NICE National Institute for Health and Care Excellence

10 year surveillance (2017) – Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (2007) NICE guideline CG53

Stakeholder consultation comments form - proposal for 'no update'

Consultation on the proposal for 'no update' opens on: 9am Monday, 10 July 2017

Comments on proposal to be submitted: no later than 9am Monday, 24 July 2017

Please enter the name of your registered stakeholder or respondent organisation below. Please use this form for submitting your comments to NICE. 1. Please put each new comment in a new row. 2. Please note – we cannot accept comments forms with attachments such as research articles, letters or leaflets. If we receive forms with attachments we will return them without reading the comments. If you resubmit the comments on a form without attachments, this must be by the consultation deadline. 3. If you wish to draw our attention to published studies, please supply the full reference. 4. NICE is unable to accept comments from non-registered organisations. If you wish your comments to be considered please register via the NICE website or contact the registered stakeholder organisation that most closely represents your interests and pass your comments to them.	
Organisation name – Stakeholder or respondent	Hope 4 ME & Fibro Northern Ireland
Disclosure Please disclose whether the organisation has any past or current, direct or indirect links to, or receives funding from, the tobacco industry.	Nothing to disclose.
Name of commentator:	Sally Burch

Developing NICE guidelines: the manual gives an overview of the processes used in surveillance reviews of NICE clinical guidelines.

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
1	Do you agree with the proposal not to update the guideline?	**NO**	1. Hope 4 ME & Fibro Northern Ireland have been campaigning for some time to have graded exercise therapy (GET) and cognitive behavioural therapy (CBT) removed from the NICE guideline CG53 for "CFS/ME". These therapies, when applied to patients with myalgic encephalomyelitis (ME), are widely reported to cause harm[1],[2],[3]. Many of our members have reported being harmed by medical pressure to exercise. E.g. One young man was put on an exercise bike by a neurologist, and the exertion caused him to collapse, vomiting, on the floor. The NICE guideline CG53 was used as justification for this patient's treatment. This situation cannot be allowed to continue – it is time the CG53 guideline was reviewed and the recommendation for GET removed. 2. Patients worldwide support the removal of CBT and GET from the NICE guideline CG53. At the time of writing the ME Association petition, calling for a review CG53, has collected over 15000 signatures[4] in the few days allocated for the consultation period. This substantial plea should not be ignored by those in control of NICE. CG53 is not working for patients. The guideline should therefore be reviewed immediately. 3. We regard patients who meet either the Canadian Consensus Criteria (CCC[5]) or the International Consensus Criteria (ICC[6]) to have the disease called ME. The Oxford criteria,

[1] ME Association Survey http://www.meassociation.org.uk/wp-content/uploads/2015-ME-Association-Illness-Management-Report-No-decisions-about-me-without-me-30.05.15.pdf
[2] Tom Kindlon: http://iacfsme.org/PDFS/Reporting-of-Harms-Associated-with-GET-and-CBT-in.aspx
[3] StopGET stories of harm from GET: http://www.stopget.org/sign-now/about-us/
[4] ME Association Petition https://www.change.org/p/petition-the-nice-guideline-for-cfs-me-is-unfit-for-purpose-and-needs-a-complete-revision
[5] Canadian Consensus Document: http://www.investinme.org/Documents/PDFdocuments/Canadian_ME_Overview_A4.pdf
[6] International Consensus Document: http://www.investinme.org/Documents/Guidelines/Myalgic%20Encephalomyelitis%20International%20Consensus%20Primer%20-2012-11-26.pdf

