

**Briefing for [REDACTED] Head of NICE Sponsorship, Department of Health and Social Care, on the development of the NICE ME/CFS guideline**

<b>Content:</b>	<b>From</b>	<b>Dr Paul Chrisp, NICE, Director of the Centre for Guidelines</b>
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## 1. Background

NICE is due to publish an update to its ME/CFS guideline on 18 August 2021.

Key issues include:

- The differing views of some professional groups (that the evidence supports cognitive behavioural therapy CBT and graded exercise therapy GET as ‘treatments’) with some patient groups (that GET – as defined in the guideline – can be harmful and that CBT should not be used as a ‘treatment’ for ME/CFS but as therapy which aims to improve wellbeing and quality of life and may be useful in supporting people who live with ME/CFS to manage their symptoms). A biopsychosocial (BPS) model of ME/CFS is the fault line that bitterly divides opinions in ME/CFS. The BPS model looks at biological, psychological and social factors to explain why disorders occur
- Some stakeholders have suggested that the evidence for GET that did not use a diagnostic criteria that includes post exertional malaise (PEM) as essential was inappropriately downgraded.
- That the guideline makes recommendations for providing appropriate support and rehabilitation delivered in an individually tailored programme focused on personal goals agreed between the person living with ME/CFS and those providing their care. It highlights that these programmes should combine a range of physical, cognitive and psychological approaches depending on the patient's preferences and priorities.

## 2. Timeline

September 2006: Publication of draft guideline to improve the diagnosis and management of chronic fatigue syndrome/ myalgic encephalomyelitis (or encephalopathy) (CFS/ME) in adults and children.

22 August 2007: Guideline [published](#).

March 2009: Judicial Review finds in favour of NICE

20 September 2017: NICE announces that it is to review and consult on its guideline on the diagnosis and management of MS/CFE.

10 November 2020: NICE published its [draft updated guideline](#).

4 August 2021: Embargoed release sent to stakeholders.

18 August 2021: Updated guideline published.

### **3. Development of the first guideline and updated guideline**

#### **First guideline**

A new guideline to improve the diagnosis and management of chronic fatigue syndrome/ myalgic encephalomyelitis (or encephalopathy) (CFS/ME) in adults and children was launched on 22 August 2007, following a draft guideline in September 2006.

#### **Response by Action for ME**

The charity expressed disappointment that the guidance placed undue emphasis on two treatments - cognitive behavioural therapy and graded exercise therapy - for which they considered the underlying evidence to be inadequate and unrepresentative. They said that many patients have reported little or no benefit from CBT and others have experienced seriously adverse effects from GET.

#### **Judicial Review judgement March 2009**

A joint claim was made by two patients: Fraser and Short. This was not a legal challenge against the recommendations themselves or against NICE, but about specific parts of the process that NICE followed. The grounds of the claim were:

- that the guideline was produced by a development group which appeared to be, or was, biased
- the guideline was irrational compared to the evidence on which it purported to be based
- the guideline was irrational because it didn't consider the nature of CFS/ME; the GDG didn't take proper notice of the WHO classification of CFS/ME and the GDG recommended a treatment (CBT or GET) which is not justified if given to a person not suffering from a psychiatric condition to the exclusion of other treatments.

The High Court ruled in favour of NICE and dismissed all grounds.

#### **2017 announcement of review**

On 20 September 2017) NICE announced that it was to review its current guideline on the diagnosis and management of chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). The decision followed a public consultation with patient and professional groups.

The message from stakeholders was that the continuing debate about the causes of this condition, the validity of the evidence base and the best approach to treatment argued for a review of the guideline.

NICE reviewed appointments to the guideline committee in response to more than 1,700 stakeholder concerns about impartiality and concluded that they were appropriate. The make-up of the committee was carefully reviewed by a COI (community of inquiry) panel chaired by NICE's CEO and judged to be acceptable.

We included 5 lay members on the guideline committee, rather than the usual 2, to reflect the importance of patient groups in ME/CFS and to give people with a range of experience, such as different severities of illness, of carers, and of young people with ME/CFS, the opportunity to contribute.

### **10 November 2020: NICE published draft updated guideline**

The draft guideline made separate recommendations for children and for people with severe or very severe ME/CFS. It recognised that ME/CFS is a complex, multi-system, chronic medical condition where there is no 'one size fits all' approach to managing symptoms, particularly where there is the potential for an intervention to benefit some people but cause harm in others.

