

National Institute for Health and Clinical Excellence
 CFS/ME consultation draft
 29 September – 24 November 2006
 General comments from stakeholders

Status	SH organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	25% ME Group	54	FULL	General		<p><u>Some statements in the draft document are welcome e.g. :</u></p> <p>General principles of care – emphasis on the importance of an individual/collaborative approach and the patient’s right to refuse treatments he/she deems to be inappropriate. (However, non-compliance with a CBT/GET regimen should not affect payment of welfare benefits and should be without detriment to receiving other aspects of treatment.)</p> <p>Highlighting the importance of balancing “activity” & rest - although for most people with ME/CFS, that it is common sense approach anyway - and something that has been the foundation of M.E. self help literature for many years.</p> <p>Highlighting the importance of sleep management – however, in many cases night time sleep disruption occurs as a symptom of ME and afternoon rest actually aids night-time sleep.</p> <p>Assistance with provision of blue badge and/or wheelchair is welcome, (although some may question the “proviso” of it being “part of an overall management plan”.) NB. Practical help along these lines (and assistance with benefits) may be THE most important</p>	<p>Noted with thanks.</p> <p>Diagnostic criteria While it is generally recognised that it is</p>

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					<p>thing that a clinician/healthcare professional can do for an individual with moderate/severe ME.</p> <p><u>However, the guidelines fail to adequately address a number of key areas:</u></p> <p><u>Diagnostic criteria</u></p> <p>There is no reference to the WHO neurological classification for M.E. and PVFS (section G93.3 of ICD 10) - something that the DoH accepts, and was acknowledged by Health Minister Lord Warner in a letter to Countess of Mar 11th Feb 04: "...chronic fatigue syndrome is indexed to the neurology chapter and fatigue states to the mental health chapter."</p> <p>The guidelines appear to recognise the heterogeneous nature of the illness, but then fail to address sub grouping under the ME/CFS "umbrella", and offer a 'one treatment fits all' approach. Many of the research papers used to inform the guidelines (and many others that weren't) acknowledge the existence of sub groups e. g. (Jason 2005) - An author who is referenced more times than any other in the document!</p> <p>Until an adequate definition of ME/CFS is agreed, what constitutes "evidence based medicine" is in dispute. The 'Canadian Criteria': 'A Clinical Case Definition and Guidelines for Medical</p>	<p>heterogeneous, the evidence does not allow distinctions between sub-groups with regard to the diagnosis or management of the condition.</p> <p>Please see the relevant sections of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see relevant section of revised guideline.</p>
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					<p>Practitioners' (Carruthers 2003) was produced by a team of international specialists in ME/CFS, with experience of over 20,000 patients. These guidelines are widely believed to be the most detailed and comprehensive definition of ME/CFS in the world, and they barely merit a mention! By comparison the NICE guidelines appear to endorse an extraordinarily weak definition of ME/CFS which amounts to chronic unexplained fatigue + ONE other symptom.</p> <p>The mildest form of Post Viral Fatigue Syndrome cannot, and should not, be lumped together with most types of M.E. There is a world of difference between "moderate" & "mild" ME/CFS. There is a lack of awareness of severe ME, and this has major implications for what constitutes appropriate treatment for this group of patients.</p> <p>There is no reference to the different phases of the illness, ie those in a 'recovery phase' – something we believe to be hugely important. That factor MAY enable SOME to follow SOME of the prescribed advice given here, but NOT in an acute phase of illness. Too much activity in the acute stages of the illness may actually make the condition worse. Indeed exercise in the normal sense of the word usually has little or no role to play during this very early stage - in fact, an</p>	<p>The evidence</p> <p>Please see the relevant sections of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see relevant section of revised guideline.</p>
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					<p>inappropriate exercise programme is very likely to make the illness worse. What may be required most of all at this stage is good old-fashioned convalescence and the establishment of purpose-built convalescence homes for ME/CFS patients throughout the country?</p> <p>There is a lack of awareness of symptoms; there needs to be more emphasis and acknowledgement of 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 M.E. experience.</p> <p><i>The Evidence</i></p> <p>The overriding message sent out here to healthcare professionals, with no special interest in ME/CFS, (not to mention the media) is that all patients need to do to get well, whatever the stage of illness, is to change their beliefs and exercise more. This is quite unrealistic and indeed misleading.</p> <p>Whilst we understand that the “evidence” presented is largely based upon RCTs, the recommendations for “treatment”, are extremely disappointing and appear to be built upon the flimsiest of “evidence” from a very small number</p>	
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					<p>of trials, reliant upon weak diagnostic criteria. None/or very little of this seems to accord with patients' experience. The emphasis on CBT & GET is seriously out of kilter with patient experience – which seems to have been comprehensively ignored - and there is a totally inadequate review of other aspects of ME/CFS management.</p> <p>It appears that NICE have started with the hypothesis that CBT works, and then attempted to support that hypothesis. Many of the recommendations for treatment appear to be based upon the opinion that ME/CFS is maintained by abnormal illness beliefs and behaviour - rather than conventional evidence. The reality is that patient evidence included in the CMOs report (2002) suggested that 65% found CBT unhelpful, and 50% were made worse by GET.</p> <p>The Guideline Development Group should also take note of recent research evidence on CBT which found that CBT did not offer any significant overall benefit when compared to education and support and standard medical care (ref: Cognitive behaviour therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme. Health Technology Assessment. 2006 Oct; 10: number 37. Another very recent study (Quarmby et al 2006) also found that the efficacy of</p>	
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					<p>CBT in a clinical setting compared unfavourably with results in RCTs.</p> <p>Many will conclude that the evidence presented to review panel was selective. Why for example is there no mention (apart from economics) of Ridsdale (2001) paper that found “Counselling and CBT to be equivalent”? For a significant number of people with M.E., the opportunity to talk to someone about their condition and how it affects their life etc without the underlying premise that the listener knows best, would be more acceptable. We understand that this study was given a high validity score.</p> <p>Neither does there appear to be any mention of Black and McCully (2005) that suggested that CFS patients have an “activity limit”. This is an important paper, and certainly accords with patient experience that many will hit a ‘glass’ ceiling. NICE need to be aware that many patients, naturally keen to get well, may feel obliged to follow rigid exercise/activity programmes and there is good evidence to suggest that this has been responsible for a number of very severe relapses in patients, who believed they were doing the right thing.</p> <p>We can see no reference to the 25% ME Groups 2004 Analysis Report, in</p>	<p>Presentation of information and language</p> <p>Please see the relevant sections of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see the relevant section of the revised guideline, where much of the language has been revised in response to stakeholder comments.</p>
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					<p>the FULL guidelines, (which we understand to have been submitted): where 93% of members surveyed found CBT “unhelpful” & 95% found GET “unhelpful”. (70% found pacing helpful.)</p> <p>Importantly the NICE questionnaire to the wider group, disagreed that a programme consisting of increases of aerobic exercise (GET) was appropriate for moderately affected adults. To then go on to suggest that this should be a treatment of choice (whose choice?) is ridiculous and likely to lead to conflict between health practitioners and patients.</p> <p>The dismissal of “pacing” as a management strategy in favour of CBT/GET appears to be seriously out of touch with patients’ experience. There is also no mention of ‘switching’. For many, this is an important illness management strategy: by changing from one ‘activity’ to another at regular intervals, and using different muscle groups, activity may be maintained for longer periods.</p> <p>At its simplest level this may mean switching from using the eyes to read/focus and then to the ears (& brain) to listen to radio/music. We understand that this technique is taught at the National ME Centre.</p> <p><u>Presentation of Information &</u></p>	<p>Omissions</p> <p>Please see the relevant sections of the</p>
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					<p><u>Language</u></p> <p>In the NICE of the document, which is the one most people will read/extract information from, a number of things are not made sufficiently clear. Most importantly the very limited efficacy of CBT. Eg p203 (FULL Guidelines) state that: “The GDG did not regard CBT or other behavioural treatments as curative or directed at the underlying disease process, which remains unknown. Rather such treatments can help SOME (our caps) patients cope with the condition and consequently experience a(n) improved quality of life.” This needs spelling out loud and clear in the NICE version, and any subsequent NICE reference guide.</p> <p>Similarly the FULL Guidelines deal with prognosis: suggesting that perhaps only 5-10% achieve total remission – but this is not at all apparent in the NICE . There is an over-emphasis on work related rehabilitation and advice in what should be a health guideline. We are concerned that this will put undue pressure on patients and clinicians to achieve perceived ‘positive’ outcomes – but in reality these measures seem to be more about politics than health.</p> <p>The draft document is littered with references to ‘psychological aspects’ of</p>	<p>stakeholder comments specifically addressing this topic for a response to your comments. Please also see the relevant section of the revised guideline.</p>
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					<p>the illness, giving the clear indication to everyone reading it, that that is the way this condition should be treated. There is a ludicrous amount of stereotyping, with numerous references, to risk of deconditioning, prolonged bed rest, fear of activity, all of which is not only patronizing and offensive to patients, but reflects a single (psychosocial) perspective of the illness. Many patients with ME/CFS who were previously very active, sports minded, remain well-motivated despite the limitations of their illness and completely reject this model. They ALL want to get well. Positive thinking is part of their lives.</p> <p>The persistent use of the phrase “setback” and what it implies, seriously diminishes the severity of the illness.</p> <p>This implies a slight ‘blip’ - relapses can be major and easily brought about by overdoing activities; viruses; stresses and other bodily reactions to hormonal imbalances/drugs/allergens/intolerance s etc. A major relapse can incapacitate for weeks, months or years.</p> <p>(Earlier this year, we heard of the first recorded death in the UK from “Chronic Fatigue Syndrome” – it seems highly likely that this wasn’t the first case.)</p> <p>There is no mention of common causes of “setbacks”: infection, over-exertion, General anaesthetics, surgery, and</p>	
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					<p>some types of vaccinations.</p> <p><u>Omissions</u></p> <p>There is little or no information on pain management, something that for many people with ME/CFS is a more disabling symptom than fatigue.</p> <p>The advice on diet is woefully inadequate. All 3 patient testimonies included in the FULL guidelines referred to issues of diet/food intolerances.</p> <p>The value of complementary therapies/pharmacological interventions (especially for pain) for symptom control are also inadequate.</p> <p>There is no reference to current international research into gene expression, which has already identified abnormalities in gene expression in patients with ME/CFS.</p> <p>It's glaringly apparent that it was too early for NICE to draw up these guidelines and quite how they are going to help in their current form must be seriously in doubt. We feel it's unlikely to reassure anybody that the NHS is taking this illness/group of illnesses seriously. In fact patients will probably be even more likely to seek help and support in the private sector. When contrasted to the Canadian Guidelines this draft fails very badly indeed.</p>	
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SH	25% ME Group	120	FULL	General +(p. 58 and p. 174)	3 Table 1	<p>I am extremely concerned that the GDG have sidelined 'pacing', as it 'is not clearly defined' despite the AfME Membership Survey 2001 * showing its strong support with PWME.</p> <p>'Pacing your activities Helpful = 89%'</p> <p>The GDG should urgently identify a working definition from current practice and published articles, and promote 'pacing'.</p>	'Pacing' has been added to the recommendations and defined in the glossary.
SH	Action for M.E.	1	General			<p>Please note that we offer an overarching analysis first, followed by comments on the FULL and then the NICE er guidelines. We ask that comments made in relation to the FULL guidance are also noted for the NICE version, although disparities between the two have been noted where possible.</p> <p>As part of our consultation process with our constituents we undertook an online survey on the NICE guidelines, which ran from 30th October 2006 to 13th November 2006, with 335 responding (FULL details are attached). Where relevant we have incorporated data from this survey into our comments.</p> <p>We also undertook a focus group with those members who undertook NICE 's own survey, as a part of the guideline development process. Their views have also been incorporated into our responses, where relevant.</p>	Noted with thanks.

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SH	Action for M.E.	2	FULL/NICE	General	<p>Action for M.E. believes that effective guidelines are required to ensure that M.E./CFS is properly diagnosed, treated and managed. We recognise that these draft guidelines are still a work in progress and further work needs to be done. We commend some aspects of the document, in particular the points addressing patient-centred care, partnership with patients and individually tailored management approaches. However, we have deep concern at the lack of emphasis on the physicality of the illness and the promotion of CBT and GET as the first treatments of choice at the expense of a comprehensive and individually tailored package of symptom management.</p> <p>We wish to work collaboratively to facilitate the development of a robust and workable document that incorporates the views of people affected by the illness, is usable for practitioners, and offers best practice advice on the care of people with M.E./CFS.</p> <p>The guideline's General principles of care are to be welcomed and we note the following as useful and appropriate recommendations.</p> <ul style="list-style-type: none"> • The patient-centred approach at the heart of the guidelines • The emphasis on an individually tailored management approach to 	<p>Noted with thanks.</p> <p>Issue 1. Useful and appropriate recommendations</p> <p>Noted with thanks</p>
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						<p>healthcare (e.g. FULL section 6)</p> <ul style="list-style-type: none"> • The need for partnership between the patient and the healthcare professional in the management of the illness (e.g. FULL 5.4.5.1) • A clear commitment to the patient being in charge of their goals and pace of treatment • Regular contact between the health professional and the patient (e.g. p137 FULL) • Regular and frequent reviews are good practice. (e.g. FULL P195 6.3.6.28) • The recommendation for multidisciplinary working • The recommendation to healthcare professionals to aim to establish a supportive and collaborative relationship with the patient, their family and carers (e.g. FULL 4.3.6.2) • The explicit acknowledgement that patients can withdraw from or refuse suggested treatment or management techniques “without detriment to the provision of other aspects of care” (e.g. FULL 4.1.1.1) • The recognition of the positive role of special services and also the vulnerability of their status (Note 	
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					<p>given in FULL guidelines p37 and omitted in NICE – which we would like to see amended)</p> <ul style="list-style-type: none"> • Recommendations re. healthcare practitioners: communications and activities reflect those given in the GMC's Good Medical Practice booklet. • The need for schools and employers to be better educated about M.E./CFS but with information provided with 'informed consent' (e.g. FULL P21 22-26). • That a designated healthcare professional should be identified as responsible for coordinating care for each adult or child with M.E./CFS (e.g. NICE P10 1.1.1.2) • The commitment to continuity of care (e.g. NICE P10 1.1.1.2) • We welcome the recommendation that assistance should be provided in negotiating the healthcare, benefits and social services systems • Much of the information presented in the key priorities sections of the guidelines is useful and the assumptions outlined in P208 6.44 establish the parameters of the guidelines and a best practice perspective. However, these need 	<p>Issue 2. Deep concerns</p> <ul style="list-style-type: none"> • The guideline refers to the NSF for Long-term Conditions. • The purpose and remit of the guideline is very different from that of the CMO report, which was not a document with the remit of changing practice. • The full guideline is a reference document. This is required for background and transparency. However, as you point out, the aim is to produce a document that healthcare professionals will read and use. The Quick Reference Guide (QRG) based on the recommendations in the NICE guideline will be published and sent to relevant healthcare professionals. As with other QRGs, it will contain only the advice needed to manage the condition and more digestible.
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					<p>to be placed at the beginning of a final document</p> <p>There are, however, deep concerns about the following points, which should be addressed as part of the consultation process.</p> <ul style="list-style-type: none"> • The guidelines should be placed clearly within the context of the National Framework for Long-term Conditions. • The context developed and expressed by the CMO report has not been properly reflected in the guidelines. • The guidelines are too long and cumbersome to be effective for the average practitioner and that it is doubtful that GPs will have a clear understanding of the research context on which recommendations are based. <ul style="list-style-type: none"> • The discrepancies between the long and the NICE versions are confusing. For example, the implicit 	<ul style="list-style-type: none"> • We have addressed inconsistencies where these occur. • We have made it clearer that no therapy is a cure and that different approaches should be tried. • With regard to CBT and GET we have placed them as part of an individually tailored programme. 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 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. • We have stressed throughout an individually tailored programme, however, this is a national guideline and we do have to give some detail about the programmes suggested. • We have revised the statement about
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					<p>rejection of the psychosomatic viewpoint given in the FULL guidelines (P202) is not included in the NICE version. This should be addressed.</p> <ul style="list-style-type: none"> • The guidelines need to stress that no individual therapy is proven effective for all patients and that there needs to be a portfolio of treatments and symptom control available appropriate to need. • The guidelines tend to place CBT and GET in isolation, and not as part of a comprehensive and individually tailored management package incorporating a range of necessary treatment relief. This is despite the commentary in the FULL guidelines executive summary (P2220-21). <ul style="list-style-type: none"> • A comprehensive and individually tailored management package 	<p>therapies of choice to reflect more accurately the intention of the GDG.</p> <ul style="list-style-type: none"> • The statements about CBT have been revised based on stakeholder comments. It is made clear in the recommendations that no intervention is a cure for CFS/ME. • We recognise that the evidence base is limited. NICE guidelines are based on the best available evidence at the time. The guideline will be revised regularly and new evidence reviewed. • We have made it clear that the trials did not generally recruit people who were severely affected. • Having reviewed the evidence, the GDG did not conclude that one diagnostic criterion was preferred. This has been
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					<p>regarding treatment and symptom control needs to be developed.</p> <ul style="list-style-type: none"> • The recommendation for CBT and GET as first therapies of choice for the mild and moderately affected implies a “one size fits all” management approach and negates other symptom management. Our survey found 51% strongly disagreed and 27.6% disagreed with the statement that CBT and GET should be therapies of first choice for those with mild to moderate M.E. • The statement in the FULL guidelines (P202) – that CBT is not directed at illness beliefs, the underlying disease process or is regarded as curative is omitted from the NICE er guidelines. • The scientific study of M.E./CFS is a rapidly developing field where little is known at present. There is a paucity of research across the field with available evidence limited and focused on particular areas .The recommendation of CBT and GET as therapies of first choice suggests that, of a range of possible therapeutic approaches, they are the two which emerge as being most effective, whereas the reality is that there has been very little 	<p>made clearer in the guideline. The Canadian criteria are based on a consensus.</p> <ul style="list-style-type: none"> • No evidence was found that clearly differentiated different management approaches by sub-groups. In addition, the view of the GDG was that severity may change for an individual. Therefore the approach taken was that any strategy should be individually tailored. The criteria for tailoring care are detailed. • We found little detailed information on recovery rates, what we found is included in the guideline. The GDG wished to be realistic but optimistic. • As previously stated, there is no evidence was found that clearly differentiated different management approaches by sub-groups. Once again, the guideline stresses an individual approach. We have stressed that people who are severely affected may need outreach care. • Your next three points address availability of resources and will be referred to the NICE implementation team.
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					<p>clinical trial activity involving other treatment or management approaches. There is, therefore, no basis for comparison. In our survey 46.9% strongly disagreed and 29% disagreed with the statement that there is 'clear evidence' supporting GET and CBT as therapies of first choice.</p> <ul style="list-style-type: none"> • The research used as a basis for the recommendations did not include individuals who are severely affected. • Diagnostic Criteria remains a contentious issue, with many questioning the omission of the Canadian criteria and noting the need to develop a more focused and mutually acceptable definition for patients and healthcare practitioners. • Sub groups are inadequately dealt with – e.g. mild and moderate are 'packaged' together. 	<ul style="list-style-type: none"> • With regard to terminology, please refer to the guideline, which has been revised in light of stakeholder comments. • 'Understanding NICE Guidance' will be made available at publication for patients. The guideline asks healthcare professionals to give patients the names of local and national groups.
					<ul style="list-style-type: none"> • There is an implicit assumption that most people will recover or improve 	

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						<p>relatively quickly, yet we know that a significant number have been ill for ten years or more. 49.6% of respondents to our survey have had M.E./CFS for over 10 years and 25.6% have been ill for 5-10 years.</p> <ul style="list-style-type: none"> • The extent of how badly impacted the severely affected are by this illness is not clearly articulated in either the long or the NICE guidelines, and information relating to their treatment is limited. This falls NICE of the stated aims of the guideline (FULL P21). 68% of those who responded to our survey defined their illness as 'severe' when it was at its worst. And when asked if they thought there were sufficient outreach services for the severely affected, 68.2% strongly disagreed and 18.7% disagreed. • There are not the available resources – specialist services, trained staff etc. – to ensure the guidelines are properly implemented. In our survey 76.8% strongly disagreed and 12.9% disagreed with the statement that there are sufficient specialist services for the treatment of M.E./CFS. • There is a recommendation that if specialist services exist in a region, 	<ul style="list-style-type: none"> • The 8 weeks given for responses was the standard NICE process. We agree that the timeframe is tight for everyone! • We note your comments about Internet access.
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						<p>financial cost does not seem to be a good reason for keeping someone with an uncertain diagnosis in primary care. (P115 2-5). How realistic is this recommendation given PCTs' financial resources and planning processes?</p> <ul style="list-style-type: none"> • The training required for healthcare professionals to establish a suitable level of expertise in caring for people with M.E./CFS must be much more clearly delineated. Inexperience in this area can have a profoundly damaging effect. In our survey 75.6% strongly agreed and 20.6% agreed that training requirements for health professionals caring for people with M.E./CFS should be clearly defined. • Many of our constituency were distressed by certain terms and language used in the documentation, as they felt that this indicated a lack of understanding of the illness and/or an unhelpful view of it. One example can be found in the FULL Executive summary, P21. This is ironic, given the emphasis the guidelines give regarding a universally accepted terminology. • While the emphasis on provision of 	
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						<p>information has been welcomed, our recent survey has shown that the vast majority of respondents (85%) self-sourced requisite information, rather than it being provided by healthcare practitioners. The role of the voluntary sector in information dissemination has not been properly noted in either the FULL or NICE er guidelines (NICE P6)</p> <ul style="list-style-type: none"> • Both the long and NICE versions of the guidelines presented the M.E./CFS community with issues - the timeframe for response was limited for people experiencing extreme fatigue - they simply cannot do things as quickly as most groups. • Please note that not everyone has access to the Internet. We are also very aware - partly as a consequence of developing on-line surveys for our membership – that many people with M.E./CFS have trouble using PCs for any significant length of time. It is, therefore, not a particularly appropriate mode of communicating lengthy or complex material. (See P 259 7.4.1). 	
SH	Association for Psychoanalytic Psychotherapy	1	FULL/NICE	General		please find attached the comments from APP (Association for Psychoanalytic Psychotherapy in the NHS) whilst we	Evidence was not found for the effectiveness of counselling for patients with CFS/ME.

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	in the NHS (APP)					welcome the guideline, we are concerned that NICE is misleading patients and health professionals on the question of CBT as the treatment of choice patients who suffer from CFS, and health professionals who try to care for them, are faced with a great deal of uncertainty in the evidence and unknowns in the causes and understanding of how to help this condition it is clearly unhelpful for people to be given misleading advice, or to have their expectations raised on a false basis: there is no evidence which supports CBT as having better outcomes relative to other psychological therapies; there is some evidence to support counselling having better outcomes, and being more cost-effective than CBT; there is also evidence that many CFS sufferers do not find CBT suitable as a treatment I have made these comments on the form itself, but I would be grateful if you would bring this to the attention of the GDG Chair also yours sincerely Jeremy Clarke NICE Lead, APP	
SH	Association of British Neurologists	1	FULL	General		I have been asked by [X] of the ABN to comment on this guideline.	Noted.
SH	Association of British Neurologists	2	General	General		I have been approached by a number of other stakeholders (patients' groups and charities) for my comments on this guideline because of my recognised	Noted.

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						expertise in this area.	
SH	Association of British Neurologists	3	General	General		The comments below represent my personal views	Noted.
SH	Association of British Neurologists	4	FULL	General		The draft guideline is fundamentally flawed because it presupposes certain interventions (CBT and GET) to be highly effective in CFS/ME for routine clinical use despite lack of adequate evidence	Please see the relevant sections of the section of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see relevant section of revised guideline.
SH	Association of British Neurologists	5	FULL/NICE	General		The guideline is also selective in its review of existing literature and is heavy influenced by psychiatric view of the condition. Indeed, it almost seems to the reader that a select group of psychiatrists with a polarised view of this complex condition is directing the development of the guideline from “behind the scene”.	The guideline was developed according to the NICE processes detailed on their website.
SH	Association of British Neurologists	36	FULL			There has been no review of General pain and post-exercise pain management	The search identified all evidence for patients with CFS/ME.
SH	Association of British Neurologists	39	FULL	General		The draft guideline reflects an incomplete and psychiatrically polarised view of CFS/ME	Please see the relevant sections of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see relevant section of revised guideline.
SH	Association of British Neurologists	41	FULL			The importance of appropriate diagnosis of CFS/ME from common psychiatric conditions has not been mentioned even once	The importance of recognition of concomitant psychiatric disease is stated and the importance of its treatment.

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SH	Association of British Neurologists	42	FULL			No where in this guideline the exclusion criteria for CFS/ME (e.g. psychotic depression, Generalised anxiety disorder, somatisation disorder) have been adequately defined and properly discussed	The importance of recognition of concomitant psychiatric disease is stated on p. 105, and the importance of its treatment on p. 186.
SH	Association of British Neurologists	44	FULL/NICE	General		The guideline needs to be thoroughly revised to reflect our current understanding of this condition rather than the supposition of the psychiatrists	Please refer to the guideline, which has been revised.
SH	Association of British Neurologists	45	FULL/NICE	General		It would be immoral for NICE not to recognise the huge dissatisfaction about this draft guideline among most patients, carers and clinicians	Please refer to the guideline, which has been revised.
SH	Association of British Neurologists	46	FULL			The GDG should not redefine CFS/ME to “fit in” CBT and GET as the recommended treatment options	The guideline has not done so.
SH	Association of British Neurologists	47	FULL/NICE	General		Listen to patients	Noted.
SH	Association of Young People with ME	1	FULL	General P. 26 General	Bottom, dark blue box	On a first scan read – the view that a busy clinician will have – the draft FULL Guideline is rather disappointing. It's length and complexity risks the busy practitioner looking only at the first piece of Management: 'Priority Recommendations' at the bottom of page 21. AYME believes the GDG wants to offer the patient choice, and to show supportive and open collaboration with their clinician as shown on page 86,	The guideline recommendations will be summarised into a Quick Reference Guide (QRG). This will be sent to relevant healthcare professionals and make the guidance more accessible. The full guideline serves as a reference document and will be available on the NICE website. The General Principles of Care details the principles of shared decision-making and patient involvement. It would make the recommendations very long and repetitive if this information was repeated in each

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					<p>4.3.6.3, but much of the wording elsewhere is very prescriptive and is at odds with patient choice. The first recommendation at the bottom of page 21 gives the impression there is no need to look further than CBT or GET for treatment options.</p> <p>Terminology - Activity Management</p> <p>The term 'Activity Management' as a management approach in its own right is relatively new, even though its principle is used in all the management approaches. We are all aware that the terms CBT and GET are very unpopular amongst the CFS/ME community and if faced with them patients will often turn away instantly. Historically CBT and GET were often administered most inappropriately, with patients encouraged to exercise well beyond their limits, causing severe relapses, especially in the severely affected. The fact that both CBT and GET, when delivered by a trained therapist, involve carefully graded activity management needs to be flagged up very early and loudly.</p> <p>When one is referring to Activity Management as a treatment approach in its own right, it needs capitals. Therefore page 26 bottom, dark blue box must have capitals on Activity Management.</p> <p>Whilst AYME understands that</p>	<p>recommendation. In the shorter QRG this should be clearer.</p> <p>Terminology – Activity Management</p> <p>The GDG recognises that there is a great deal of confusion about terminology. We agree that the terms 'Graded Exercise Therapy' (GET) and 'Cognitive Behavioural Therapy' (CBT) have 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. The programmes have 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 GDG considered not using the term GET but decided that this would cause further confusion.</p>
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					<p>evidence-based management approaches such as CBT and GET must obviously be included in a NICE document, we are concerned that other, less structured approaches, such as 'Activity Management', do not lend themselves to rigorous research, and have therefore been sidelined somewhat in research terms. Gentler approaches, away from Graded Exercise, are popular with children and young people because they allow more opportunity for vital social and or educational activities. They also suit the severely affected as they are much more individual and are very patient-centred, which is most necessary for this very ill group. There is undoubtedly some excellent CBT programmes in existence for mildly and moderately affected patients, but there is a risk that 'old style' CBT therapists will continue with outdated views if it's not clearly explained that careful, paced increase in activity levels, is the way forward. In either case, most of our very severely affected members have found these programmes to be totally unsuitable for their needs. AYME has young members who are so severely affected they are tube-fed, and who can faint if they raise their head from the pillow for more than a few seconds. The draft Guidelines does not address this very severe end of the illness spectrum, yet this is the most challenging form of CFS/ME and</p>	<p>AYME would like to see the term 'Activity Management' used as a recognised management programme</p> <p>Please see relevant section of revised guideline. It is now under the Specialist Management section and referred to in the section for people with severe CFS/ME.</p>
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					<p>could be helped greatly if these guidelines were to better describe the symptoms of and management techniques for very severe CFS/ME and the fact that it can affect children, not just adults, this badly. It is doubly important for clinicians to have information about the severe form of the syndrome in young children, as this helps prevent child protection concerns becoming an issue for the medical team, the family, and for Social Services. It would save a lot of pain, anger and resentment, not to mention public time and money in the unnecessary investigation and legal prosecution of cases, which to date have all been resolved as unfounded. We feel that sadly, the current draft does nothing to move the plight of these most difficult cases forward, and we would urge the GDG to address this issue specifically, to help prevent future CFS/ME families with very severely affected children experience the same unnecessary problems.</p> <p>Anecdotal evidence</p> <p>AYME would like the dearth of research evidence for the severely affected to be flagged up earlier and louder. We would also hope that more attention is given to the anecdotal evidence of Activity Management. The evidence-based research on management is often restricted entirely to CBT and/or GET,</p>	
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						which will bias management proposals if anecdotal evidence isn't included. It should be explained that research studies on CBT and GET only involve patients who are physically able to attend research clinics, meaning that few, if any, include the severely affected and/or children. In addition, the population studies are small. In the absence of research on the popular Activity Management, one must take notice of anecdotal evidence from patients, or at least offer a more Generalised first recommendation (see below).	
SH	BRAME Blue Ribbon for the Awareness of ME	1	FULL/NICE	General		Whilst we acknowledge and welcome that there is a need for guidelines for good practice from NICE, these documents in their present forms are totally unacceptable. The illness described within these bears no resemblance to ME/CFS, and the recommendations, we fear, will harm more patients than they help. Given that the Hippocratic oath begins with 'first do no harm' – this shows that this document is unusable.	Noted.
SH	BRAME Blue Ribbon for the Awareness of ME	2	FULL/NICE	General		Why has "Encephalopathy" been used here, as 'Myalgic Encephalopathy' is not recognised by WHO or the DoH, and is not used within the patient population? Those patient groups which flirted with this terminology have now all reverted back 'Encephalomyelitis', especially given the research evidence	The title was in the remit for the Department of Health.