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			have been shown to over diagnose[7] patients with "CFS" (Note: In the USA ME, is often referred to as CFS). This over diagnosis means that many trial subjects, selected via Oxford criteria, do not have the disease ME, yet the outcomes of these trials are still used to inform ME care decisions. The removal of all Oxford based studies from the list of studies informing the knowledge base for ME/CFS has been recommended by the Institute of Medicine (IOM) report "Beyond Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Redefining an Illness"[8], and we agree with this stance. The USA Agency for Healthcare and Research Quality (AHRQ) has further issued an Addendum[9] to its 2014 ME/CFS evidence review. This Addendum downgrades the conclusions on the effectiveness of cognitive behavioural therapy (CBT) and graded exercise therapy (GET). There can be no doubt that the CG53 guideline needs to be reviewed in light of this new understanding. 4. We regard the name "chronic fatigue syndrome/myalgic encephalomyelitis" (CFS/ME) to be misleading. Putting the words "chronic fatigue" at the front of the disease name gives a misleading impression to medical professionals. Indeed, the "fatigue" premise behind the name "chronic fatigue syndrome" ensures that many patients without the defining feature of post exertional symptom exacerbation[10] will also receive a "CFS/ME" diagnosis. This dilutes the perceived severity of the disease ME, and is consequently detrimental to all those with ME, and particularly the most severely affected. Misdiagnosis (perhaps because of the inclusion of the word "fatigue" in the name) is an ongoing problem[11]. The CG53 guideline does not help this. The guideline needs to be reviewed, and we suggest the prefix "chronic fatigue syndrome" is removed.

[7] Oxford Criteria http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1353578
[8] IOM report: http://www.nationalacademies.org/hmd/Reports/2015/ME-CFS.aspx
[9] AHRQ downgraded CBT & GET: https://effectivehealthcare.ahrq.gov/ehc/products/586/2004/chronic-fatigue-report-160728.pdf
[10] CCC, ICC and IOM – as ref 5, 6 & 8 above.
[11] Natalia Palacios et al. http://www.tandfonline.com/doi/full/10.1080/21641846.2017.1323576

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			5. The recommendations for CBT and GET have now been deleted from the clinical guidance recommendations in: a) The USA Center for Disease Control guidelines[12] b) The Health Service Executive in Ireland guidelines [13] By doing this, these two countries have acknowledged the inappropriateness of using psycho-social therapies as a primary treatment for a physiological disease such as ME. The premise behind CBT and GET is summarised in the 2011 PACE Trial[14] Here is what the PACE Trial has to say about these therapies: **CBT:** *"CBT was done on the basis of the fear avoidance theory of chronic fatigue syndrome. This theory regards chronic fatigue syndrome as being reversible and that cognitive responses (fear of engaging in activity) and behavioural responses (avoidance of activity) are linked and interact with physiological processes to perpetuate fatigue. The aim of treatment was to change the behavioural and cognitive factors assumed to be responsible for perpetuation of the participant's symptoms and disability."* **GET:** *"GET was done on the basis of deconditioning and exercise intolerance theories of chronic fatigue syndrome. These theories assume that the syndrome is perpetuated by reversible physiological changes of deconditioning and avoidance of activity. These changes result in the deconditioning being maintained and an increased perception of effort, leading to further inactivity."* (Note the PACE trial refers here to "CFS", but the premise of these therapies is also applied to "CFS/ME".) This makes it clear that CBT and GET are based on psycho-social assumptions about the nature of ME. Now that the IOM report[15] considers ME as systemic exertion intolerance disease (SEID) these therapies should be regarded as obsolete. It is time the UK followed the lead of the above enlightened countries and ceased to recommend either

[12] USA Center for Disease Control guidelines now don't include GET & CBT - https://www.cdc.gov/me-cfs/index.html
[13] Health Service Executive (Ireland) website have removed ref to NICE guidelines http://www.hse.ie/eng/
[14] PACE trial https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3065633/
[15] IOM report – as ref 8 above

