

# Questions that must be answered

A response to the NICE Guideline Scope  
Myalgic encephalomyelitis (or encephalopathy)/chronic  
fatigue syndrome: diagnosis and management

May 2018

Support Group for  
Severe M.E. Sufferers



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(May 2018)

# Questions that must be answered

## 25% Severe ME Group & Stonebird

### Summary:

The Guideline Scope is characterised by the questions that it DOES NOT ASK and the distinctions it fails to make. *Until the following questions are answered there is a danger that the Scope will have very little to do with Myalgic Encephalomyelitis and so will be unsafe for patients.*

- Q1. What does the term “ME/CFS” mean in this document?
- Q2. What is the aetiology and pathogenesis of ME?
- Q3. How can people with ME be separated safely from people with psychiatric chronic fatigue?
- Q4. What are the FULL symptoms of ME ?
- Q5. How can we safely identify the illness ME with all its symptoms and how can we discern what is co-morbid or a relevant part of the illness?
- Q6. Will NICE acknowledge that there is not one appropriate Disability & Assessment scale currently and that a person approaching ME from a biopsychosocial view will interpret it differently?
- Q7 Will The Scope consider the quality of underlying research to ensure that neurological ME, not generalised fatigue has been studied and check the criteria used to identify participants in any trials to clarify this?
- Q8. Specifically, what are the dangers of ANY intervention for people with ME, especially the most severely affected ? Will NICE offer guidance on Risk Assessment?
- Q9. What are the risks, dangers and considerations for any recommendations?
- Q10. What is the safest method of monitoring for people with ME?
- Q11. What does NICE mean by a “cost-effective pathway” : is it a biomedical or a psychosocial one?
- Q12. What exactly does NICE mean by “evidence” when there is so little evidence available, especially in Severe ME?
- Q13. How can NICE ensure the guidance is safe for people with ME, to protect them from psychiatric misinterpretation?
- Q14. What is needed to be done to ensure that people with ME have equal and safe access to services?
- Q 15 How can the most physically ill patients be protected from psychiatric misinterpretation?
- Q16.How can the most ill, particularly those with complex symptom involvement, be ensured and enabled to have adequate and thorough testing on the same level as Rare Diseases?
- Q17. What extra precautions and flexibility do people with Severe ME need to ensure that they are thoroughly tested for their serious symptoms and co- morbid conditions in a sensitive and safe way?
- Q18. Will NICE make the distinction between chronic fatigue and ME overt?
- Q19. How can the Scope ensure that the most Severely Affected who are too ill to be tested will be given proper clinical diagnosis, recognition and support of their symptoms, not misinterpreted as refusing tests or wrongly interpreted as MUS?
- Q20. Why is Counselling not being considered in the Scope, as appropriate psychological support ,rather than highly inappropriate CBT, based upon wrong illness belief?

**NICE : The Department of Health and Social Care in England has asked NICE to**

*develop guidance on diagnosing and managing myalgic encephalomyelitis (or encephalopathy)/ chronic fatigue syndrome (ME/CFS).*

**Our Response:**

The use of multiple names enables different interpretations. Our first question is this :

**Q1. What does the term “ME/CFS” mean in this document?**

ME, an organic neurological disease, is classified under WHO ICD G93.3; it can be fatal . "CFS", on the other hand, defined through the now discredited Oxford Criteria, which are no longer used in the USA, and the CDC/Fukuda Criteria, describes no distinct patient group.

The label “ME/CFS” is not formally acknowledged or classified by the WHO; it has no ICD Code. The WHO ICD-10 code as used in UK, Australia, Europe and other countries, has 'CFS' in the index only, indexed to G93.3; 'CFS' does not appear in the Tabular list, i.e. the main body of the classification listings, at that code. In ICD-10 'CFS' is not the same as 'Fatigue syndrome,' which is classified at F48.0 Neurasthenia under "Mental and behavioural disorders "

This distinction is not made in the Scope.

“ME” must be properly defined and identified in the scope, it cannot be assumed that people know what they are talking about because the name “ME” has been so compromised and confused, misinterpreted and misused.

