National Institute for Health and Clinical Excellence
CFS/ME consultation draft
29 September – 24 November 2006
Comments on Chapter 3

Status	Organisation	Order no.	Document	Page No.	Line no.	Comments	Responses
SH	25% ME Group	115	FULL	55	12–26	Simon Lawrence (25% ME GROUP), states : "To date, all patient reporting compiled by the ME charities has clearly shown that these therapies have been unhelpful or even caused harm in a significant number of sufferers. This is true for ME patients right across the spectrum of the disease. Indeed, from one of our own surveys, entitled Severely Affected Analysis Report, compiled in March 2004, it was found that, "…of the 39% of our members who had actually used Graded Exercise Therapy, a shocking 82% reported that their condition was made worse by this treatment. On the basis of our members' experiences we question whether GET is an appropriate approach for patients with ME. It is worth noting that some patients were not severely affected before trying GET. Thus, it is not only people with severe ME who may be adversely affected by this form of treatment." Also further findings from the Report referred to above showed that a massive	We have revised the recommendations, and reflected the need to offer individualised management and to discuss all potential benefits and harms.

						95% (415/437) of our members found GET to be an unhelpful form of treatment for their condition and similar figures were noted for CBT, with a massive 93% (407/437) who found this form of treatment unhelpful for their condition. We therefore question why these forms of treatment are still being considered as suitable for ME patients.”	
SH	25% ME Group	116	FULL	55–76		The experiences of people with ME/CFS are consistently disregarded: how could any rational person believe that such profound illness as depicted in these pages should not be appropriately investigated and that the first line management approach for such patients should be behavioural modification?	We have revised the recommendations, and reflected the need to offer individualised management plans and the need to recognise the physical nature and the impact of symptoms.
SH	25% ME Group	117	FULL	56	12–18	There is patient reporting concerning difficulties with Pharmacological treatment, which is probably due to Multiple Chemical Sensitivities; something that this Guideline does highlight. The immune system problems in ME probably have a lot to do with this.	Noted.
SH	25% ME Group	118	FULL	57	25–26	A recent patient survey undertaken by the 25% ME GROUP (2004), reported 70-75% of patients found Pacing the most helpful management of their	Noted with thanks

						condition and this is also recorded at an even higher rate by AfME.	
SH	25% ME Group	119	FULL	58	General	I am extremely concerned that the GDG have decided to favour the limited and contentious results in the CBT and GET research over the clear survey (AfME, Membership Survey, 2001 *****) and the majority of feelings of those PWME expressed in community websites and Support Group forums. ‘CBT Helpful = 7% Graded Exercise Made worse = 50%’	Evidence from patient surveys may have serious biases but, balanced with the research evidence, we have recommended that individual management should be offered, and that all potential benefits and harms should be discussed.
SH	25% ME Group	121	FULL	59	9	I strongly believe that the GDG should recommend the innovative use in Information Communication Technology (ICT) in seeking ways to inform and involve PWME. This should be more clearly reflected throughout the document. This would acknowledge the fact that due to their isolation, and lack of alternatives, many PWME have created their own online communities, and it is often their preferred method of communication	We have recommended that people be given information about local and national support groups, and that information should be provided in a format appropriate to the individual.
SH	25% ME Group	122	FULL	63 75	7 10	Should it be *Disability* Living Allowance?	Revised.
SH	Action for M.E.	18	FULL	55	3.2.1–3.2.12	As noted, patient responses have not been integrated into the guideline recommendations.	This and other patient evidence (such as from the wider questionnaire and through the patient

							representatives on the Guideline Development Group) has been considered throughout when drafting the recommendations.
SH	Association for Psychoanalytic Psychotherapy in the NHS (APP)	11	FULL	56–57	29, line 1	despite this finding, plus good evidence for homeopathy from a high quality RCT, there is no place in the recommendations for alternative therapy - this contradicts the underlying General principle 4.1.1.1 that patient preference should be given due respect; the same point applies to choice of psychological therapy - though the guideline is hampered because the surveys have not asked this question - why not?	We have noted the need to take into account patient preference. The Guideline Development Group considered that evidence from 1 RCT only was not sufficient to make a recommendation; however, we have noted that, although such therapies are not recommended as care provided by the NHS, individuals may find complementary therapies helpful.
SH	Association of Young People with ME	8	FULL	55: Patient's exper-iences	Section 3	The excellent Patients' Experience section should be enlarged to include personal stories from health workers and educationalist (and parents?). AYME has several excellent, succinct articles which have been published in the parent newsletter LINK and available on our web-site www.ayme.org.uk Section 3 is excellent. It points out that patients wish to follow an Activity Management approach and not a Graded Exercise programme. AYME would	Noted, but we have included only the testimonies that were in the consultation version from GDG members. Please also see the revised recommendations.