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			CBT or GET in the CG53 guideline. 6. Much of the research supporting CBT and GET (for the treatment of ME or CFS/ME) suffers from scientific flaws. These flaws can include: the premise on which the research is based; the selection of subjects, the methods used; and the interpretations of the study outcomes. The PACE Trial[16] and subsequent publications have been widely criticised[17] for a plethora of errors[18] and these errors have not been adequately addressed by the PACE authors in their responses[19]. Scientific review of other studies supporting the use of CBT and GET, is likely to throw up similar problems[20]. Following scientific scrutiny of these studies, the basis for the inclusion of CBT and GET as treatment recommendations are unsupported by science. The removal of CBT and GET from CG53 is essential to preserve the scientific integrity of all NICE recommendations. 7. We were disappointed when reviewing the evidence for this surveillance document, to find that the review panel only assessed the abstracts of the publications they considered, rather than the full documents. The quote below demonstrates that the team were not even prepared to look beyond the abstract when they had a question in mind about one of the studies. Quote from page 12 of 56 of the document[21]: *"However, it was not clear from an assessment of the abstract if diagnostic validity and reliability were tested."* This lack of curiosity would not be acceptable in a student essay, so why it is acceptable here is unclear. This suggests that the decision not to review CG53 is based only on a shallow review of the

[16] PACE trial – as ref 14 above
[17] Carolyn Wilshire: A critical commentary and preliminary re-analysis of the PACE trial http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1259724
[18] David Tuller Trial by Error series: http://www.virology.ws/mecfs/ and letter re PACE Trial recovery paper: http://www.virology.ws/2017/03/13/an-open-letter-to-psychological-medicine-about-recovery-and-the-pace-trial/
[19] Keith Geraghty http://journals.sagepub.com/doi/10.1177/1359105317714486
[20] GETSET review by Todd Davenport: http://www.workwellfoundation.org/wp-content/uploads/2017/07/GETSET-Trial-in-MECFS-L1.pdf
[21] Surveillence proposal consultation document July 2017 – Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (2007) NICE guideline CG53

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			evidence, and that little effort has gone into the appropriate investigation of the situation surrounding ME. Therefore, a more thorough and meaningful review is required. 8. We are concerned that the review panel have preferentially considered only one type of evidence. It is well known that there are currently two schools of thought regarding ME. The PACE Trial[22] authors favour the psycho-social premise and therefore their CBT and GET treatments are designed assuming that no physiological disease lingers after the initial illness-triggering incident. This contrasts strongly with scientists who are studying the measurable physiological abnormalities in ME[23] as part of an ongoing disease process. The two situations are as different from each other as the idea of a "Flat Earth" is from the recognition of the Earth as a spherical planet. Reading this review document, we are concerned that whilst the CG53 review panel mention the various physiological studies, they simply ignore them when considering whether to review the guideline. This level of bias is a major concern to patients everywhere. If there are indeed patients who suffer from a psycho-social fatigue (and who would therefore benefit from CBT and GET) then is important to separate out these "chronically fatigued" patients from genuine ME patients, who have ongoing physiological problems with exercise, and for whom GET and PACE-style CBT are contra-indicated[24]. Again, we call for an in depth and appropriately informed review of CG53. We also call for an independent investigation into to the membership of the review panel and the topic expert team, to ascertain why such an inherent psycho-social bias dominates.

[22] PACE trial – as ref 14 above
[23] Examples of studies showing physiological abnormalities can be found in the references section of this blog from the USA National Institute of Health here: https://directorsblog.nih.gov/2017/03/21/moving-toward-answers-in-mecfs/
[24] Chronic fatigue syndrome: assessment of increased oxidative stress and altered muscle excitability in response to incremental exercise https://www.ncbi.nlm.nih.gov/pubmed/15715687

