NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Surveillance programme

Clinical guideline
CG53: Chronic fatigue syndrome/myalgic encephalomyelitis

Publication date
August 2007

Previous review dates
August 2010

Current status
On static list (since February 2014)

Challenge to surveillance decision
A letter to the Centre for Clinical Practice Centre Directorraised the publication of the following three reports in the USA that might have implications for the CFS/ME guideline:

- Smith MEB, Nelson HD, Haney E, Pappas M, Daeges M, Wasson N, McDonagh M. Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. Evidence Report/Technology Assessment No. 219. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 15-E001-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2014. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

- IOM (Institute of Medicine). 2015. Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an illness. Washington, DC: The National Academies Press.

- Recommendations from the HHS Chronic Fatigue Syndrome Advisory Committee. August 2015.

Action taken
The Surveillance Team Clinical Adviser reviewed the three reports alongside the guideline and the current recommendations. A view on the impact of the reports on the guideline recommendations can be found in Appendix 1. Feedback was also sought from the GDG Chair who indicated that TBC.

Comment [redacted]: Our process doesn't stipulate that it should be done, although with this topic I think it's worth getting a GDG view. They've been pretty responsive to me in the past. I've been contacting [redacted]

Surveillance recommendation
Through the evaluation of the US reports cited above, there are likely to be changes in the diagnostic criteria in this field that will have implications for the guideline in the future, but not until after the proposed 2 year validation of the diagnostic criteria is completed.

The Director of CCP had already decided that the surveillance review for CG53 should be brought forward to 20XX. The proposal is to continue with that plan.

Key findings

	Potential impact on guidance

	Yes	No
Evidence identified through challenge to surveillance decision	✓	
Feedback from Guideline Development Group Chair		TBC

Remain on static list	Transfer to active list	Change review cycle
✓		✓

Appendix 1

Summary of evidence	Impact on guideline recommendations
The AHRQ report[1] concluded that: • None of the current diagnostic methods have been adequately tested to identify patients with ME/CFS when diagnostic uncertainty exists. • Rintatolimod improves exercise performance in some patients (low strength of evidence) • counselling therapies and GET have broader benefit but have not been adequately tested in more disabled populations (low to moderate strength of evidence) • other treatments and harms have been inadequately studied (insufficient evidence). More definitive studies are needed to fill the many research gaps in diagnosing and treating ME/CFS.	There is no clear impact on the guideline recommendations for the following reasons:- • Changes to diagnostic criteria might have implications for the applicability of any research used to inform the current guideline. This report did not recommend a particular change. • Rintatolimod has been granted orphan designation (EU/3/15/1480) for the treatment of Ebola virus disease but has no license for the treatment of CFS/ME and would not usually be considered in a clinical guideline. • CG53 recommends individualised psychological therapy, and GET for people with mild or moderate CFS/ME.
The IOM report[2] considered the diagnostic criteria for CFS/ME and proposed the following: Diagnosis requires that the patient have the following three symptoms: 1. A substantial reduction or impairment in the ability to engage in preillness levels of occupational, educational, social, or personal activities that persists for more than 6 months and is accompanied by fatigue, which is often profound, is of new or definite onset (not lifelong), is not the result of ongoing excessive exertion, and is not substantially alleviated by rest, 2. Post-exertional malaise,* and 3. Unrefreshing sleep* At least one of the two following manifestations is also required: 1. Cognitive impairment* or 2. Orthostatic intolerance * Frequency and severity of symptoms should be assessed. The diagnosis of ME/CFS should be questioned if patients do not have these symptoms at least half of the time with moderate, substantial, or severe intensity.	The proposals differ from the recommendations for features suggesting the possibility of ~~CFS/~~ME/CFS in CG53 and from the approach to diagnosis in CG53. It is likely that the proposed criteria would also differ from the inclusion criteria for studies of interventions for people with ME/CFS~~CFS/ME~~. It is difficult to predict the effect this might have on the recommendations in CG53. However, it is worth noting that this is a proposal, and must be interpreted alongside the subsequent recommendations of the HHS Chronic Fatigue Syndrome Advisory Committee.
The report[3] of the HHS Chronic Fatigue	If the recommendations of the report are

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Syndrome Advisory Committee made a number of recommendations for a US audience on the need for further research in this field, particularly around • biomarkers and objective diagnostic tests • gaps in basic, translational, clinical and epidemiological research to improve the understanding of the condition(s) • research on treatments for people meeting newly proposed diagnostic characteristics • standardised assessment and measurement tools The Committee also made some amendments to the proposed diagnostic criteria in the IOM report, including changing "unrefreshing sleep" to "sleep disturbances", added some features, expanded definitions, and recommended a period of two years' validation of these. The report made a number of recommendations regarding treatment and care, but also recommended that clinical practice guidelines be developed.	followed, the proposed diagnostic criteria will have been evaluated by the end of 2017. It may be too early to try to interpret the implications of the proposed changes until then. Noting that the Committee recommendations differ from the proposal made by the IOM, it seems quite possible that further changes may occur as a result of validation. One of the recommendations on treatment and care called for a "Declaration that the disease is not the result of fear-based avoidance of activity and that cognitive behavioural therapy (CBT) and graded exercise therapy (GET) for this purpose are inappropriate". CG53 recommends individualised use of these interventions, and does not recommend any particular assumptions about the cause of the disease. Therefore the impact of this statement is unclear.

Overall Impact

Taken together, these three reports may have important implications for the CFS/ME guideline, but there is a suggested two year validation of the proposed changes to diagnostic criteria and it would be premature to update the guidance until there is a consensus in the UK and preferably internationally about the adoption of the proposed changes. The new criteria may affect the interpretation of all preceding evidence that may have used different inclusion criteria for study participants. It is not possible to tell how this might affect the recommendations.

1. Smith MEB, Nelson HD, Haney E, Pappas M, Daeges M, Wasson N, McDonagh M. Diagnosis and Treatment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome. Evidence Report/Technology Assessment No. 219. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 15-E001-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2014. www.effectivehealthcare.ahrq.gov/reports/final.cfm.
2. IOM (Institute of Medicine). 2015. Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an illness. Washington, DC: The National Academies Press.
3. Recommendations from the HHS Chronic Fatigue Syndrome Advisory Committee. August 2015.