It stressed the need for a tailored, individualised approach to care based on establishing a partnership between the person with ME/CFS and those providing their care that allows joint decision making and informed choice.

The draft guideline also highlighted the importance of ensuring that people remain in their 'energy envelope' when undertaking activity of any kind. It recommended that a physical activity programme, in particular, should only be considered for people with ME/CFS in specific circumstances.

The draft guideline said that any physical activity programme should begin by establishing the person's physical activity capability at a level that does not worsen their symptoms. It also said a physical activity programme should only be offered on the basis that it is delivered or overseen by a physiotherapist or occupational therapist with training and expertise in ME/CFS and is regularly reviewed.

Because of the harms reported by people with ME/CFS, as well as the committee's own experience of the effects when people exceed their energy limits, the draft guideline said that any programme based on fixed incremental increases in physical activity or exercise, for example graded exercise therapy (GET), should not be offered for the treatment of ME/CFS.

Similarly, based on criticisms in the evidence from patient experience of CBT being used as a treatment for ME/CFS, the draft guideline emphasised that it is not a treatment or cure for the condition. However, as a supportive psychological therapy

which aims to improve wellbeing and quality of life, the draft guideline said CBT may be useful in supporting people who live with ME/CFS to manage their symptoms. It should, therefore, only be offered in this context.

With respect to the recommendation in the current guideline on ME/CFS on graded exercise therapy (GET), our position was that we would allow the committee to fully consider all the evidence before updating any recommendations.

The committee considered the findings/conclusions of the PACE trial with other evidence about the place of GET as a treatment for ME/CFS. However, because of the harms reported in the qualitative evidence, as well as the committee's experience of the effects when people exceed their limits in exercise capacity, the committee recommended that people with ME/CFS should not undertake a physical activity or exercise programme unless it is delivered or overseen by an occupational therapist or physiotherapist who has training and expertise in ME/CFS.

The charity ME Action UK put out a statement classing the draft guideline's advice against "any programme based on fixed incremental increases in physical activity or exercise, for example graded exercise therapy" as an improvement.

Following the ME/CFS stakeholder consultation, NICE received 4,037 comments from 74 stakeholder organisations. The recommendations regarding graded exercise therapy (GET) and energy management received a significant number of comments. Broadly, patient organisations were pleased to see a recommendation specifically stating that GET should not be offered, while a number of professional groups expressed concern on the basis that GET has a role in the care of some people with ME/CFS and that removing GET as an option potentially leads to a reduction in ME/CFS services.

Professional organisations were concerned about the wording in the draft guidance which stated CBT should not be offered as a treatment or cure for ME/CFS. They felt that this removed a potential therapeutic option. While the committee continued to affirm that CBT is not curative, the reference to 'treatment' in the recommendation has been removed in recognition of the fact that CBT can still be said to treat symptoms.

Some lay groups were concerned about the prominence given to CBT despite the wording indicating that it is not curative. The recommendations in this section have been reworked for clarity but ultimately it was felt that a number of recommendations are appropriate in order to ensure that where CBT is offered, it is done so appropriately.

### **Summer 2021: Towards intended publication of the updated guideline**

In the run-up to the intended publication of the updated guidance on 18 August, NHSE/I and other professional groups have said that they cannot support the guideline and that service provision may be affected. Despite the fact that the Guidance Committee (GC) reached consensus on its recommendations, 3 professional members resigned from the GC after it was signed off.

The challenge for guidelines in complex interventions like this with limited evidence and no clearly agreed diagnosis is in finding the balance between methodological rigour and practical, implementable recommendations that support patient care and have the confidence of clinicians and commissioners.

NICE has been meticulous in following its methods and processes and the committee did their best to produce a guideline that they support and which NICE GE signed off. However, in this instance a guideline has been produced that professional groups will not support, and therefore will not be used to help patients receive the care they need. Because of the range of concerns raised with the final guideline, we need to take time to consider next steps and understand in more detail the reasons behind this lack of support. We will hold conversations with professional and patient stakeholder groups to do this. We need to do this so that the guideline is supported. Despite the intention being to try to build support for the guideline among professionals, this is likely to result in significant concern among ME/CFS patient groups.

## **Annex 1: ME/CFS**

ME/CFS is a relatively common illness, affecting over 250,000 people. The condition can be disabling, involving a complex range of symptoms, the most common being fatigue, but including headaches, sleep disturbance and muscle pain.