						like to see the Guidelines showing a collaborative approach with the printed patients' experience and recommend Activity Management.	
SH	BRAME Blue Ribbon for the Awareness of ME	65	FULL	55–76	3.1–3.3	3. Experience of People with CFS/ME: Given the information in this section, both within the results of patient surveys (including those sent in to you that you have not included), and the patient testimonies, why have these been so blatantly ignored when writing the rest of the Guidelines? Why are you not learning from patient experience that says GET and CBT do not work, and can be harmful, when instead they are recommended as the most suitable? Why have the flawed results of research based on the experiences of 777 people (we won't say ME/CFS sufferers, as by using the Oxford Criteria I am not sure that all these people actually could be counted as having these illnesses) been accepted against the testimony and views of thousands of patients?	Evidence from patient surveys may have serious biases but, balanced with the research evidence, we have recommended that individual management should be offered, and that all potential benefits and harms should be discussed.
SH	BRAME Blue Ribbon for the Awareness of ME	66	FULL	55–59	3.2	3.2 Summary of Submissions by Stakeholder Organisations: We are disgusted to see that the vital patient evidence sent in by the 25% Group, which provides	This has now been added.

						evidence on the severely affected, has been ignored and left out of this section – is this because the results go so against your recommendations, in particular within the management section. The 25% Group proved that people are harmed or not helped by CBT and GET; with 93% finding CBT unhelpful and 95% finding GET harmful/unhelpful, with over 82% of respondents harmed by GET, some of which were made severely affected by GET when previously they were only mildly or moderately affected. To not include this vital information exhibits a biased view of patient experience and evidence, in an attempt to reinforce the behavioural approaches to the illness in your recommendations.	
SH	BRAME Blue Ribbon for the Awareness of ME	67	FULL	58–59	3.2.9	3.2.9: Gaps in current treatment and care provision: Whilst you highlight the gaps in current treatment and care provision, throughout the document, you fail to address these issues, or to give useful advice and recommendations. There is minimal advice on symptom relief, nutrition, pain management, multidisciplinary care and telephone support. Quality of life and one to one	Please see the revised recommendations.

						support are not addressed, and, without mention of one of the most helpful forms of self management – pacing/energy management, how can self-management be practised? The guideline’s view of self-management as GET and CBT is totally unacceptable.	
SH	British Dietetic Association	2	FULL	57 ? 		We note the discrepancy between the results of the surveys of patient groups – showing that a large number have found dietary change helpful (59% in one survey and 65% in the other) and the final recommendations for dietary input in the guideline.	We have recommended the use of exclusion diets and the input of a dietician where appropriate.
SH	British Paediatric Mental Health Group of the Royal College of Paediatrics and Child Health	1	FULL	55		The personal testimonies (Ch3) present a vivid account of the severe disease. It would be helpful to have a view from someone less severely affected (75 % of patients). There are many articulate young people who could contribute this – for example a member of AYME. It is important to realise that many people do make a FULL recovery.	Noted, but we have included only the testimonies that were in the consultation version. And people should be aware that there are many other sources of patient testimonies available.
SH	College of Occupational Therapists	30	FULL	55–56		The inclusion of summaries of submissions from stakeholder groups is important in presenting a balanced view. However, due to the size of the document and difficulties with concentration, many patients may only read the	We considered it appropriate to present the full guideline in the chapters as we did during validation (ie with the patient evidence and research evidence separately). But all evidence was

						early sections. Although the document goes on to provide evidence that particular interventions, such as CBT and graded exercise can be beneficial if carried out by an appropriate professional, this may be missed. Also it is not known for those people who felt the intervention made them worse whether the intervention was carried out be a professional with an understanding of CFS/ME. **Suggestion:** Would it possible to present the patient evidence alongside the research evidence base to allow people to make a more balanced comparison of the background information?	considered when making recommendations. The 'Understanding NICE Guidance' version (aimed at a lay audience) 'translates' the recommendations and is a much shorter document.
SH	College of Occupational Therapists	31	FULL	56	24	Featherstone 1998 and Hughes 2002 not included in the reference list.	Noted and added.
SH	College of Occupational Therapists	32	FULL	59–76	N/A	It is disappointing that **all** the personal testimonies give negative feedback about services. This isn't a true reflection across patients currently accessing NHS services.	Noted, but these were the experiences of the individuals.
SH	Invest in ME	81	FULL	57	10 onwards	*- 3.2.5 Diet* • "A total of 73% of those who had indicated that they had tried some form of dietary therapy said that it had helped them and only 2 said that it had made them worse." *(Report on Survey of Members of*	Noted, and although supplements are not recommended as care provided by the NHS, individuals may find supplements helpful.

