

**ME/CFS guideline stakeholder workshop subgroup discussions:
Friday 25th May 2018**

Area of scope	Stakeholder views
<p>Title: Current title of the guideline: Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management</p>	<p>Getting the title right was of key importance for all stakeholders both in terms of engaging the patient community and enabling professionals. The majority of stakeholders agreed that both ME and CFS should be included in the title, with one group of stakeholders suggesting only ME (and not CFS) should feature as the title.</p> <p>Whereas the majority of stakeholders felt ‘ME’ was the globally accepted term for this area, one group of stakeholders felt Encephalopathy was an outdated and meaningless term. They did however acknowledge that ME may be the preferred term lots of the relevant research is done using the name CFS which is why it is crucial to be clear with the title. A further group questioned the term malaise and felt it didn’t capture accurately the symptoms people experience. Post-exertional malaise is a currently used term which should be considered for the search strategy search terms.</p> <p>A number of stakeholders felt the forward slash was inappropriate and it should be replaced with ‘AND’.</p> <p>Stakeholders also felt strongly about the need to be clear and accurate in the descriptions/definitions of conditions as there can be misleading information in relation to what constitutes fatigue and the vast range of diagnostic criteria for these conditions make it complex.</p> <p>A number of other conditions were raised as being important to consider/include:</p> <ul style="list-style-type: none"> • Sleep dysfunction • cognitive difficulties • Postural orthostatic tachycardia syndrome (POTS) • Joint hypermobility syndrome • Post-exertion amplification of symptoms <p>Endocrine / neuroendocrine disorders</p>

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<p>Population</p> <p>This guideline is for:</p> <ul style="list-style-type: none"> • people using services, their families and carers, and the public • all health and social care professionals <p>It may also be relevant for:</p> <ul style="list-style-type: none"> • education services • occupational health services • voluntary sector organisations 	<p><u>COMBINED RESPONSES</u></p> <p>One group underlined the relevance of occupational health doctors and the NHS choices office to this guideline.</p> <p>A further group of stakeholders raised issues with access to services for many people and the geographical variations that exist across services. This group felt that constraints on services for CFS/ME are disproportionate compared to other conditions.</p>
<p>Who is the focus:</p> <p>Groups that will be covered:</p> <ul style="list-style-type: none"> • Children, young people and adults with suspected or diagnosed ME/CFS <p>Specific consideration will be given to</p> <ul style="list-style-type: none"> - Children, young people and adults with severe symptoms <p>Groups that will not be covered</p> <ul style="list-style-type: none"> • People for whom a diagnosis of ME/CFS has been excluded 	<p><u>COMBINED RESPONSES</u></p> <p>The majority of stakeholders discussed the exclusion of people who have previously diagnosed with MS/CFS due to the co-morbidities that people experience and this could therefore miss people who should be covered by the guideline/accessing care for their CFS/ME. For example, if POTS or depression is diagnosed, this does not exclude CFS/ME.</p> <p>One group of stakeholders felt that the specific groups for consideration should be:</p> <ul style="list-style-type: none"> • Children and young people • People with severe symptoms • Older people • Families where there is more than one person with the disease <p>A further group felt that stratifying specific groups by their symptoms/conditions would be more helpful for example:</p> <ul style="list-style-type: none"> • Those experiencing post-exercise malaise and those who do not; • post-viral fatigue syndrome often constitutes the triggering cause of ME/CFS and thus, people with post-viral fatigue syndrome should be included in the group of people with a 'suspected' diagnosis.

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<p>Settings</p> <p>Settings that will be covered</p> <ul style="list-style-type: none"> All settings where NHS or social care is provided or commissioned 	<p><u>COMBINED RESPONSES</u></p> <p>Some stakeholders felt that school could be added (due to involvement from CAMHS, paediatricians, and social workers in schools) so that the guidance covers those professionals and enables them to correctly identify children can affected by CFS /ME.</p>
<p>Key areas that will be covered</p> <ul style="list-style-type: none"> Identification and assessment before diagnosis Diagnosis of ME/CFS Management of ME/CFS Monitoring and review Information, education and support for people with suspected ME/CFS, their families and carers <p>Areas that will not be covered</p> <ul style="list-style-type: none"> The management of comorbid conditions The specific management of symptoms where NICE guidance already exists 	<p><u>COMBINED RESPONSES</u></p> <p>Stakeholders were in agreement that all the key areas stated should be covered. There were some additional areas emphasised by a number of stakeholders:</p> <ul style="list-style-type: none"> Service delivery - aspects of service delivery and comparison of models of delivery. There is a desire for an accreditation scheme for services, training for healthcare professionals and for NICE to develop a standardised assessment tool and a core minimum standard of care to be developed. Medications - symptom control should be included and the different treatments for symptoms/ co-morbidities e.g. POTS within ME might be different to POTs in someone without ME. Medication intolerance. <p>Some stakeholders disagreed with the suggestion to exclude management of co-morbid conditions as this impacts on all other areas such as management and treatment. There was a suggestion that symptomatic care should be included.</p>
<p>Economic aspects</p> <p>We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective.</p>	<p><u>COMBINED RESPONSES</u></p> <p>One group of stakeholders felt that potential interventions that make outcomes worse would have an economic impact. A further group wanted to acknowledge the cost impact of access to benefits and support depending on the label given in diagnosis.</p>

