. We believe the guidance should address tertiary care. Firstly it could be argued that leaving out tertiary care would discriminate against the severely disabled. Secondly we believe the current scientific evidence suggests that efficacious management interventions in secondary care are also efficacious in tertiary care, although the latter studies are usually open case series.	This has now been clarified.
SH	St Bartholomew's Hospital Chronic Fatigue Services	5	4.3 Clinical management	We agree that the guidance should not address fibromyalgia and associated disorders.	Noted with thanks.
SH	St Bartholomew's Hospital Chronic Fatigue Services	6	4.3 Clinical management	"Graded activity" should explicitly be "graded activity and exercise therapies". This is because it is vital that the guidance specifically addresses therapeutic exercise since there are more RCTs of this therapy than any other	Changed.

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				and there is more misunderstanding and suspicion of this approach than any other in the field.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	7	4.3 Clinical management	CBT and GET should be listed explicitly and covered individually in the guidelines	These terms will be searched.
SH	St Bartholomew's Hospital Chronic Fatigue Services	8	4.3 Clinical management	I wonder if there should not be some reference to service provision or models of care even if only to express opinion that these are provided as part of integrated multidisciplinary team approach	While a very worthwhile topic, it would be very difficult to address this in the time.
SH	St Bartholomew's Hospital Chronic Fatigue Services	9	4.3 Clinical management	graded activity – is this pacing? Guidelines should cover both.	Both have now been added.
SH	St Bartholomew's Hospital Chronic Fatigue Services	10	4.3 Clinical management	It is essential that evidence based therapies are prioritized and emphasized over complementary therapies where there is little or no evidence of efficacy.	Noted.
SH	Syner-Med (PP) Ltd	1	General	As CFS/ME is a potentially problematic diagnosis it would be useful to identify other potential diagnosis. Within this could be included anaemia and factors that may contribute to or precede overt anaemia. This could include. Folate, B12 and the measurement of iron status. Iron status is not easy to measure and the measurement of serum ferritin as a surrogate of iron status though routine is not very reliable. Normal or elevated ferritin levels may indicate high levels of iron, or inflammation. Even if the ferritin level representative if iron in store this doesn't mean it is available for haemoglobin or other uses. Recent studies have shown improvements iron supplementation leading to improved performance in non anaemic individuals.	Noted with thanks.
SH	The Young ME Sufferers Trust (Tymes Trust)	1	3 a	Under "Clinical Need for the Guideline" we would request that the potential severity is mentioned. Something like: "In severe cases the patient may be profoundly weak and	This has now been mentioned.

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				<p>need liquid feeding.” We request this because “debilitating fatigue” does not spell out the dramatic severity referred to in the CMO’s working group report. Doctors are still mistaking severe CFS/ME in children for a case of child abuse and child protection procedures are still being initiated due to a lack of recognition that the illness can actually be this severe. Although this document is the scope, and not the guideline itself, we feel that severity should have a mention in what is, we believe, the first description of the illness that NICE will have published.</p>	
SH	The Young ME Sufferers Trust (Tymes Trust)	2	4.2 c) bullet point 3	<p>Under “Healthcare setting”, we would remind NICE that the Dept for Education has produced statutory guidance for education professionals called “Access to Education for Children and Young People with Medical Needs”. To obtain home tuition, pupils are expected to have to have a medical recommendation. Without any guidance for doctors on when and why support may be needed for home tuition, or distance (virtual) learning, either as an adjunct to or instead of school attendance/attendance at a hospital school, things will not improve from the present situation where the majority of families are under intolerable stress in trying to get necessary provision. See the distressing statistics in our report “The Forgotten Children” at www.tymestrust.org</p> <p>This has immediate relevance for their health We would advise NICE that educational demands are known by paediatricians to be a key cause of relapse in children, and may in reality be the main cause, although so far no-one has carried out research on this issue. We therefore request that Statement 4.2 c) should be modified to read: “The guideline will also have relevance for the practice of those working in:...” (continued)</p>	Please see the revision in section 4.3 d.