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						now available proving inflammation within the Central Nervous System. Therefore 'Encephalopathy' should not be used within this document and should be removed throughout.	
SH	BRAME Blue Ribbon for the Awareness of ME	3	FULL/NICE	General		<p>In the opening paragraph the first thing that should be mentioned is that ME has been listed and recognised as a neurological condition by the World Health Organisation since 1969. It was officially recognised as such by the Royal Society of Medicine in 1978, and by the Department of Health since 1987. How can you write clinical guidelines which ignore the fact that ME and ME/CFS are classified as neurological illnesses, surely this is vital for the doctors to understand? Not to mention this fact, belittles the illness and the neurological and central nervous system symptoms in particular.</p> <p>The CDC states that "<i>CFS can be as disabling as multiple sclerosis, lupus, rheumatoid arthritis, congestive heart failure and similar chronic conditions</i>". The severity of the illness has also been likened by researchers/doctors to AIDS and cancer.</p> <p>Given the WHO classification of ME/CFS as a neurological illness, and the CDC recognition of the severity of the illness in comparison to other medical conditions, how has all this been ignored?</p>	Please see the relevant section of revised guideline where this is discussed.

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SH	BRAME Blue Ribbon for the Awareness of ME	4	FULL/NICE	General	<p>Not to give credence and recognition of the Canadian Guidelines, the most comprehensive clinical diagnostic criteria, and which provides a wealth of evidence based advice, created by worldwide experts on these illnesses is diabolical.</p> <p>To even mention the Oxford criteria is an insult, as these criteria include chronic fatigue from whatever source and explicitly exclude those with the neurological symptoms suffered by patients with genuine ME or ME/CFS, the very patients which you are supposed to be describing and advising on. The Oxford criteria have led to a wealth of research which is flawed and invalid, and on which you have based the management part of this guideline. The Oxford criteria have enabled ME/CFS to basically become a dustbin diagnosis for anyone with unexplained fatigue and maybe one or more symptoms.</p> <p>The Canadian guidelines ME/CFS diagnostic criteria allows for people to be correctly diagnosed with this illness and managed accordingly, but it also gives people who do not fit all the diagnostic criteria a diagnosis of idiopathic chronic fatigue syndrome, which still allows people to be continually assessed and managed by both GPs and clinics, whilst allowing a distinction between the two groups. We</p>	<p>While there is some good evidence-based advice in the Canadian guidance that is included in this guideline, much of it is consensus-based rather than evidence-based.</p> <p>Please see the relevant section of revised guideline where the diagnostic criteria are discussed.</p>
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						are not saying that the clinics, and GPs, cannot treat/manage everyone within the clinics, but that a distinction should be made between those who fulfil the diagnostic criteria and those that do not. However by trying to produce a guideline that also allows for the treatment of those who do not fulfil the diagnostic criteria you are in essence producing a guidance that is not suitable for those who actually have the illness. Therefore it is not fit for its designated purpose and is extremely unhelpful, not only for the patients, but for all medical professionals.	
SH	BRAME Blue Ribbon for the Awareness of ME	5	FULL/NICE	General		Most of the symptoms are medically explained through current bio-medical research evidence showing ME/CFS to be a neurological condition with a genetic susceptibility eg. Grey/white matter reduction and reduced blood flow to the brain as well as damage to the HPA axis to name just four. Anyway, why do “medically unexplained illness/symptoms” have to go hand in hand with psychiatry/hysteria when all it means is that, as yet, scientific/research has not come up with the answers? Why are the lessons of Multiple Sclerosis being so readily forgotten? MS was for years a “medically unexplained illness” labelled as “hysterical paralysis”, until science medically explained the illness and symptoms.	Aetiology is beyond the scope of the guideline.

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SH	BRAME Blue Ribbon for the Awareness of ME	6	FULL/NICE	General	<p>Terminology/language:</p> <p>The terminology and language used throughout the document reinforces the negative stereotypes still held by many in the medical profession about ME/CFS. There is constant belittling of patients and their symptoms, as well as constant questioning of the patients willingness to improve – this is insulting.</p> <p>The only real, recognisable, description of the illness can be found within the patient testimonies, the one section which medical professionals will probably not read. They are, therefore, being left with the view that ME/CFS is a condition which can simply be treated by exercise and a change in the patient’s belief that they are ill. This document was supposed to rid us of these prejudices, not to reinforce them and allow for multitudes more patients to be harmed. With the exception of the patient testimonies, the guidelines convey the impression that patients with this illness are people who are a bit tired and are perceived as malingerers who do not really want to get better. If the writers/doctors actually knew anyone with the genuine condition, and actually took time to set aside their prejudices and listen to them would know that this could not be further from the truth. People with ME/CFS are extremely ill and are hungry for a life</p>	Please see the relevant sections of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see relevant section of revised guideline.
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					<p>that their body denies them.</p> <p>There is a considerable body of evidence which shows that all patients want to get well and aim to return to normal activities. Whilst holding on to hope of remission, they must also face reality that, this might not be possible, this does not mean that they do not 'want' to get well. To refuse a treatment, in particular exercise regimes, is not 'fear of activity/exercise', rather an understanding of the abilities of their body and a consciousness that exercise, probably through experience, causes severe relapses. I would say that all patients push themselves. By learning their personal limitations, they know what levels can be achieved without relapse. This means that the true expert of ME/CFS is the patient themselves, and it should be recognised by medical professionals, instead of enforcing their views of what they believe is right, based on flawed evidence, which is both undesirable and counter-productive for the patient.</p>	
SH	BRAME Blue Ribbon for the Awareness of ME	7	FULL/NICE	General	<p>A recommendation needs to be made for research into the use of anaesthetics for people who have ME/CFS, particularly the severely affected. Given the high sensitivity, and potential damage, that can be done when using anaesthetics, advice is needed by doctors as to the safest anaesthetics which can be used eg. non-adrenaline</p>	<p>The GDG is limited in the number of research recommendations it can put forward. Those in the document were those that they prioritised.</p>

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						based, or lower histamine level anaesthetics. Advice also needs to be given on the use of oxygen during General anaesthetics (see research by Paul Cheney, FULL, 139-140, GET)	
SH	BRAME Blue Ribbon for the Awareness of ME	8	FULL/NICE	General		There is no mention within the document, nor a description of, the three stages of any chronic condition, and how they affect the sufferer and the way they are treated. Each patient has to go through, and jump between, the different stages of the illness, the acute (symptoms are developing and evolving), the chronic (illness pattern is clearer) and the recovery stage (patient's body is more able to tolerate an increase in activity). The way you would manage an ME/CFS sufferer, who may be mildly affected but in the acute stage of their illness, is completely different to how you would manage the same mildly affected sufferer in the chronic or recovery stage of their illness.	No evidence was found to support a different approach to management based on these groupings.
SH	BRAME Blue Ribbon for the Awareness of ME	9	FULL/NICE	General		It is very evident throughout this document that the patients, and their testimony/experience and expertise of their illness, is being ignored, or just given lip-service. Given that the Government is so intent on patient partnership/patient-led NHS, it is extremely sad to see this ignored, for the "medical professionals know it all" approach.	There were three patient representatives on the GDG, the questionnaire and the stakeholder consultation.

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SH	BRAME Blue Ribbon for the Awareness of ME	10	FULL/NICE	General	There is a lack of acknowledgement of the presence of sub-groups and that more research is needed into this. BRAME has found that those sufferers who contact us with more predominantly gastro-intestinal problems are more likely to go into remission, or improve, than those whose symptoms are primarily neurological/central nervous system, why is this type of information on sub-groups being ignored? The GDG had the Jason et al paper on sub-groups which says that we can move no further forward with this condition until research is done into sub-groups. There is a mention that this is an umbrella illness and yet no call for research into, or recognition of sub-groups, and how this changes the way the illness is managed.	While it is generally recognised that it is heterogeneous, the evidence does not allow distinctions between sub-groups with regard to management of the condition. The GDG is limited in the number of research recommendations it can put forward. Those in the document were those that they prioritised.
SH	BRAME Blue Ribbon for the Awareness of ME	11	FULL/NICE	General	There is so much documented evidence out there which has been compiled by three of this country's most eminent and committed ME doctors, which are being ignored: Dr Melvin Ramsay wrote the seminal work on the Royal Free Disease Outbreak, which indicated the pathogenic nature of the illness, and with Dr Elizabeth Dowsett created the first diagnostic criteria for ME. Dr Dowsett has written numerous papers over fifty years about ME and	Noted.

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						<p>has dedicated her life to caring for those affected by the illness and to disseminate information about the bio-medical nature of the illness (Dr Dowsett is medical advisor to BRAME).</p> <p>Dr John Richardson also worked with Dr Ramsay. He also dedicated his life, until the week before he died, to his ME patients. He wrote an excellent documenting his work on this illness and the evidence he compiled from this patients and this should be read and taken notice of: "Enteroviral and Toxin Mediated ME/CFS and Other Organ Pathologies". Dr Richardson also founded the Nightingale Research Foundation, based in Newcastle, which is dedicated to bio-medical research and has an annual conference for doctors and researchers.</p>	
SH	BRAME Blue Ribbon for the Awareness of ME	13	FULL/NICE	General		<p>We have used the term ME/CFS throughout the remainder of this response to keep in line with NICE 's terminology however BRAME believes ME and CFS to be two different illnesses which share similar symptomology as recognised by the CDC. However the lines between the two nomenclatures have been blurred in recent times due to medical journals requesting all research into ME uses the nomenclatures CFS or ME/CFS only.</p>	Noted.
SH	BRAME Blue	14	FULL/NICE	Gene		One of our patrons had the following	Noted with thanks.

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	Ribbon for the Awareness of ME			ral	<p>comments to make on the NICE guidelines:</p> <p><i>"I have very careFULLy studied the contents of your Draft CFS/ME Guideline and am, to put it mildly, amazed that so much time and effort can have been expended in order to produce such an unsatisfactory document. There seems to be no indication whatever that members of the Guideline Development Group have even begun to scratch the surface of understanding of the problem which they are tasked to resolve. Frequently, the use of inappropriate language in relation to CFS/ME patients and their illness is manifest. The Group have simply perpetuated the myths that have been around for many years and have done so much to damage the prospects of return to any kind of normal life for CFS/ME sufferers.</i></p> <p><i>I doubt that you can have avoided being aware of the tide of opposition to the Draft Guidelines from members of the ME community. I wonder whether you can comprehend just how hurt and insulted they feel? For years they have been denigrated and denied medical treatment and benefits that the rest of our population expect when they fall ill. They have pinned their hopes on the integrity of NICE , hoping that, at last, someone with influence will listen to them and recommend decent medical,</i></p>	
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					<p><i>financial and social care provision. Instead they find that all the old prejudices are recycled; their predicament is watered down by the inclusion of people who do not suffer the same illness: there is still an insistence that, like rats on a treadmill, they can be 'trained' to respond as certain professionals who, for some strange reason have been accorded undue deference, think they should. That age-old instruction to doctors to: 'Listen to the patient: they will probably tell you the diagnosis.' seems to have been forgotten in this welter of almost incomprehensible paperwork."</i></p>	
SH	BRAME Blue Ribbon for the Awareness of ME	15	FULL/NICE	General	<p>One of our medical advisors had the following comments to make on the NICE Guidelines:</p> <p><i>"I have read the NICE draft guidelines and the comments from BRAME. To me the matter represents the sense of patient and carer frustration I see on a daily basis in my own clinical practice. My clinical practice started some 25 years ago and represents 7,000 new patient with many individuals followed up to the present day.</i></p> <p><i>Our service sees some 400 new patients per year and would see more if our host PCT did not have strict service level agreements with PCT's in terms of patient numbers. The annual prevalence for the population covered</i></p>	Thank you for your comments. These are addressed specifically below.

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					<p>would suggest that we have a patient pool of 6,000. Many of these are unrecognised or probably treated by their GP's and tend to be at the milder end of the spectrum.</p> <p>Much of the available literature with regards to management, especially GET/CBT, is limited to less than 3% (GET) of the annual prevalence of this condition. In some papers the method of patient selection is unclear and has been subject to exclusion eg coexisting secondary depression and significant sleep disturbance.</p> <p>Nowhere in the document does it indicate that individuals with low levels of activity have poor concentration and memory and are unlikely to be able to engage with a CBT therapist for instance for 45-60 minutes and may consume much of their energy just attending a clinic. For this reason I always audio tape consultations as many patients are exhausted physically and cognitively after 30 minutes or so.</p> <p>The reluctance to accept the biomedical model suggested in the Canadian document is unhelpful. Neuro-endocrine mechanisms are regularly challenged as not making sense. The determinants of blood flow/pressure include VIP, substance P, neuropeptide Y and calcitonin gene related peptide (CGRP). CRH is also implicated in</p>	<p>Issue: Poor concentration and memory</p> <p>Audio-taping is recommended where there is poor concentration and memory.</p> <p>Issue: The biomedical model of Canadian Guideline</p> <p>Aetiology is beyond the scope of the guideline.</p> <p>Issue: Investigations</p> <p>The GDG would agree that these investigations are useful in individual circumstances and it is advised that investigations should be based on the individual. The GDG did not think that they should be generally recommended for all patients.</p>
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					<p><i>temperature control and so on.</i></p> <p><i>Ferritin, folate and B12 are useful in the more severely affected patients and others who maybe using various exclusion diets. Sub clinical iron deficiency in those with heavy menstruation can be detected. In mixed mild deficiencies ie iron and folate the MCV maybe normal and the associated anisocytosis can often only be picked up from a high RDW which is often not included in the reports to the clinician.</i></p> <p><i>If abnormalities are found they should be repeated as clinically indicated.</i></p> <p><i>The advent of new symptoms should be assessed and if necessary further screening to eliminate other underlying or new conditions should be carried out. There are reports of fatalities due to complications of this illness.</i></p> <p><i>Significant numbers of patients are extremely sensitive to medication some to the point where few, if any, medications are tolerated. Treatment should always commence with small doses in this group. One has to be open minded and have access to a full range of medication. What works for one patient will not necessarily work for another. Further, some approaches to treatment do seem to have an impact be it placebo or otherwise. Patient selection has to be taken with care but a small number of patients can respond</i></p>	<p>Issue: Advent of new symptoms</p> <p>We have noted the need to assess new symptoms and investigate as appropriate</p> <p>Issue: Sensitivity to medication</p> <p>The guideline states that some patients may experience this and sensory hypersensitivity but no evidence was found that this is generally the case.</p> <p>Issue: Relapses</p> <p>Some of the possible causes have been added to the guideline.</p>
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					<p><i>to antivirals eg recurrent zoster.</i></p> <p><i>It is important to realise that some relapses following over activity, disintegration of sleep pattern and intercurrent infection, especially the later, can be profound and long lasting. In these the whole process of rehabilitation can be slow over months and sometimes longer if at all.</i></p> <p><i>You have rightly highlighted the impact on carers of the severely affected but have not stressed the problems with sensory hypersensitivity. This includes working in darkened rooms with token lighting or the fact that houses are not 'hoovered' for years due to hyperacusis. Similarly a few individuals are sensitive to commonly used cosmetics and household chemicals.</i></p> <p><i>The vast majority of the patients when seen will have activity levels of less than 20% of normal on bad days (often bed/sofa days) and less than 30% of normal activity on a better day. Most of this group (95%) will fulfil the Canadian guidelines on diagnosis as well as CDC 1994.</i></p> <p><i>Prognosis in this illness is Generally regarded as poor. At any one time we have 20-25 severely affected patients – these are bed bound and dependent on parents/spouses and often others for their care. Several are subject to enteral feeding. Each patient is unique</i></p>	
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						<i>and one has to use all of ones pharmacological skills to try and alleviate symptoms. For many the simple process of opening their bowels especially if they are constipated will leave them exhausted for 2-3 days or longer. Some broad guidelines on day to day management would be a sensible addition to this document.</i>	
SH	BRAME Blue Ribbon for the Awareness of ME	193	FULL	General		<p>Whilst we do not agree with, nor advocate, GET for the ME population, we hope that any therapist will fully inform patients of all the scientific evidence and risks they are putting on their health by undertaking a course of GET.</p> <p>It is wrong to talk of recovery, as this implies that you can cure people. It is well documented, including throughout the CMO Report (2002), that there is no cure for ME/CFS. Patients may, over a long period of time, make a substantial improvement, or go into remission, but they are always at risk of having a relapse/set back.</p> <p>Advocates of CBT/GET say that you should be positive for patients, but patients have to live with reality and for therapists to give false hopes can have a very negative effect and impact on patients when a relapse occurs.</p>	Noted with thanks.
SH	BRAME Blue Ribbon for the Awareness of	266	FULL/NICE	General	Conclusion	We cannot condone or endorse these guidelines. They are completely unacceptable and must be rewritten.	Please see substantially revised guideline.

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	ME					<p>They fail to give any accurate and usable information and advice about the reality of the illness; how to diagnose, how to manage and how to monitor patients. Given that this is what the guidelines are for – they have failed at every turn.</p> <p>Both the FULL and the NICE guidelines, along with any other guidance based on these, need to be COMPLETELY REWRITTEN.</p> <p>As all the evidence we have included in our response proves, THESE GUIDELINES ARE COMPLETELY UNACCEPTABLE.</p>	
SH	BRAME Blue Ribbon for the Awareness of ME	267	FULL/NICE	General	Recommendations	<p>In conclusion BRAME makes the following recommendations:</p> <p>That these guidelines:</p> <ol style="list-style-type: none"> 1. Are completely rewritten to take into account all the bio-medical and patient evidence. 2. Acknowledge the WHO ICD classification G93.3 of ME and ME/CFS as neurological illnesses, which are recognised by the Department of Health. 3. Acknowledge that CFS/ME (as interpreted by UK psychiatrist) is different from ME/CFS (as outlined in the 2003 Canadian Guidelines) – there is a great difference between the two. 	Please see substantially revised guideline where many of your criticisms have been addressed. However, much of what you suggest is beyond the scope of the guideline and the guideline process.

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						<ol style="list-style-type: none"> 4. Acknowledge the severity of the illness, and its symptomology, and include more of the severe neurological symptoms. 5. Acknowledge that the wealth of bio-medical evidence proves that this is a physiological organic illness, even though the precise aetiology and pathogenesis is not yet known. 6. Call for urgent, and substantial, government funding into the bio-medical aetiology and pathogenesis of ME and ME/CFS (as was done, and failed to be acted upon, following the CMO Report on ME/CFS 2002). 7. Call for no more funding to be given to the psychiatrists and psychologists – this is a physical illness and no more money should be wasted on these inappropriate behavioural approaches, in particular CBT and GET. 8. Acknowledge that this is not, nor has it ever been, a psychological, psychiatric, behavioural, somatic or functional condition, nor is it a chronic fatigue state. 9. Remove from the guidelines all the psychiatric/illness belief insinuations and the inappropriate and insulting language and terminology used throughout. These only serve to
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						<p>reinforce the erroneous negative stereotypes of ME/CFS.</p> <p>10. Recommend the immediate removal of the Oxford Criteria, and that it stopped being used in all future research.</p> <p>11. Recognise that research based on participants selected using the Oxford criteria are flawed, and the results cannot be used and extrapolated for the ME/CFS patient population.</p> <p>12. Remove the new diagnostic criteria NICE have created.</p> <p>13. Call for the countrywide utilisation of the Canadian Clinical Guidelines (2003) and for the use of their diagnostic criteria in both a clinical and research setting.</p> <p>14. Acknowledge sub-groups, and call for more research into this area – as Jason et al (1999) says in his paper on sub-groups, until these can be discovered, and acknowledged, we can move no further forward.</p> <p>15. Acknowledge that CFS is used as an umbrella term for many, as yet, identified and unidentified conditions which share similar symptomology, and call for further research into this.</p>	
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						<p>16. Acknowledge that no-one should be forced into management plans/treatments – and that non-participation does not prejudice against further care, benefits and insurance claims.</p> <p>17. Acknowledge that there is no cure for ME/CFS, nor is there a management suitable for all.</p> <p>18. Acknowledge that patient evidence shows that CBT and GET are the management of 'last choice' not first. These should be removed from the document altogether, as patient evidence shows them to be harmful/unhelpful.</p> <p>19. Acknowledge that the use of CBT utilising illness beliefs, targeting the causation of the illness, is unacceptable.</p> <p>20. Acknowledge the damage done by exercise and GET programmes – particularly the unbelievably dangerous advice to raise heart rates/aerobic exercise, taking into account all the bio-medical and patient evidence showing this is dangerous.</p> <p>21. Acknowledge that patient evidence – the truth always lies with the patient, often at a cellular level – so do not ignore what they have to say. This evidence is vital and</p>	
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						<p>should be utilised, particularly where clinical based evidence is not available.</p> <p>22. Identify, and call for the abolition of, the erroneous forcible removal and sectioning of children and adults by doctors who disbelieve in the physical nature of this illness.</p> <p>23. Call for research into the mortality rates, and that ME and CFS should be listed on death certificates, allowing for epidemiological research into the true numbers of death from this illness, therefore allowing for red-flags to be produced, and particular sub-groups to be identified as being at risk.</p> <p>24. Call for ME/CFS to be a notifiable illness, along with the level of severity/functionality, which would help to identify some real epidemiological statistics, and allow for proper provision to be made by the NHS.</p> <p>25. Call for proper provisions to be made for severely affected, but particularly the long-term severely affected. There are so many studies showing the extremely poor prognosis for this group, along with a lack of care and services.</p> <p>26. Recognise that the nature of this</p>	
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						<p>illness is the same whether you are a child or an adult, the only difference being the length of time needed for symptoms before diagnosis and more sensitivity towards management.</p> <p>27. Call for the end of always including child/family psychiatrists/psychologists for children – they have a neurological illness – this is not appropriate.</p> <p>28. Recognise that there should be no clinics run based on the erroneous behavioural/psychiatric principle, and that these should be taken over and run by those doctors who truly understand the illness and would run it along the bio-medical line.</p>	
SH	BRAME Blue Ribbon for the Awareness of ME	268	FULL/NICE	General	Concluding Comments	<p>YOU MUST LISTEN TO THE PATIENT EVIDENCE AND BIO-MEDICAL RESEARCH.</p> <p>YOU MUST URGENTLY REDRAFT/REWRITE THESE GUIDELINES TO REFLECT AND ADDRESS THE REAL ORGANIC ILLNESS ME/CFS IS.</p>	Noted.
SH	BRAME Blue Ribbon for the Awareness of ME	269	FULL/NICE	General	Concluding Comments	<p>If after reading all the comments and evidence that we, and other groups and individuals have sent to NICE , you are still in any doubt about the harm done by medical professionals, DWP and social services taking the psychiatric/behavioural approach, rather</p>	Noted.