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<p>Key issues and questions</p> <p>1 Identification and assessment before diagnosis</p> <p>1.1 In whom should ME/CFS be suspected?</p> <p>1.2 What is the most clinically and cost effective method of assessing people with suspected ME/CFS?</p> <p>1.3 Can disability or assessment scales aid the identification of people with ME/CFS?</p> <p>1.4 What are the barriers and facilitators to the identification of ME/CFS?</p>	<p><u>COMBINED RESPONSES</u></p> <p>This was seen to be a very important area by stakeholders and one that needed a great amount of consideration. There were a range of suggestions provided by stakeholders with regards to what should be included when looking at this clinical area.</p> <ul style="list-style-type: none"> • Advice and information at the early stages of diagnosis or even pre-diagnosis was deemed as being important • Information on the prognostic indicators and aetiology to help guideline treatment was felt important to include. • Assessment tools - self-reporting severity scoring tools were suggested as being helpful in assisting clinicians in the consultation process.
<p>2 Diagnosis of ME/CFS</p> <p>2.1 What tests are clinically and cost effective in supporting or excluding a diagnosis of ME/CFS?</p> <p>2.2 In people with suspected ME/CFS how accurate are the criteria used to establish diagnosis?</p>	<p><u>COMBINED RESPONSES</u></p> <p>There were varying opinions about the accuracy of the criteria used to establish diagnosis. Some felt that the criterion for malaise was accurate whereas other stakeholders felt that all criteria required further revision.</p> <p>There was consensus around the importance of recognising differential diagnosis and the reality of co-morbidities. There was a suggestion of looking at ME vs CFS subgroups.</p> <p>Some stakeholders suggested that clinical signs and blood tests should be included.</p> <p>Being more precise with diagnosis was deemed as crucial.</p> <p>Children were highlighted as an important group, as were hard to reach groups.</p>

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<p>3 Management of ME/CFS</p> <p>3.1 What is the clinical effectiveness and cost effectiveness of pharmacological interventions for people with ME/CFS?</p> <p>3.2 What is the clinical effectiveness and cost effectiveness of non-pharmacological interventions for people with ME/CFS (including dietary supplementation, graded exercise therapy, pacing, the Lightning Process and psychological interventions such as CBT)?</p> <p>3.3 What is the clinical and cost effectiveness or self-management strategies such as heart rate monitors for people with ME/CFS?</p>	<p><u>COMBINED RESPONSES</u></p> <p>3.1 What is the clinical effectiveness and cost effectiveness of pharmacological interventions for people with ME/CFS?</p> <ul style="list-style-type: none"> • Impact of drug and chemical hypersensitivity in people with ME and CFS and how this effects use of medications– for example vaccinations and treatments for comorbid conditions; • Need more research to allow treatments to be recommended <p>3.2 What is the clinical effectiveness and cost effectiveness of non-pharmacological interventions for people with ME/CFS (including dietary supplementation, graded exercise therapy, pacing, the Lightning Process and psychological interventions such as CBT)?</p> <ul style="list-style-type: none"> • Supportive care and management should be included (OT, mobility support) • Social care interventions • Dietary supplementation • Coordinated care and prompt referrals <p>Lightening process was regarded as inappropriate by some stakeholders; however, there was some agreement between stakeholders that the examples were leading and unnecessary.</p> <p>3.3 What is the clinical and cost effectiveness or self-management strategies such as heart rate monitors for people with ME/CFS?</p> <ul style="list-style-type: none"> • Awareness in the family, carers... in terms of management • Pain and sleep management • Activity/exercise management however one group emphasised that exercise can cause harm