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			9. We are concerned that throughout CG53, there is a recommendation for the "education" of medical professionals. However, this apparently laudable suggestion is some-what moot without describing the nature of the education to be provided. Should this "education" promote the view that patients can heal themselves through their own efforts in completing GET and CBT then that "education" will, in our view, be worthless. Medical professionals need to recognise the physiological limitations imposed upon ME patients by the disease. Health care professionals should not be encouraged by inappropriate NICE recommendations to push patients to exercise more. Patients have clearly articulated the harms[25] they have experienced from GET and CBT. The IOM panel[26] reviewed thousands of documents to conclude that *"exertion of any sort (physical, cognitive, or emotional)—can adversely affect patients in multiple organ systems"*, yet the NICE surveillance review has discounted the validity of these reports, whilst still accepting as valid, psycho-social studies based largely on subjective patient outcomes. If the "education" of medical professionals is to be based on this psycho-social approach to ME, then it is likely that patients will continue to report problems with the treatments they receive. CG53 is obviously not fit for purpose while these harms continue to occur. 10. Graded exercise therapy as a name, implies that conventional "exercise", should be followed by the patient. The guideline then suggests that this exercise should be progressed up to 50-70% of maximum heart-rate, once the patient has been successful with low key exercise of up to 30 minutes. However, many ME patients find even the most basic non-exercise tasks place their heart-rates well above the 50-70% range[27]. It seems that the guideline was written assuming that patients would not try to reach the 50-70% range themselves, when in fact the reverse is the case, and heart rate monitors are instead needed to prevent patients exceeding this heart-rate range on trivial activities. The CG53 guideline does not caution medical

[25] ME Association Survey - as ref 1 above
[26] IOM report - as ref 8 above
[27] Workwell presentations on heart rates http://www.workwellfoundation.org/research-and-latest-news/

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
			professionals about this issue, nor are the use of heart-rate monitors regularly suggested to patients. Members of our charity have found heart-rate monitoring to be helpful[28], and whilst no useful treatment is yet available, we believe that heart rate monitoring could help mild and moderate patients to safely manage their activities, thereby reducing the likelihood of further decline. To make better use of heart-rate recommendations, the CG53 guideline needs to be carefully re-drafted, taking into consideration both patient experience, and studies from clinicians with knowledge of the physical limitations of ME and of exercise physiology[29]. This would require that CG53 is reviewed. 11. Considering the two schools of thought for ME (see point 8 above), it would seem to us that there are likely to be two cohorts of patients currently being subsumed under the umbrella term "CFS/ME". Patients with an ongoing physiological disease process, who are unable to exert themselves without significant exacerbation of all their symptoms, are likely to have ME as defined by the CCC or ICC. Whilst ill, these ME patients will never benefit from GET or CBT (note: CBT is often applied to ME patients to persuade them to increase their activities in a manner similar to GET). However, patients who are more generally chronically fatigued (e.g. suffering from lifestyle burnout, fatigue resulting from depression, or perhaps a slow recovery after a fully resolved illness) might benefit from GET and CBT programmes as they restore a better lifestyle balance. We suggest that the review of CG53 considers how the guideline addresses this dichotomy. Perhaps it is time to consider that the same treatments are not applicable to both cohorts of patients? This would obviously require a complete review of CG53 with perhaps the creation of a brand-new guideline for ME. This way ME could be clearly separated from the more generalised chronic fatigue.

[28] Slide share on HR monitoring by Sally Burch: https://www.slideshare.net/SallyBurch/heart-rate-monitoring-and-nice-guideline-for-me
[29] Workwell studies – as ref 27 above

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			12. Severe ME is not appropriately covered in the current version of CG53, and the profound sensitivities of these patients are very poorly recognised by frontline medical professionals. Anecdotally we have heard of patient symptoms being discounted once the patient reveals that they have ME. We have also heard how patients within a hospital setting have been denied wheelchairs or appropriate assistance on the basis of ME not being a serious condition. As one carer told us, *"The prejudice we have experienced from neurologists, doctors and consultants, has been devastating."* Patients with severe ME are very susceptible to the extra exertion required for medical appointments, and the concentration required to respond to questions can be sufficient to cause a significant later exacerbation of all their symptoms. The system makes little provision for quiet and darkened resting spaces, and appropriate home visits are difficult to access. The CG53 guideline does not go far enough in describing the types of accommodations that might help the severely affected to access care. Many severely affected patients report to us that visiting their doctor worsens their condition to the point that they wish they had not attended, and consequently these patients become almost invisible to the system, because their fragile state prevents them from accessing appropriate care. Patients tell us that they are afraid of their inactivity being interpreted as a form malingering, and further that they fear a psycho-social interpretation being applied to their condition. The parents of children with severe ME sometimes find that false allegations of child abuse[30] are made against them. This can be due to a failure of the authorities to comprehend the nature of severe ME, as a highly disabling and intractable disease.