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					<p>than the bio-medical approach, to this illness, please go back and read [X]'s letter (FULL, 107 & 108: Box 2), and the following letter from [X], who also sadly lost her [X] to ME. Following her comments are some of the testimonies she has collected from those affected by ME/CFS.</p> <p>“NICE Draft Consultation Document</p> <p>M.E. is a severe illness which has a devastating effect on sufferers and their families/carers. NICE has the opportunity to alleviate the pain, isolation and grief felt by sufferers but it appears to be taking no notice whatsoever to the voice of the patient groups. The NICE group appears to be over represented by those with a mental health bias. In the past, those suffering from MS, Parkinson's, and Epilepsy were considered to be suffering from mental illness. At present ME sufferers are treated in the same fashion.</p> <p>Numerous surveys have found that Graded Exercise and CBT have a detrimental effect on sufferers yet, NICE are recommending that these treatments are the most effective.</p> <p>The Government wishes to lower the unemployment figures. . Sufferers are dependant on receiving Benefits in order to live so those refusing such treatment will have their Benefits cut. However to force an ME sufferer to</p>	
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					<p>undertake Graded Exercise programmes will cause many to relapse – the moderately ill will become severely ill.</p> <p>Many ME sufferers will be forced to make the choice of undertaking a Graded Exercise programme, having a severe relapse but maintaining their benefits, or refusing the treatment, which they know to be detrimental to their health, losing their benefits and finding it impossible to manage financially.</p> <p>The current manner in which ME sufferers are treated has had a devastating effect on my family. [X], a long-term ME sufferer, died by her own choice on [x] - her [x] birthday. Her condition was in fact better than it had been for many years, but she was due to re-apply for her DLA benefit, which enabled her to live an independent life. The stress associated with such applications caused major relapses.</p> <p>At previous applications she had been treated in such a horrendous and disbelieving manner, that she said that she would never ever apply again. Her course of action meant that she never had to.</p> <p>There appeared to be no statistics of ME sufferers who have either committed suicide or have felt suicidal. Following her death, I asked people to</p>	
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					<p>contact me to let me know if they had felt suicidal, as a result of pain, isolation, helplessness, benefit issues, or grief for the life they had lost as a result of this cruel illness. The response was overwhelming. I attach extracts from just a few of the replies, which makes extremely harrowing reading. It gives a clear indication of the manner in which ME sufferers are currently living.</p> <p>Money should be made available to find the cause of this illness and, in particular, a diagnostic test. If such a test was found, ME Sufferers would no longer be treated with such disbelief and hostility.</p> <p>It is illogical for NICE to recommend a treatment for an illness when the cause has not yet been found. Will those whose condition will deteriorate as a result of the NICE Guidelines be able to claim compensation? Rather than saving money, the current recommendations could cost the Government far more in the long term.</p> <p>It is my opinion that the current NICE guidelines should be scrapped.</p> <p>BRAME - These people below do not have depression, not in the clinical sense, they may have reactive depression. Clinical depression means</p>	
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					<p>that even if your circumstances changed you would not stop being depressed – these people have reactive depression – if you could give them belief, support, empathy and care, if you could stop the battles and scepticism/disbelief which they are constantly faced with by medical professionals and the DWP, if you could take away the intense unrelenting pain they are in – they would, if they could, be jumping for joy – well if not, at least they would be able to cope with and start to live their illness and have a better quality of life.</p> <p>Extracts from register compiled by [X], highlighting the severity of this aspect of the illness:</p> <p>“[X] died by her own choice, on her [x] birthday [x] She had been an ME sufferer for many years and had experienced tremendous problems when applying for benefits. It is difficult to apply for DLA with an illness which is invisible, and fluctuates in severity from day to day. She began to feel that she was a burden on her family. Her ME was actually getting a bit better but she was no where near well enough to return to work. She vowed she would never apply for DLA again, as she had been treated in such a horrendous manner. Her action meant that she didn't have to. The police did try to get her partner for 'Assisted Suicide'. We</p>	
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					<p>miss here every day but respect her decision.”</p> <p>“[X], died as a result of an overdose of Morphine. It was his third attempt to end his life as he was experiencing such a low quality of life and was in constant pain. His wife [X], who had nursed him for many years was charged with manslaughter, but thankfully she was acquitted”</p> <p>“[X], an extremely affected sufferer for [x] years, chose to die. She stopped eating. It took her 56 days to be released from her pain. Her death is one of the few deaths to be attributed to ME. “</p> <p>“ME sufferer 'took own life' – inquest</p> <p>An ME sufferer took her own life after becoming frustrated at a lack of medical help for her condition, a [x] inquest heard.</p> <p>....., aged [x], hanged herself outside her family home.</p> <p>The inquest heard she had made previous attempts to end her life. She had been unable to work because she had suffered from chronic fatigue syndrome for [x] years.</p> <p>She had shown some improvement after treatment at the UK's only ME hospital in Essex, but had been refused funding by the local health authority for</p>	
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					<p>further treatment there and her condition deteriorated. She later cut her wrists and two days later she was admitted to a psychiatric ward at [x] hospital - part of a link up between health authorities in [x] and [x]. She discharged herself on [x] and died three days later. Her husband told the inquest: "She meant to take her own life. She'd had a relapse and she totally despaired of anybody listening to her or understanding her illness. Most GPs treat it as depression - which it isn't, in my opinion. We'd had the local authority refusing funding, doctors saying she was and wasn't depressed and promises made but not carried through."</p> <hr/> <p>"I am sorry to say that I warned and begged the DLA to change its attitudes to ME from 1992 to 1999, during hearings, letters, phone calls, via ministers, party leaders, etc. I warned and warned that people would be dying because of their inhumane treatments of us, that suicides would result. My heart is so profoundly pained that the humanity wasn't available to listen, learn and avoid. I can make information available to anyone who needs it. Eg: In [x] while I was in hospital for weeks due solely to complete collapse brought on by years of refusals to grant me my</p>	
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					<p>legal DLA rights and the care that bought, DLA workers were handing my forms round the offices laughing at the answers - reason? I was so sick they didn't believe the answers were real and thought the facts written were comedy fiction, so it became a departmental joke. I was told that because I was living in body circumstances that (they thought) no one could live through I must be making it up. Everything I'd written was true and was later legally proved. By [x] we were still arguing. This time I could still get no DLA and it wasn't until I was admitted into hospital for up to 6 months that they relented - I actually entered the hospital with over a third of my suitcase FULL of the legal papers I was going to need to take to a DLA hearing I was then booked to be at going straight from my hospital bed.</p> <p>Had I endured this and they'd have learned it would have been OK. It doesn't surprise me that they didn't learn. The shock of the real costs is staggering. Anyone remember when the Child Protection Agency first started targeting the responsible, paying up fathers and some committed suicide? Farmers killed themselves over the results of the foot and mouth crisis. Government policies/departments can be loaded guns and the absence of continuing responsibility is terrifying and nauseating."</p>	
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					<p>“I developed M.E. after encephalitis in [x]. At that time I was a FULLtime [x],. It was devastating for all of us. I suddenly was too ill to care for myself let alone continue to work. I’m now [x], [x] years plus into the illness and it has been a nightmare. [x] children now live and work away, first, the illness makes coping with *any* sort of stress and upset much harder. In my case I had the most horrendous neurological pain and I was bedbound with it from [x] to [x]..</p> <p>In [x] when I was still bed bound, my DLA care was turned down as a doctor at my surgery thought I should have been much improved after [x] years ill! The stress of going to tribunal, with help, was terrible, I could not see, hear or speak properly and my advocates were impatient as everything took so long. My carer was advised to take me, wrapped up and supported in a wheelchair to the tribunal so the panel could see how ill I was. I got higher rate care in five minutes but it took more than a year to get well enough to leave my bedroom again. There were many times I despaired of getting any normality to my life again and I felt a big nuisance to everyone.....</p> <p>Currently I am waiting for a DLA doctor to visit. The first doctor did not turn up for the arranged appointment. Age concern helped fill in my forms they say</p>	
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					<p>I'm entitled to get higher rate care. I get anaphylaxis shock from severe chemical allergies and blackouts from dysautonomia and often need someone to stay overnight in case I need to get to medical help. I'm terrified the DWP will put me through the hoops because they see "M.E." on my dx. My health just won't allow me to cope with a tribunal. Yet I really need the care. Currently my daughter is paying for private carers and a lot of medical bills and she can't go on doing that. There is so much pressure.</p> <p>I am a Christian and I am sure that has been the main influence on my not taking my life, but it has been very hard. I have even planned what I was going to do, very coolly, no one around would suspect as I would want it to succeed. I cannot be a proper mother to my grown up children, more a burden now, not the lively, clever mum who brought them up. I often can't chat with them on the phone, can't visit to share a bit of their lives."</p> <hr/> <p>"My wife's response to the question would she have ended her life was that without myself and her sister around to help 24 hours a day she thinks she probably would.</p> <p>The accumulation of disbelief from all sectors of society. Doctors are the worst. Especially the one's who work for</p>	
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					<p>the Benefits Agency and the actual Benefits Agency themselves. The constant pain and all the associated medical problems.”</p> <hr/> <p>I think about suicide every single day, because, for me, my life has ended. I know how to do it, have more than enough pills, and intend to leave my body in as 'tidy' a condition as possible. I have no 'future', apart from a life of pain and exhaustion and poverty.</p> <p>My <u>only</u> reason for living is my husband, who has [x]., and he has begged me not to kill myself, because he still wants to go on living for the time being, and will not be able to manage if I go.</p> <p>I was a [x] but had to give up work [x] years ago when I could no longer understand the documents on my desk - even ones I had drafted! I have spent the last [x] years lying down 22-23 hours a day. My life is hell. I cannot read a newspaper, nor can I watch TV, because I quickly succumb to 'brain fog'.....</p> <p>We struggle to exist on meagre benefits - I was denied an ill-health pension by my firm, on the grounds that M.E. is not 'life-threatening', like cancer. I could not afford the legal fees to appeal against the decision, and my mind has just</p>	
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					<p>'gone', so I could not do the necessary work myself</p> <p>The only contact we have with other humans is when we manage to get to the supermarket, or my husband sees our G.P., and we are totally shattered afterwards. It takes us a week to recover from such 'outings'.</p> <p>When I told the G.P. how I was feeling about suicide, he referred me to a psychiatrist. This man confirmed that I was 'sane', but I was depressed because of ME. I tried anti-depressants for a year. They may have elevated my mood, but did nothing for any of my other symptoms, and, as I was now getting severe side-effects, I have stopped taking them.</p> <p>What is also hard about ME is that no-one seems to understand how ill I feel. I look almost 'normal' apart - from pallor and the circles under my eyes. I can still walk around the supermarket, and I can still drive. People don't see how I really am - collapsed on the floor of the lounge, barely able to make it to the kitchen to prepare our meals, and, as for housework - forget it. I hate living in a tip, but we cannot afford a cleaner. Some people, including relatives, think that I may just be trying for 'sympathy', because my husband has a 'worse' disease than I. Fortunately the psychiatrist ruled that out. What they</p>	
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					<p>don't understand is that only a lunatic would willingly give up a very well paying job just to lie on the floor and reduce her husband to penury.....</p> <p>In summary, what makes it difficult for me is:</p> <ol style="list-style-type: none"> 1 hostility and ignorance about the disease from medical professionals and DWP; 2 poverty; 3 social isolation; 4 the effects of ME itself.” <hr/> <p>“I have been ill since late [x] and in early [x] my health deteriorated dramatically - I went from being semi-housebound to being largely bedbound and my pain became severe. I was no longer well enough to go for the limited outpatient treatment I had been getting and there was nothing to replace it. Over the next 12 months we (mainly my family) battled with the health authority who promised treatment at home, then said I needed to go to a specialist inpatient unit - but the promises never came to anything. By this stage my mental fatigue was so severe that I could only manage to talk for less than two minutes, and could only manage that with an hours rest before and after. It was terrible not even having the energy to talk with my wife. I</p>
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					<p>was going down hill, my pain was ever-present, there was no prospect of help and I became very depressed. I suspect that some of this will be familiar.</p> <p>Gradually, I began to contemplate suicide. It wasn't that I actually wanted to kill myself so much as being dead seemed a much option better than living as I was; a much more peaceful option too. And I started to think about the practicalities, whether my insurance policy would pay out etc. After a month or so I did tell my wife, who told my GP, who came to see me and said that he wasn't surprised as I was his practice's most severely disabled patient and I was getting the least help. However, he managed to get me admitted to a local hospital as an emergency case and some of the people who had been promising to see me at home actually came to see me. Soon after, the health authority agreed to fund my inpatient treatment and life began to improve for me.</p> <p>This doesn't have a completely happy ending in that although I made progress I have also had several very bad relapses, I'm still severely affected and my wife has left me. I haven't really felt suicidal again but, having been there myself, I completely understand why someone would want to end their life."</p>	
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					<p>_____</p> <p>“I have been suffering from ME for the last [x] years or so, and was medically retired from my career as a [x] in [x]. Prior to this time I was extremely independent, travelled extensively, worked very hard and played hard too! This illness has robbed me of my independence, mobility, continence, career, financial independence, credibility and "place in society". I have certainly felt suicidal on many occasions, and though the illness has been very difficult to bear, with pain and the numerous other symptoms, I think that many other factors have played the major role in these feelings.</p> <p>I was extremely ignorant about ME prior to my illness, despite being a [x], holding a degree and a management qualification...not to mention 22 years in the health service. I was to find to my cost, that this ignorance was widespread among so called professionals. Originally, all thought that I was suffering from MS, and I was treated with some respect and sympathy. However, immediately that the diagnosis of ME was made, I was treated very differently! Despite the fact that my symptoms were the same. This goes on to this day e.g.. if I am out in my wheelchair, people may ask " Oh you poor thing, you're so brave, what's</p>	
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					<p>the matter?", if I am brave enough to say "ME", then the whole atmosphere changes. As if I am there by choice, am psychologically unstable, and need to get on with life. This usually followed by stories of people who have had ME for 6 months or so, recovered and are now leading productive lives.</p> <p>The social isolation is very difficult to bear, as colleagues etc. either disappeared, or gave up contact after a few years or months. After all, with illness, you should either die or recover! The benefits agency has been a major cause of stress and desperation to me. Refusing benefits, tribunals, re-applications every 18 months, and all of this with the inference of fraudulence which is not even disguised. Additionally, in order to claim my NHS pension, which was initially refused, I had to appeal twice. All of this has meant that I have had only six months respite in the last seven years from form filling, waiting for decisions, appealing against decisions, or paying solicitors.</p> <p>The medical profession have been another source of great pain, treating me with hostility and total lack of respect and disbelief. There is also the great divide between all of the information that is available to us, as patients, and the knowledge base of the professionals. I have often wondered how they have the audacity to call</p>	
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						<p>themselves specialists! There is always the inference that you are suffering from a psychiatric condition, that you are hysterical and fraudulent, and that all problems are psychosomatic, and that you are gaining something from the illness. I think that I am not alone in my total avoidance of hospitals and the medical profession as a whole, which means, of course, that most of us are totally unsupported. If, for example, a patient with another chronic condition became depressed, then it would be acceptable for the doctor to treat the depression knowing that is secondary to the illness. There would be no thoughts of curing the original illness, only treating the depression that has resulted from it. However, with ME, I feel that a reactive depression is often misdiagnosed. Who would not be depressed, with all of the lifestyle changes inherent in severe ME? Especially with the social rejection, financial insecurity, psychological abuse from the caring professionals, lack of basic social services care, and grief for the life that is lost? I feel that we are frightened to admit to feelings of depression for fear of reinforcing the belief in ME as a psychiatric condition, and if we do admit to it, then are treated as if "they were right all along" and the whole illness will disappear with anti-depressants!</p>	
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					<p>So, in summary, I think that the consequences of the illness are far worse than the illness itself...and that is desperate enough. I hope that this has been of some help to you.”</p> <hr/> <p>“Suicide is a very difficult subject to talk about, but I am willing to do so. I used to be a [x] and looked after those with [x] till I caught ME [x] long years ago this month. I have over the years thought about suicide and on one occasion a few years ago tried to take my own life.</p> <p>I think it was more a cry for help but to be honest I am not sure.</p> <p>What lead me to that act was sheer desperation. Being ill and no one believing me except my Husband. The illness itself and coping with it, the strain it had on my lovely husband. My family becoming more distant and the isolation, no care and benefits at the time. So there was mounting debts and stress between us and on our marriage.</p> <p>As the years passed by I felt I had achieved nothing in my life that the years were wasted! That there was no hope and people did not really understand my illness, what was worse was trying to get benefits! Every time I have a review I would worry if I will still get my money that I so desperately need.</p>	
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					<p>One thing that seems to depress people is the filling in of those forms, it concentrates on the negative, even asking how many times you go to the loo every day and how long your need help while you are there. It's humiliating and by the time you have finished filling them in you feel worthless. If you don't get the benefit you feel even worse.</p> <p>A lack of "life" has at times made me think of suicide because I am severely affected and bed bound most of the time. My husband works (and I would not have that any other way I think helps him keep his sanity :) I do have now some care coming in but I worry about my future I am in constant pain. So at times I think why should I continue, I think I do because of my Husband if I did not have him I know I would not be here.</p> <p>When I have a relapses I go through a grief process every time, its painful and you don't know if you will come out of that relapse.</p> <p>I don't know if I have made much sense or have been of any help I am going through a relapse at the moment and find it hard to write and express myself well, but I do hope you can bring this sensitive issue to light its been hidden for far too long. I do think people with ME who feel suicidal do not go to there GP because many think they are only</p>	
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					<p>suffering from depression or a mental illness in the first place!</p> <hr/> <p>“I was very saddened to hear the tragic outcome of your daughter’s battle with ME. I am [x] now and have had ME for the last [x] years and ME has sunk me to the depths where suicide has invaded my thoughts although I’ve never attempted it.</p> <p>But there are many factors that lead a once happy go lucky young lad as myself to contemplate such things. The way the disease manifests itself in particular, especially the cognitive deficits and brain fog where I feel my personality, intellect and independence have been robbed from me and I feel I am a puppet where ME pulls the strings and not me anymore. Of course the physical fatigue also brings one down. But the medical profession has exacerbated the situation - its ignorance, non-acceptance and playing down of ME. I have been through at least 20 Drs on three continents over [x] years, most fobbed me off, saying I didn’t fit into any of their pigeonholes and that therefore it had to be in my head. For [x] years of ME I thought I was the only person in the world with my illness and with it, although with family support, I fought a very lonely</p>	
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					<p>uphill battle.</p> <p>A glimmer of hope has kept me going, that one day soon I will be unchained of this nightmare but it is hard to have hope with the current mentality and lack of research being done. I must say it is improving but not fast enough.”</p> <hr/> <p>“I am a [x] year old woman with M.E., and yes, I have felt suicidal during the worst years of the illness. The reason I felt that way at the time was that I had been completely bedbound for years, lying in a dark room, unable to do anything but lie still with my eyes closed most of the time, and after so many years of this I felt there was no hope of recovery. Before I fell ill (at age [x]), I was a healthy, active, creative person with no history of depression. But when I was at my lowest physically, I simply felt the quality of my life had been reduced to such an extent that life was a nightmare. I was unable to do the things I love (writing, reading and translating), I had very limited social contacts because I was unable to talk for more than 15 minutes at a time, I could not watch TV or listen to the radio or concentrate my thoughts properly. I had had to return to my parents' house for care, as I was not receiving proper care in my own home in [x], and I felt I</p>	
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					<p>was a burden to the people around me. The illness had also put a severe strain on my finances, which certainly added to my anxiety.”</p> <hr/> <p>“I am so sad to hear about your daughter and I absolutely feel that any progress or awareness that can be made about this dreadful disease the better. I am too, unfortunately, a sufferer aged [x]. I think have had it for about [x] years but possibly [x]+ although "they" Drs, consultants etc really have no idea.</p> <p>You ask about the suicidal thoughts and yes they occur quite often - purely because, I think, that you are feeling so horrendous (shattered, ill and Generally low) and know that is not going to end and no one will/can help unless you pay a lot of money! I have found the NHS to be more than useless which in itself is frustrating and depressing!</p> <p>I am fortunate to have an extremely supportive husband and young daughter and family which helps considerably.”</p> <hr/> <p>“May I first offer you my sincere condolences. I can't imagine the pain you must be suffering. All I can try to</p>	
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					<p>say is that your daughter no doubt felt she was relieving you of HER suffering - this is how I've felt, and I can assure you that it is an expression of enormous love, possibly the greatest love any human being can feel for another.</p> <p>Last autumn I seriously considered suicide. I came as far as having the pills in my hand.</p> <p>I had other things in my life, apart from my condition, that may have contributed - a major family 'bust-up', for one, and a move to an area I've never lived in before. But the main reason was the condition itself.</p> <p>My GP had given me sleeping pills as I was having such problems sleeping. I went to take one, and it just struck me all of a sudden - why not take all of them? I was suddenly overwhelmed by my situation and all I could see was (a) what a burden I was to my husband and kids and (b) that there was no other way out, because I've tried them all.</p> <p>Doctors have always told me "you'll improve" when they send me for various treatments - but I don't. When I don't, it's like they don't want to know me anymore. It's even somehow inferred that it's my 'fault' I haven't improved - I didn't do the exercises properly, I didn't do them enough, I gave up too soon, etc etc.</p>	
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					<p>So far, every doctor has refused to state that its unlikely I'll ever return to normal, which would enable me to claim on my permanent-disability insurance, something that would at least enable me to start 'coping' with my condition. Instead, I am left in this limbo of not being able to move forwards in either direction - either preparing for a life with a disability, or preparing to go back to 'normal' life.</p> <p>What stopped me, of course, was the thought of what my death would do to my children and my husband. They are all wonderful and understanding, but I know they would try to blame themselves in some way if I had taken the pills. I couldn't do that to them. I honestly still feel that without me, their lives would take off in all sorts of directions that at the moment are impossible because of me - but I simply can't bear the thought that my child might think "she left me".</p> <p>I saw a psychologist soon afterwards, privately - who was no help whatsoever. He said, "Nothing's worth killing yourself over". I just thought, Oh Yes There Is, how about the prospect of the next 5-6 decades spent in agonizing pain that the doctors can't do anything about/don't really believe you are suffering? How about knowing your children are going without experiences due to the fact that their mother is</p>	
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					<p>disabled? How about your husband having to give up a career he loves because his wife is disabled</p> <p>Knowing my family is 'disabled' because of my conditon is the most terrible part of having ME. Their lives are constantly affected because I can't do the sort of things that other wives/mothers do. By committing suicide I would have seen it as an act of relieving my family of the burden my conditon inflicts on them. I don't know, of course, but I would think this is what was going through your daughter's mind, too.</p> <p>The last thing I would say is - suicide is, 9 times out of 10, a sudden, knee-jerk decision. It's not something you contemplate over a long period of time - it just suddenly hits you, out of the blue, and for some reason it really makes sense. You aren't thinking in terms of what people will go through when you are 'discovered' - you only think "the world really will be a better place without me". Its not even self-pity</p> <p>- its more like common-sense: There is a problem, the problem is You - remove the problem, everyone goes back to normal.</p> <p>Of course, I know it doesn't actually work out like that - but when you are in that place, this is how your mind works. People often say suicide is the cowards way out, a selfish act - but its not. It's</p>	
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					<p>amazingly loving and caring and thoughtful, possibly the ultimate expression of love . . . its just that the pain of loosing someone close to you gets in the way, and it's almost impossible to understand how someone you love could hurt you so badly by taking their own life. I hope, in a small way, that I might have shed some light on that question for you.”</p> <hr/> <p>“The benefits office is a nightmare as once you have been on incapacity pay for a while you have to be assessed, that adds extra pressure and in the end my husband told me not to go for the assessment as I was worrying about it but we could have done with the money. We had to remortgage our house and I felt terribly guilty about it all.”</p> <hr/> <p>“When I became sick I lost my job as a [x] and my girlfriend. The relationship with my brother too broke down. I had to move back home and become dependant on my parents again at the age of [x].</p> <p>I have tried unsuccessfully to take my own life three times by taking overdoses and the last attempt I used a razor</p>	
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					<p>blade to slit my wrist. At the time I was labelled as depressed which was a wrong diagnoses.</p> <p>Anyhow the reasons for doing so were poor quality of life. I was socially isolated, could not function properly, fatigued and in pain. I was not clinically depressed at the time of the suicide attempt which was confirmed by a psychologist. I simply chose to try and take my own life because I had had enough of the pain and fatigue.</p> <p>In short the main factors which drove me to the attempt were: loss of job, loss of girlfriend, social isolation. I could have coped if I could have held down a job and was able to go out and socialise but I could not at the time. Love makes everything bearable and when my girlfriend gave up on me it was the straw that broke the camels back.</p> <p>I still consider taking my own life to this day as it is my right. If it were not for my father I would have done so. I am only staying alive for him and I am hoping I will get better.”</p> <hr/> <p>“I have felt as suicide would be a way out of the pain, and to rid this world of another useless human being. I still try to "do" what I can around the house to ease the burden on my understanding and loving wife, who is the only reason for me to still be alive, I just can't hurt</p>	
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					<p>her that much, but I don't know if the time will ever come when I just won't be able to carry on.</p> <p>All my life I have worked hard and paid into a system for the help of the needy and now I need the help of that system they don't want to know me, firstly by refusing Disability Living Allowance and also questioning my Incapacity for work, even though my G P admits that I am in no physical state to work and issues me with Doctors Certificates.”</p>	
SH	British Association for Counselling and Psychotherapy (BACP)	1	FULL	General	<p>BACP notes that the GDG has made every effort to include patient views in the development of the guideline and to emphasise the need for the patient to stay in control of his or her treatment programme.</p> <p>We also note that the biopsychosocial model acknowledges the role of both external and internal influences on the development and recovery from CFS (p. 135). We agree that entrenchment and polarisation of viewpoints about a physical or psychological origin of CFS undermines relationships that support recovery (p.134).</p>	The guideline followed the NICE process with an additional step of piloting a questionnaire.
SH	British Dietetic Association	1	General		Thank you for giving The British Dietetic Association the opportunity to comment on this guidance	Noted.
SH	British Dietetic Association	3	General		We wish to highlight importance of optimum vitamin D status not only for vulnerable groups of CFS patients	There is now a recommendation about referral to a dietitian for advice on supplementation where appropriate.

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						(adolescent, severely affected and housebound) but also for those with unexplained lower extremity muscle weakness. More evidence is appearing linking low vitamin D status to lower extremity muscle weakness and immunity. A reduction in activity/exercise is part of the condition; and we would recommend the use of Vitamin D supplementation of at least 10 mcg.	
SH	British Dietetic Association	4	General			The patient surveys indicate that dietary change helped 59-73% of patients. Most of our recommendations re diet and supplements are negative recommendations. The BDA feels that inclusion of some of the comments above would help redress this balance.	The dietary section has been substantially revised under the supervision of the dietician on the GDG and based on stakeholder comments.
SH	British Infection Society	1	FULL/NICE	General		On behalf of the British Infection Society I would like to endorse our support for these guidelines. A few minor amendments have been suggested as below.	Noted with thanks.
SH	Cambridgeshire Neurological Alliance	1	FULL	General	All	We, as a Neurological Alliance and forum for charities and people with concern in respect of Neurological Conditions, have grave concern regarding the Chronic Fatigue Syndrome / Myalgic Encephalomyelitis (CFS/ME) NICE Draft Guidelines.	Please see revised guideline.
SH	Cambridgeshire Neurological Alliance	2	General	General	All	Firstly, NICE purport these Guidelines to be in relation to CFS/ME which, in its very definition, is a Neurological Condition. Yet, these Guidelines	A discussion of classification has been added.

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						contain no reference to the World Health Organisation (WHO) classification of “CFS” and “ME”, listed under WHO-ICD-10 G93.3, as a “disorder of the nervous system”.	
SH	Cambridgeshire Neurological Alliance	4	FULL/NICE	General	All	In summary, CFS/ME Draft NICE Guidelines appear based on an attempt to bring into the arena of Long-Term Conditions a ‘cost-effectiveness’ approach as a mere ‘quick-fix’ to show a ‘balancing-of-the-books’ for the NHS, rather than what the actual patient – in this case, the M.E. Patient requires and indeed, should by the very nature of the illness, be entitled to. It cannot be professed, imagined or even seen, that a “treatment”, “cure” or “prevention” of neurological conditions can be through “Graded Exercise Therapy” (GET), “Cognitive Behavioural Therapy” (CBT) and “Exercise Therapy” (ET). Yet, it is noted throughout the NICE CFS/ME 269 page Draft Guidelines that these alleged “therapies” do exactly that, in that GET/CBT/ET is a “treatment” and “cure”. Furthermore, the evidence that is quoted as a basis for the NICE Guidelines, appears to strongly promote GET/CBT/ET treatments and therefore, appears not only biased, but also flawed, skewed and somewhat “thrown-together,” with a lack of the numerous medical and scientific research references that span more than fifty years regarding some of the world-	Noted.

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						renown Microbiologists, Virologists, Neurologist, Haematologists and immunologists in respect of ME and CFS/ME	
SH	Cambridgeshire Neurological Alliance	5	FULL/NICE	General	All	It is noted, that many of the apparent “concocted” notions on CFS/ME being “managed, treated and cured” are the same named persons as those who appear as a very small group (trio, almost) of Psychiatrists, well known to have strong links with Medical Insurance companies, Department of Work & Pensions (DWP) Pharmaceutical companies, with their “wonder-cure” of “GET/CBT/ET”. And often do not declare the “Conflict of Interest” element, neither the “Vested Interests” involved, when promoting the very “cure and treatments” services they have convinced NICE will work with CFS/ME. When, in fact, these “therapies” are the outcome of the same persons’ “research” studies, paid positions, within certain Pharmaceutical companies, DWP and NHS arenas.	Noted.
SH	Cambridgeshire Neurological Alliance	6	FULL/NICE	General	All	It is equally noted, that despite numerous medical and research references to CFS/ME being a neurological condition with immunological, endocrinological and physiological abnormalities, stemming more than fifty years by UK and international Scientists. This research in the field of Immunology, microbiology, virology, neurologists and	Noted.

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						other leading Specialist Consultants, have been largely gone unnoticed and/or ignored by NICE in their compiling this 1st Draft Guideline document, as none of these papers, references, or indeed, the researcher's names in those fields, appear referenced or referred to.	
SH	Cambridgeshire Neurological Alliance	8	FULL/NICE	General		Therefore, how is it possible, that CBT/GET/ET appears "universally adopted" by NICE to "treat" a neurological condition, of which, CFS/ME is by its very definition? There is enough scientific basis for recognition of the neurological, endocrinological, immunological and neurological aspects of CFS/ME. Yet, NICE appear to have elected to ignore that in favour of the "GET/CBT/ET", based on a few dubious studies that were in fact not carried with the proper CFS/ME defined patient Group. Those studies that did use "CFS/ME defined patients" actually had documented figures and facts of the high rate of these patients who dropped out, due to relapse.	Noted.
SH	Cambridgeshire Neurological Alliance	10	FULL/NICE	General		The Cambridgeshire Neurological Alliance therefore, regrettably, is unable to support or endorse the NICE CFS/ME Draft Guidelines in its present state. To add, these Guidelines appear entirely unfit for purpose. For reasons as set out by a number of leading M.E. Charities; The 25% M.E. Group for the	Please refer to the guideline, which has been revised.

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						Severally Affected, Invest In M.E., BRAME, The Young M.E. Sufferers Trust, Tymes Trust, MERGE and, a number of other M.E. charities and organisations. We, as a health representing organisation, simply, cannot endorse a Health Guideline of this nature when it does not even acknowledge that CFS/ME is a neurological condition, as defined and classified by the World Health Organisation, UK Chief Medical Officer's Report on CFS/ME, January 2002, numerous UK Government Ministerial, MPs from both the House of Lords and House of Commons.	
SH	Chronic Fatigue Research Unit at King's College London	1	FULL/NICE	General		We welcome this draft report and extend our congratulations to the authors. It is an impressive document, well referenced and researched, and will we believe lead to much needed improvements in the standards of care for patients with this illness. . We commend the decision to continue with an evidence based approach in the face of what we know will have been considerable pressures to do otherwise. Overall, we find the Guidelines sensible and practical – they accord both with the scientific evidence and our own extensive clinical experience. The CFS Research Unit was formed in 1994, and has published over 100 peer reviewed original research papers, whilst our NHS service dedicated to CFS has now	Thank you very much.