						Local ME Groups, Cooper, 2000) • 59% found dietary changes helpful; 25% were uncertain and 16% reported feeling worse. n=354 *(Action for ME, Members Survey, 2003*) IiME Comment: This is interesting as supplements are not in the recommendations.	
SH	Invest in ME	82	FULL	57	17 onwards	- *3.2.6 Bedrest* • “Complete bed rest did make 10% of respondents worse. Yet 37% said they were helped a lot by doing this. Total bed rest helped a total of 74% of respondents who had done this.” (Report on Survey of Members of Local ME Groups, Cooper, 2000) • Rest, including bed rest, helped 90%.n=354 *(Action for ME, Members Survey, 2003)* IiME Comment: Strange, then, that the emphasis of these guidelines seems to be to get pwme out of bed and back to work with GET being offered, despite the comments above.	Please see the revised recommendations on the appropriate use of rest.
SH	Invest in ME	83	FULL	58	1 onwards	*3.2.8 General comments:* Even the least successful regime, graded exercise did help 39% of the respondents to some extent.	Evidence from patient surveys may have serious biases but, balanced with the research evidence, we have recommended

						IiME Comment: How does this statement tally with the table in this section where 26% said it made them worse and 67% say no change! What about 50% of those using GET who were made worse – how much worse? These comments are really skewing the results. 91% said resting made them better – this should be stressed especially as NICEare recommending exercise to aid recovery and stating that rest is not to be used as an aid to recovery.	that individual management should be offered, and that all potential benefits and harms should be discussed. Also, please see the revised recommendations on the appropriate use of rest.
SH	PRIME Project (Partnership for Research in ME/CFS)	4	FULL	58	10	During our engagement with people with ME/CFS and their carers in this project PRIME has been collecting their questions and issues for the last 2 years. Many of these questions and issues relate to treatment and care provision, and these are consistent with the gaps identified in the draft guidance. However, PRIME would add to this list with: • The positive/negative impact of a diagnosis • More information on disease progression	Noted, and these are issues as noted in the cited survey. We have also addressed some of these issues in the full guideline and the recommendations.

						- The role and effectiveness of complimentary therapies - The impact of attitudes from health professionals and society - Information needs for patients and carers and health/social care/educational professionals and employers.	
SH	PRIME Project (Partnership for Research in ME/CFS)	5	FULL	59	10	The primary data from 40 interviews of people with ME/CFS are available on the PRIME web site. These have the advantage over the NICE testimonials in that: - They were purposively sampled to find "hard to reach" groups (such as the severely affected) - The interviews can be searched by age, sex, severity, duration of illness or by Theme (see below) - Ethical approval was obtained for the study We strongly recommend that the GDG consult this database under each clinical topic they are addressing to find relevant patient experiences. The PRIME Team will be happy to assist. About the Themes From PRIME's original data	Thank you.

						source of interviews with people with ME/CFS the research team undertook a ‘light touch’ thematic analysis of the transcripts. 18 themes (including 2 sub themes) were identified from the data. Many of the themes correspond or are similar to the themes being investigated by NICE. They are: Causes and factors Diagnosis Period prior to diagnosis Symptoms Coping Strategies Impact on family Impact on social Life Impact on education Impact on employment Impact on home life Experiences of the health care system – sub categories on positive and negative experiences General experiences, feelings and impacts Spirituality/Religion Treatment Positive outcomes Recovery Relapse Ideas for future research Family members with ME/CFS Whilst there are many similarities between the testimonials in the guidance, and the extracts	

						in the PRIME Patient Experience Database, we would suggest that for such a complex condition, a wider variety of experiences would give a far better understanding of the context within which the empirical evidence, that makes up a large part of the evidence base for these guidelines, will be implemented. For example, in the 'treatment' extracts alone there are over 70 extracts that describe different types of treatments and interventions (in context) and how the interviewees felt that they had helped or hindered their progress. They range from nutritional/dietary approaches, pacing, self management courses, acupuncture, physiotherapy, autogenics, homeopathy, herbalism, a variety of medicines including antidepressants, osteopathy, graded exercise therapy, vitamin B 12 injections, cognitive behaviour therapy, adrenal and thyroid related medicines, Chinese medicines, nutritional and vitamin supplements, 'Mickel' therapy, TENS machine, massage, relaxation, yoga, and	