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<p>4 Monitoring and review</p> <p>4.1 What is the most clinically and cost effective method of monitoring people with ME/CFS?</p> <p>4.2 What is the most clinically and cost effective method of reviewing people with ME/CFS?</p>	<p><u>COMBINED RESPONSES</u></p> <p>There were varied responses to this question, including:</p> <ul style="list-style-type: none"> • Include advice on how to avoid deterioration • Harm to patients should be reported/recorded for all treatments (not just drugs) • Triggers for worsening • Should include referral and specialist clinics
<p>5 Information and support for people with suspected and diagnosed ME/CFS</p> <p>5.1 What information and support to people with ME/CFS and their families/carers require?</p>	<p><u>COMBINED RESPONSES</u></p> <p>There was consensus around the need for practical information about how the condition(s) impact on other areas of life for example, driving, pregnancy, vaccinations, and access to other services (dental and ophthalmic care) in addition to the provision of equipment and disability aid.</p> <p>It was also considered to be necessary to have a section for carers.</p> <p>Issues regarding addressing stigmas were also felt to be an important area by one group of stakeholders.</p>

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<p>Main outcomes</p> <ul style="list-style-type: none"> • Quality of life • Pain • Fatigue • Physical functioning (a person’s ability to do everyday tasks and activities) • Psychological well-being • Care needs 	<p><u>COMBINED RESPONSES</u></p> <p>In the main, the outcomes listed were accepted with some discussion of the subjectivity/objectivity of some tests. A range of additional outcomes were suggested:</p> <ul style="list-style-type: none"> • Cognitive functioning was suggested by the majority of stakeholders • 2 day test • Actometers (mentioned by a majority of stakeholders - could come under physical functioning) • Immune system testing before and after exercise is objective/ walking tests • Participation in workforce and life-balance • Sleep measures • Impact on family/ siblings <p>The following concerns were also raised:</p> <ul style="list-style-type: none"> • Concerns about un-blinded trials (risk of bias) • Return to work not a good measure • The outcomes suggested seem to be those that can be measured by survey – this is problematic

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<p><u>GC composition</u></p> <p>(positions could be full or co-opted)</p> <ul style="list-style-type: none"> • GP x2 • Physician with an interest in ME/CFS e.g. neurologist, infectious diseases, immunologists x3 • Psychologist • Occupational therapist • Physiotherapist • Dietician • Paediatrician x2 • Nurse with a specialist interest in ME/CFS • Social worker • Lay member x4 <p>• Do you have any suggestions for involving people with more severe ME/CFS in the guideline?</p> <p>1.</p>	<p><u>COMBINED RESPONSES</u></p> <p>There was some consensus about the need for specialist input on the guideline committee, however the types of specialists varied. Suggestions for specialists included:</p> <ul style="list-style-type: none"> • Endocrinologist • Rheumatologist • Internal medicine • Molecular/biochemical specialist <p>There was also consensus across the majority of stakeholders to include more physicians.</p> <p>Additional suggestions raised by individuals (no consensus) were:</p> <ul style="list-style-type: none"> • Dietician – should be nutritionist • Epidemiologist with an interest in ME • Lay members – should have a young person, older people and representation from people with different severity. In case of a severe person, a primary carer can cover if he/she can't attend the meeting. • Include someone who sees severely affected patients, those with long-standing conditions and C&YP • OT or a physio <p>There was a difference in opinion about the inclusion of a psychiatrist on the committee with some in favour and others opposing.</p>
<ul style="list-style-type: none"> • What issues in relation to people's experience of being treated for ME/CFS could the guideline address? <p style="padding-left: 40px;">Issues for MS and ME populations should be taken into consideration</p>	<p><u>COMBINED RESPONSES</u></p> <p>The issues raised were:</p> <ul style="list-style-type: none"> • Patient experience • Supportive psychological therapy (to help coping) – NOT illness beliefs.
<p>Further questions – a minority of stakeholders provided responses to the following questions:</p>	

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Are there any specific equality considerations that the guideline needs to take into account?	Issues for MS and ME populations should be taken into consideration
Are there any critical clinical issues that have been missed from the Scope that will make a difference to patient care ?	The aforementioned issue of co-morbidities was considered missing.
Are there areas of diverse or unsafe practice or uncertainty that require addressing?	No particular areas of unsafe practice were named. However, the need to identify and include those within 'Do Not Do' recommendations was raised.
Other issues raised during subgroup discussion for noting:	There was concern over the quality of existing evidence as well as the potential stigmatisation of families and children diagnosed with ME/CFS.