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						been in existence for fifteen years, and has seen over 3,000 patients during that time, so we think we can speak with some authority on both counts.	
SH	Chronic Fatigue Research Unit at King's College London	11	FULL	General		There has been speculation in the press recently about causes of death in CFS, with a piece in the New Scientist and elsewhere repeating the unverified claim that CFS is associated with premature death from various causes, such as cancer, heart disease and renal failure. To date this has been purely anecdotal, but there is now a paper looking at death rates - Smith W, Noodan, C., Buchwald, D. Mortality in a cohort of chronically fatigued patients. Psychological Medicine 2006;36:1301-1306.. its conclusion "CFS does not appear to be associated with increased all-cause mortality or suicide rates. Clinicians, however, should carefully evaluate patients with CF for depression and suicidality" seems to us to be clinically relevant.	The GDG discussed this and decided that a formal suicide risk assessment should not be done routinely for every patient but may be needed in certain cases.
SH	Chronic Fatigue Research Unit at King's College London	12	FULL	General		We have only just seen this – came out yesterday we think, and sadly none of us are fluent dutch speakers, but it might be relevant : Torenbeek M, Mes CA, van Liere MJ, Schreurs KM, ter Meer R, KortlevenGC, Warmerdam CG. Favourable results of a rehabilitation programme with cognitive behavioural therapy and graded physical activity in patients with the	Noted with thanks

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						chronic-fatigue syndrome [Dutch]. Ned Tijdschr Geneeskd. 2006 Sep 23;150(38):2088-94.	
SH	College of Occupational Therapists	1	FULL/NICE	General		<p>Statement from the College of Occupational Therapists:</p> <p>The comments submitted below are those of a highly expert group of Specialist Occupational Therapists with considerable experience of working with people who have CFS/ME. The College of Occupational Therapists FULLY supports their comments/suggested amendments and would strongly recommend that they be given serious consideration and are incorporated into the next draft of the guideline.</p> <p>The main concerns include:</p> <ul style="list-style-type: none"> ▪ Utilising activity as a therapeutic modality is a key theme in the guidelines, however the General tone in relation to activity is that this is a simple process, not requiring the training that CBT or GET would involve. ▪ The role of occupational therapy in relation to work has been completely overlooked. ▪ Most importantly core skills of occupational therapists, such as using activity as a therapeutic tool have been portrayed as cognitive 	Noted. An occupational therapist, nominated by yourselves for their expertise, was part of the GDG and contributed to the development of the guideline.

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						<p>behaviour therapy (page 185).</p> <p>As a result of the comments listed below, the College has serious reservations about the suitability of this guideline. Furthermore, the College believes that its implementation would compromise essential services in this client group.</p> <p>We look forward to receiving the developers' responses to these comments.</p>	
SH	College of Occupational Therapists	14	FULL	General		<p>While recognising that current evidence predominantly relates to GET and CBT, there seems to be a disappointing level of details for recommendations for use of Pacing/APT (which is clearly a substantial consideration as it is part of PACE trial), and Activity Management, both of which are widely reported in anecdotal evidence. Furthermore, there seems to be no mention of Lifestyle Management, which is disappointing because without it we cannot safe guard elements for instigating in the future? Or, is Activity Management here synonymous with Lifestyle Management? If so, there are still omissions eg.</p>	<p>Evidence from trials in development will be included in any updates. Currently no evidence was identified for Adaptive Pacing Therapy.</p>
SH	College of Occupational Therapists	20	FULL	General	General	<p>Who is expected to read the guidelines? In places it seems to be directly addressing the patient, e.g. within setbacks it says 'don't panic'.</p>	<p>Please see relevant section of revised guideline.</p>
SH	College of	72	FULL	Gene	Overall	<p>It is very confusing as the definitions of</p>	<p>The guideline has been restructured to reflect</p>

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	Occupational Therapists			ral	presentat ion of therapies	<p>different therapies are repeating themselves.</p> <p>Suggestion:</p> <p>Patients find the different use of labels for the same basic therapies very confusing and alienate them from NHS Services. The labels have been drawn from the need to research distinct variables, which in the real world of clinical practice are maybe not so distinct. As NICE is making recommendations for practice, would this not be an opportunity at this stage to move away from the terminology debate.</p> <p>Instead of separating out CBT, GET and activity management, could you distil from the evidence/research the common core components of a therapeutic approach to CFS, including sleep management and managing setbacks. This core approach can be used for any level of illness and must be done by a suitable qualified and experienced professional, e.g. Occupational Therapist, Physiotherapist, psychologist etc.</p> <p>Then go on to describe distinct qualities of some approaches, such as use of exercise or exploring underlying schema, which may be helpful on top of the basic approach.</p> <p>The whole approach of the guidelines</p>	this comment.
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					<p>seems to imply you need the most specialist intervention first and if this doesn't work (e.g. for severely affected) the more General CFS approaches, should this not be the other way round?</p> <p>This would be more acceptable to patients, more in keeping with current clinical practice and more cost effective for the NHS.</p>	
SH	College of Occupational Therapists	99	FULL/NICE	General	<p>Comments below from an specialist occupational therapist based at the only CFS Service in Northern Ireland:</p> <p>It is important to highlight that NICE guidelines have only recently been introduced to Northern Ireland. This document is a step forward and hopefully will encourage further services to be developed over here (e.g. at present there are no children services). As a senior occupational therapist facilitating a Graded Activity Group Therapy 8 week programme, I am aware of the frustrations encountered by sufferers of this condition caused by lack of understanding and resources.</p> <p>Our own regional service was established in 2000 and feedback from patient satisfaction questionnaires has been positive. We are a small team consisting of one Consultant Psychiatrist and one Senior Occupational Therapist. However, it has been highlighted by group members that travelling has been</p>	Noted with thanks.

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						<p>difficult and this adds to the evidence for more local management and resources.</p> <p>I am in total support of the above comments made by my colleagues.</p>	
SH	College of Occupational Therapists	100	FULL/NICE	General		<p>The College recognises that there is definite need for national guidelines on the diagnosis and management of CFS/ME, and there is much helpful and useful information here. However, in order to ensure their suitability for a range of practitioners, we would highly recommend that the above issues be addressed.</p> <p>Due to the number of comments raised, we would like to suggest that a further draft is circulated to stakeholders for consultation prior to its publication.</p>	Noted.
SH	Counselling and Psychotherapy Trust	1	FULL/NICE	General		<p>I am writing on behalf of the trust to note the artificial divide between GET and CBT. CBT is a wide framework and we feel that it is restrictive and artificial to try define approaches such as GET (which is essentially a behavioural therapy programme) separately, when they are frequently delivered as a component within an integrated CBT framework. The real danger lies is the fact that definition of GET as a separate area could well lead to any number of 'lay' practitioners offering support, without adequate knowledge or skills. In this respect, as someone who works extensively with CFS/ME sufferers,</p>	Noted.

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						development of behavioural programmes can be very complex and errors can have severe detrimental effects. The Trust believes that more emphasis should be placed on the competence of the practitioners involved (i.e. preferably Chartered Clinical or Counselling Psychologists) rather than artificially 'packaged' treatment regimes, as competent professionals will integrate evidence based approaches within their treatment programmes as a matter of course. On the other hand, no amount of definition or detailed descriptions of treatment options are likely to result in successful treatment by those with inadequate levels of knowledge and skills.	
SH	Department of Health	1	General			I wish to confirm that the Department of Health has no substantive comments to make on this consultation.	Noted.
SH	Department of Health, Peninsula Medical School	1	FULL	General		Overall, this draft guideline represents an impressive piece of work. This has been made more complex by the dearth of high level data. I have been generally impressed by the way in which the large areas which lack that evidence have been addressed through consensus process, etc. Inevitably, there are some substantive issues of emphasis and content, which I have outlined below. But I wish to record here my view that the approach has been thoughtful, balanced and carefully considered. I hope that the comments below can be	Noted with thanks.

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						seen as helpful ways of further enhancing the quality of the final version. Thank you.	
SH	Ferring Pharmaceuticals Limited	1	FULL	General		We have no comments	Noted.
SH	Invest in ME	1	FULL	General		<p>Introduction</p> <p>Invest in ME (IIME) is a UK charity registered in May 2006, that is run by people with Myalgic Encephalomyelitis (ME) or parents of children with ME on a totally un-paid, voluntary basis.</p> <p>The sole objectives of IIME in reviewing the NICE Draft Guidelines are to ensure that people with ME and their families receive appropriate treatment; that Myalgic Encephalomyelitis receives whatever public funding is necessary to allow proper diagnosis, treatment based on science evidence and not vested interests, and for a cure for this devastating illness to be developed.</p> <p>IIME have reviewed the NICE Guidelines (Chronic fatigue syndrome/Myalgic encephalomyelitis: diagnosis of chronic fatigue syndrome/Myalgic encephalomyelitis in adults and children) and wish to record the enclosed comments.</p> <p>Although NICE has taken two years to formulate these proposed Draft</p>	Noted.

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						<p>Guidelines, liME, along with the ME community, have been limited to two months to respond with comments.</p> <p>Within the constraints of this deadline, while enduring ME and caring for ME sufferers, we have provided this response with as much detail as we are able and we submit this response document to NICE for consideration.</p> <p>Itemised comments referencing the Draft Guidelines text can be found in Section 5 of this response.</p> <p>We have submitted the comments in this document to NICE .</p>	
SH	Invest in ME	2	FULL	General		<p>Summary of liME Comments on These Guidelines</p> <p>People with ME (pwme) hope that their illness will be taken seriously by the medical profession as the neurological illness that is ME and that research is publicly funded to provide early diagnosis, treatment, and eventually a cure.</p> <p>liME find the NICE draft guidelines document a travesty of the real requirements for people with ME and their carers.</p> <p>We believe these guidelines provide little to further the treatment of ME and this is, essentially, an opportunity missed by those entrusted with the responsibility for producing these</p>	<p>Please see revised guideline. Please see the relevant sections for specific responses to your comments.</p> <p>With regard to the content of the guideline, and the guidance on GET and CBT, the GDG 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 and programmes.</p>

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					<p>guidelines.</p> <p>The NICE draft guidelines lack any vision in moving forward the treatment of people with ME (pwme).</p> <p>Although we agree, and welcome the areas of the guidelines which state that the patient/carer is in control of actions and decisions relating to the illness, the statement that “treatments which are offered allow the person with the CFS/ME to refuse without compromising the further therapeutic relationship” must apply always.</p> <p>We agree, and welcome, the offer of information about ME support groups. Although we have doubts about the use of the NHS Expert Patient web site as it contains erroneous information.</p> <p>We cannot accept that these guidelines use as broad a section of fatigue states as possible in describing ME.</p> <p>Psychiatric paradigms are referred to and recommended as therapies and as treatments for ME despite ME patients and groups stating they are ineffective or harmful.</p> <p>In fact Graded Exercise Therapy (GET) has been shown to be harmful or useless yet it is wrapped up into a psychiatric paradigm to allow vested interests to perpetuate the same old myths about ME. The Draft Guidelines explicitly state that “There was strong</p>	
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					<p>agreement that persistent, debilitating, post exertional fatigue characterised the condition”, yet the Draft Guidelines still recommend GET as a therapy/treatment.</p> <p>Cognitive Behaviour Therapy (CBT) is being recommended as a treatment and the Draft Guidelines disingenuously compare CBT for CFS/ME to the usage by cancer patients and others. Yet CBT is not offered as first line treatments for these illnesses which NICE are recommending here for CFS/ME. Where CBT is offered to cancer patients then it is not the same type of CBT as is being proposed here for CFS/ME.</p> <p>liME strongly disagree with the priority recommendation that the therapies of first choice should be Cognitive Behaviour Therapy (CBT) or GET. It is incredible that this should be a recommendation at all, since the Draft Guidelines document a lack of evidence and yet produce more policy-based evidence making.</p> <p>Even results from patient group surveys, which show rest made people feel better and GET made them worse, are given a spin which skews the result.</p> <p>liME are left wondering why NICE sees fit to create this “spin”, since it benefits nobody in the long run and pwme and the medical profession are at the receiving end of more erroneous</p>	
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					<p>information.</p> <p>The use of other treatments such as supplements and alternate medicines are not recommended even though patient experiences, as evidenced in this document and elsewhere, show them to be useful to some.</p> <p>The current and previous biomedical research is seemingly ignored.</p> <p>There is obvious bias in these guidelines – so much that it is impossible to take some of the statements seriously.</p> <p>Out of interest one can see how skewed is the analysis. In these guidelines –</p> <ul style="list-style-type: none"> • 68 pages cover CBT, GET, Activity Management and other self management techniques (pages 138 – 204). • 28 pages cover pharmacological interventions – (pages 205 – 233). • 14 pages cover Dietary interventions and supplements (pages 234 – 248) • 4 pages cover Complementary therapies (pages 249 -253) <p>Doesn't this say something about these guidelines? Are the objectives and the result already predetermined before the</p>	
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						publication?	
SH	Invest in ME	4	FULL	General		<p><i>Terminology</i></p> <p>The terminology may be crucial in dealing with ME, especially as GPs, paediatricians, other healthcare personnel and the media use different terms.</p> <p>These guidelines state -</p> <p style="padding-left: 40px;"><i>‘Appropriate and agreeable terminology and understanding is important when making a diagnosis and establishing a therapeutic relationship.’.</i></p> <p>liME totally agree with this statement.</p> <p>So it is even more surprising that NICE remains committed to perpetuating the terminological mess around ME.</p> <p>Perhaps the principal problem is that ME/CFS is not a “clean” diagnosis. Indeed, the terms Myalgic Encephalomyelitis (ME) and Chronic Fatigue Syndrome (CFS) mean different things to different people. None of the professionals in medical schools use the term “ME”, they use CFS since the 1994 definition of CFS - flawed though it is - has come to be the dominant catch-all definition.</p> <p>These guidelines could have moved this issue on by using and recommending the term recognised and used by the WHO – under ICD 10 G93.3. However,</p>	Please see revised guideline.

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					<p>NICE has chosen to ignore this international definition.</p> <p>The Draft Guidelines also refer to research into chronic fatigue. Let us be unequivocal - Chronic Fatigue is a symptom, not a disease or illness. This means that the guidelines and evidence are flawed as we are supposedly dealing with CFS/ME. Indeed the lack of precision in the document allows CFS to be used sometimes and CFS/ME at other times.</p> <p>It also allows “encephalopathy” to be used, which merely serves certain organisations or individuals who benefit from having as wide a set of paying subscribers/patients as possible.</p> <p>liME suggests that Myalgic Encephalopathy does not exist, save in the fictional arguments between parties with vested interests in maintaining vagueness.</p> <p>liME believe that NICE should have had the courage, and the morals, to demand that the proper terminology is to be used by all healthcare staff. ME/CFS is the name that should be used. Instead, by its own statements and by its recommendations, NICE has allowed itself to be seen as hypocritical in stating the need for consistent terminology yet allowing the current subterfuge to continue.</p>	
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						This alone undermines the draft guidelines and the integrity of NICE .	
SH	Invest in ME	6	FULL	General		<p><i>Management</i></p> <p>liME find this section one of the most disappointing – and quite biased. The true agenda for these guidelines seems to be illustrated in this section.</p> <p>The comments in the management section are often worthless as they seem to be dealing with patients suffering from burn-out rather than from a neurological illness. They also seem to be contradictory with a great deal of print sometimes emphasizing the use of psychological therapies such as GET and CBT and at other times stating that the choices are the patients’.</p> <p>The complete disparity between the amount of space given to non-psychological treatments/therapies as compared to psychological treatments/therapies shows an obvious and unscientific bias in these Draft Guidelines. The information on CBT and GET in these guidelines often seems to read more like propaganda than a scientific, analytical review of management aids.</p> <p>The bias shown in favour of psychological therapies undermines the value of these Draft Guidelines.</p> <p>The Draft Guidelines contain an inordinate number of pages on</p>	<p>Management</p> <p>Please see relevant section of revised guideline for a response to your comments.</p> <p>The GDG recognises that there is a great deal of confusion about terminology. We agree that the terms ‘GET and ‘CBT’ have 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. The programmes 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.</p>

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					<p>research that shows the organic nature of ME and which will likely dictate the diagnosis and treatment of ME.</p> <p>For example, the work of Prof Puri at the Hammersmith Hospital is indicating a “fingerprint” marker using elevated Choline levels in brain chemistry SPECT-scan results. There is also the work by Dr Spence at ME Research UK that shows post-exertional oxidative stress that appears to be unique to neurological ME.</p> <p>Careful consideration should be given to the inclusion of related NICE guidelines, since there are a number of related psychological and clinical illnesses. The differentiation should clearly distinguish ME from other fatiguing syndromes and illnesses. It should be remembered that ME has been found to have inflammation of the brain and central nervous system and that pathology will provide increasing evidence. Some charities are proposing to support a protocol for pathologists where evidence is collected. NICE should consider this further in the Draft Guidelines.</p>	
SH	Invest in ME	8	FULL	General	<p>GET</p> <p>A primary recommendation for treatment of ME/CFS in the NICE draft guidelines for those who are "mild to moderately affected" are</p>	<p>Please see the relevant sections of the section of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see the relevant section of revised guideline.</p>

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					<p>Cognitive Behavioural Therapy (CBT) and GET. In making this recommendation, the Guideline Development Group seem to be ignoring credible evidence that such treatments are potentially dangerous for those who suffer from this illness, particularly in the case of GET.</p> <p>Of particular concern is a mounting body of evidence that shows that exercise or over-exertion can worsen the health of ME/CFS sufferers and that, as such, GET has the potential to induce relapse, rather than being an effective recuperative therapy.</p> <p>GET, as practiced today with ME patients, does not take into account a patient's preferences. How can a recovery be an objective with the use of GET when the causes of ME are unknown? Yet this is what the NICE guidelines propose.</p> <p>GET cannot be recommended for severely, or even moderately affected ME patients. It is tantamount to inviting diabetics to take more sugar. This is where the NICE agenda for imposing psychological therapies onto ME patients shows the basic irresponsibility behind the policy.</p> <p>Whilst activity management is essentially a common-sense approach to managing symptoms GET is totally unacceptable. What benefit does GET</p>	
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					<p>hold for a tube-fed, incontinent, bed bound patient? The proposition is risible.</p> <p>It is well known that those who perform GET studies do "cherry-pick" their patients (i.e., choose only those patients well enough to be able to exercise in the first place and thus contribute to the overall 'success' of the trials). <u>No severely affected ME patients have ever been shown to benefit from the use of GET.</u></p> <p>Every medication has to have a list of side-effects – these need to be stated here also with reference to GET. GET needs to carry a government health warning for ME patients.</p> <p>If NICE continue to recommend GET then they have to shoulder some of the responsibility for the consequences. In light of the evidence presented, it is possible that use of GET for those with ME/CFS will ultimately be self-defeating. By increasing the risk of relapse and increasing overall health risks rather than reducing them, it is dangerous for patients and risks increasing the burden of illness posed by ME/CFS on society at large.</p> <p>We are left to wonder about the litigation that will follow if these guidelines ever see the light of day as a standard method for treatment of ME</p>	
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						<p>patients.</p> <p>Will the chair of these NICE guidelines be willing to be held responsible for any damage that will inevitably result from using GET on severely affected patients by healthcare staff who will likely be unconvinced of the biological nature of ME?</p> <p>1 Late in the preparation of liME's response we received an email from a correspondent to liME ([x]). We have included this as <u>Appendix 4</u> as we feel it provides more analysis and information regarding the use of GET for pwme.</p>	
SH	Invest in ME	9	FULL	General		<p>Supplements and Alternative Medicines</p> <p>The NICE guidelines provide an incredibly poor and limited summary on supplements as aids in managing ME.</p> <p>Supplements are dismissed with little research or attempt to analyse.</p> <p>Yet they can be a useful part of the diet for pwme who cannot cook always or who cannot eat properly and could benefit from such supplements (fish oils, vitamin C, multi-vitamins etc.) - surely this is a negligent oversight from NICE .</p> <p>In some places the use of supplements is rejected and is not considered worthy of more investigation (page 234) - "evidence is insufficient to</p>	<p>Supplements and alternative medicines</p> <p>Please note that the text full guideline is the background the guidance to the NHS is in the recommendations. The GDG found insufficient evidence to recommend nutritional supplements or complementary therapies routinely. Please refer to full guideline. It is acknowledged, however, that some individuals may find them helpful.</p>

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						<p>support a beneficial effect of dietary supplements”</p> <p>and (Page 249) -</p> <p>“the GDG agreed that they could not be recommended for the management of CFS/ME”</p> <p>Yet in other places in these guidelines it is stated that there may be a use for them (Page 263) -</p> <p>“There may be a need for use of prescribable supplements or where there are severe problems, tube feeding may be required.”</p> <p>It becomes totally confusing which recommendations are meant to be used. Imagine how GPs must react when reading these guidelines!!</p> <p>The inconsistency is appalling.</p>	
SH	Invest in ME	10	FULL	General		<p>Other Points</p> <p>NICE recommend against resting after a relapse or during the illness. This shows little understanding of the real world.</p> <p>During the early onset of ME rest is of paramount importance.</p> <p>The wording by NICE is easily able to be misconstrued, or misunderstood, by healthcare staff lacking in real knowledge of ME and will severely impact many ME patients if promoted</p>	<p>Please see the relevant sections of the section of the stakeholder comments specifically addressing this topic for a response to your comments. Please also see the relevant section of revised guideline.</p>

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						<p>via these guidelines.</p> <p>The emphasis on exercise at the expense of proper rest is appalling. Guidelines such as these ought to be for the benefit of the patient. These guidelines do not fulfil this objective.</p>	
SH	Invest in ME	13	FULL	General		<p><i>Implementation</i></p> <p>One section which was included in the NICE version but not present in the FULL was implementation.</p> <p>As for the cost of all of the psychological therapies (posing as treatments) are concerned it is difficult to understand how this will be paid for with an estimated 250,000 people suffering from CFS/ME in the UK, especially considering the low priority and lack of funding given to ME in the past. To have sparse resources squandered on therapies which the ME community do not need or want is an appalling waste.</p> <p>Perhaps implementation should consider what is the need of the medical community, especially clinicians to assist in the diagnosis of ME and the exclusion of related non-specific fatiguing conditions.</p> <p>The greatest factor in the UK and the Rest of the World is the lack of a clear diagnostic tool and the mixing of patient cohorts with numerous fatiguing</p>	A cost–impact tool will be published with the guideline.

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						<p>conditions.</p> <p>The use of the WHO ICD-10 G93.3 for Myalgic Encephalomyelitis and the development of a “fingerprint test” possibly based on the elevated levels of Choline in the brain blood chemistry, which has been the only unique identifier found to-date, could be used and validated.</p>	
SH	Invest in ME	14	FULL	General		<p><i>Document Structure</i></p> <p>We find the FULL of the guidelines document poorly structured and cumbersome to read. They are very unwieldy and the shortened version is probably the only version which will be read FULLY. This would then lead to the FULLer guidelines being ignored as regards supporting evidence. But if this evidence is flawed then the whole draft is suspect.</p> <p>The way the document is composed, with recommendations all over the place, references everywhere, sections which should be broken down into more manageable entries and tables and pagesets of varying formats – the whole document is badly formatted. Even a healthy person would find it difficult to read the FULL.</p>	<p>The guideline recommendations will be summarised into a Quick Reference Guide (QRG). This will be sent to relevant healthcare professionals and make the guidance more accessible. The full guideline serves as a reference document and will be available on the NICE website.</p>
SH	Invest in ME	15	FULL	General		<p>Guideline objectives</p> <p>These were the stated aims of the document as written on Page 21 Executive summary and</p>	<p>NICE guidelines are subject to ongoing evaluation. Your comments will be referred to the Implementation team.</p>

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					<p>recommendations Aims of the guideline.</p> <p>It is appropriate to determine if these objectives were met by this draft document.</p> <p>The Guideline Development Group developed this guideline with the aims of -</p> <p><i>Increasing the recognition of CFS/ME</i></p> <p>It is doubtful if this has been met as it provides nothing new for sufferers and carers.</p> <p>The few places where the document has requested that healthcare professionals take the illness seriously and that the recognition of this is paramount is good.</p> <p>Essential research showing the multi-system nature of ME is not discussed – enteroviruses, orthostatic intolerance, oxidative stress – none of these are allowed to be discussed in detail. Yet without a basic understanding or awareness of the pathology of the illness how are healthcare staff supposed to recognise the true nature of ME. Increasing the recognition of ME can only be achieved by increasing the knowledge of the illness itself.</p> <p>However, the recommendations that once again force non-functional and biased psychiatric therapies as a management technique will lead to</p>	
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					<p>more harm and probably contribute to fostering even more antagonism between healthcare staff (especially those who are untrained in ME) and the patient/carer.</p> <p>Increasing recognition of the illness could also have been assisted by the use of the correct terminology – as detailed by the WHO. ME/CFS is the correct term and myalgic encephalomyelitis is the correct name for the acronym ME. By pandering to organisations and individuals, who have a vested interest in using other terms, NICE does nothing but harm to itself as the consensus amongst patients will be that NICE cannot be trusted.</p> <p><i>Influencing practice in the 'real world'</i></p> <p>It is doubtful if this has been met as it provides nothing new for sufferers and carers.</p> <p>By immediately stating that CBT and GET are the most useful therapies NICE has shown it is not willing to move the issue of ME into an area which offers any real hope of progress.</p> <p>These guidelines will not influence practice but will lead to already established myths being perpetuated. The lack of a decision on endorsing one set of diagnostic guidelines – the '<i>more stringent</i>' Canadian guidelines – is a travesty. It seems that NICE is intent on</p>	
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					<p>using as broad a definition for ME as possible.</p> <p>This will result in little change in the 'real world'.</p> <p>The absence of emphasis on the lack of funding for biomedical research into ME will not help to alter the government's position on this subject and therefore gives little to change the current unsatisfactory position where patients are given possible harmful GET. It will not inform healthcare staff of the missing link in research into ME – funding for biomedical research.</p> <p>It shows little awareness of other biomedical research being carried out or performed in the past. It should include references to new research in this area so that healthcare staff can be aware of the overwhelming evidence of the neurological source of this illness.</p> <p>The guidelines state that a patient/carer can refuse any therapy without it impacting the relationship with the healthcare practitioner(s). We would like to see this occur but we are afraid that it will not.</p> <p>In the face of insurance companies and DWP staff forcing an ME patient to undergo potentially harmful or useless GET or CBT then we doubt if these guidelines are forceful enough to avoid this happening.</p>	
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					<p>In such instances recourse to litigation will be the only possibility for ME patients.</p> <p>It might have been useful for these guidelines to detail what avenues are open for legal aid for ME patients who wish to challenge insurance companies and healthcare staff who insist on ME patients undergoing GET or CBT against their will.</p> <p>The guidelines make little headway in influencing 'real world' issues such as insurance companies forcing claimants with ME to undergo psychiatric therapies.</p> <p>The guidelines do little to influence 'real world' issues such as the requirements from the DWP to go through elaborate processes to prove they are ill.</p> <p>The guidelines do little to influence 'real world' issues such as the need for parents to battle with schools for the rights of their children with ME.</p> <p>Will NICE state that nobody should be refused insurance and sick benefit if they refuse to take anti-depressants or CBT/GET?</p> <p><i>Improving access to appropriate services, and supporting consistent service provision</i></p> <p>It is doubtful if this has been met as it provides nothing new for sufferers and</p>	
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					<p>carers. Little is given in support of ME patients in their dealings with DWP staff and no reference is made regarding how ME patients are meant to deal with the harassment and bias of insurance companies who propose psychiatric treatment for ME.</p> <p><i>Emphasising the need for multidisciplinary working</i></p> <p>These guidelines patently fail to achieve this due to the concentration on psychological therapies at the expense of real research of published biomedical research papers.</p> <p>Although there are a few statements stating that multi-disciplinary working is required in dealing with ME patients the bias toward psychological therapies, and the amount of space given to these therapies in these guidelines, means that there is little credit given to non-psychiatric disciplines in treating and managing ME.</p> <p><i>Improving care for patients, and particularly for those severely affected</i></p> <p>The guidelines offer little for severely affected. There is no provision for specialist treatment – simply rehashed dogma relating to therapies which are entirely inappropriate for severely (and moderately) affected pwme.</p> <p>There is little here for carers.</p>	
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					<p><i>Providing guidance on 'best practice' for children with CFS/ME</i></p> <p>Here it fails abjectly. The best practice is not psychiatric therapies where the onus is on the patient to attend meetings with psychiatrists. It does little to move the debate on.</p> <p><i>Balancing guidance with the flexibility and tailored management, based on the needs of the patients</i></p> <p>By emphasising GET and CBT as primary treatments it is not possible to state that these guidelines help in basing management on the needs of patients. Its predilection for asserting that activity and exercise help ME patients already undermines any confidence that the ME community may have about the impartiality of these guidelines.</p> <p><i>Facilitating communication between practitioners and patients, and their families or carers.</i></p> <p>It cannot be said to achieve this as the emphasis on psychological therapies posing as treatments using heavily skewed data will inevitably influence GPs and paediatricians – especially if they have little time available for ME patients. The subject matter is skewed to allow a multitude of fatigue-related patients to be included in this study. If it purports to be for ME then the studies</p>	
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						need to use patients with ME – not CFS or other fatigue conditions.	
SH	Invest in ME	16	FULL	General		<p>Conclusion</p> <p>NICE had a real opportunity with these guidelines to improve the future for patients with ME. After all, two years and unknown costs were expended in their preparation.</p> <p>Yet these guidelines fail on a number of levels and give no real help to a GP or paediatrician to make an informed evaluation or provide any useful treatment. They are, in fact, an appalling shambles of perpetuated myths, psychiatric dogma, outdated practices and prejudice.</p> <p>One walks away from this document wondering whether the National Institute of Clinical Excellence needs to be renamed to the National Institute of Clinical Expediency.</p> <p>The document shows little new thinking and is clearly lacking in impartial analysis of all areas of research into ME. How can this profess to have consulted patients or used real experience? Who was elected to be part of NICE committee?</p> <p>The lack of comment on epidemics and vaccinations shows how lacking in vision, scope and thoroughness has been the work carried out by NICE .</p> <p>The lack of analysis of the extensive</p>	Please see substantially revised guideline.