[30] Tymes Trust: http://www.tymestrust.org/pdfs/falseallegations.pdf

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			It seems the CG53 guideline does not sufficiently protect severe ME adults and children from such poor and unequitable treatment, nor from the assumption by some medical practitioners that their disability is a choice, or a mental health issue. Finally, there is no acknowledgement of the very severe ME state[31] where immobility, tube-feeding, paralysis, muscle spasms, severe cognitive dysfunction, and profound intractable pain may regularly affect the sufferer, such that they are too unwell to even tolerate the presence of family members in the room. That this very severe state may persist for years on end is not well recognised. These patients and their carers are left feeling abandoned by the health care system. CG53 therefore needs to be urgently reviewed.
2	Do you agree with the proposal to remove the guideline from the static list?	**YES**	We agree that the guideline needs to be removed from the static list, however, we do not agree with the reason that the review panel have chosen for proposing this action. The "FITNET" study[32] identified in the surveillance review as, *"important ongoing research"* has caused consternation within the ME community and most especially amongst parents of children with ME. Some of these parents are members of our charity, and have voiced their considerable concerns to us. David Tuller has explained many of the problems with the FITNET study on Virology Blog[33] noting that it is an unblinded study relying on subjective outcomes, with weak subject selection

[31] Description of very severe ME – Whitney Dafoe: http://stanmed.stanford.edu/2016spring/the-puzzle-solver.html
[32] FITNET study: http://www.isrctn.com/ISRCTN18020851
[33] David Tuller explains the problems of the FITNET study: http://www.virology.ws/2016/11/21/trial-by-error-continued-the-new-fitnet-trial-for-kids/

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			criteria (no post exertional malaise required), which operates on the premise that no ongoing disease process is present. This hardly seems like a gold standard trial worthy of the description of "important research", and for which a NICE guideline should be removed from the static list in anticipation of its results. Further problems with the FITNET study were noted in David Tuller's follow up article[34] where he introduces the matter stating, *"I guess people get upset when researchers cite shoddy "evidence" from poorly designed trials to justify foisting psychological treatments on kids with a physiological disease."* We take the view that the FITNET study is not worthy of consideration in updating CG53, and as such it is not a valid reason to remove CG53 from the static list. However, there is sufficient evidence that the multiple studies supporting GET and CBT should be regarded as scientifically flawed. This is an ongoing issue, but it is our view that science will eventually prevail and papers such as the PACE Trial and its spin-offs will be retracted. We are not alone with this view: an open letter[35] addressed to Richard Horton and The Lancet calls for a retraction of the PACE paper, and a petition from ME Action[36] signed by over 12000 has also called for retraction. A challenge like this to the science behind GET and CBT, along with the reported harms in the MEA survey[37], and the massive patient concern over the inclusion of these therapies in CG53 as

[34] David Tuller – second post on FITNET problems: http://www.virology.ws/2016/11/28/trial-by-error-continued-a-follow-up-post-on-fitnet-nhs/
[35] Open letter to Dr Richard Horton and The Lancet: http://www.virology.ws/2015/11/13/an-open-letter-to-dr-richard-horton-and-the-lancet/
[36] ME Action petition: https://my.meaction.net/petitions/pace-trial-needs-review-now
[37] ME Association Survey - as ref 1 above