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SH	The Young ME Sufferers Trust (Tymes Trust)	3	4.3 c	<p>Under "Clinical management" we would request a rewording of the statement preceding the list of interventions on which there are to be recommendations.</p> <p>This is a matter of linguistics. On such a sensitive issue, great sensitivity needs to be used in the language. At the moment this sentence actually means that there is "good" evidence to support all the listed interventions.</p> <p>In practice, those RCTs that are available have many limitations. To refer to the evidence as "good" and then list four therapies, suggests that a value judgement has already been made about these therapies, whereas this is to be part of the NICE process. The York review did not say that there was good evidence for all these interventions in quite the same way as this short sentence (and as a result of information I supplied, the York stance on the definitive study which it originally commended was to be modified in the online version). The process of preparing the NICE guidelines will presumably also evaluate studies that have been published since the York review.</p> <p>We would suggest two alternatives. We prefer option 1.</p> <ol style="list-style-type: none"> 1) Use the sentence almost as it stands and give no examples of the therapies that will be included. So it would read "The recommendations will also cover interventions, including those where good evidence is available." There may be no need for a list here, since that list will be available when the guidelines are published. 2) If a list is considered necessary, then modify the sentence to read: "The recommendations will also cover interventions, including those which have already been the subject of study, and comment 	<p>Interventions will be based on good evidence as defined in the NICE technical manual. I have tried to make it clearer that issues will be addressed; that is, the evidence will be reviewed and discussed by the GDG, and then recommendations made where appropriate.</p>

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				<p>on their use. These will include:" - then the list follows here.</p> <p>Neither of these alternatives would appear to prejudge the issue. We must emphasise that a particular reason why we make this recommendation is that there is worry and concern amongst patients that the NICE guideline will rubber stamp interventions that they have found by experience is not suitable for them and therefore may not be suitable for many others. The issue of sub-groups is relevant to this.</p>	
SH	The Young ME Sufferers Trust (Tymes Trust)	4	General	The issue of sub-groups needs a mention somewhere in the scope, as this has such relevance to interventions.	The issue of subgroups is in section 4.1.1 and is overarching the remainder of the scope.
SH	The Young ME Sufferers Trust (Tymes Trust)	5	General	<p>Without making the document too long, we feel there should be mention in the scope of patient choice on management options. Whilst the NICE guideline is for medical professionals, it would be helpful to have a statement that, in particular because there is as yet no curative treatment, the issue of patient choice on how to manage the illness will be key. We do not feel that this is explicit in 4.2 d)</p> <p>Again, we give this advice based on patient perception that the guideline will "tell" doctors what do "do to" them, despite the mention of self-care in 4.2 d) which is perhaps not as reassuring as it could be for many. It is essential that patients can have confidence from the beginning in this procedure. (continued)</p>	This principle will be fundamental to the guideline
SH	The Young ME Sufferers Trust (Tymes Trust)	6	General	We hope these comments are helpful and productive and we congratulate those who have so succinctly summarised the process and the issues in the first draft. We hope they will view our comments favourably.	Noted with thanks.
SH	Welsh Association	1	4.1.1.	Guidelines need to address one treatment does not suit	Noted with thanks.

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	of ME & CFS Support			all. These guidelines need to warn of possible harm to a subset of patients from Graded Exercise/Activity programmes.	
SH	Welsh Association of ME & CFS Support	2	4.2.c	There is concern that these guidelines will not cover the work of but be relevant to various agencies in particular education, social services and the DWP. Our concern is that in giving guidance to doctors they need to have due regard for the laws governing sick children (differ in England and Wales) etc and on the impact their guidance will have on patients ability to claim the relevant benefits and to also access appropriate social care.	The guideline will cover advice that health care professionals may give but we do not have the remit to advise the DWP or Social Services
SH	Welsh Association of ME & CFS Support	3	4.3.	In the case of children absence of improvement or total resolution of symptoms does not constitute harm or neglect.	Noted with thanks.
SH	Welsh Association of ME & CFS Support	4	4.3.a	We understand this guidance will not cover those with a diagnosis of Post Viral Fatigue Syndrome. In not including this patient group in these guidelines it may lead to inappropriate management and treatment of this group. The World Health Organisation classify PVFS alongside ME and CFS in ICD10 at G93.3.	Post Viral Fatigue Syndrome will be used at a search term.
SH	Welsh Association of ME & CFS Support	5	4.3c	We would like to see Pacing included in this list of interventions as a management tool of its own standing.	This has now been included.
SH	Welsh Association of ME & CFS Support	6	4.3.c	In 'Rehabilitation strategies' we would like to see included in the discussions the different forms rehabilitation takes e.g. gradual return to school recognising that this will not be right for some young people, gradual return to work, retraining in the workplace for a more appropriate position, retraining in education before seeking more appropriate employment, for young people who have not completed their compulsory education appropriate educational opportunities to allow them to take up places in FE	This is now noted.

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				colleges or University.	
SH	Welsh Association of ME & CFS Support	7	4.3.d	Dietary advice	This is now included.
SH	Welsh Association of ME & CFS Support	8	General	These guidelines need to allow for the difference in governance between England and Wales. They also need to take into account the effects of devolution and the differences in provision in health, education and social care between England and Wales.	Noted. The Welsh Assembly Government is a stakeholder on this and all guidelines.