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					<p>biomedical research also shows a lack of rigorous control exercised in the formulation of these guidelines.</p> <p>lIME cannot endorse these guidelines as they will condemn people with ME to a false and perilous future which will again be dominated by psychiatrists and the institutionalised psychiatric dogma which pervades many organisations and healthcare departments.</p> <p>We urge NICE to withdraw this document and reconvene with representative scientists, researchers, patient groups and others who are in contact with the 'real world' of ME suffering. This will obviously prove embarrassing to the lead of NICE and will unlikely be listened to – despite a chorus of patient complaints with which these guidelines are likely to be met.</p> <p>Yet what is the purpose of producing a set of guidelines which are unusable and which will be criticised for the bias they contain?</p> <p>They will serve neither patient or healthcare practitioner.</p> <p>NICE state in these guidelines that they wish for the patient and medical community to work together. They will achieve the opposite with these guidelines.</p> <p>By maintaining the intention to authorise</p>	
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					<p>these guidelines NICE will not only do an injustice to a new generation of ME sufferers - they will also herald the end of NICE as any form of reliable guidance for ME.</p> <p>Failing a revision of these guidelines Invest in ME recommends that all ME patient groups, charities and people with ME and their carers walk away from these NICE guidelines. They will do more damage than ever before.</p> <p>Invest in ME have recommended in this review that a lawyer should be added to the NICE governing group to represent ME patients and their families.</p> <p>liME will also be seeking advice on whether NICE are liable for damages if some of the recommended psychological therapies are forced on ME patients which then cause degradation in health.</p> <p>To repeat the comments of one of our correspondents if NICE does not see the depth and breadth of the failures and omissions in the draft guidelines, following the consultation process, then a judicial review must be inevitable.</p> <p>Should these guidelines be implemented without substantial change or revision then Invest in ME urges all ME support groups to notify their GPs/Paediatrics departments/PCT staff that these are merely guidelines and</p>	
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					<p>that individual healthcare staff are able to accept ME support group information to extend necessary tests, as appropriate.</p> <p>By the date at which NICE have proposed that all submissions regarding the draft guidelines are to be received from stakeholders it will be exactly one year to the day since [x] died from ME. It is a sobering thought that in this century in the UK such an event could occur. These NICE guidelines will do nothing to prevent more deaths.</p> <p>As they stand these NICE guidelines are, to use a topical phrase, not fit for purpose.</p> <p>As [x] of the Norwegian ME Association states –</p> <p>“If the map doesn't match the terrain, it is the map that is wrong and not the terrain.”</p> <p>These guidelines are unacceptable and Invest in ME will do everything in its power to oppose them as they currently stand.</p>	
SH	Invest in ME	17	FULL	General	<p>Itemised Comments on Guidelines Document</p> <p>The following chapter includes comments on individual lines in the FULL of the guidelines which we feel need to be corrected or reviewed. Due to the format of the document it is not</p>	Noted.

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						<p>possible to comment on every section. liME have done their best, though, to constructively review all of the evidence within the constraints of time and energy.</p> <p>The comments relate to the draft guidelines by page and line number, as appropriate.</p>	
SH	Invest in ME	207	FULL	General		<p>Appendix 1 – [x] Norwegian ME Association</p> <p>At the IACFS medical conference in Madison, Wisconsin in October 2004, professor Charles Lapp chaired the clinical session. He started the session by saying that "CBT has become a dustbin word". He could not have said it better.</p> <p>I am reading your comments and arguments on the IMEGA-e and I am concerned. With respect, I believe that you don't seem to understand that as far as CBT and GET goes, there are now A and B versions of both. The B-versions are coping strategies, and not CBT or GET. This must be made very clear. When CBT is recommended and argued that it has proven helpful in the treatment of cancer or diabetes or whatever other recognised organic disease, it is coping strategies and not the CBT the psychiatric lobby is promoting. They, in contrast, believe that ME-patients are suffering from a</p>	<p>Noted with thanks. Please refer to the NICE Technical Manual for the criteria for evidence and to the scope of this guideline that details what is included and excluded.</p>

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					<p>'behavioural problems".</p> <p>The usual interpretation by doctors and health personnel of CBT and GET as treatments is that ME-patients suffers from "avoidance behaviour" and "catastrophic thoughts/thinking". At a meeting recently for doctors and health personnel in this country (Norway), ME was the topic and how to treat them. The patients were ridiculed and stigmatised.</p> <p>"What should we do? They won't take antidepressants. Perhaps the best thing would be to commit them to psychiatric hospitals for their own good".</p> <p>This is a result of the recent report from the Norwegian "NICE " which stated clearly that all studies on CBT and GET are weak, but to get this message across they would have to read the report which they don't.</p> <p>Now the psychiatry lobby here is running courses on how to "best treat ME-patients" and taking advantage of GPs uncertainties, confusion and lack of knowledge.</p> <p>We know for a fact that a lot of GPs are totally confused by all the different messages, even when they take ME seriously.</p> <p>If you don't agree 100 per cent with the NICE guidelines, please, please make your protests in the strongest possible</p>	
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						<p>way! We did – we pulled out in protest although we agreed in parts of the report, and we went to the press. At the same time we released our comments on our website: key point, NICE version and FULL.</p> <p>2 It has not been negative as many believed. On the contrary - we have had a lot of support from many sources in the health services and the medical profession. They have read our 'FULL' (most read; we see that on the statistical recording) where we argued our points with reference to the medical literature with links to the original articles whenever possible. If the map doesn't match the terrain, it is the map that is wrong and not the terrain.</p> <p>Appendix 2: Reference on Epidemics</p>	
SH	Invest in ME	209	FULL	General		<p>Appendix 4 – Letter from [X and X]</p> <p>I am writing to you with regard to your recent release of draft guidelines for the</p>	Noted with thanks. Please refer to the NICE Technical Manual for the criteria for evidence and or the scope of this guideline, detailing

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					<p>treatment of CFS/ME.</p> <p>While I have reservations about several of the recommendations made, I feel that the recommendation of Graded Exercise Therapy (GET) as one of your therapies of first choice is the most inappropriate. If included in the final draft of the guidelines, it would represent the very worst medical practise.</p> <p>Such practise has severe negative implications for the health, well-being and long term prospects for those, like myself, who have the illness. I have enlisted the help of [x], a biologist (who is thankFULLy thankfully healthy), as principal author of a review of the scientific case for NOT recommending exercise as a form of therapy for those with CFS/ME, a copy of which I have attached to this message.</p> <p>This paper draws on a variety of references, the majority of which have been published in established, peer-reviewed scientific and medical journals. By setting them within the context of exercise as therapy for CFS/ME, we hope that the persuasiveness of the arguments presented will dissuade NICE from recommending the use of GET, or any form of exercise therapy, in their final draft of the guidelines for the treatment of CFS/ME.</p>	<p>what is included and excluded.</p>
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					<p>The charity Action for ME have made estimates about the annual cost of CFS/ME to the UK economy. They range from £3.4 to £6.4 billion a year. The use of GET may well add to this cost. It certainly won't decrease it.</p> <p>The physiology of exercise intolerance in patients with myalgic encephalomyelitis (ME) and the utility of graded exercise therapy</p> <p>[X] and [X][†]</p> <p>ABSTRACT – This review discusses the suitability of graded exercise therapy for the treatment of myalgic encephalomyelitis (ME), based on current knowledge of the underlying physiology of the condition and the physiological effects of exertion on ME patients. A large body of peer-reviewed scientific literature supports the hypothesis that with ME an initial over-exertion (a period of metabolic stress) in conjunction with viral infection depletes concentrations of the metabolic regulator glutathione, initiating a cascade of physiological dysfunction. The immune system and muscle metabolism (including the muscles of the cardiovascular system) continually compete for glutathione, inducing a state of constant stress that renders the condition chronic. The impairment of a range of functions means that subtly different suites of symptoms are</p>	
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					<p>apparent for different patients. Graded exercise therapy has proven useful for a minority of these, and the exacerbation of symptoms for the majority is not subjective but has a physiological basis. Blanket recommendation of graded exercise therapy is not prudent for such a heterogeneous group of patients, most of which are likely to respond negatively to physical activity.</p> <p>Following exercise, patients with myalgic encephalomyelitis (ME) uniquely exhibit exacerbated symptoms and a suite of measurable physiological changes indicative of stress (sub-optimal metabolic performance; e.g. reduced respiration and heart rate, increased glycolysis and lactic acid production, and concomitant limitation of activity¹⁻⁵). Although these symptoms may not be universal⁶, a significant subgroup of ME patients are affected in this manner⁷. The issue of exercise is critical for the treatment of the condition as one school of thought recommends “graded exercise therapy” as a General remedy for ME whilst another recognises that exercise intolerance may have an underlying physiological cause that may actually be aggravated by physical exertion. This difference of opinion influences policy: graded exercise therapy is one of the principal recommendations of the current NICE</p>	
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					<p>draft guidelines for the treatment of patients “mildly to moderately affected” by ME (p. 21, lines 20 to 23) ⁸ .</p> <p>Although recent General reviews of ME exist ⁹⁻¹¹ , our aim is to specifically review evidence for the mechanisms by which physical activity affects ME patients, and to investigate how graded exercise therapy may help or hinder recovery.</p> <p>Although no single randomised controlled study has yet attempted to investigate every aspect of ME, the combined weight of empirical evidence to date indicates that the condition is characterised by a complex series of events involving reserves of metabolic regulators such as glutathione, muscle metabolism and the cardiovascular system. A significant body of literature suggests that these imbalances are associated with a dysfunctional immune system impaired by viral infection. Indeed, a hallmark of ME is a range of symptoms, varying in extent between patients, suggesting that a range of functions are impaired to greater or lesser degrees.</p> <p>ME typically follows a flu-like illness, with elevated concentrations of viral particles subsequently detectable in blood and muscle tissues ¹² . Post-viral fatigue is a well established possible consequence of infection by a range of</p>	
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					<p>different viruses¹³⁻¹⁷, with enteroviruses specifically implicated in the case of ME – elevated concentrations of viral RNA sequences resembling coxsachie virus¹² B are detectable in muscle tissue . Furthermore, the majority of the limited number of ME patients so far treated with antiviral drugs (interferons) were able to return to work following treatment¹⁸, also suggestive of a persistent ‘smoldering infection’¹⁹ .</p> <p>Crucially, post-viral fatigue is not related to the muscle disuse and deconditioning that can result from the initial period of illness¹² . Indeed, the mechanism underpinning post-viral fatigue is a multifaceted physiological imbalance.²⁰</p> <p>Nijs and co-workers²⁰ found that, for ME patients, graded exercise resulted in faulty regulation of the immune system, specifically increased activity of the enzymes “elastase” and “RNase L”. RNase L is a key component in the cell’s virus detection system and is up-regulated in response to viral infection. However, elastase degrades RNase L and is normally involved in removing it from the cell when concentrations are too high. Why should both be highly expressed in ME patients? Elastase is activated and degrades the RNase L in the absence of metabolic regulators such as glutathione. (Glutathione is an</p>	
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					<p>amino acid complex that modifies enzyme activity throughout the body, and ME patients exhibit either lower concentrations or an imbalance ²¹⁻ between its active and inactive forms ²³ .) Thus the simultaneous over-activation and mis-regulation of this part of the immune system can be explained by glutathione depletion. A range of factors contribute to glutathione depletion in the General population, including infection, the oxidative stress induced by strenuous or sustained exercise, and the long-term elevation of the stress hormones cortisol and ²⁴ adrenalin . Furthermore, glutathione is also involved in sustaining respiration (i.e. the production of chemical energy compounds such as ATP in the mitochondria) thereby providing energy for active tissues such as muscle. Thus muscle tissue effectively competes with ²⁵ the immune system for glutathione – sustained physical activity reduces the amount of glutathione available to the immune system, resulting in immune dysfunction. Conversely, an overactive immune system reduces the amount of energy available for muscle tissue, also exacerbating oxidative stress, and can account for both the chronic fatigue and pain (by inducing lactic acid production) that characterise ME. Thus, following an initial period of stress, glutathione</p>	
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					<p>concentrations may be too low for the optimal function of both the immune system and muscle tissues, paving the way for both persistent viral infection and fatigue, both of which feedback from each other to render the condition chronic.</p> <p>This situation is compounded by the fact that glutathione not only has a supporting role in the immune response but also directly inhibits the replication of enteroviruses by blocking the formation of one particular protein (glycoprotein B) shared by all – including coxsachie viruses. Indeed, glutathione concentration is a major factor influencing the expression of other persistent viral infections such as ^{26,29} HIV . Thus glutathione depletion not only suppresses the immune system, it leaves the body particularly defenceless against enteroviruses. Sustained exercise or stress can deplete glutathione concentrations to the point where viral RNA is no longer prevented from replicating, aiding either an initial infection or the renewed replication of previously blocked viral RNA present in ^{27, 29} muscle tissue and blood . Thus glutathione depletion is a strong candidate for 'the trigger for reactivation ³⁰ of endogenous latent viruses' in ME . A small number of studies demonstrate that foods rich in glutathione or direct</p>	
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					<p>glutathione injection help to relieve fatigue in ME patients, and may clear active viral infections^{31, 32} .</p> <p>Although the above studies have concentrated on skeletal muscle, the heart (and the postural leg muscle involved in pumping blood back to the heart) is not exempt from glutathione depletion. Thus the above mechanism can also account for the range of cardiovascular problems associated with ME, including orthostatic (standing) intolerance (reviewed by Spence and Stewart³³). Patients with orthostatic intolerance 'have continuous disability and commonly have exercise intolerance'³³ .</p> <p>Together, this evidence suggests that chronic fatigue in ME is symptomatic of the following sequence of events: a period of infection or strenuous physical or mental activity results in glutathione depletion; this renders the immune system relatively ineffective, particularly against enterovirus infection; the immune system becomes constantly activated (and inefficiently governed) because it has insufficient resources (glutathione) to completely rid the body of viral particles; the constantly elevated energy demand of the immune system detracts from other metabolic functions (particularly energy-demanding systems</p>	
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					<p>such as skeletal muscles and the cardiovascular system); limitation of respiratory and cardiovascular systems further locks the patient into a vicious cycle of inefficient energy production and use; increased reliance on anaerobic metabolism leads to lactic acid production and associated muscle pain.</p> <p>Clearly, the performance of energy-demanding activities such as exercise can only aggravate this situation. Indeed, 82 % of ME patients in a recent study stated that graded exercise therapy worsened their condition, and only 5 % found it useful (compared to 70 – 75 % of patients who found either pain management or ‘pacing’ of daily activities useful)³⁴. Furthermore, the Canadian Clinical Treatment Protocol warns that “externally paced ‘Graded Exercise Programs’ or programs based on the premise that patients are misperceiving their activity limits or illness must be avoided”³⁵. If exercise is so detrimental, why is graded exercise therapy often recommended as a treatment for ME? Firstly, many of the studies cited here are recent, and the information and implications have perhaps not yet filtered up to policy makers. Secondly, the reclassification of ME as an ambiguous ‘chronic fatigue syndrome’ (CFS) by members of the</p>	
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					<p>psychiatric profession assumes that the symptoms have no physiological basis and are best treated with the traditional psychiatric method of facing and overcoming a problem, rather than direct removal of the problem at source. However, this approach jumps from hypothesis to treatment without investigating the mechanisms involved, perhaps explaining why “no psychiatrist has ever cured an ME patient using psychiatric treatments”¹⁹. Psychiatry, by definition, should not have authority over the treatment of physiological disorders, particularly those that occur chiefly in muscle tissues. Graded exercise therapy is founded on, and perpetuates, the myth that ME patients are simply malingering, while most are frustrated by their incapacity to satisfactorily conduct critical aspects of daily life³⁴.</p> <p>ME is a heterogeneous disorder that affects different patients to varying degrees and with subtly different suites of symptoms. At best, graded exercise therapy has relieved symptoms for (but not cured) a tiny minority of patients, whilst the weight of empirical evidence indicates that exercise has direct and persistently negative impacts on the physiology and quality of life of a significant subgroup of ME patients. Any universally applied therapy is</p>	
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					<p>unlikely to address the heterogeneity of ME, and graded exercise is particularly unsuitable as it may worsen the condition, and should not be Generally recommended without a high degree of confidence that it will not be applied to susceptible patients: it is difficult to conceive of a more inappropriate therapy for ME. By increasing the risk of relapse and overall health risks, rather than reducing them, graded exercise therapy also risks increasing the burden of illness on society at large. The present review suggests that an approach based on treatment of the underlying physiological dysfunction will be more fruitful.</p> <p>Abbreviations</p> <p>ATP = Adenosine triphosphate, RNase L = 2',5'-oligoadenylate (2-5A) synthetase/Ribonuclease L</p> <p>Appendix 4 - Literature cited</p>	
SH	LocalME	91	FULL/NICE	General	<p>SUMMARY</p> <p>The consensus of opinion of LocalME respondents is that we cannot support the current NICE Draft Guideline whilst it:</p> <ul style="list-style-type: none"> <input type="checkbox"/> promulgates a psychosocial theory of ME/CFS 	Please refer to the guideline, which has been revised.

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					<ul style="list-style-type: none"> □ 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). <p>Without major changes to the current draft guideline 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).</p> <p>By adopting the NICE Guidelines, whilst failing to 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</p>	
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					<p>or strictly defined CFS may result in avoidable, possibly irreversible harm to some patients currently subsumed under an unnecessarily broad diagnostic label.</p> <p>The draft guideline is clearly aimed at 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.</p> <p>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 sufferers.</p> <p>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.</p>	
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SH	ME Research UK (formerly MERGE)	1	FULL/NICE	General	<p>The draft produced by the Guideline Development Group (GDG) is unsafe and unsatisfactory (“unfit for purpose”) because it does not engage with key issues involved in the diagnosis and management of ME/CFS. We shall briefly outline the areas where core difficulties arise, before presenting a line-by-line critique of the limitations. These areas can be divided into the following:</p> <ol style="list-style-type: none"> 1. The problem of the diagnostic rubric and the need for research-based subsets. 2. The skewing of the RCT evidence-base examined by the GDG, and the devaluation of evidence from scientific studies and surveys. 3. The limitations of the evidence base for non-specific management and coping strategies. <p>1. Problem of diagnosis and the need for research-based subsets</p> <p>As the draft guidelines point out, ME/CFS is a diagnosis of exclusion based on a collection of vaguely defined symptoms that it shares with other illnesses. While the GDG has tried in good faith to fulfill its remit – to suggest guidelines for “diagnosis and management” – it has failed to ask what the “diagnosis” means and which patients or groups of patients it</p>	<p>Issue 1. Diagnostic and terminology</p> <p>The broad range of symptoms listed initially was there to raise awareness that the individual <i>may</i> 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.</p> <p>While it is generally recognised that it is heterogeneous, the evidence does not allow distinctions between subgroups with regard to management..</p> <p>Please see substantially revised diagnostic section of the guideline where many of these issues have been addressed.</p>
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					<p>contains. Without addressing these issues, the guidance is no more than the blind leading the blind round in circles.</p> <p>Terminology is the 'hot' issue in ME/ CFS: it energises the debate between patients and healthcare professionals, and it impacts on patient management, clinical practice, and the results of clinical trials (which are heavily dependent on the entrance criteria used to recruit subjects). The issue can be simply put. The original case description of the illness, myalgic encephalomyelitis (ME) (Acheson, 1959; Dowsett et al, 1990) referred to a condition, commonly of infectious onset, characterised by:</p> <ul style="list-style-type: none"> ♦ Exercise-induced myalgia and fatigue precipitated by trivial exertion (physical or mental). ♦ Neurological disturbance, especially of cognitive, autonomic, and sensory systems. This could include impairment of short-term memory and loss of powers of concentration, usually coupled with emotional lability, nominal dysphasia, disturbed 	
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						<p>sleep patterns, dysequilibrium and/or tinnitus.</p> <ul style="list-style-type: none"> ♦ An extended and relapsing course with fluctuation of symptoms, usually precipitated by either physical or mental exercise; typically, the symptoms vary capriciously from hour-to-hour and day-to-day with varying involvement of the cardiac, gastro-intestinal, and lymphoid systems. <p>Since the late 1980s, however, the medical profession has been urged by a small subset of its members to adopt the term Chronic Fatigue Syndrome (CFS), a more wide-ranging diagnostic category which includes patients whose dominant symptom is medically unexplained, on-going, or chronic fatigue (in conjunction with several other physical or psychological symptoms) who might be not necessarily would fulfil the original criteria for ME.</p> <p>There are now several definitions of CFS, all still unvalidated in 2006; the Guideline Development Group (GDG)</p>	
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					<p>has mentioned these (Full Guideline, page 111-2), but has not grasped their significance. In the USA, the 1994 CDC case-definition of CFS is currently utilised (Fukuda et al, 1994), supplanting its predecessor, the 1988 CDC criteria. However, in the UK, a frequently-used case definition is the 'Oxford criteria' (Sharpe 1991) which can include patients with no physical signs and inadvertently selects subgroups of patients with high levels of psychological diagnoses (Katon & Russo 1992; Freiberg 1999). Since the adoption of a particular case-definition of CFS will greatly influence the outcome of particular studies, it is perhaps no surprise that groups researching biopsychosocial management and coping strategies have tended to use the broader Oxford criteria, whereas groups outside the UK (mainly in the USA) have tended to use the Fukuda et al 1994 definition for their biomedical research.</p> <p>Today – whichever definition is used – the term ME/CFS (or CFS/ME which the GDG prefers) is an impossibly wide "umbrella term", based on a collection of vague non-specific symptoms shared with other illnesses, that contains different patient groups. The issues surrounding the establishment of CFS as a diagnostic category, and the inaccurate and biased characterisations</p>	
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					<p>of CFS that have subsequently arisen, were well-reviewed a decade ago by Jason et al (1997), and their key points are still valid:</p> <p>“...A significant complicating factor in understanding the dynamics of this illness is that there are probably different types of illnesses now contained within the CFS construct... We believe that it is crucial for CFS research to move beyond fuzzy recapitulations of the neurasthenia concept and clearly delineate precise criteria for diagnosing pure CFS and CFS that is comorbid with psychiatric disorders. It is also necessary to better differentiate CFS from other disorders which share some CFS symptoms but are not true CFS cases.”</p> <p>Importantly, many people with ME/CFS across the world point out a key fact, namely that though they are “diagnosed” and placed under the ME/CFS umbrella:</p> <ul style="list-style-type: none"> ♦ Fatigue is not their primary problem: musculoskeletal pain and post-exertional myalgia along with other physical signs are far more prominent, corresponding more closely to the classical definition of ME. 	
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					<ul style="list-style-type: none"> ♦ The World Health Organisation International Classification of Diseases (ICD) has, since 1969, classified ME separately as a neurological problem (ICD 10 93.3), with 'CFS' incorporated into the current ICD as a sometime synonym for ME. The chronic fatigue states per se are listed under mental and behavioural disorders (F 48.0), a category which specifically excludes ME/PVFS/CFS. <p>It is now recognised by clinical champions – and by most charities representing patients in the UK and overseas – that there is a strong, perhaps overwhelming, case for unpacking the term 'ME/CFS' and reclassifying and renaming in accordance with more specific clinical criteria (e.g., De Becker et al 2001; Tan et al 2002). Indeed, the further categorisation or substratification on the research-based subsets, or the need for it, is so often alluded to in the scientific literature on ME/CFS (vide http://www.cfids-cab.org/MESA/subsets.html) that it is</p>	<p>Issue 2. RCT data</p> <p>We have followed the NICE methodology and hierarchy of evidence.</p> <p>Please refer to the Methodology chapter for a discussion of the potential biases of patient surveys.</p>
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					<p>now a commonplace (though this body of literature has eluded the GDG). Examples in the past two years alone include: Jason, Neuropsychology Review 2005; Natelson, Clinical and Diagnostic Immunology 2005; de Lange FP, Neuroimage 2005; Baraniuk, BMC Neurology 2005; Kaushik N, J Clin Pathol 2005; Nijs J, Med Sci Sports Exerc 2005; Chia J, Journal of Clinical Pathology 2005; Lange G, Neuroimage 2005; Reeves, BMC Med 2005).</p> <p>Alongside this groundswell for change, there have been attempts to revise the CDC-1994 criteria directly (e.g., Reeves 2005), including suggestions for subclassification by mode of onset – rapid post-viral onset versus gradual onset – given that there appears to be a genetic basis for this distinction. In addition, the recent Canadian Consensus Document produced by the Expert Medical Consensus Panel in Canada (Carruthers 2003) was a valiant first attempt at arriving at an evidence-based yet historically consistent system of subgrouping patients based on their specific symptoms and signs. As these authors say, “The CDC [1994] definition, by singling out severe, prolonged fatigue as the sole major (compulsory) criterion, de-emphasized the importance of other cardinal symptoms, including post-exertional malaise, pain, sleep disturbances, and</p>	
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					<p>cognitive dysfunction. This makes it more difficult for the clinician to distinguish the pathological fatigue of ME/CFS from ordinary fatigue or other fatiguing illnesses". The lack of any substantive allusion to this Canadian Consensus Document (2003) in the current GDG guidelines is a serious omission, and one which diminishes the authority of the GDG.</p> <p>Our key point is that CFS/ME or ME/CFS is a wide umbrella term recognised by clinical champions, patient charities, leaders of ME/CFS support groups, and scientific researchers to contains many different patient groups. Without addressing this core issue, the efforts of the GDG to give diagnostic and management guidance that goes beyond the recommendation of anodyne, non-specific interventions will be inadequate and probably constitute misguidance.</p> <p>2. The skewing of the RCT evidence-base examined by the GDG, and the devaluation of evidence from scientific studies and surveys.</p> <p>While RCTs are the best evidence of "efficacy", there is a particular problem in the case of the diagnostic rubric ME/CFS. The large majority of "good quality" RCTs have examined the use of the non-specific management and coping strategies cognitive behavioural</p>	
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					<p>therapy (CBT) and graded exercise therapy (GET). Such trials are very expensive to conduct, and their authors have had the impetus – and been able to access the resources – to conduct them. This means that systematic reviews, such as that conducted by the GDG and ancillary staff – building on Whiting 2001, Mulrow 2001 and Chambers 2006 – find that the most prominent RCT evidence is for these non-specific management and coping strategies which (by their very non-specificity, with inadequate blinding and in the absence of a truly indistinguishable control intervention) are prone to result in mildly positive outcomes. The fact that these trials of CBT and GET have had relatively unspectacular results is less important to reviewers than the fact that they are "positive".</p> <p>In short, the accepted strategy of looking at formal "evidence" is flawed in ME/CFS because the evidence-base is skewed towards the small group of mildly positive RCTs. It is not a case of finding the "best" evidence garnered from the work of a range of biomedical and biopsychosocial scientists working on a level playing field, but rather finding quite modest evidence in a forgotten field put there by proponents of one model of the illness – the biopsychosocial model – a construct</p>	<p>Issue 3. Non-specific management and coping strategies</p>
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					<p>which contrasts with the biomedical model which implies that a primary disease entity exists and that biopsychosocial aspects are secondary (the two models discussed in the report to the UK Chief Medical Officer in 2002). Contrast this situation with, say, breast cancer which has been well supplied with funding for biomedical trials, and in which meta-analysis can arrive at a best estimate of treatment effects from a large number of different studies, including replicate investigations on different populations by different research groups. Breast cancer with the formal evidence-base that currently exists for ME/CFS would be no less a physical illness, and the non-specific management and coping strategies would be no more specifically effective for the underlying disease. Our point is that a NICE guideline on the diagnosis and treatment of breast cancer in the face of such an evidence-based would not be meaningful, or fair to the patients.</p> <p>A corollary of this is that the importance of evidence from non-RCT scientific studies is diminished or discounted. There is no need for us to list here the range of biomedical investigations already conducted on people with ME/CFS – these have already been flagged for the attention of the GDG, and a FULL database of over 3000</p>	<p>The clinical trials of CBT and GET have shown improvement in people with CFS/ME and therefore the GDG recommended these as therapies.</p>
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					<p>abstracts exists at http://www.meresearch.org.uk/. Most are not RCTs or controlled trials, and come lower in the hierarchy of research evidence, but given the paucity of clinical trials in ME/CFS (a function of lack of the basic funding needed to test hypotheses) and the skewing of the small RCT evidence-base that exists, they do, in fact, represent a considerable body of evidence that biomedical investigation can uncover, within a subgroups of people with ME/CFS, biological anomalies that might well help to explain many of the clinical features associated with the illness and indicate areas for therapeutic treatment.</p> <p>Similarly, patient survey evidence is largely discounted because, in the GDG's words (FULL guideline, page 43/269, line 22), "surveys from self selected respondents are subject to bias and not necessarily representative of the wider population of people with CFS/ME". Of course, surveys come low in the hierarchy of research designs, since they are not deemed valuable for determining causation or the true effect of treatment, and tend to come from apparently "self-selecting" group of people with self-reported symptoms. However, there are two things to be said.</p> <p>First, the evidence for the</p>	
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					<p>effectiveness of non-specific management and coping strategies is itself gathered by self-selecting professionals promoting their areas of expertise with access to central funding, and who also have difficulty ascribing causation or determining the true treatment effects.</p> <p>Second, such soft survey data contains real, hard experience – the experience of thousands of patients who have no access to funding for trials, and no way to publish their experience in the scientific literature. And while they are limited as formal evidence yet they are surely not meaningless or valueless. When they say –as in one large survey (CMO report 2002, page 49) – that only 7% of respondents found CBT “helpful”, compared with 26% who believed it made them “worse”, the remaining 67% reporting “no change”, they are not joking, and nor are the 79% of patients in the same survey who answered that they had severe pain sometimes, much of the time, or all of the time. Clearly, community-based surveys can be very useful for describing the experiences of people with severe and less severe ME/CFS and can help uncover widespread areas of concern (such as the lack of community care provision), or highlight areas where new research is needed (such as the urgent need for</p>	
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					<p>pain relief). In short, they can provide a systematic record of individual suffering, and point to ways to alleviate it. In this regard, they should be taken seriously by the GDG.</p> <p>ME Research UK and the wider ME/CFS community are not alone in pointing out such concerns. The central point was well put in recent letter (The Guardian, Oct 26 2006) by Dr Stilgoe of Demos, and Prof Irwin and Dr Jones; "The experiences of patients and the professional judgments of doctors are important. It is not a simple battle between evidence and anecdote....NICE needs to do more than just look at published science. It needs to start listening to people, patients and doctors".</p> <p>3. The limitations of the evidence base for non-specific management and coping strategies.</p> <p>As the recent review by Chambers et al (2006) – which informs and is informed by the deliberations of the GDG – shows, there have been only 5 trials of CBT which have a validity score >10, one of which is negative for the intervention; and only 3 RCTs of GET with a validity score >10. The total number of available trials is small; numbers are relatively low; no trial contains a "control" intervention adequate to determine specific</p>	
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					<p>"efficacy"; and their results are relatively modest (for example, one of the flagship trials (Prins 2001) described as having "cure of chronic fatigue syndrome as its explicit goal of therapy", reported no improvement on the fatigue severity endpoint in 56/83 patients after 8 months and in 38/58 after 14 months. The result was significantly better than in the control groups, but was modest nevertheless). In addition, some of the studies (particularly those on GET) have used the Oxford criteria (Sharpe 1991) for diagnosis, a rubric which allows selection of patients with chronic fatigue states, raising the question of the applicability of their results to patients with specific symptoms and signs. Again, the heterogeneity of the trials, the potential effect of publication or funding bias for which there is some evidence, and professional doubts about the evidence base for some behavioural therapies themselves give grounds for caution as regards the usefulness of this evidence-base to direct the management of people with ME/CFS. A recent commentary in the British Medical Journal (Bolsover 2002) is particularly relevant to the deliberations of the GDG: "Until the limitations of the evidence base for cognitive behavioural therapy are recognised, there is a risk that psychological treatments in the NHS will</p>	
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					<p>be guided by research that is not relevant to actual clinical practice and is less robust than is claimed.”</p> <p>These concerns have been echoed by reviews in the past, which have recommend caution in interpretation of the evidence-base: Whiting et al. 2001 stated, "all conclusions about effectiveness should be considered together with the methodological inadequacies of the studies. Interventions that have shown promising results include CBT and GET"; and Mulrow et al. 2001 stated, "...it is unlikely that the beneficial effects of such General treatments are specific or limited only to patients with CFS. In other words, although these therapies may help some people with CFS, their effectiveness does not help establish an underlying aetiology or cause of CFS". Indeed, a large body of both professional and lay opinion considers that these essentially adjunctive techniques have little more to offer than good medical care alone, and questions what specific additional therapeutic value they bring. As Carruthers et al (2003) have pointed point out: "The question arises whether a formal CBT or GET program adds anything to what is available in the ordinary medical setting. A well informed physician empowers the patient by respecting their experiences,</p>	
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						<p>counsels the patients in coping strategies, and helps them achieve optimal exercise and activity levels within their limits in a common sense, non-ideological manner, which is not tied to deadlines or other hidden agenda.”</p> <p>It would be referable for NICE and the GDG to recognise that specific, rigorous, evidence-based recommendations for treatment cannot be made at present than to incorporate an inadequate evidence-base into established guidelines which feed into clinical care and government policy to the detriment of people with ME/CFS.</p>	
SH	ME Research UK (formerly MERGE)	31	FULL and NICE FULL FULL FULL	General P. 203 37/8 138	1 24 5	<p>Comparisons between the FULL guideline and the NICE Guideline</p> <p>Since the shorter NICE guideline is the one read by 99% of interested parties, including healthcare professionals, it is important that the caveats of the FULL be reproduced in the NICE . These include:</p> <p>...The GDG did not regard CBT or other behavioural treatments as curative or directed at the underlying disease process, which remains unknown. Rather, such treatments can help some patients cope with the condition and consequently experience a improved quality of life....</p> <p>...substantial number of patients will</p>	<p>An abridged document that healthcare professionals will read and use will be developed. The Quick Reference Guide (QRG) based on the recommendations in the NICE guideline will be published and sent to relevant healthcare professionals. As with other QRGs, it will contain only the advice needed to manage the condition. The full guideline will be available on the NICE website with the background information.</p>