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			demonstrated by the current MEA petition[38] calling for a review of CG53, should be sufficient reason to for immediate review, and certainly for the removal of CG53 from the NICE static list. Biomedical research is however in progress and this type of research is likely to produce better outcomes for patients in the future. The studies[39] linked in the IOM report (that lists some 9000 biomedical studies on ME) should not be discounted by the review panel, but rather highlighted as potential optimism for the future. Yet, we were surprised that the review panel seemed only to consider papers supporting the psycho-social premise for ME, and so would again like to call for an independent investigation into the makeup of the review panel, and the topic expert team for CG53.
3	Do you have any comments on areas excluded from the scope of the guideline?	**YES**	As recorded in both the above sections, we have noticed considerable bias to towards the psycho-social approach for the treatment of ME reflected within the review panel decision making process. We feel that this bias should not be tolerated by NICE. The following organisations have rejected the notion that ME is a behavioural, or mental health issue: • The World Health Organisation[40] recognises ME as a neurological (ie physiological) disorder. • The Department of Health recognised ME as an organic disease, in November 1987[41] • The Royal College of General Practitioners has agreed to stop classifying ME as a mental health disorder[42]

[38] ME Association Petition – as ref 4 above
[39] IOM report – as ref 8 above
[40] World Health Organisation. ICD10 section G93.3
[41] Hansard: 27th November 1987:353
[42] Royal College of General Practitioners letter to ME Association: http://www.meassociation.org.uk/2008/07/rcgp-agrees-to-stop-classifying-cfs-as-a-mental-health-disorder/

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			• The Royal College of Paediatrics and Child Health also recognises ME is not a mental health issue[43] • And NICE itself recently confirmed in a letter to Greg Crowhurst, that it does not regard ME as a mental disorder[44] However it was recently brought to our attention that Improving Access to Psychological Therapies (IAPT) [45] is managing the CG53 NICE guideline for CFS/ME on behalf of NHS England! This does not make sense. The anomaly clearly demonstrates the lack of clarity from NICE about the nature of the disease "CFS/ME". Certainly, the other conditions listed beside CFS/ME on the IAPT page would suggest that IAPT and NICE regard ME as a behavioural or mental health condition. This is totally unacceptable, and also in complete opposition to NICE's assertion to Greg Crowhurst that NICE does not regard ME as a mental health condition[46]! No wonder then, that the review panel and topic experts considered only the psycho-social approach to ME. If, by remit, these individuals are "improving access to psychological therapies" then it should be obvious that they will disregard all biomedical evidence towards the understanding of ME. NICE should be very concerned about this situation. This substantial bias surely challenges the integrity of the whole NICE brand? We suggest that NICE needs to address this concern as a matter of urgency. We call for an urgent independent investigation into the makeup of the NICE review panel for CG53.

[43] Royal College of Paediatrics and Child Health letter to ME Association: http://www.meassociation.org.uk/2011/04/5817/
[44] NICE confirmation to Greg Crowhurst that ME is not a mental disorder: http://stonebird.co.uk/NICE/index.htm
[45] Improving Access to Psychological Care (IAPT) https://www.nice.org.uk/about/what-we-do/our-programmes/nice-advice/iapt#conditions
[46] NICE letter to Greg Crowhurst – as ref 44 above.

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			We further call for a review of the topic expert team working on the CG53 guideline. Are they also biased towards the psycho-social approach? Are they perhaps using their "expert" status to influence the review panel into making choices favouring a behavioural approach to ME? We find this situation so unsatisfactory that we now call for both the topic expert team and the review panel for CG53 to be disbanded. We call for CG53 to be removed from the management of IAPT, and for a new team of topic experts and guideline reviewers to be selected from amongst scientists and medical professionals who are free from the influence of the behavioural or mental health approaches to ME. CG53 must not be left in the charge of individuals who deny the physiological abnormalities that drive the disease process in ME. Only once this has happened, will ME patients start to regain confidence in a health service that is currently failing to meet their needs.
4	Do you have any comments on equalities issues?	**YES**	<u>The following commentary was prepared by Andy Hugh and Nancy Van Hoylandt:</u> **There is a disparity between NICE and the CDC/IOM guidance. This could result in a breach of Human Rights if the NICE recommendation for no update goes forward. However, there is a possibility to bring about a resolution, should an appropriate review of the NICE guideline take place.** **Currently the two guidelines have opposing views.** **"*persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability."*** *UNCRPD - Article 25: Health.*