The Scope must make it clear :

**a. Is it talking about Myalgic Encephalomyelitis or a range of conditions under the umbrella term “CFS” ? No one is safe with an umbrella term. They will respond differently to any management recommendations potentially endangering the lives and the health of different sections of a wider poorly defined disparate group of patients, under an umbrella term.**

**b. Do “ME” and “CFS” mean the same? Is it “ME” and “CFS” or are they identical? Does “CFS” actually mean “ME”? It has to be recognised that different clinicians interpret these terms differently and do not have the same understanding concerning the illness, prognosis or potential for recovery. There is no cure - there are no treatments for ME!**

NICE needs to identify specifically what it means when it uses these terms. It must be made clear which illness is actually being offered guidance for. You cannot assume people are talking about the same thing when using these labels.

You do not necessarily need to have “fatigue” to have Myalgic Encephalomyelitis; the term ‘chronic fatigue’ was not associated with the illness at all, until after the name was changed from ME to Chronic Fatigue Syndrome (CFS) in 1988 in the US.

If someone has any other physical disease, for example Cancer, there will be a consistent recognition of the symptoms and an understanding of what is required. Unlike people with ME, patients with Diabetes or Cancer or Multiple Sclerosis do not have to contend with

interchangeable names and unsafe treatment protocols or completely different interpretations and understanding of their disease because of psychiatric influence.

The previous NICE Guideline CG53 was fundamentally flawed, which is why it was rejected as unfit for purpose, upon publication by virtually every ME Group. Two errors - a lack of commitment to the biomedical research, plus a disinterest in the medical truth of ME from the beginning, led to a gross psychiatric skew and an inappropriate focus upon only one symptom: fatigue.

**These failures must not be repeated:**

- A failure to provide adequate guidance for diagnosis, specifically not separating ME from CFS (or ensuring CFS is seen and treated as equal, not including CF) and Chronic Fatigue.)
- A failure to include experts from all the relevant professional groups on the Guideline Development Group, particularly those with biomedical expertise in diagnosing and treating people with Myalgic Encephalomyelitis, not vague fatigue, burn out or tiredness).
- A failure to study the aetiology and pathogenesis of ME, which meant that thousands of papers could not be discussed as part of the process.
- A failure to give patients' / carers' views equal weighting and status, as subsequently confirmed by two members of the GDG.

NICE "guideline" CG53 was more appropriate for patients suffering from idiopathic fatigue, as outlined by the WHO at ICD-10-F48, not patients with ME: a serious disabling neurological, multi-system dysfunction disease, classified by the WHO at G93.3. Yet the name Myalgic Encephalomyelitis was tacked on the end of it.

People with ME must no longer be continued to be harmed by wide, inaccurate, vague definitions.

**Q2. What is the aetiology and pathogenesis of ME?**

This will not be the same for Chronic Fatigue.

**Q3. How can people with ME be separated safely from people with psychiatric chronic fatigue?**

This must happen to ensure safe diagnosis and treatment protocol.

NONE of the issues, below, that the draft Scope raises can be answered until it makes it very clear exactly what illness or condition it is talking about, including an acknowledgment of the full range of physical symptoms that people actually experience:

*Identification and assessment before diagnosis*

*Diagnosis of ME/CFS*

*Management of ME/CFS*

*Monitoring and review*

*Information, education and support for people with suspected and diagnosed ME/CFS, their families and carers*

*NICE : Areas that will not be covered*

The management of comorbid conditions

**Q4. What are the FULL symptoms of ME ?**

It is a nonsense to have a guideline based on only one, nonessential symptom -fatigue. Clarification of symptoms inclusive of ME is required so that they are not mistakenly disregarded as “co-morbid”.

**Q5. How can we safely identify the illness ME with all its symptoms and how can we discern what is co-morbid or a relevant part of the illness?**

**NICE : Key issues and draft questions**

While writing this scope, we have identified the following key issues and draft question related to them:

Identification and assessment before diagnosis

*In whom should ME/CFS be suspected?*

**Our Response:** This cannot be answered without identifying what “ME/CFS” means.

*NICE : Can disability or assessment scales aid the identification of people with ME/CFS?*

**Our Response:** It depends upon who is answering this question - there are a range of different scales that will be chosen by different clinicians promoting different pathways, for example the Chalder Scale or the Hummingbird disability scale. This is why a distinction must be made to separate chronic fatigue and the psychosocial interpretation from neurological ME and a biomedical understanding.

