



Surveillance report 2017 – Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management (2007) NICE guideline CG53

Surveillance report

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Contents

Surveillance decision	3
Reason for the decision	3
How we made the decision.....	4
Pre-consultation.....	4
Stakeholder consultation.....	4
Themes from stakeholder comments	5
NICE Surveillance programme project team	8

Surveillance decision

We will plan a full update with a modified scope of the guideline on [chronic fatigue syndrome/myalgic encephalomyelitis \(or encephalopathy\)](#) (NICE guideline CG53).

Reason for the decision

Assessing the evidence

Initial assessment of the evidence against the guideline scope indicated that there was no clear signal that the identified new evidence would result in changes to the recommendations (see [appendix A](#): pre-consultation summary of evidence from surveillance). Following a [stakeholder consultation](#) on the proposal to not update the guideline, broader issues with the guideline were highlighted that called into question the guideline scope and its current relevance.

After further consideration of information from stakeholders including new evidence (see [appendix B](#): summary of evidence highlighted to NICE during consultation, and [appendix C](#): stakeholder consultation comments table) alongside the evidence identified through the surveillance review, NICE has decided to fully update the guideline with a modified scope.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the evidence and views of topic experts, we decided that a full update with modified scope is necessary for this guideline.

See [how we made the decision](#) for further information.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on a surveillance review and stakeholder consultation conducted 10 years after the publication of NICE's guideline on [chronic fatigue syndrome/myalgic encephalomyelitis \(or encephalopathy\)](#) (NICE guideline CG53) in 2007.

For details of the process and update decisions that are available, see [ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual](#).

Previous surveillance update decisions for the guideline are on our website.

Pre-consultation

Evidence

We found 62 studies in a search for randomised controlled trials and systematic reviews published between 1 August 2010 and 3 January 2017. We also included 24 publications identified by members of the guideline committee who originally worked on this guideline. A further 9 studies were identified through post-publication communications.

Sixty studies identified in previous surveillance 3 years after publication of the guideline were also considered.

From all sources, we considered 155 pieces of evidence to be relevant to the guideline.

See [appendix A](#): pre-consultation summary of evidence from surveillance for details of all evidence considered, and references.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline and other correspondence we have received since the publication of the guideline.

Stakeholder consultation

Thirty nine stakeholder organisations responded to consultation. See [appendix C](#) for stakeholders' comments and our responses. There was a good mix of organisations covering patient organisations, professional bodies and providers of services including: royal colleges (Paediatrics

and Child Health, Psychiatrists, Physicians, and GPs), hospitals, professional associations, universities and patient associations.

Of the responding organisations, 9 agreed (none of which were patient associations) with the decision not to update the guideline and 30 disagreed. In addition to specific comments on the detail of the consultation document, approximately 300 pieces of evidence were highlighted, 13 of which met criteria to be included in the evidence summary for the surveillance review (see [appendix B](#): summary of evidence highlighted to NICE during consultation for details of the potential impact of this additional evidence on the guideline).

See [ensuring that published guidelines are current and accurate](#) in developing NICE guidelines: the manual for more details on our consultation processes.

Themes from stakeholder comments

Several themes emerged from the comments received at consultation which are detailed below. Stakeholders highlighted concerns with the existing guideline related to diagnosis, and interventions for treatment and management. Additionally, stakeholders raised issues around service delivery in respect to variation in practice, definitions and particular sub-groups that the current guideline does not differentiate between.

Definitions and aetiology

- Aetiology is outside the current scope. However many stakeholders raised the issue in respect to its impact on diagnosis and treatment.
- Interventions recommended in the guideline are based on the biopsychosocial model. Stakeholders raised that since 2007, much has changed with respect to biomedical knowledge. Biological models based on measurable abnormalities may need greater consideration.
- Newer terms for the disease are proposed e.g. US Institute of Medicine 2015 propose 'systemic exertion intolerance disease' (SEID) whilst other stakeholders advise that myalgic encephalomyelitis should be the preferred term.
- Severe ME is not well covered in the guideline and can cause profound issues. Some stakeholders indicated that parents of children with severe ME sometimes find that false allegations of child abuse are made against them due to poor understanding of symptoms, care and treatment by healthcare professionals and schools.

Diagnosis

- Oxford criteria (used to recruit to many studies included in the guideline) and NICE criteria are too broad.
- Newer diagnostic guidelines from the US Institute of Medicine (2015) and International Consensus Criteria (2011) are different from NICE criteria. Specific paediatric criteria have also recently been proposed.
- Late diagnosis is an issue.
- Concerns have been expressed over misdiagnosis and overlap with other conditions e.g. pernicious anemia, Ehlers-Danlos syndrome, and Postural Tachycardia Syndrome.
- Consideration of new research on metabolomics and biomarkers may be warranted.

Implementation, and information and support needs

- There is variation in primary care management, and there is evidence of unequal access to specialist services.
- Stakeholders noted that NICE's evidence reviews are not up to date, therefore patients are not receiving the full picture on recommended treatments (such as studies that have shown inefficacy of cognitive behavioural therapy [CBT] or harms of graded exercise therapy [GET]), nor being told about alternative treatments, which may affect informed consent.
- Greater support for GPs (many of whom feel ill-equipped in this respect) is needed to help with diagnosis, to provide accurate information (for example evolving evidence on risk and benefit of treatments), and to consider what an 'individualised management plan' might look like in practice.

Treatment

General

- A large volume of new evidence since 2007 needs to be incorporated.
- A separate section for children within the guideline should be considered.

CBT and GET

- **Against CBT and/or GET**

- The US Centers for Disease Control and Prevention have dropped CBT and GET from their list of recommended treatments for CFS/ME.
 - Evidence was cited of harms of GET, and pacing should be considered as an option.
 - Key trials (particularly PACE [Pacing, graded Activity, and Cognitive behaviour therapy; a randomised Evaluation], but also Cochrane reviews of CBT and GET) have been criticised for inflating the efficacy of interventions. Issues include that some studies only require fatigue in the case definition, which may incorporate other fatiguing conditions with the potential to complicate results.
 - There may be distinctions between people with CFS and with ME that should be accounted for.
 - Patient surveys appear to contradict findings from randomised controlled trials and systematic reviews regarding the safety and efficacy of CBT, GET and pacing.
- **In favour of CBT and/or GET**
 - Large randomised controlled trials such as PACE and GETSET, and Cochrane reviews, appear to support the guideline recommendations on CBT and GET.
 - A hospital department supplied data that patient reported outcome measures completed by patients receiving >18 sessions of CBT and/or GET improved 60% on the SF-36 (a patient-reported general health outcomes scale).

Other interventions

- Additionally, stakeholders highlighted other interventions not currently covered in the guideline that NICE should consider. These included:
 - Structured exercise programmes, for example the Klimas programme.
 - Complementary and alternative therapies: co-enzyme Q10, magnesium supplementation, herbal medicine, acupuncture, the Perrin osteopathic treatment, gentle yoga/meditation and acupuncture/acupressure.
 - Pharmacological treatment: rintatolimod, rituximab and anakinra.
 - Faecal transplantation.

NICE Surveillance programme project team

The NICE project team would like to thank the topic experts who participated in the surveillance process.

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