Some people have relatively mild symptoms and can still manage daily activities with additional rest, while others have a serious illness that severely affects their everyday lives and may be housebound. The pattern of a person's symptoms, and their severity, can vary from day to day, or even in the same day.

Most people with CFS/ME will improve over time, and the prognosis in children and young people is more optimistic.

It is not clear what causes ME/CFS and there is no diagnostic test or universally accepted definition for the condition. Indeed, many people with ME/CFS consider the name 'chronic fatigue syndrome' too broad, simplistic and judgemental. What is clear is that people with ME/CFS report a lack of belief and acknowledgement from health and social care professionals about their condition and related problems, which may lead them to be dissatisfied with care and to disengage from services. A strong theme in the evidence was the lack of knowledge, understanding and current training that health and social care professionals have about ME/CFS. This guideline will address these issues by recommending that all health and social care staff who deliver care to people with ME/CFS should be trained so they are able to recognise the condition and provide the care in this guideline.

## **Annex 2: GET and PEM (Graded Exercise Therapy and Post Exertional Malaise)**

PEM is widely acknowledged in ME/CFS specialist practice as being a characteristic feature of ME/CFS. However, not all diagnostic criteria include PEM as a criterion. Or if they do, it is not one which is essential. Following a review of the diagnostic literature the committee set out criteria for diagnosis which include PEM as an

essential component. The diagnostic criteria recommended by the committee are similar to those published by the Institute of Medicine in 2015, the key difference being that cognitive difficulties are also listed as essential in the NICE guideline whereas the IOM has either cognitive impairment or orthostatic intolerance as a required fourth feature. The difficulty for interpreting the evidence is that in the trials that do not use a criteria that has PEM as essential (and therefore a 100% ME/CFS population), numbers of people with PEM are rarely reported. The committee does not assume that people recruited to trials do not experience PEM, they just do not know how many if the information is not reported. Where this is the case, the trial population could include people that do not have ME/CFS and this makes it difficult for the committee to be confident of the benefits and risks of the interventions on people with ME/CFS.

Using GRADE the committee agreed that evidence without this information would be 'indirect', acknowledging this uncertainty about the population. As such the evidence was considered taking this into account. GRADE (Grading of Recommendations, Assessment, Development and Evaluations) is a transparent framework for developing and presenting summaries of evidence. It is the internationally recognised approach to evidence reviewing and is a key element of NICE's methodological approach on all of its guidelines.

After considering the stakeholder comments the committee agreed to revisit the evidence for the intervention reviews further, scrutinising the information on PEM reported in the quantitative and qualitative evidence and the application of indirectness and relevance. This did not result in any change to the recommendations.

### **Annex 3: PACE Trial**

The PACE Trial study (short for "Pacing, graded Activity, and Cognitive behaviour therapy; a randomised Evaluation") was a large-scale and controversial trial of treatments for people with CFS and ME.

The PACE study compared standardised specialist medical care (SMC) alone to SMC plus CBT or GET.

Recruitment of patients began in March 2005 and data collection was completed in January 2010. The main study outcomes were published in The Lancet in 2011.

### **Annex 4: 17 August 2021 media statement**

#### **NICE pauses publication of updated guideline on diagnosis and management of ME/CFS**

NICE has today (17 August 2021) taken the decision to pause publication of its updated guideline on the diagnosis and management of myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS).

The guideline recognises that ME/CFS is a complex, multi-system, chronic medical condition where there is no 'one size fits all' approach to managing symptoms. The causes of ME/CFS are still poorly understood and because of this there are strong views around the management of this debilitating condition.

Because of issues raised during the pre-publication period with the final guideline, we need to take time to consider next steps. We will hold conversations with professional and patient stakeholder groups to do this. We need to do this so that the guideline is supported.

NICE has used its usual rigorous methodology and process in developing this guideline but despite the best efforts of the committee, that followed these to the letter to bring together the available evidence and the real, lived experience and testimony of people with ME/CFS, we have not been able to produce a guideline that is supported by all.

We want to thank everyone who has contributed to this guideline and particularly the committee and the patient groups who have worked so diligently. However, unless the recommendations in the guideline are supported and implemented by professionals and the NHS, people with ME/CFS may not get the care and help they need.

In order to have the desired impact, the recommendations must be supported by those who will implement them and NICE will now explore if this support can be achieved.

Ends