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			Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME) is listed in the World Health Organisation classification of diseases, ICD-10, under report code G93.3 [47] as a Neurological Illness and there are proposals for its inclusion in ICD-11 [48] as a disease of the nervous system of viral causation. The United Kingdom as a member state of the World Health Organization (WHO), is expected to comply with the WHO Nomenclature Regulations 1967 [49]. <u>National Institute of Health and Care Excellence (NICE) Guidelines – UK</u> The National Institute for Health and Care Excellence (NICE) have guidance CG53 [50] from 2007, for the diagnosis and management of CFS/ME (Chronic Fatigue Syndrome/Myalgic Encephalomyelitis), states: ***"There is no one way of managing CFS/ME that helps everyone but there are several options to try (see Managing CFS/ME)."*** [51][52]. and in their guideline it is stated: ***"1.1.1.3 Healthcare professionals should be aware that – like all people receiving care in the NHS – people with CFS/ME have the right to refuse or withdraw from any component of their care plan without this affecting other aspects of their care, or future choices about care."*** ***"1.6.2.4 Cognitive behavioural therapy (CBT) and/or graded exercise therapy (GET) should be offered to people with mild or moderate CFS/ME and provided to***

47 http://apps.who.int/classifications/icd10/browse/2016/en#/G93.3
48 http://apps.who.int/classifications/icd11/browse/f/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f569175314
49 https://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/141126w0001.htm
50 https://www.nice.org.uk/guidance/cg53/chapter/1-guidance
51 https://www.nice.org.uk/guidance/cg53/ifp/chapter/What-is-CFSME
52 https://www.nice.org.uk/guidance/cg53/ifp/chapter/managing-cfsme

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			those who choose these approaches, because currently these are the interventions for which there is the clearest research evidence of benefit." So, NICE acknowledge that there is no treatment that helps everyone. This is an acknowledgement that 'experimentation' is necessary to find out if a NICE treatment recommendation will help or not. There is a distinct failure to recognise any impact on the patient should treatment fail. NICE also acknowledge a right to refuse or withdraw from any component of care, however, in practice, paediatricians do not understand why a parent would refuse a treatment designed to help their child and this does result in false allegations of child abuse [53], numbers of which have risen dramatically over the last few months [54]. There is significant dispute as to whether one of the NICE treatment recommendations, Graded Exercise Therapy (GET) is therapeutic as will be seen later, however, the lack of acknowledgement by NICE of children's rights to prevent experimental treatments being forced on them without the children or parents facing false allegations is a particular issue. Such breaches of human rights cause unnecessary suffering for both the child and the family as a whole; a situation that urgently needs addressing in the NICE guidance. One key point to note is that NICE suggest that there is evidence of benefit from the use of their treatment options, yet, GET is clearly experimental because they admit it may not help and moreover, they do not cover the negative effects or possibility of harm when the therapies don't work. The same is of course true for Cognitive Behavioural Therapy (CBT) in the way it is applied in practice. Trials such as FitNET-NHS use planned increases in mental exertion, which is clearly no different to GET. NICE recognise that mental, physical or emotional exertion affects patients. NICE describes, in part, the implementation of Graded Exercise Therapy as follows:

53 http://www.tymestrust.org/pdfs/falseallegations.pdf
54 https://twitter.com/JaneCColby/status/886255772639916032

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			1.6.2.13 People with mild or moderate CFS/ME should be offered GET that includes planned increases in the duration of physical activity. The intensity should then be increased when appropriate, leading to aerobic exercise (that is, exercise that increases the pulse rate). So, the NICE message with respect to GET is that increases in exertion should be the goal and planned with an aim to exercise in the aerobic energy zone. According to a number of studies of which a couple are referenced, there is a physical block in the metabolism of aerobic energy [55][56] in those with CFS/ME and scientists warn of the abnormal response to exertion and that aerobic activities should be avoided [57][58][59]. It is clear that the NICE guidelines, have not taken into consideration the biomedical findings that demonstrate the potential for harm in the aerobic energy zone. NICE are clearly intent on ignoring and dismissing the plethora of harms from GET that have been reported, seemingly because they'll only recognise harms reported in trials. NICE state [60]: ***"From all sources, we considered 155 publications to be relevant to the guideline. Peer - reviewed study reports were assessed by abstract. "*** which is not so many publications given the IOM used approximately 9000 papers (see below) and yet NICE state: ***"We did not find any evidence related to management of setbacks/relapses."***