Our concern is that most Disability & Assessment Scales are too behavioural; severity for example, is not always about being bed-bound. Especially for the most severely affected a scale that takes into account Symptom Severity is required.

**Q6. Will NICE acknowledge that there is not one appropriate Disability & Assessment scale currently and that a person approaching ME from a biopsychosocial view will interpret it differently?**

*What are the barriers and facilitators to the identification of ME/CFS?*

**Our Response :** This is an excellent question. Currently the overwhelming barrier is the longstanding influence of psychiatry and their claim without any basis, that the WHO classified neurological disease Myalgic Encephalomyelitis (ME) is a “Somatoform” disorder.

Of particular concern here is the JCMPH misinformation to commissioners that ME is MUS. The concept of “MUS” was first introduced in 2003 with a warning that doctors who believe that their “MUS” patients are medically ill, are in danger of causing them iatrogenic harm; patients would be made worse if the doctor ordered investigations. (Williams 2017)

**NICE: Management of ME/CFS**

What is the clinical 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)?

**Our Response :** Why are CBT and GET included here, given the MEA 15000 signature response to NICE? Why have they not already been withdrawn?

The £5 million PACE Trial which set out to test these two psychiatric 'therapies' did not prove effective. The ME Association has called for CBT and GET to be removed as primary interventions for ME patients. Graded Exercise Therapy is probably the worse possible intervention for people with ME, almost certain to do harm.

We do not understand how the “*Lightning Process*” has suddenly come to be included quite literally out of the blue, given it was not mentioned in CG53 and that the U.K. Advertising Standards Authority has found its claims to be misleading and unsupported by the available evidence. Is its sudden inclusion, we wonder, related to the SMILE Trial? Many of the SMILE Trial participants had symptoms of anxiety and depression, which happen to be very responsive to nonspecific support. (Geraghty 2017) To extrapolate the results to people with ME would be a disaster, given the abundant evidence from numerous surveys that “CBT is ineffective and that GET is unacceptable and sometimes harmful for people with ME. (Williams 2016)

It should be noted that “*Dietary Supplementation*” especially in Severe ME might be a clinical requirement, not just a boost, because patients do not have enough essential vitamins and minerals, for example CoQ10.

**Q7 Will The Scope consider the quality of underlying research to ensure that neurological ME, not generalised fatigue has been studied and check the criteria used to identify participants in any trials to clarify this?**

It is not enough to claim this is “CFS/ME research”. The underlying criteria for inclusion must be identified and chronic fatigue studies excluded, even if they use the name “ME”, in order to safe guard ME patients from mistreatment.

**Q8. Specifically, what are the dangers of ANY intervention for people with ME, especially the most severely affected ?  
Will NICE offer guidance on Risk Assessment?**

**Q9. What are the risks, dangers and considerations for any recommendations?**

*What is missing here is a statement that ME is currently incurable and untreatable.*

**NICE : Monitoring and review**

*What is the most clinically and cost effective method of monitoring people with ME/CFS?*

*What is the most clinically and cost effective method of reviewing people with ME/CFS?*

**Q10. What is the safest method of monitoring for people with ME?**

**Most traditional methods are not safe for they demand interaction, that especially in Severe ME, cannot safely be sustained.**

Many people do not understand the enormous danger of deterioration in ME!

This needs to be recognised.

**NICE : Information and support for people with suspected and diagnosed ME/CFS?**

*What information and support do people with ME/CFS and their families / carers require?*

**Our Response: This depends ultimately upon WHAT illness, WHAT criteria are being used and WHETHER psychiatry has been excluded from front-line intervention in ME. And what severity of illness?**

The literature is full of advice on Pacing etc, but you only need to spend a split second or so in the presence of someone with Severe/Very Severe ME, to know how inappropriate and useless, techniques like Pacing are in that situation.