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					<p>pursue a fluctuating course with periods of relative remission and relapse, and a significant minority become severely, and perhaps, permanently disabled....</p> <p>.... recovery rates of 8% to 63% (median 40%), with FULL recovery being rare (5–10% achieving total remission)...</p> <p>...the GDG considered that patients should take the lead on any behavioural approaches to manage their CFS/ME. The objectives of any programme must be agreed with the patient who must understand the aims and objectives and must be willing to take part....</p>	
SH	ME Research UK (formerly MERGE)	32	FULL and NICE	General	<p>OMISSION</p> <p>The Analysis Report (2004) by the 25% ME Group for Severe Sufferers which was submitted to the Guideline Development Group previously, is not mentioned in either the FULL or the NICE guidance. This reported that 93% of respondents found CBT unhelpful and that GET was found to be unhelpful by 95%.</p> <p>It may be, as the FULL guideline says (page 43/269, line 22), "surveys from self selected respondents are subject to bias and not necessarily representative of the wider population of people with CFS/ME". But this report is still valuable and FULL of meaning, coming from a group representing 1200 house and</p>	We have added in the results from this survey. Thank you.

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						<p>bedbound people with ME/CFS, and does not deserve to drop off the edge of the evidential world.</p> <p>THIS DOCUMENT SHOULD BE REINSTATED.</p>	
SH	ME Research UK (formerly MERGE)	33	FULL and NICE	General		<p>OMISSION</p> <p>There is a need for clear criteria for referral to psychology/psychiatry services. The guideline draft is vague regarding the circumstances under which a patient can be referred for cognitive behavioural/graded exercise and other similar interventions, and for psychiatric/psychological assessment. We understand this to be an area of great concern for some people with ME/CFS, and so we feel that precise criteria for such referrals should be published as part of the final guidelines.</p> <p>Openness is a key element of modern NHS reform, and the publication of clearly-defined criteria would be both a major step towards reassuring parents and carers, and a signpost for professionals working in this area. The concern of some people with ME/CFS is that unless this is done, most cases will be referred for psychology/psychiatry services routinely. Given some of the statements in the current draft – which can read as thinly-veiled invitations to uncover psychological dysfunction – these concerns may, in fact, be valid.</p>	It is made clear in the guideline that all patients will be offered a referral to specialist services.

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SH	ME Research UK (formerly MERGE)	34	FULL and NICE	General		OMISSION The GDG fails to make a positive statement about the entitlement of people with ME/CFS to Disability Living Allowance/Incapacity Benefit. This is a perplexing issue for the many thousands of people with this illness who rely on disability benefits.	This is beyond the scope of the guideline, which is directed at the NHS.
SH	Royal College of General Practitioners Wales	1	FULL	General	General	Overall this is a good review of the situation with CFS/ME but it has a major weakness that we attempt to correct in the comments below from RCGP Wales	Noted with thanks.
SH	Royal College of Nursing	1	General			The Royal College of Nursing welcomes the opportunity to review these draft guidelines.	Noted.
SH	Royal College of Nursing	2	General			One of the potential difficulties the services will have implementing the guidelines is that at present, within the new CFS/ME services, very few patients are offered 'pure' CBT, GET or activity management. Most patients are assessed individually, and then offered components of all 3 interventions depending on their symptoms, level of function and severity.	Your comments will be referred to the implementation team.
SH	Royal College of Nursing	13	General			The FULL guideline is very long but the NICE excludes some of the important points related to self-management strategies, CBT, GET and Activity management which health professionals need to know to be able to offer appropriate treatment. There are also some important points for the	Noted.

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						care of the severe patients that appear to be missing from the NICE guideline. In practice, few health professionals will turn to the FULL guidelines for initial information.	
SH	Royal College of Nursing	41	FULL	General		'CFS' is often used in document where term 'CFS/ME' applies.	Noted and revised.
SH	Royal College of Nursing	42	FULL	General		Regarding testimonies: it would be good to include a testimony from an adolescent. Also a testimony from someone who recovered within a shorter time-frame.	Selection of individuals beyond the GDG members would have proved difficult. There are many testimonies available on websites.
SH	Royal College of Nursing	43	FULL	General		When describing severity levels, add 'education' alongside 'work'.	Please see relevant section of revised guideline.
SH	Royal College of Nursing	44	FULL	General		Significantly more children recover, compared with adults with CFS/ME. Most children make significant improvements and many recover FULLY from CFS/ME. There should, therefore, be more emphasis throughout this document on the potential for recovery for children and young people with CFS/ME. A positive testimonial from a recovered adolescent would be useful.	Noted. We have highlighted the better prognosis for children. We have included only testimonies in the consultation version. However, we do note that there are many examples of personal testimonies available and these may be useful to patients.
SH	Royal College of Nursing	45	FULL	General		Children and young people with CFS/ME should be cared for by those with both expertise in caring for this particular age group, and expertise in caring for patients with CFS/ME. Supporting documents that should be referred to include the NSF and 'Every Child Matters'.	This is general advice, not specific to CFS/ME. We have added reference to the National Service Framework for children..

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SH	Royal College of Nursing	46	FULL	General		More guidance could be provided regarding transition to adult care, and that many young people will have recovered and will therefore not require transition to adult care.	There is now a reference to the transitional care document.
SH	Royal College of Paediatrics and Child Health	1	General	General		We have received detailed comments from members on this guidance in addition to analysing it in relation to our own guideline (Evidence Based Guideline for the Management of CFS/ME in Children and Young People), which was written specifically for children and young people and was published in December 2004. Before moving on to the specific items in your draft, we would like to make the following General points.	Noted.
SH	Royal College of Paediatrics and Child Health	2	FULL	General		Prescribing Medication for Children: The guideline makes a number of specific recommendations relating to medication (e.g. Amitriptyline) which must be prescribed with caution in children, yet we note that only 63/219 participants in the consensus process were healthcare professionals and it is unclear how many of these 63 had any experience of managing children and young people with this condition. In addition, as the scope of the guideline is down to children aged as young as five years, such prescribing must be evaluated rigorously, and it is not evident from the from the guideline what level of evidence has been used for such recommendations. This point	The guideline group were responsible for the content of the guideline. There were two paediatricians on the GDG.

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						becomes even more pertinent when your guideline recommends the use of an unlicensed drug for such young children (melatonin), again with no indication of the level of evidence behind such a recommendation.	
SH	Royal College of Paediatrics and Child Health	3	FULL	General		Multi-agency working: The management of such a multi-factorial and chronic illness in children must be a multi-agency one and specifically any management plan must include the parents and the patient. This point is not clarified in the document often enough. As the children referred to will almost all be in FULL time education (i.e. up to 16 years), this is a vital component of the management. This is an example of where the clear distinction between the needs of children with this condition, and those of adults diverge, and is not explicit within the guideline.	This is best practice for all child healthcare, but we have added in further detail on this.
SH	Royal College of Paediatrics and Child Health	4	FULL	General		Engaging with the family: In General we are disappointed about how few references there are to the child as part of a family who clearly are key to ensuring the success or otherwise of the recommended interventions and in fact undertake much of the 'management' of the condition in children The NICE guidelines should refer practitioners to the RCPCH guidelines for managing CFS/ME in children and	This is best practice for all child healthcare, but we have added in further detail on this.

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						<p>young people which covers topics such as engagement with family.</p> <p>E.g. RCPCH guidelines 3.3.1 'Early engagement of the family, as well as maintaining a therapeutic alliance throughout the illness is crucial for successful implementation of the management plan.'</p>	
SH	Royal College of Paediatrics and Child Health	5	FULL	General		<p>Delphi Methodology Process. Further to the email sent to [NICE] on the 4th September (copy attached with this response), we have the following concerns regarding the consensus methodology process:</p> <ul style="list-style-type: none"> • The methodology is difficult / impossible to interpret from the information given. Clearly this needs to be clarified as it seriously undermines the document in it's current form. For example, there are several occurrences where a consensus appears to have been reached in one round but the question has gon on to the next round (e.g. p101 d, p 121 (8), p122 (2 and 3)). In at least one situation it appears that a statement reached an agree consensus in the first round but then continued to the second round where it reached a disagree consensus (p 129 (5)). • There was no breakdown of how many of the panel were paediatricians or healthcare 	Your comments are noted. The formal consensus procedure was carried out with the GDG and the results of the questionnaire illustrated. Due to time constraints in responding to comments and revising the guideline, it has not been possible to do further work on clarifying this.

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						<p>professionals with experience of managing CFS/ME in children and young people.</p> <ul style="list-style-type: none"> From looking at the results within the main guideline it did not appear that 20% of the statements agreed by the GDG were then subsequently went for confirmation by the wider group. Several of those who reviewed the guideline commented that they found the mixing of the evidence statements, with the clinical scenarios and the tables of the consensus results within the FULL document confusing and distracting. 	
SH	Royal College of Paediatrics and Child Health	6	FULL	General		All staff working with children should know how to be supported if the youngster has CFS/ME to enable them to have a community-based programme locally delivered. This could lead to fewer patients with severe disease and the requirements for disability management	The guideline recommends that healthcare professionals be familiar with the condition.
SH	Royal College of Paediatrics and Child Health	7	FULL	General		Many paediatricians would not perceive that five-year-olds have the same disease pattern and requirements for treatment as children of secondary school age. The cognitive and neuro-development of children needs to be considered. Very few studies mention children of primary school age, and therefore we should not assume that	Noted, and we have added in some reference to this.

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						this younger age group should be managed in the same way.	
SH	Royal College of Paediatrics and Child Health	8	FULL	General		The document often refers the 'specialist in CFS/ME' although we couldn't easily find a definition of what such a person might be or the skills or competencies that they should have.	It is beyond the scope of the guideline to define competencies. This is for implementation.
SH	Royal College of Paediatrics and Child Health	9	FULL	General		For many interventions there is a lack of evidence of efficacy – although in many instances there is also a lack of evidence of no effect. This might be more clearly emphasised.	This problem is not confined to research in this area.
SH	Royal College of Paediatrics and Child Health	10	FULL	General		<p>There is a danger of relying solely on information from systematic reviews of clinical and randomised trial reports for non-pharmaceutical treatments that are not easily defined or replicated, such as CBT and GET. It is only by reading the actual paper describing the RCT does one see how the approach described as CBT and GET differs from study to study.</p> <p>There were only two RCTs involving children and young people. Though these are described in the systematic review as CBT, both studies adapted the intervention for children to include the whole family.</p> <p>The NICE guidelines do not distinguish between managing CFS/ME in adults and for children and young people. It needs to be made clear here that for children and young people the</p>	Noted, and this is particularly highlighted for interventions in children. However, there are also inherent problems in assessing the effectiveness of interventions using methods other than RCTs.

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						<p>approach to CBT and GET is slightly different to adults, and the importance of involving the whole family.</p> <p>There have also been concerns expressed regarding whether CBT delivered in RCTs are able to be effectively replicated when rolled out into the community. A recently published article, which may not have been picked up in the literature searches, investigates this in more detail and is attached with our response.</p>	
SH	Royal College of Paediatrics and Child Health	11	FULL	General		<p>The Department of Health have recently published the CFS/ME Service Investment Programme Report 2004 – 2006. This report sets out the progress made to establish during the last two years new specialist services for people with CFS/ME throughout England. It seems sensible to incorporate their findings and experiences into these guidelines.</p>	There is reference to this in the document.
SH	Royal College of Paediatrics and Child Health	12	FULL	General		<p>The referencing in the document is very unclear. For example, on page 110 statement 5.3.1.5 mentions a study with no reference either at the statement or through reading the clinical evidence summary.</p> <p>Also there is no reference section in the contents but at least two in the text (page 135 and 266) both starting at reference 1!</p>	Noted and revised.

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SH	Royal College of Physicians of London	1	NICE /FULL	General		Unlike other NICE Guidelines, this document is a consensus document, with evidence base limited to cognitive behavioural therapy (CBT) and graded exercise therapy (GET). The area of chronic fatigue syndrome (CFS) is poorly supported by evidence based clinical research. It is important that the “consensus” nature of this document is highlighted, as it may be used in its own right as a source of evidence base, eg in the diagnostic, health planning or medico-legal arenas. For example, The Guideline Development Group of twenty five included one nutritionist. Therefore, this presupposes that the information on nutrition and CFS, is based on a consensus of one?	<p>The consensus development is detailed in the methodology section.</p> <p>The GDG for this guideline was larger than usual to reflect the varied input into this condition.</p> <p>The guideline has been subject to a wider questionnaire and to the stakeholder consultation.</p>
SH	Royal College of Physicians of London	2	NICE /FULL	General		The consensus Guideline Development Group of twenty five, with one exception, did not include any single expert in major aspects of CFS, ie clinical aspects and/or research. Similarly the specialty of neurology was represented by a single neurologist, so a broad consensus for this consultation document would be difficult.	See comments above.
SH	St Bartholomew's Hospital Chronic Fatigue Services	1	General	General		The CFS/ME service at St Bartholomew's Hospital is a new NHS service established in 2005, which incorporated two well established services at the hospital.	Noted.
SH	St	2	FULL	Gene		We warmly welcome this guideline and	Noted with thanks indeed.

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	Bartholomew's Hospital Chronic Fatigue Services			ral		many of its recommendations. It is well written and researched and will be extremely useful for both patients and clinicians.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	3	FULL	General		This impressive draft serves many functions. Most importantly it serves to recognise this condition & educate specialist and non-specialist healthcare professionals across primary, secondary & tertiary services, using the best available evidence.	Noted with thanks.
SH	St Bartholomew's Hospital Chronic Fatigue Services	4	FULL	General		<p>Overall the content of the document is comprehensive, capturing the essence of our current understanding of CFS/ME; that is the necessity for a multi-disciplinary approach to assessment and treatment of CFS/ME in accordance with the biopsychosocial model of onset and maintaining factors for CFS/ME.</p> <p>This biopsychosocial approach is well established in the management of chronic pain. Pain management programmes, based on cognitive and behavioural principles, are the treatment of choice for people with chronic pain disorders (The British Pain Society. Recommended Guidelines for Pain Management Programmes for adults (provisional). The British Pain Society, June 2006, http://www.britishpainsociety.org/)</p>	This has been revised based on stakeholder comments.

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SH	St Bartholomew's Hospital Chronic Fatigue Services	5	FULL	General		We would like to see greater emphasis on those recommendations that are supported by the best available evidence , reviewed in the York university CRD updated systematic review. Since the systematic review provided substantial support for only two treatment approaches, CBT and GET, we suggest that it is important that the recommendation supporting these interventions is placed high up in the list of recommendations, if not the very first one.	Following consultation, the guideline has been restructured so that it will be more clearly understood.
SH	St Bartholomew's Hospital Chronic Fatigue Services	6	FULL	General		We could not find any guidance about risk assessment for suicide. This is a major omission, since patients diagnosed as suffering from CFS/ME do sadly commit suicide. We would be happy to help NICE in this matter with a screen developed for this purpose for the PACE trial, by Professor [X] with his permission.	The GDG discussed this and decided that a formal suicide risk assessment should not be done routinely for every patient, but may be needed in certain cases.
SH	St Bartholomew's Hospital Chronic Fatigue Services	7	FULL	General		Related to this, guidance on when to refer to or involve child and adolescent or adult mental health services is Generally absent, and, again, we suggest this is a major omission, which needs rectifying.	The guideline cross-refers to the other NICE mental health guidelines that address this issue.
SH	St Bartholomew's Hospital Chronic Fatigue	8	FULL	General		RCTs of CBT and GET did not test " self-management " strategies, but those therapies delivered by appropriately qualified and trained therapists. The words "self-	Noted and revised.

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	Services					management” should be deleted whenever they qualify CBT and GET.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	9	FULL	General		<p>The only RCT of CBT using a group approach showed that the treatment was no better than either usual medical care or supportive listening in improving physical function, one of its two primary outcomes, which it was designed to improve (O'Dowd H, Gladwell P, Rogers CA, Hollinghurst S, Gregory A. Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme. Journal: Health Technol Assess. 2006 Oct;10(37):1-140). A non-randomised waiting list control trial of group delivered CBT found only modest effects on fatigue and negative effects on function (Bazelmans E, Prins JB, Lulofs R, van der Meer JWM, Bleijenberg G. Cognitive behaviour group therapy for chronic fatigue syndrome: a non-randomised waiting list controlled study. Psychotherapy & Psychosomatics 2005;74:218-24). Therefore the guideline should more emphasise the importance of individualised therapy, rather than group approaches to CBT. To our knowledge, no RCT of group delivered GET has been published, so there is even less evidence to support a group for GET. These findings make logical sense and are consistent with the rest of the guideline, which emphasises</p>	Noted and revised.

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						repeatedly the importance of an individualised approach.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	10	FULL	General		It surprised us that more General advice was not offered regarding the usefulness of physiotherapists in helping patients beyond a simple GET programme. Interventions can include helping with comorbid conditions such as hyperventilation and working on improving balance and core muscle strength. Although these approaches are not supported by RCTs, they should command consensual support within the GDG.	Noted with thanks, but the view of the GDG is that these specialised services may be appropriate in some circumstances but could not be routinely recommended in a national guideline.
SH	St Bartholomew's Hospital Chronic Fatigue Services	11	FULL	General		In a similar way, the guideline makes little mention of the utility of occupational therapists to provide functional assessments and provide functional and occupational rehabilitation programmes, which can include return to work/study programmes, which both anecdotally and in audits, our patients report as helpful.	Noted with thanks, but the view of the GDG is that these specialised services may be appropriate in some circumstances but could not be routinely recommended in a national guideline.
SH	St Bartholomew's Hospital Chronic Fatigue Services	12	FULL	General		And to complete the trio, clinical psychologists can provide evidence based therapy to improve self-esteem, depression, and anxiety disorders, which use CBT as well as other therapies, such as cognitive analytical therapy, motivational interviewing, and Eye Movement Desensitisation Reprogramming.	Noted with thanks, but the view of the GDG is that these specialised services may be appropriate in some circumstances but could not be routinely recommended in a national guideline.

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SH	St Bartholomew's Hospital Chronic Fatigue Services	13	FULL	General		Although there is significant advice regarding pharmacotherapy, all of which is based on little evidence, there is little guidance on the use of family therapy and other systemic interventions (such as couple therapy), which we find can be essential to aid recovery in the patient and provide support for the family or carer. Anecdotally we find this particularly to be the case in younger patients still living with their parents.	No evidence was found for these therapies with regard to patients with CFS/ME.
SH	SWAME (South West Alliance for ME)	1	General			General note on page numbering. NICE . In the version downloaded, pages go 1 of 48, 2 of 48, 1 of 48, 2 of 48, 3 of 48 etc and finish at 46 of 48. That is, the cover and contents are numbered one and two so the page headed introduction should be 3, however it actually is numbered one. In the page quotations We have continued to use the numbers as they appear in this downloaded version. We mention this here in case there is any confusion.	Thank you for pointing this out!
SH	SWAME (South West Alliance for ME)	2	FULL/NICE	General		This is the response of SWAME, the South West Alliance for ME. Our constituent groups across Cornwall, Devon and Somerset have provided patient representation and have been involved in the development of the new NHS CFS/ME services before they started and ongoing since initiation. Research within the groups via questionnaire has enhanced the	

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					<p>information and feedback for the CFS/ME services.</p> <p>SWAME responds to NICE draft guidelines with direct information from group data, patient experience, group membership and NHS services for CFS/ME. In the words of one of our younger members, we welcome this situation “that somebody is taking this illness seriously” and respond to the draft guidelines with that in mind.</p> <p>Constructive Statements</p> <p>We support the emphasis on the importance of an individual/collaborative approach and the patient’s right to refuse treatment he or she deems to be inappropriate. This is extremely important as the ‘expert patient’ is in a position to know that certain management approaches are not currently achievable by them. It is of prime importance that the medical team continue to support a patient and provide clear outlines for welfare benefits and access to adapted educational provision or work situation. The “smoothing of the path” for practical help (benefits/ blue badge / wheelchair / stair lift / home help / education at home / transport to school) is one of the most important actions of the clinician/healthcare professional for all individuals with ME.</p> <p>We note the use of the term ‘exercise’</p>	<p>Issue 1. Constructive statements</p> <p>Noted with thanks.</p>
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					<p>throughout the documents but our experience is that patients, their families and carers and often healthcare professionals in the new CFS/ME services are aware that it is the level, type and length of activity that is the prime consideration. Exercise is a term that relates more to an ordinary well population.</p> <p>Regularly the feedback from patients, their families and carers is that sleep is significantly affected in this illness. This seems to relate to quality, length and sleep cycle. It is noticeable that sleep is not adversely affected by sleep in the day if the person is at the level of requiring additional daytime sleep; indeed appropriate rest periods during the day often improve night-time sleep. It is regularly reported that sleep is quickly affected by the person exceeding their current sustainable activity capacity.</p> <p>We, and as far as we are aware other stakeholders also, have referred repeatedly to the Canadian Guidelines Overview, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Clinical Case Definition and Guidelines for Medical Practitioners, An Overview of the Canadian Consensus Document. Carruthers and van de Sande, 2005 (20 A4 pages). A UK A4 version of this document was printed in April 2006. We still have</p>	<p>Issue 2. Concerns</p> <p>Please see substantially revised guideline where many of your criticisms have been addressed.</p>
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					<p>some spare copies and we and the West Midlands Consortium would like to supply these to the Guidance Development Group and Guidance Review Panel sufficient for each member to have a hard copy. Please contact [X] to arrange delivery.</p> <p>Concerns</p> <p>We are very concerned about the overall message that is being communicated via the draft guidelines to healthcare professionals/ patients and their families and carers / social and educational services and the media. This is that the prime means of getting well, at whatever level of the illness, is to change the patient's beliefs and encourage them to exercise more.</p> <p>The guideline also needs to be very clear that all advice given is related to management and not cure. Although we all hope that each patient is provided with person-specific care, management and practical support, which will best support whatever level of recovery can be made.</p> <p>The guideline needs to address the complex and crucial evaluation of each patient's current sustainable activity, ie all the contents of their daily life. No management or symptomatic support can be made without knowing the patient's real baseline of all activities. Support on working this out and</p>	
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					<p>developing a person-specific management plan, including symptomatic support, is a necessarily time-consuming process for the clinician and patient. As every patient says, adjusting to, recognising and functioning within their current capacity is “very hard work” and needs careful support from all involved with the patient.</p> <p>We note that the term “relapse” adequately and appropriately describes what happens when a patient’s situation deteriorates following a period of stability whereas the term “setback” is neither adequate nor appropriate and meaningful for the situation.</p>	
SH	SWAME (South West Alliance for ME)	15	General		<p>In order also to include some positives, the following notes various points working chronologically through the NICE . Although where points have already been made above with reference to specific theme, we have tried not to duplicate. We’ve done this only for the NICE since, broadly speaking, the NICE contains all the recommendations whereas the FULL additionally elaborates on how the recommendations were reached. For practical use we are anticipating that most health professionals would use the NICE , or even the quick reference guide once it is developed. It is a point of concern that the quick reference guide appears not to be subject to</p>	Noted with thanks.