						Psionic medicine. Any clinical practice can only succeed if it is clinically effective, cost effective and acceptable to patients. The development and application of well-developed patient-reported outcome measures, that capture issues of relevance to patient experience of health and health care, is essential to informing this process.	
SH	Royal College of Nursing	25	FULL	59	7	Add use of e-mail as an option alongside use of telephone to deliver care and support.	This has been added to the recommendations in the guideline.
SH	Royal College of Paediatrics and Child Health	38	FULL	55		The personal testimonies (Ch3) present a vivid account of the severe disease. It would be helpful to have a view from someone less severely affected (75 % of patients). There are many articulate young people who could contribute this – for example a member of AYME. It is important to realise that many people do make a FULL recovery.	Noted, but we have included only the testimonies that were in the consultation version. And people should be aware that there are many other sources of patient testimonies available.
SH	St Bartholomew's Hospital Chronic Fatigue Services	37	FULL	55	14–19	It’s useful to hear about experiences of ME group members and to know that it’s not CBT itself which is the problem.	Noted.
SH	St Bartholomew's Hospital Chronic Fatigue Services	38	FULL	55	21+	Graded exercise therapy. The guideline should also summarise the further survey results of AfME members, which were included in their 2003	We have added details of this survey to the section.

						survey of members. Here is the relevant quote, with no changes made to the format: • **“Graded Exercise Therapy (GET):** *GET is one of the most controversial of the rehabilitative approaches, and is usually supervised by physiotherapists. As was reported by the CMO’s Working Group, practice varies enormously.* When those who had had GET in the last 3 years were examined in more depth, a high proportion had never in fact GET as reported in research studies e.g. 11 Had NO professional input *(had they therefore paced themselves ?)* – mostly with positive outcomes 6 Were supervised by occupational therapists – **all with negative outcomes** 3 Had been sent to the gym- **all negative outcomes!** • *This appears to show that outside the major M.E. centres, who does it and to what standard is a lottery. Suggesting that the issue may not*	

						the be value of GET, but what type and the quality of the therapist. This would certainly support the evidence given to the CMO Report, and if true could explain why harm is not found through research trials (conducted in the best centres) but is found through surveys of peoples experiences – few having had access to the best centres.” Action for ME, Members survey 2003 (you already have the reference.) These further clarifying findings are rarely mentioned by those who quote the overall findings that a large number of AfME members found exercise interventions or advice damaging or unhelpful. Yet, they provide an explanation for why there is a discrepancy between the RCT findings and certain patient group beliefs. We suggest it is very important to include these data.	
SH	St Bartholomew's Hospital Chronic Fatigue Services	39	FULL	59	10 +	We do not feel the testimonies reflect the FULL spectrum of this disorder or the capacity for patients to recover with appropriate evidence based treatment. Where any patient representatives on	Noted, but we have included only the testimonies that were in the consultation version. And people should be aware that there are many other sources of patient

						the GDG recovered patients? If not this might explain why this section does not provide a comprehensive set of views of the patient experience. We suggest you balance this section by obtaining views of recovered patients, and we may be able to help you with this. See for instance: http://news.bbc.co.uk/1/hi/health/6120514.stm	testimonies available.
SH	Stockport PCT	8	FULL	58	3–4	Useful table comparing responses of patients to different management and treatment options.	Noted with thanks.
SH	Stockport PCT	9	FULL	58	10–13	Gaps in current treatment and care provision – symptom relief; nutrition; pain management – this is also our experience locally.	Noted and one of the aims of this guideline is to address such gaps
SH	The British Psychological Society	35	FULL	68	21	This case history describes the phenomenon associated with ME referred to as the ‘ceiling effect’, or the ‘plateau’. Pacing is the only strategy which takes account of this.	Noted
SH	The British Psychological Society	36	FULL	72	29	Raised ESR suggests an illness other than CFS, or a co-morbid disorder. This is not typical of CFS. Consider a footnote.	Noted, but this describes the particular experience of one individual.
SH	The Chartered Society of Physiotherapy	5	FULL	58	3	If 50% get worse with GET why suggest as first line of treatment?	Please see the revised recommendations
SH	The Chartered Society of Physiotherapy	6	FULL	59–76	3.3	It is not really appropriate to have individual patient testimonies in a clinical guideline aimed at health professionals	Noted.
SH	The Chartered	16	FULL	57	22	Hopefully, this statement	Noted, and please see

	Society of Physiotherapy				3.2	will be qualified later in the document as we are trying to get patients out of their beds rather than in!	the detailed recommendations on the appropriate use of rest and the potential harms of unlimited bed rest.
SH	Welsh Association of ME & CFS Support	46	FULL	58	8	This should read 34% not 39%	These were two different surveys.