Here you need to know how to create a physical environment where there is the maximum possibility for a positive and helpful interaction, engage with and make a difference in the person's life see and meet their need and importantly get it right, not cause harm. This the MOMENT Approach. (Crowhurst 2013)

**Q11. What does NICE mean by a “cost-effective pathway” : is it a biomedical or a biopsychosocial one? Each approach will yield a very different result, both have conflicting information, support and methodology.**

All of the questions above are a nonsense until you identify WHICH illness, WHICH pathway.

**NICE : Main outcomes**

*The main outcomes that may be considered when searching for and assessing the evidence are: Quality of life (for example EQ-5D, SF-36)*

*Pain*

*Fatigue*

*Physical functioning (a person's ability to do everyday tasks and activities)*

*Psychological well-being*

*Care needs*

*NICE quality standards and NICE Pathways*

*NICE quality standards*

*NICE quality standards that may need to be revised or updated when this guideline is published*

**Our Response :**

It is extremely concerning that there is:

- **No recognition of specific symptoms here, other than pain and fatigue, which raises alarm bells that NICE's focus is still fatigue oriented, not neurological.**
- **No recognition of the specific biomedical pathway required.**
- **No recognition that severity means different approaches may be needed, different levels of understanding, that a very different approach is required for homebound people!**

Care Needs will be viewed differently depending upon the interpretation of ME as a physical disease or a mental health condition. It is ESSENTIAL that NICE adopts a biomedical interpretation of ME, not a psychosocial misinterpretation which will greatly endanger particularly the most ill. This must not happen.

**Q12. What exactly does NICE mean by “evidence” when there is so little evidence available, especially in Severe ME?**

**Q13. How can NICE ensure the guidance is safe for people with ME, to protect them from psychiatric misinterpretation?**

**Q14. What is needed to be done to ensure that people with ME have equal and safe access to services?**

For example :

- A commitment to help not harm people with ME.
- The complete banishment of the psychosocial attitude, interpretation and approach to ME.
- An acknowledgment of the profoundly physically disabling disease with an honest prognosis, not one based on hopeful fantasy.
- An appropriate and universally acknowledged definition of ME, with detailed criteria for identification, such as the ICC, which calls for a separation of ME from CFS specifically, so that there is no more confusion over who has it and who does not.
- A biomedical mobile home bound visiting service, that recognises those who cannot attend hospitals.
- No perfumes to be worn by anyone who is going to interact with someone with ME, this includes all medical staff and carers.
- An in depth understanding of how to specifically approach - or not - people with severe to profound hypersensitivities to noise, light, chemicals, drug, touch, movement, to motion sensitivity specifically, with awareness and an understanding and commitment to the MOMENT approach to care and interaction.
- A recognition of equality of personhood.
- A partnership approach.

- A reinstatement of the VP1 test or a better one developed to identify enteroviral infection and other physiological tests - ie heart rate, oxygen, blood pressure monitoring
- A commitment to offer better ME testing and thorough investigation of all symptoms without prejudice.
- A full recognition, investigation and respect of all physical symptoms of Myalgic Encephalomyelitis, including paralysis, which enables a full focus on the whole disease, not a biomedical misinterpretation, still only fatigue- focussed in origin.
- Better identification, investigation, support and recognition of co-morbid diseases, with awareness, taking into account the complications of treatment, resulting from having ME.
- An intent to identify the physiological issues underpinning all symptoms of ME, not just using guess work, assumption, experimentation or ignoring there are any.
- An awareness and acknowledgment of the impact and dangers of anaesthetic and drugs on people with ME.
- Better testing to help identify which specific diseases have been previously ignored or overlooked, with access to scans and tests that in other illnesses are easily recognised as needed and provided for, such as SPECT and PET scans, for those able to tolerate them, with an understanding that sadly, some may be too ill to tolerate testing and must not be harmed or interpreted as resisting or refusing tests.
- An effort to ensure flexibility of availability and timings of any consultations, without prejudice if cancelled, due to the specific severity and complexity people face because of their illness.
- An understanding of the risk involved in any interaction or treatment, with a serious risk assessment undertaken for each person, before anything is suggested or undergone.
- Proper monitoring and support for any treatments suggested or offered. A commitment to engage safely with each person, taking time to comprehend specific communication issues and the dangers of not understanding them or not following instructions regarding when or how to engage, when to stop, when to wait etc
- The creation of a mobile unit, able to do specific, needed tests in situ.
- The acknowledgment by NICE and the NHS that this is a WHO recognised neurological disease.
- The correct language to be used in any report writing; being clear that people are not refusing tests, treatments, services, rather that they are too ill, too frail, too sensitive etc to engage with a service, specifically with no misinterpretation or misrepresentation.
- An honest recognition of how any interaction, test or treatment might impact - including the post exertional impact upon someone specifically with ME.
- Dietary input, understanding food sensitivity in ME and recognising the complex gastric issues.
- Emergency back up with access to medical advice from doctors and nurses who are aware of the severity of illness and recognise how to safely approach and support people with ME who are in health crisis.