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						consultation.	
SH	SWAME (South West Alliance for ME)	31	FULL and NICE	General		<p>Conclusion</p> <p>Because of the history of this illness, the widespread lack of understanding, and the extent to which patients have suffered due to wrong or poor quality information amongst health professionals, there is a special need for care with the language used and the hidden messages conveyed.</p> <p>Although there are several positive and useful individual points of guidance, overall the document is unacceptable. Major amendments are needed, as indicated above.</p> <p>Research evidence is extremely weak, exceptionally so in comparison with other conditions for which NICE has prepared guidance. There is hence a case for thinking beyond the box of the normal NICE strictly gold-standard-evidence-based protocols, giving more weight to patient evidence and consensus evidence such as the Canadian Diagnostic and Treatment Protocols. Considering the small number of (also questionable) research studies upon which this NICE draft guidance has been based, it is clear that the Canadian consensus approach, based on practical experience with large numbers of patients has much more to offer and produced an infinitely superior, practical and more useful</p>	<p>Please see revised guideline where many of these points have been addressed.</p> <p>As with other guidelines, the methodology used was that detailed in the NICE Technical Manual.</p>

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						clinical guidance document, which additionally has proved widely acceptable to patients.	
SH	SWAME (South West Alliance for ME)	33	FULL	General		<p>Appendix B</p> <p>DOES GRADED EXERCISE THERAPY IMPROVE POST-EXERTIONAL MALAISE IN CFS?</p> <p>Susanna Agardy</p> <p>Source: (31.03.05)</p> <p>http://listserv.nodak.edu/cgi-bin/wa.exe?A2=ind0503e&L=co-cure&T=0&P=1616</p> <p>accessed 24.11.06</p> <p>People with CFS/ME are being increasingly urged to exercise to improve functioning. For example, in the Medical Journal of Australia, Prof. Andrew Lloyd has announced that 'one can safely conclude ...that graded physical exercise should become a cornerstone of the management for patients with CFS'1 unless they are severely ill.8</p> <p>In the same editorial the problem of post-exertional malaise is acknowledged: 'the cardinal phenomenon of fatigue in CFS is characterised by a marked and prolonged exacerbation of symptoms following minor physical activity.'1. As CFS/ME people with this problem know, this exacerbation is often delayed and</p>	<p>Again, these are important points, but the evidence does not enable us to specify which patients with which symptoms will benefit from each programme.</p> <p>We have noted the need for tailored treatment with appropriate review and monitoring. Patient refusal or withdrawal is stressed, along with patient control.</p>

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					<p>brings into play many symptoms. This should be enough to indicate that there is something extraordinary, rather than just exacerbated fatigue happening here. It can be serious enough to stop sufferers from entering exercise experiments or to cause dropping out of them.</p> <p>Three studies, two of them British^{2, 3} and one Australian⁴, have been cited as providing evidence for the benefits of GET. All of the studies found significant improvements in fatigue and functioning of a large proportion of CFS participants who completed a graded exercise program compared with controls who did stretching or relaxation or received medical care. Patients' beliefs about the physical cause of their illness were found to change with their improvements in fatigue when used together with CBT², or their improvement was interpreted in this light ⁴.</p> <p>To what extent can the results of these studies be Generalised to people with post-exertional malaise?</p> <p>1. Two of the studies, which are often quoted, show no evidence of directly addressing what we know as post-exertional malaise and do not even mention it.^{2, 3} These studies used the Oxford Criteria of 1991 for CFS formulated by the Oxford Consensus</p>	
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					<p>Meeting.5</p> <p>The syndrome definition in the Oxford Criteria for CFS does not include post-exertional malaise. Another section of the Oxford Criteria mentions that '.it should be stated whether the fatigue is greatly increased by minor exertion.'⁵, but there is no requirement to include subjects who have this problem. There is no mention of 'increased fatigue' in the studies. In any case, this amorphous and confusing term fails to do justice to the phenomenon of post-exertional malaise.</p> <p>Only Wallman seems to refer to the problem in stating that there was 'no relapse' during the course of treatment.⁴ Wallman required doctors' certificates to state that patients met the Fukuda Criteria⁶. Although these criteria include post-exertional malaise it is not an essential criterion.</p> <p>None of the authors show evidence of having ascertained whether the subjects in fact suffered from post-exertional malaise prior to the treatments. Therefore, these studies leave themselves open to the interpretation that at least some subjects in the studies did not suffer from post-exertional malaise to begin with.</p> <p>2. Fulcher³ excluded people with sleep disorders, a well-recognised feature of</p>	
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					<p>CFS/ME according to the Oxford⁵, Fukuda⁶ and Canadian⁷ Criteria. This could have further excluded CFS/ME sufferers who have post-exertional malaise as part of the syndrome.</p> <p>3. The studies by Fulcher³ and Wallman⁴ began with pre-treatment assessments including aerobic capacity and target heart rates involving treadmill or cycle testing. These tests would be likely to cause a degree of relapse in most people with post- exertional malaise, for many of whom aerobic exercise is having a shower, or even less activity. The authors seem oblivious to the contradiction of giving CFS sufferers sustained aerobic exercise, maximal or submaximal, before they underwent the careFULLy designed graded exercise program. Yet, no complaint or problem is reported.</p> <p>4. The studies are subject to volunteer bias, that is, people who feel well enough to do exercise or think they can perform in such a study will participate and those who are more severely affected will exclude themselves. This may be unavoidable, but the conclusions able to be drawn will be limited.</p> <p>These studies do not justify claims which imply that graded exercise assists in overcoming the effects of</p>	
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					<p>post-exertional malaise. They also cast no light on the problem of sufferers who fail to improve or get worse following exercise. They cannot be Generalised to the population of CFS/ME sufferers.</p> <p>Perhaps the experimenters have not paid attention to post-exertional malaise because they subscribe to the belief system which dictates that most of the limitations to CFS/ME people doing exercise reside within their 'dysfunctional' belief systems and the consequent assumed deconditioning. Where selection of subjects ignores and excludes post-exertional malaise (as with the use of the Oxford Criteria), the experimenters' belief system is perpetuated and remains unchallenged.</p> <p>For GET studies to have credibility for sufferers of post-exertional malaise they need to demonstrate that the subjects suffered from this problem before and not after the study. This would mean using the Canadian Criteria⁷, which requires the presence of post-exertional malaise for a diagnosis of CFS/ME. The studies would also need to take into account variables such as stage and severity of illness and correlate the responses to exercise with some of the physical abnormalities which have been discovered. While there is any ambiguity about this crucial issue people with post-exertional malaise cannot but reject the Generalisations</p>	
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					<p>from these studies.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Lloyd AR. To exercise or not to exercise in chronic fatigue syndrome? No longer a question [editorial]. Med J Aust 2004; 180: 437-438. 2. Powell P, Bentall RP, Nye FJ, Edwards RHT. Randomised controlled trial of patient education to encourage graded exercise in chronic fatigue syndrome. BMJ 2001; 322: 1-5. 3. Fulcher KY, White PD. Randomised controlled trial of graded exercise in patients with the chronic fatigue syndrome. BMJ 1997; 314: 1647-1652. 4. Wallman KE, Morton AR, Goodman C, et al. Randomised controlled trial of graded exercise in chronic fatigue. Med J Aust 2004; 180: 444-448. 5. Sharpe MC, Archard LC, Banatvala JE, Borysiewicz LK, Clare AW, David A, et al. A report-chronic fatigue syndrome: guidelines for research JR Soc Med 1991;84:118-21. 6. Fukuda K, Straus SE, Hickie I, et al. The chronic fatigue syndrome: a comprehensive approach to its definition and study. Ann Intern Med 1994;121: 953-959. 7. Carruthers BM, Jain AK, De Meirlier K, et al. Myalgic encephalomyelitis/chronic fatigue 	
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					<p>syndrome: clinical working case definition, diagnostic and treatment protocols. J Chronic Fatigue Syndr 2003; 11: 7-116. Available at: www.mefmaction.net/documents/journal.pdf (accessed Sep 2004).</p> <p>8. Lloyd AR, To exercise or not to exercise in chronic fatigue syndrome? [Letter] Med J Aust 2004; 181 (10): 578-580.</p>	
SH	The Association for Family Therapy	11	FULL	General	<p>Overall, had a systemic family therapy perspective been included in earlier phases of these discussions, this document might have useFULLy included references to the ways in which the strengths, understandings and resources of parents, carers and other significant relationships can be an extremely valuable resource in supporting those with CFS/ME.</p> <p>It might also have acknowledged that when a family member is ill, close others are affected by and affect their experiences. If unsupported, these relational connections may sometimes fuel difficulties, often unwittingly, and/or suffer under the strain.</p> <p>AFT believes that treatment services need to acknowledge and work with people's important relationships as well as with the individual. This relational, systemic focus is key to the development of services that</p>	This is a generalised approach that may be helpful, but there was no evidence to recommend it routinely.

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						<ul style="list-style-type: none"> ○ tailor support to the child and young person's particular needs, capacities, contexts and circumstances ○ support the child and those upon whom the child depends for care <p>It is important to recognise that the majority of information on CFS/ME comes from studies with adults and information regarding the treatment of children and young people is limited.</p> <p>Important areas for further study include the impact of the condition on families, particularly siblings; the development of the condition in more than one child in a family; the effectiveness of involving the family as a resource in treatment might enhance our knowledge and understanding</p>	
SH	The British Psychological Society	1	FULL/NICE	General		<p>These guidelines cover a particularly complex area but the drafts do not really reflect this. We know that the CFS population is heterogeneous. That is Generally accepted. However, there appears to be an assumption in the drafts that any differences between subgroups are of no clinical significance. In other illnesses, differences are taken into account when determining management. This is true for diseases like breast cancer, and psychiatric disorders like depression.</p>	<p>While it is generally recognised that it is heterogeneous, the evidence does not allow distinctions between subgroups with regard to diagnosis or management of the condition.</p>

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					<p>Why should CFS be different?</p> <p>We need to address the issue of heterogeneity before determining best practice. For example, we know from research that there is a difference between the populations selected using the 1988 and 1994 CDC criteria (e.g. De Becker et al 2001, Jason et al 2001). We also know that there is a difference within the population who fulfil the current (1994) criteria (e.g. Kennedy et al 2004). And there is a difference between the Oxford criteria and equivalents and the 1994 criteria (see comments by Stouten 2005 re Swanink et al 1995, Song and Jason 2005). The additional minor criteria matter.</p> <p>The draft acknowledges that differences have been found between patients who fulfil the 1994 criteria for CFS and the criteria for ME, with the latter reporting more neurological symptoms than the former.</p> <p>The first subgroup we might therefore distinguish within the CFS population is the subset with ME. Given there is no evidence of a clinically significant difference between ME and post-viral syndrome, one could combine these two as ICD-10 has done (G93.3). ME/PVFS is associated with reduced blood flow to the brainstem, as well as muscle abnormalities (both structural</p>	
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					<p>and functional) and infection (e.g. Costa et al 1995, Innes 1970, Lane et al 1998). Some doctors refer to myalgic encephalopathy, thus recognising the evidence of disease in the brain. In ICD-10, ME is listed alongside other encephalopathies. This was not changed in 2006. Natelson et al's identification of a subset with evidence of encephalopathy within the CFS population supports the existence of this subset in the USA (Natelson et al 2005).</p> <p>Definitions of ME such as that of Dowsett and Ramsay could be evaluated and offered to GPs.</p> <p>Findings such as those by Innes 1970, McGarry et al 1994, Lane et al 1998, Natelson et al 2005 and Paul et al 1994 are difficult to explain in terms of the CBT model and underline the need for a more flexible approach to the illness. The evidence of ongoing infection and immune activation in this subgroup, plus studies of structural changes in muscle tissue and the effects of exercise on muscle strength (not documented as yet in CFS) means that GET (and challenging somatic attributions) may not be appropriate in this subgroup and that the draft needs to assess alternatives to exercise programmes, such as pacing.</p> <p>The second group we might distinguish</p>	
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					<p>is the subset with a clear history of stress. The onset in these cases tends to be gradual and many patients report an increased frequency of colds and flu plus the delayed recovery from those infections, until one illness proves to be the 'final straw'. The subset with stress-related fatigue are likely to have abnormally low morning cortisol levels, they tend to feel tired all the time and do not report the marked diurnal fluctuations of people with ME/PVFS. As a result of the complications of stress (e.g. effects on the adrenal gland, HPA axis, see work by Dinan and colleagues), the prognosis for this subset is less favourable than for acute onset post-viral fatigue (e.g. Levine et al 1997).</p> <p>Unlike the group with ME and their neurological symptoms, there is no evidence that the patients with chronic stress have adverse reactions to the CBT and the exercise programmes proposed in the draft.</p> <p>The recognition of the subgroup with chronic stress is consistent with the existing literature on the effects of stress on the immune system in General (Glaser et al 2005), and does not rule out a role for stress as a perpetuating factor in ME/post-viral fatigue.</p> <p>The issue of subgroups is dealt with in</p>	
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					<p>more detail by Jason et al (2005).</p> <p>The existence of subgroups goes some way to explaining the apparent discrepancy between the results of the CBT trials and the reports from the patients cited in the draft. There are no trials of CBT or GET which show that these interventions are effective in patients with ME or strictly-defined (CDC 1988) CFS. All the trials showing benefits selected their patients using broader criteria (Oxford, CDC 1994). None reported an improvement in somatic symptoms. This aspect of the literature on CBT should be included in the draft.</p> <p>Science also provides us with a number of plausible reasons why any type of graded activity might not help subgroups like ME. ME is associated with an abnormal response to exertion which can last for more than 24 hours. Based on the findings of Paul et al (1999), any exercise during the 'recovery' period may well make these patients worse. This is supported by the work of Black and McCully (2005). The following points from their article deserve serious consideration:</p> <p>"Over the first 4-10 days of walking the subjects with CFS were able to reach the prescribed activity goals each day. After this time, walking and total activity counts decreased...Unlike our previous</p>	
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					<p>interpretation of the data, we feel this new analysis suggests that CFS patients may develop exercise intolerance as demonstrated by reduced total activity after 4-10 days. The inability to sustain target activity levels, associated with pronounced worsening of symptoms, suggests the subjects with CFS had reached their activity limit.”</p> <p>One solution may be to refer to chronic fatigue syndromes. Plurality would make it possible to consider the needs of some subgroups and to offer General recommendations for each. Logically, one might argue that the post-viral group studied by Hickie et al (2006) is likely to require a different approach to patients whose fatigue reflects long term stress. Do we really want to offer a comparatively expensive intervention such as CBT to patients whose attributions are consistent with the history of their illness, who have a positive attitude and who are as active as their illness allow them to be (see cases 1 and 2)? Is this not over-treatment? On the other hand, patients with chronic stress may well benefit from CBT or counselling, plus relaxation and a good diet.</p> <p>The complexity of CFS provides us with a real challenge. However, these drafts focus on the common denominators only. After more than ten years of</p>	
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					<p>research on subgroups, we can surely begin to differentiate to some degree, e.g. between post-viral CFS with neurological symptoms and chronic stress. Psychologists can provide further guidance on the symptoms and management of chronic stress, if required.</p> <p>Re pacing. If patients like those studied by Black and McCully and Paul et al cannot sustain a programme focused on increasing activity, doctors should be able to offer a reasonable alternative, like pacing. However, the most commonly used version of pacing has not been included in this draft. This is a significant omission, which leaves those who cannot increase activity levels without the care they require. It may lead to a rejection of orthodox medicine, and feelings of hopelessness and despair.</p> <p>Psychologists have been studying self-management interventions which include pacing for several years, and early reports are promising. One such study was included in the CRD review but the summary did not make it clear that the programme favoured pacing over graded exercise (Goudsmit 1996).</p> <p>To summarise, the drafts allude to the heterogeneity of the population but ignore this issue in the recommendations regarding diagnosis</p>	
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						and management. They overlook the subgroups who cannot sustain a graded activity protocol. The recommendations for CFS are therefore a little like offering everyone with headaches an aspirin plus advice to reduce stress. It's fine for a lot of patients, but not good enough for those with migraine, cluster headaches and brain tumours. Medicine differentiates between different forms of breast cancer and depression. Differences are not dismissed and we should not dismiss them with regard to fatigue syndromes.	
SH	The British Psychological Society	2	FULL	General		There are case studies suggesting that an early return to training after a viral infection can bring on CFS .See Sport & Exercise Psychology and Cripps, B. (1995) Exercise Addiction and Chronic Fatigue Syndrome: Case Study of a Mountain Biker, in Exercise Addiction: Motivation for Participation in Sport and Exercise. Eds. Annett, J. Cripps, B. and Steinberg, H. BPS Leicester. ISBN 1 85433 2015. It is not clear if these athletes respond as well to CBT and GET as other patients with CFS. We suggest seeking the opinion of Sport psychologists.	This is beyond the scope of the guideline.
SH	The British Psychological Society	3	FULL	General		Although 'Mindfulness' is mentioned in the glossary (page 11), We cannot see any mention in the guidelines of the very promising pilot study looking at Mindfulness-based Cognitive Therapy:	Noted and revised.

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					<p>Surawy C, Roberts J, Silver A. The effect of mindfulness training on mood and measures of fatigue, activity, and quality of life in patients with chronic fatigue syndrome on a hospital waiting list: a series of exploratory studies. Behavioural and Cognitive Psychotherapy 2005;33:103 –09. They adapted the MBCT approach by Segal, Williams and Teasdale that has been shown to be effective in reducing relapse rates in depression, and adapted it specifically for CFS. By their third group they were getting effect sizes comparable to those found in RCTs of standard CBT for this condition. We think that the NICE guidelines should mention this intervention as an approach that warrants further investigation.</p> <p>In the NICE guidelines on page 198 Mindfulness is referred to as a form of relaxation, which we think is misleading. Mindfulness is about paying attention to the present moment in a non-judgemental way (and indeed the glossary definition is consistent with this). This might sometimes result in the person feeling more relaxed, but that is not the primary aim. Mindfulness-based CT teaches mindfulness in addition to other cognitive / behavioural skills to help the patient cope more effectively.</p> <p>The growing evidence for various therapeutic options (see also Thomas et</p>	
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						al 2006) highlights the need for a more flexible approach to CFS. NICE should allow qualified and experienced therapists such as chartered psychologists to offer tailor-made rehabilitation programmes to suit individual needs and preferences. The guidelines recommend an activity programme which has not yet been subjected to a controlled trial, so is clearly open to reasonable ideas. Where there is at least one sound controlled trial to support the use of a specific intervention, experienced specialists should be permitted to offer this option if they consider this to be appropriate and beneficial in individual cases. This would also permit us to offer well-established therapies such as client-centred counselling.	
SH	The British Psychological Society	4	FULL	General		There is no discussion of multidisciplinary approaches which combine most if not all of the interventions discussed here - what about the evidence-base and cost-effectiveness of such interventions? If this is not available, at least mention of the combined utility of these interventions, and its probable improvement (through combined gains but perhaps being less cost-effective) in CFS symptoms and gains	The guideline recommends the referral to specialist care, which we have defined as a multi-disciplinary team (MDT) with expertise.
SH	The British	57	NICE /FULL	Gene		See NHS Centre for reviews and	Noted.

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	Psychological Society			ral		<p>dissemination (2002) "Effective Healthcare – interventions for the management of CFS/ME", vol 7, no 4, University of York.</p> <p>And FULL available from University of York by Bagnall, Whiting, Wright and Sowden.</p>	
SH	The British Psychological Society	72	FULL	References		<p>References</p> <p>Akagi, H., Klimas, I and Bass, C. Cognitive behavioral therapy for chronic fatigue syndrome in a General hospital - feasible and effective. General Hospital Psychiatry, 2001, 23, 254-260.</p> <p>Bazelmans E, Bleijenberg, G., van der Meer, JWM and Folgering, H. 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.</p> <p>Black, CD and McCully, KK. Time course of exercise induced alterations in daily activity in chronic fatigue syndrome. Dynamic Medicine, 2005 Oct 28. 4, 1, 10.</p> <p>Bonner D, Ron M, Chalder T, Butler S and Wessely S. Chronic fatigue syndrome: a follow-up study. Journal of Neurology, Neurosurgery, and Psychiatry 1994; 57: 617-621.</p>	Noted.

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					<p>14, 3, 277-289.</p> <p>Stouten, B. Chronic fatigue syndrome: a clinical and laboratory study with a well-matched control group. <i>Journal of Internal Medicine</i>, 2004, 256, 265-267.</p> <p>Thomas M, Sadlier M and Smith A. The effect of Multi Convergent Therapy on the psychopathology, mood and performance of chronic fatigue syndrome patients: a preliminary study. <i>Counselling and Psychotherapy Research</i> 2006, 6, 2, 91-99.</p> <p>Van Essen, M and de Winter, LJM. Cognitieve gedragstherapie by het vermoeidheidssyndroom (cognitive behaviour therapy for chronic fatigue syndrome). Report from the College voor Zorgverzekeringen. Amstelveen: Holland. June 27th, 2002. Appendix B. Table 2. p. 57.</p> <p>Wessely, S., Chalder, T., Hirsch, S., Wallace, P and Wright, D. The prevalence and morbidity of chronic fatigue and chronic fatigue syndrome: a prospective primary care study. <i>American Journal of Public Health</i>, 1997, 87, 1449-1455.</p> <p>Wright, B., Ashby, B., Beverley, D., Calvert, E., Jordan, J., Miles, J., Russell, I and Williams, C. A feasibility study comparing two treatment approaches for chronic fatigue syndrome in adolescents. <i>Archives of</i></p>	
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						Disease in Childhood, 2005, 90, 369-372 Quarmby, L., Rimes, KA., Deale, A., Wessely, S and Chalder, T. Cognitive-behaviour therapy for chronic fatigue syndrome: Comparison of outcomes within and outside the confines of a randomised controlled trial. Behaviour Research and Therapy, 2006, October 27; [Epub ahead of print], doi:10.1016/j.brat.2006.08.019.	
SH	The Chartered Society of Physiotherapy	15	FULL	General		CFS/ME patients must find a satisfactory level of physical and mental activity that they can sustain day after day without leading to a prolonged increase in their symptoms i.e. activity management, before any increase in either physical or mental activity is possible. Any such increases may include GET incorporating pacing to allow for any reaction and subsequent management of symptoms to the increases	Noted.
SH	The Chartered Society of Physiotherapy	18	FULL	Chapter 6.3	General	Everything is covered in very discrete “bundles” e.g. CBT/GET/activity management, but there is little discussion that these approaches can actually be used in conjunction with one another, and this may enhance the guideline further.	Please see relevant section of revised guideline.
SH	The Chartered Society of Physiotherapy	21	FULL	General		Can we clarify which name is preferable to use and identify that CFS/ME falls within the umbrella of neurological	We refer to ‘NSF Long-term Conditions’.

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						conditions? Given the complexity of problems, do we need to promote a case management approach based on the Long Term Care model.	
SH	The Royal Society of Medicine	6	General			NICE may be commended for these well-balanced evidence-based recommendations	Noted with thanks.
SH	University of Manchester	2	FULL	General		Following on from the above comment, we are currently testing (in a randomised controlled trial – the FINE Trial) a pragmatic rehabilitative treatment which includes a programme of gradually increasing activity, for patients with CFS/ME in primary care. As we are treating patients at home, we are able to offer treatment to patients across the spectrum of severity, including to patients who are non-ambulatory, housebound or even bed-bound. We are not powered to stratify by illness severity (mild/moderate/severe/v. severe) but we are stratifying by whether patients are ambulatory or not. We anticipate that the findings of our trial will contribute to future recommendations for the treatment of severely affected patients.	Noted. This trial will be considered for the update.
SH	University of Manchester	6	FULL	General		The consultation document is very long. We anticipate that some stakeholder organisations or individuals who might have provided comments will have been put off from doing so by the length and	Noted.

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						complexity of the document.	
SH	Waveney PCT	1	FULL	General		<p>Great Yarmouth and Waveney PCT hosts the Norfolk & Suffolk ME/Chronic Fatigue Syndrome services.</p> <p>The service assesses approximately 400 new patients per year. The team includes GPwSI, a clinical lead, specialist occupational therapy, specialist physiotherapy and administrative support.</p> <p>Our approach to therapy is:</p> <ul style="list-style-type: none"> • Activity management – attempt to remove boom and bust activity pattern, establish an achievable baseline of activity with graduated increases in normal activity using the patients stated goals. In more mildly affected patients controlled exercise is encouraged. Exercise is also incorporated when previously exercising patients so wish. 60-70% of our patients have activity levels of less than 30% of normal on good days and often less than 10% on bad days. At any one time we will have 20-25 severely affected patients who are bed bound and totally dependent upon others. Most encounters are one to one but group work involving all aspects of management are also held on a regular basis. • Improving sleep patterns – Sleep hygiene works for some but many 	Noted with thanks.