- A specific nursing protocol for ME, based on understanding of the disease process and severity, the danger of deterioration, the environmental challenges etc., a MOMENT approach. (Crowhurst 2014)

## **Conclusion:**

Under the powerful influence of the UK psychiatric lobby, there are countless daily cases of psychosocial abuse and needless suffering to ME patients; who have been grossly neglected for decades.

Because of the imposition of the CFS label upon their disease, people with ME are seriously deprived of proper medical tests, treatments and research. Essential tests are proscribed in CG53. This is both cruel and unacceptable, it wrecks lives, it leaves numerous patients suffering for decades with no hope of a cure or treatment.

A much better effort must be made to look at underlying physiology, especially in the more severely affected.

**Q 15. How can the most physically ill patients be protected from psychiatric misinterpretation?**

**Q16. How can the most ill, particularly those with complex symptom involvement, be ensured and enabled to have adequate and thorough testing on the same level as Rare Diseases?**

**Q17. What extra precautions and flexibility do people with Severe ME need to ensure that they are thoroughly tested for their serious symptoms and co-morbid conditions in a sensitive and safe way?**

**Q18. Will NICE make the distinction between chronic fatigue and ME overt?**

**Q19. How can the Scope ensure that the most Severely Affected who are too ill to be tested will be given proper clinical diagnosis, recognition and support of their symptoms, not misinterpreted as refusing tests or wrongly interpreted as MUS?**

**Q20. Why is Counselling not being considered in the Scope, as appropriate psychological support rather than highly inappropriate CBT, based upon wrong illness belief?**

CBT is currently classified as “treatment by the NHS”, despite there is no safe or universal treatment. (NHS 2017)

*Simon Lawrence and Greg Crowhurst May 2018*

### **References:**

Crowhurst G (2013) **The MOMENT Approach**, Stonebird, <http://www.stonebird.co.uk/moment.pdf>

Crowhurst G (2014) **For Nurses**, Stonebird, <http://stonebird.co.uk/nurses.pdf>

Geraghty K (2017) **The SMILE Trial Lightning Process for Children with CFS: Results too good to be true?** <https://mindthebrain.blog/2017/10/05/the-smile-trial-lightning-process-for-children-with-cfsresults-too-good-to-be-true/>

NHS (2017) **Chronic fatigue syndrome (CFS/ME)** <https://www.nhs.uk/conditions/chronic-fatigue-syndrome-cfs/treatment/>

Williams M (2016) **A response to Professor Esther Crawley’s broadcast on BBC Radio Bristol** <http://www.angliameaction.org.uk/docs/Williams-response-to-Crawley-6-November-2016.pdf>

Williams M(2017) **THE POWER OF PROPAGANDA ?** Compiled by Margaret Williams 4th February 2017 <http://www.meactionuk.org.uk/MW/2017/power-of-propaganda.pdf>

Wilshire CE, Kindlon T, Courtney R, Matthees A, Tuller D, Geraghty K and Levin B (2018) **Rethinking the treatment of chronic fatigue syndrome—a reanalysis and evaluation of findings from a recent major trial of graded exercise and CBT.** <https://bmcp psychology.biomedcentral.com/articles/10.1186/s40359-018-0218-3>