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						<p>(60%+) have evidence of alpha wave predominance comprising prolonged, vivid dreaming/nightmares, nocturnal restlessness, vocalisation and sudden waking to slight noises. The increase in REM sleep was originally confirmed by sleep studies but the reports were Generally issued with a comment of 'alpha wave predominance consistent with ME/CFS'. This pattern does not respond well to sleep hygiene techniques.</p> <p>Amitriptyline is a standby but because of its variable half life it doesn't suit all. Melatonin is particularly good for children and young people but also works in 50-60% of adults particularly if they have not been heavily pre-treated with multiple hypnotics. The 'Z' drugs especially zopiclone and zolpidem are used for 2-3 nights per week and they can be particularly useful when fatigue worsens as the working week progresses. In General the more tired the patients are the worse the sleep pattern.</p> <ul style="list-style-type: none"> • Secondary Anxiety/Depression – is treated according to standard practice and guidelines. Anxiety can be a difficult problem. The illness is stressful and if the patients are fit enough they are referred to local stress management courses.
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					<p>Appropriate liaison with psychiatric services is also carried out.</p> <ul style="list-style-type: none"> • Cognitive Behavioural Therapy – Most practitioners in this area are knowledgeable about the principles and simple practice of this approach. This is just as well as local CBT waiting lists are in excess of 9 months. A significant number of our patients who might benefit from more intensive input are also too ill, or have memory and concentration problems which make attendance at weekly or fortnightly sessions almost impossible. • Symptom Control – Pain is a significant burden for some individuals a few of whom have mixed FMS/ME. Pain can also be a significant problem in effecting the sleep pattern and we Generally address this aspect first. Mixtures of non-opiates sometimes work but if not dihydrocodeine and tramadol at night can be effective. Gabapentin is used especially if there are neuropathic qualities to the pain and this may have an impact on sleep. <p>Other symptoms are treated on an ad-hoc basis depending upon the individual impact.</p> <ul style="list-style-type: none"> • Alternative Therapies (Excluding all relaxation techniques) 	
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						<p>These are discussed if the patient wishes but the message is that activity management, sleep improvement and modified CBT when required are the cornerstones of management. Of course individuals can try what ever they want but sometimes the money could be better spent on household help.</p> <p>This simplified overview of how we run our services is a prelude to key comments.</p> <ul style="list-style-type: none"> GET/Activity Management <p>The aims and objectives are the same but the approach of graduated activity versus exercise is only one of intensity. Most patients have their own goals and these maybe more related to work, families etc rather than using energy to exercise. The two approaches should be considered under the same heading as part of a continuum. This will avoid the view that GET is the only evidence based way forward. Using a functional limitation profile (FLP) over the last nine years we have consistently shown that 60% of our patients have a range of improvement from greater than 10% in scores to a return to full time/part time work. Complete recoveries are uncommon except in the most mildly effected group. Patients who were</p> 	
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						<p>doing well can relapse and may or may not recover. Over a period of years more than a minority of patients have long term problems.</p> <p>GET also has a bad press with many patients as it has been introduced at the wrong stage of the illness. There is no evidence that it is of any value in the severely affected. Further the principle of exercise has been embraced by well meaning therapists but at such an intensity that it causes immediate relapse. We felt that your clinical care pathways have got it just right but this is not necessarily reflected in the text.</p> <ul style="list-style-type: none"> • Cognitive Behavioural Therapy (CBT) – Even if more therapists are trained over the next few years much of their time will be taken up with other mental health issues. It is possible to train staff at all levels to apply CBT principles as has been shown in respiratory and cardiovascular medicine. • Diagnosis – The use of the CDC criteria are the absolute minimum. In our clinical practice 95% of patients also fulfil the Canadian guidelines and many of the symptoms have been included in our pre-clinic questionnaire long before the Canadian publication. Some have problems with the ‘neuro endocrine’ 	
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						<p>label but 'chemical messengers' are involved in blood flow and pressure eg VIP, substance P and neuropeptide Y and these effects are not mediated by adrenergic, cholinergic or histaminergic receptors.</p> <ul style="list-style-type: none"> • The severely effected – The NICE guidelines present a unique opportunity to lay down some common sense guidelines on management. Most of this group present unique and complex problems which need to be managed within a consistent framework. This section should be expanded by a patient/therapist/doctor team before the final draft. The patient should have been bed bound for a significant part of their illness and the therapists and doctors should have extensive hands on domiciliary experience. 	
SH	Welsh Assembly Government	1	General			<p>Thank you for giving the Welsh Assembly Government the opportunity to comment on the above guideline. We are content with the technical detail of the evidence supporting the consultation and have no further comments to make at this stage.</p>	Noted with thanks.
SH	Welsh Association of ME & CFS Support	1	FULL	General		<p>The Welsh Association for ME & CFS Support has carefully considered the contents of this draft. (September 2006).</p>	Please see relevant section of revised guideline as many of these issues have been addressed.

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					<p>As stakeholders in the guideline development process we have consulted widely with local groups, their members, the wider ME/CFS community in Wales via our messageboard and by placing letters in the media in order to ascertain as broad a view as is possible.</p> <p>Our comments below represent the wide ranging comments received by ourselves to this consultation process.</p> <p>OVERALL COMMENTS</p> <p>WAMES supports the view that a guideline on the assessment and management of ME/CFS is needed and should be prepared by NICE for distribution to health professionals in England and Wales.</p> <p>We note that these guidelines do not accurately reflect the diversity in healthcare provision in Wales since devolution although NICE agreed to develop guidelines with the remit “To prepare for the NHS in England and Wales, guidance...”</p> <p>This guidance must also be agreeable to the patients who live with this illness and their parents/carers.</p> <p>WAMES is extremely disappointed in the quality of work included in the draft guidelines and believe it fails to meet the standards of NICE itself, which aim to produce objective, 'evidence-</p>	
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					<p>based' and cost-effective guidelines to clinical practice</p> <p>Unfortunately it makes many unjustified claims, includes inconsistencies, failures of logic and huge gaps in the guidance.</p> <p>Due to the patchy nature of research into CFS and ME it is not possible to provide detailed guidelines based solely on the research that fits into the specific and limited parameters that NICE lays down for research 'evidence' (e.g. minimum of 2 RCTs). The attempt to do so could only result in wildly biased results and huge gaps. In fact the Guidelines Development Group realised this because they included recommendations that have not been backed by 'evidence' (54:14), although unfortunately many were simply the beliefs of one school of thought.</p> <p>There are statements where it appears that the GDG and the ME community have reached a consensus however and we are pleased about that.</p> <p>Overall, we feel that the current (ie September 2006) version of the guideline that has been prepared by NICE is unfit for its purpose and we would not be willing to endorse it.</p> <p>Our major disagreements with these guidelines are:</p>	
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						<ol style="list-style-type: none"> 1. They are not relevant to Wales. 2. They do not acknowledge the WHO classification of ME/CFS (and PVFS) as being neurological disorders (in section G93.3 of ICD 10) - a position that the Welsh Assembly Government also accepts. Instead the NICE draft has produced a new and much wider clinical definition of ME/CFS that will include almost anyone with chronic unexplained fatigue. 3. An unbalanced coverage of CBT and GET. 4. The way in which it deals with issues affecting the severely affected. 5. 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. 6. The failure to provide any meaningful advice on symptomatic management as the illness enters a more chronic stage. <p>The confused terminology throughout the guidance.</p>	
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SH	West Midlands Consortium	1		General	<p>This is the response of the West Midlands Groups [WMG] Consortium, which combines Herefordshire CFS/ME/FMS Group, Shropshire & Wrekin ME Support Group, Solihull & South Birmingham ME Support Group, Warwickshire Network for ME, and Worcestershire ME Support Group.</p> <p>All the groups in the consortium have provided patient representation for the development of the new NHS services for CFS/ME in this region. The group members of this consortium have also collaborated with the Birmingham/ West Midlands CNCC to carry out a Needs Assessment Survey of patients throughout the region. We understand this is the first survey of this kind in England.</p> <p>The WMG consortium is, therefore, in a unique position to respond meaningFULLy to the NICE Draft Guidelines using as a reference its collective data, patient experience and feedback from both group memberships and NHS services for CFS/ME.</p> <p><u>We welcome some of the statements in the draft document e.g :</u></p> <p>General principles of care - emphasis on the importance of an individual/collaborative approach and the patient's right to refuse treatments he/she deems to be inappropriate.</p>	Noted with thanks.
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					<p>(However, non-compliance with a CBT/GET regimen should not affect payment of welfare benefits and should be without detriment to receiving other aspects of treatment.)</p> <p>Highlighting the importance of balancing “activity” & rest - although for most people with CFS/ME, that it is common sense anyway - and something that has been the foundation of M.E. self help literature for many years.</p> <p>Highlighting the importance of sleep management - however, in many cases night-time sleep disruption occurs as a symptom of ME and afternoon rest actually aids night-time sleep.</p> <p>Assistance with provision of blue badge and/or wheelchair is welcome, (although some may question the “proviso” of it being “part of an overall management plan”). NB - practical help along these lines (and assistance with benefits) may be THE most important thing that a clinician/healthcare professional can do for an individual with moderate/severe ME.</p> <p><u>However, the guidelines fail to adequately address a number of key areas:</u></p> <p><u>Diagnostic criteria</u></p> <p>There is no reference to the WHO neurological classification for M.E. and PVFS (section G93.3 of ICD 10) -</p>	<p>Issue 1. Diagnostic criteria</p> <p>The broad range of symptoms listed initially was there to raise awareness that the individual <i>may</i> 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.</p> <p>More reference to the Canadian guideline has been added. It is, however, as you say a consensus of experts and not a document predicated on the research evidence.</p>
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					<p>something that the DoH accepts, and was acknowledged by Health Minister Lord Warner in a letter to Countess of Mar 11th Feb 04: "...chronic fatigue syndrome is indexed to the neurology chapter and fatigue states to the mental health chapter."</p> <p>The lack of clarity regarding diagnostic criteria was highlighted by Dr Vance Spence, Senior Research Fellow in Medicine at the University of Dundee and Chairman of ME Research UK, in a lecture he gave in Coventry November 2005: http://www.mereseearch.org.uk/archive/coventry.html</p> <p>"The diagnostic mess that is CFS/ME is illustrated by our own research on three groups of patients with quite different onsets to their illness: "sporadic" CFS/ME cases (i.e., most of the patients in CFS/ME support groups); people who developed illness after services in Gulf War 1; and people who developed illness after apparent contact with organophosphates. While all these patients were classified as having CFS (because they fulfilled the CDC 1994 criteria for the illness), distinct psychological and biological differences could be found between them. As this paper (Kennedy et al, 2004) says, "<i>The specificity of the CFS case definition should be improved to define more homogeneous groups of patients for the</i></p>	
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					<p><i>purposes of treatment and research.”</i></p> <p>The guidelines appear to recognise the heterogeneous nature of the illness, but then fail to address sub grouping under the CFS/ME “umbrella”, and offer a ‘one treatment fits all’ approach. Many of the research papers used to inform the guidelines (and many others that weren’t) acknowledge the existence of sub groups e.g. (Jason 2005) - An author who is referenced more times than any other in the document!</p> <p>Until an adequate definition of CFS/ME is agreed, what constitutes “evidence based medicine” is in dispute. The ‘Canadian Criteria’: ‘A Clinical Case Definition and Guidelines for Medical Practitioners’ (Carruthers 2003) was produced by a team of international specialists in CFS/ME, with experience of over 20,000 patients. These guidelines are widely believed to be the most detailed and comprehensive definition of CFS/ME in the world, and they barely merit a mention! By comparison the NICE guidelines appear to endorse an extraordinarily weak definition of CFS/ME which amounts to chronic unexplained fatigue + ONE other symptom.</p> <p>The mildest form of Post Viral Fatigue Syndrome cannot, and should not, be lumped together with most types of M.E. There is a world of difference</p>	<p>Issue 2. The evidence (general)</p> <p>The review was carried out according to the NICE methodology. Please refer to the NICE Technical Manual. As you state, the remit was the diagnosis and management of the conditions. Aetiology is beyond the scope of the guideline and thus biomedical research was not reviewed.</p>
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					<p>between “moderate” & “mild” CFS/ME. There is a lack of awareness of severe M.E., and this has major implications for what constitutes appropriate treatment for this group of patients.</p> <p>There is no reference to the different phases of the illness, ie those in a ‘recovery phase’ - something we believe to be hugely important. That factor MAY enable SOME to follow SOME of the prescribed advice given here, but NOT in an acute phase of illness. Too much activity in the acute stages of the illness may actually make the condition worse. Indeed exercise in the normal sense of the word usually has little or no role to play during this very early stage - in fact, an inappropriate exercise programme is very likely to make the illness worse. What may be required most of all at this stage is good old-fashioned convalescence.</p> <p>There is a lack of awareness of symptoms; there needsto be more emphasis and acknowledgement of 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 M.E. experience.</p> <p><i>The Evidence (General)</i></p> <p>The overriding message sent out here</p>	
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					<p>to healthcare professionals, with no special interest in CFS/ME, (not to mention the media) is that all patients need to do to get well, whatever the stage of their illness, is to change their beliefs and exercise more.</p> <p>The NICE draft guidelines based on the 488 page University of York Review 2005 compiled by Bagnall et al are based solely on RCTs which had been published in “reputable” journals. Since Myalgic Encephalomyelitis was subsumed into the very broad spectrum dustbin diagnosis Chronic Fatigue Syndrome in the late 1980s, many dedicated pioneers in the M.E. field have found it impossible to get their work published in the UK. For nearly 20 years the BMJ has refused to publish any papers involving ME rather than CFS - ref: http://www.cfids-cab.org/rc/Goudsmit.pdf</p> <p>Therefore a vast database of information about the true nature of this illness has failed to meet the dubious standards set by the York review.</p> <p>Work by M.E. pioneers such as Dr Melvin Ramsay (who wrote the seminal work on the Royal Free Disease Outbreak) indicating the pathogenic nature of the illness, has been ignored, as has that by practicing doctors John Richardson and Betty Dowsett, each with over 40 years of General practice</p>	
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					<p>involving treatment of thousands of ME patients. As has published data on outbreaks of 36 epidemics of ME reported worldwide since 1918.</p> <p>Dr Les Simpson's article "Myalgic Encephalomyelitis (ME): a haemorheological disorder manifested as impaired capillary blood flow," published in the Journal of Orthomolecular Medicine in 1997, showed that ME blood is portrayed by changed red cell shape, which explained their poor filterability. The reduced rates of blood flow meant that tissues were not receiving sufficient oxygen and nutrients to sustain normal tissue function. Yet this research is ignored.</p> <p>Also ignored is research carried out by Prof. Peter Behan on muscle biopsies, which indicate viral damage to muscles; Dr Arnold Peckerman on impaired cardiac output in CFS patients (www.cfids-cab.org/cfs-inform/Coicfs/peckerman.etal.03.pdf); and American metabolic cardiologist, Dr Stephen Sinatra on heart muscle disease due to mitochondrial failure, all pointing to physical causes of the illness.</p> <p>So too does work by Durval Costa on restricted blood flow to the brain and Bell and Streeten on low blood volume and postural hypotension.</p>	
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					<p>Dr Paul Cheney from North Carolina - who has seen over 5,000 patients with (Myalgic Encephalomyelitis) / Chronic Fatigue Syndrome - states that PFO (Patent Foramen Ovale - the persistence (or the acquired re-opening) of the normal foetal opening between the right and left atria of the heart) is "tightly associated" with (ME)CFS to the order of at least 80% or more of patients.</p> <p>Recent research by ME Research UK (formerly MERGE) and CFS Research Foundation has indicated many anomalies in gene activity in CFS/ME.</p> <p>Not surprising therefore that many reviewers nominated by registered ME charity stakeholders, found the York review document a most unsatisfactory starting point to "review best evidence". Many of these RCTs involved few patients with ill-defined "fatigue" symptoms, e.g. page 90 of 487 in the York Review states, "These studies also scored lower on the validity assessment, especially one of the controlled trials which scored 1 out of a possible 20."</p> <p>Previous York reviews based on the same material provided by York University as that used in the NICE draft report have caused criticism of their scope and rigour, such as from Dr Charles Lapp medical adviser to CFIDS</p>	
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					<p>Association of America.</p> <p>“Concern over Cochrane Review of Exercise Therapy”. Ref: 09-08-2004 ImmuneSupport.com -published in ‘Interaction’ magazine of Action for ME February '05</p> <p>He found that: “The author examined 9 studies, accepted only 5, and none were from the USA and highlighted the following problems:</p> <ol style="list-style-type: none"> 1. They measured "fatigue" primarily instead of the quality of life. 2. The patients only used the CDC's criteria in two studies so it seems none were particularly severe. 3. Two of five of the studies showed between 80-92% were still working, another had 35% employed, and the others did not report this at all. 4. Only one had "rigorous exercise" and "did NOT show any improvement in subjects and had the highest dropout rate." 5. The report failed to mention that most CFS patients "could not tolerate such exercise." 	<p>Issue 3. The evidence for CBT and GET</p> <p>The clinical trials of CBT and GET have shown improvement in people with CFS/ME and therefore the GDG recommended these</p>
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					<p>6. The "experts" mentioned really was only one, "Dr. Peter White, whom I believe works closely with Wessley and Sharpe. Read biased."</p> <p>7. The study stated "exercise therapy may not worsen outcomes," but never mentioned that it "may trigger prolonged relapses."</p> <p>Sadly, this Cochrane review study once again sends the incorrect message to primary physicians - that they should exercise all PWCs and not worry about post-exertional sequelae.</p> <p>The recommendations for "treatment", are therefore extremely disappointing and appear to be built upon the flimsiest of "evidence" from a very small number of trials, (some with very high drop-out rates) and reliant upon weak diagnostic criteria as highlighted by Dr Lapp.</p> <p>In November 2006 Nancy Klimas, Professor of Medicine at Miami, and Anthony Komaroff, Professor of Medicine at Harvard (both of whom are not only clinicians but also long-time researchers into CFS/ME) attended the launch by the US Centres for Disease Control (CDC) of its "CFS Toolkit" and its campaign to advance knowledge of (ME)CFS.</p> <p>At the launch, Professor Klimas said:</p>	<p>as therapies.</p> <p>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.</p> <p>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.</p> <p>With regard to deconditioning, the GDG stresses the general risks and deleterious effects of deconditioning and inactivity such as DVT's, muscle wastage, etc. not something unique to people with CFS/ME..</p>
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					<p>"Historically, the lack of credibility afforded this illness has been a key obstacle to understanding it. Today, with solid evidence that CFS has identifiable biologic underpinnings, and with evidence that people with CFS experience a level of disability equal to that of patients with multiple sclerosis, advanced HIV disease and undergoing chemotherapy, I hope we can begin to put an end to the stigma surrounding this illness."</p> <p>Also at the launch, Professor Komaroff said about the lingering belief that (ME)CFS is psychological and somehow imagined: "That debate raged for 20 years, and now it's over". (But not in the eyes of York and NICE , apparently.)</p> <p>As reported on 3rd November 2006 by United Press International, there are over 3,000 research papers that have established (ME)CFS as a valid physiological illness, with evidence of inflammation, reduced blood flow and impaired cellular function. (Which shows how selective and poor the York Review was.)</p> <p>It was described as a "brutal" disease which often occurs in conjunction with other diseases such as lupus and Lyme disease, and its symptoms can be as severe and painful as renal failure, AIDS or multiple sclerosis.</p>	
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					<p>In the words of Dr Melvin Ramsay: "The basic fundamental tenet of the management of a case of M.E. is REST with graduated activity well within the limitations which the disease imposes."</p> <p>The emphasis on CBT & GET is therefore seriously out of kilter with patient experience - which seems to have been comprehensively ignored - and there is a totally inadequate review of other aspects of CFS/ME management. None/or very little of this seems to accord with patients' experience.</p> <p>There is an almost complete exclusion of any contribution from 'patients' and from their representative bodies. Instead, reliance is placed on discredited and potentially harmful 'management techniques'. It is inconceivable that any other serious, chronic illness would be treated with such anachronistic methods, especially bearing in mind the enormous advances which are constantly being made by medical science.</p> <p><u>The Evidence for CBT</u></p> <p>There is far too much emphasis on cognitive behaviour therapy (CBT). CBT is being presented as something that 'leads to recovery.' We have seen no evidence of this.</p> <p>We understand that CBT may help a</p>	
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					<p>CBT in a clinical setting compared unfavourably with results in RCTs.</p> <p>In a 4-year follow-up study and review of the Long-term efficacy of CBT by GPs for fatigue, Leone et al found that “fatigue and absenteeism were high in the intervention and control groups at the 4-year follow-up” and concluded that “There was also no significant difference between the intervention group and the control group on fatigue and absenteeism.”</p> <p>Psychom Res. 2006 Nov; 61(5):601-7</p> <p>Many will conclude that the evidence presented to review panel was selective. Why for example is there no mention (apart from economics) of Ridsdale (2001) paper that found “Counselling and CBT to be equivalent”?</p> <p>For a significant number of people with M.E., the opportunity to talk to someone about their condition and how it affects their life etc without the underlying premise that the listener knows best, would be more acceptable. We understand that this was given a high validity score.</p> <p>We can see no reference to the 25% ME Groups 2004 Analysis Report, in the FULL guidelines, (which we understand to have been submitted): where 93% of members surveyed found</p>	<p>recommendations in the NICE guideline will be published and sent to relevant healthcare professionals. As with other QRGs, it will contain only the advice needed to manage the condition. The full guideline will be available on the NICE website with the background information such as you mention. If this information were all in the shorter versions, they would not be read and used.</p>
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					<p>CBT “unhelpful” & 95% found GET “unhelpful”. (70% found pacing helpful.) Many who were previously ambulant are now permanently bedbound or wheelchair bound following prescribed exercise therapy.</p> <p><u>The Evidence for GET</u></p> <p>Use of the word “exercise” throughout the draft guidelines is inappropriate as most CFS/ME sufferers are already operating at or close to their energy limit to carry out normal everyday living. Most are well motivated to try and “test their boundaries”</p> <p>There is far too much emphasis on GET, and we are concerned how the word ‘exercise’ is portrayed. It is being presented as something that ‘leads to recovery.’ We have seen no evidence of this. It appears as if people with CFS/ME will become better if they increase their exercise levels every day, and yet this is impossible due to the fluctuations of the symptoms, and daily living demands.</p> <p>The CMO’s report (2002) suggested that 50% were made worse by GET.</p> <p>There appears to be no mention of Black and McCully (2005) that suggested that CFS patients have an “activity limit”. This is an important paper, and certainly accords with patient experience that many will hit a</p>	<p>Issue 6. Omissions</p> <p>The remit of the guideline is to provide advice on the diagnosis and management of the condition. The symptoms listed are those that will assist the clinician in identifying the condition. The GDG were concerned that if there were a comprehensive list, serious symptoms would not be investigated and treated promptly as there was a risk they would be regarded as ‘normal’ for a person with CFS/ME.</p> <p>Referral to a pain management clinic has been added to the guideline. Thank you for pointing this out.</p> <p>The GDG found insufficient evidence to recommend nutritional supplements or complementary therapy routinely. Please refer to full guideline. It is acknowledged, however, that some individuals may find them helpful.</p>
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					<p>'glass ceiling'. NICE need to be aware that many patients, naturally keen to get well, may feel obliged to follow rigid exercise/activity programmes and there is good evidence to suggest that this has been responsible for a number of very severe relapses in patients, who believed they were doing the right thing.</p> <p>Importantly the NICE questionnaire to the wider group, disagreed that a programme consisting of increases of aerobic exercise (GET) was appropriate for moderately affected adults. To then go on to suggest that this should be a treatment of choice (whose choice?) is ridiculous and likely to lead to conflict between health practitioners and patients.</p> <p>What is being presented as "evidence" in the UK seems to be seriously out of touch with international opinion. In a letter to the Medical Journal of Australia, Garry Scroop, Professor of Exercise Physiology, wrote: <i>"In summary, patients with CFS are not 'deconditioned'. Neither their muscle strength nor exercise capacity is different from that of other sedentary members of the community. We remain unaware of any incontrovertible evidence that the various 'exercise training' programs suggested in previous articles improve either the physiological, psychological or clinical status of people with CFS."</i> (Med J</p>	
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					<p>Aust 2004; 180: 437-438)</p> <p><u>Pacing</u></p> <p>The dismissal of “pacing” as a management strategy in favour of CBT/GET appears to be seriously out of touch with patients’ experience. A ‘pacing’ approach to energy management is required that advises people with CFS/ME how to achieve a sensible and flexible balance between activity (not exercise), and rest/relaxation. (People may need to learn how to relax). This will depend on the stage, severity and variability of their condition. This is (certainly) not what graded exercise implies.</p> <p>There is also no mention of ‘switching’. For many, this is an important illness management strategy: by changing from one ‘activity’ to another at regular intervals and using different muscle groups, activity may be maintained for longer periods.</p> <p>At its simplest level this may mean switching from using the eyes to read/focus and then to the ears (& brain) to listen to radio/music. We understand that this technique is taught at the National ME Centre.</p> <p><u>Presentation of Information & Language</u></p> <p>In the NICE of the document, which is the one most people (including most GPs) will read/extract information from,</p>	
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					<p>a number of things are not made sufficiently clear.</p> <p>Most importantly the very limited efficacy of CBT. e.g. p203 (FULL Guidelines) state that: "The GDG did not regard CBT or other behavioural treatments as curative or directed at the underlying disease process, which remains unknown. Rather such treatments can help SOME (our caps) patients cope with the condition and consequently experience a(n) improved quality of life."</p> <p>This statement needs spelling out loud and clear in the NICE , and any subsequent NICE reference guide.</p> <p>Similarly the FULL guidelines deal with prognosis: suggesting that perhaps only 5-10% achieve total remission - but this is not at all apparent in the NICE . There is an over-emphasis on work related rehabilitation and advice, in what should be a health guideline. We are concerned that this will put undue pressure on patients and clinicians to achieve perceived 'positive' outcomes - but in reality these measures seem to be more about politics than health.</p> <p>The draft document is littered with references to 'psychological aspects' of the illness, giving the clear indication to everyone reading it, that that is the way this condition should be treated. There is a ludicrous amount of stereotyping,</p>	
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					<p>with numerous references, to risk of deconditioning, prolonged bed rest, fear of activity, all of which is not only patronizing and offensive to patients, but reflects a single (psychosocial) perspective of the illness.</p> <p>Many patients with CFS/ME who were previously very active, sports minded, remain well-motivated despite the limitations of their illness and completely reject this model. They ALL want to get well. Positive thinking is part of their lives.</p> <p>The persistent use of the phrase “setback” and what it implies seriously diminishes the severity of the illness. This implies a slight ‘blip’ - but relapses can be major and easily brought about by overdoing activities; viruses; stresses and other bodily reactions to hormonal imbalances/drugs/allergens/intolerances etc. A major relapse can incapacitate for weeks, months or years. Earlier this year, we heard of the first recorded death in the UK from “Chronic Fatigue Syndrome” - it seems highly likely that this wasn’t the first case. There is no mention of common causes of “setbacks”: infection, over-exertion, General anaesthetics, surgery, and some types of vaccinations.</p> <p><u>Omissions (& Other Supporting Data)</u></p> <p>There is little or no information on pain</p>	
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					<p>management, something that for many people with CFS/ME is a more disabling symptom than fatigue.</p> <p>The advice on diet is woefully inadequate. All 3 patient testimonies included in the FULL guidelines referred to issues of diet/food intolerances.</p> <p>The value of complementary therapies/pharmacological interventions (especially for pain) for symptom control are also inadequately covered.</p> <p>In 2005, a 'Needs Assessment Survey' was carried out by the Birmingham/West Midlands CNCC in cooperation with local M.E. support groups in the West Midlands region, and one large GP practice in Birmingham. A total of 551 questionnaires were sent out (response rate 51%).</p> <p>The finished results have yet to be published; however, a summary of this report is available. The survey found that: When respondents were asked what treatments/ management strategies they thought would be of use if they were offered, information on CFS/ME topped the list with 89% of the respondents requesting this. Over 70% thought advice on pacing, diet, sleep would be of use. Only 44% wanted advice on CBT and 46% wanted advice on graded exercise/activity.</p>	
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					<p>A significant proportion of respondents who had actually tried GET & CBT, reported that it had made them worse. Many respondents had tried complementary therapies and found them to be of use and they wanted to see more of them offered by a CFS/ME service. Vitamins and minerals, scored more highly with respondents than any other complementary or conventional medications. Respondents also wanted more support concerning social care.</p> <p>It's glaringly apparent that it was too early for NICE to draw up these guidelines and quite how they are going to help in their current form must be seriously in doubt. We feel it's unlikely to reassure anybody that the NHS is taking this illness/group of illnesses seriously. In fact patients will probably be even more likely to seek help and support in the private sector. When contrasted to the Canadian Guidelines this draft fails very badly indeed.</p>	
SH	West Midlands Consortium	81	FULL/NICE	General	<p>The NICE Guidelines for CFS/ME were eagerly anticipated with a great deal of optimism by people with ME and their families, - but instead they have been met with a combination of incredulity, disbelief and dismay. There is an almost total reliance on 'mind over matter' and the appliance of exercise to treat exhaustion, in spite of a great deal of evidence (formal and informal) revealing them to be</p>	Noted.

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					<p>ineffective/harmful.</p> <p>In most spheres of life, experience is highly valued and, when consulting a doctor, the physician relies on the patient's experience to make a diagnosis. It is baffling to see how, in recommending treatments for ME, the experiences of patients are ignored or even regarded as invalid. To have taken such an approach is unprofessional, irresponsible and a completely wasted opportunity.</p> <p>The consortium of West Midlands Groups therefore rejects these Guidelines as totally inappropriate, and believes that as they stand, they are certain to cause more harm than good.</p>	
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