55 https://www.newscientist.com/article/2121162-metabolic-switch-may-bring-on-chronic-fatigue-syndrome/
56 https://www.youtube.com/watch?v=q_cnva7zyKM
57 https://www.facebook.com/griffithuniversity/videos/10154550816976005/?hc_location=ufi
58 https://www.youtube.com/watch?v=FXN6f53ba6k
59 https://www.youtube.com/watch?v=7BceGgEdMpA
60 https://www.nice.org.uk/guidance/cg53/documents/surveillance-review-proposal

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
			At some time between August and October 2016, NICE made the following statement [61]. ***"In 2015 we were told about 3 US reports that indicated there are likely to be changes in diagnostic criteria that could have an impact on the guideline recommendations. We decided to start a check of whether the guideline needs updating, and plan to publish our decision in summer 2017. We have since been made aware of new information about the 2011 PACE trial, and we will also consider that in the check. Register as a stakeholder to be informed about the decision."*** Amongst those reports was a 372-page report from the Institute of Medicine (IOM) in the US, that was based on approximately 9000 biomedical papers [62]. <u>The Institute of Medicine (IOM) Report - US</u> The Institute of Medicine were charged to do a thorough investigation into CFS/ME by the Department of Health and Human Services, the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Social Security Administration, to convene an expert committee to examine the evidence base for CFS/ME. In February 2015, the Institute of Medicine announced their report 'Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness' [63]. In their report, the IOM asserted quite firmly, that: ***"the committee recommends that the disorder described in this report be named "systemic exertion intolerance disease" (SEID). "Systemic exertion intolerance" captures the fact that exertion of any sort—physical, cognitive, emotional—can adversely affect these patients in many organ systems and in many aspects of***

61 https://web.archive.org/web/20161007032210/https://www.nice.org.uk/guidance/CG53
62 https://www.ncbi.nlm.nih.gov/pubmed/25695122
63 https://www.ncbi.nlm.nih.gov/pubmed/25695122

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			their lives. The committee intends for this name to convey the complexity and severity of this disorder. "exertion of any sort (physical, cognitive, or emotional)—can adversely affect patients in multiple organ systems" The NICE Guideline Development Group recommendation Then in July 2017, NICE stated: ***"Topic experts agreed with the conclusions of the surveillance team about the 3 US reports which were that no impact on the guideline was anticipated. They indicated that until and unless further research suggests otherwise, the NICE diagnostic criteria for CFS/ME remain valid."*** [64] and ***"We have checked this guideline and are proposing not to update it. We are consulting on this proposal. Register as a stakeholder to be informed about the final decision."*** [65] Centers for Disease Control and Prevention (CDC) – US Following the announcement of the report by the IOM in February 2015, the CDC made the following statement [66]: ***"In 2011, CDC posted the CFS Toolkit on its website to provide an easy-to-use resource for clinical care. During recent months CDC scientists had been working with CFSAC and others to revise the CFS Toolkit. After publication of the IOM committee report, CDC decided to archive the CFS Toolkit and the brochure***

64 https://www.nice.org.uk/guidance/cg53/documents/surveillance-review-proposal
65 https://www.nice.org.uk/Guidance/CG53
66 https://web.archive.org/web/20170703124425/https://www.cdc.gov/cfs/toolkit/archived.html

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			'Recognition and Management of CFS: A Resource Guide for Health Care Professionals'." In May 2017, a move in the US to officially remove GET as a recommended treatment first came from the New York Department of Health, who stated in a letter [67] to approximately 86,000 physicians: ***"In the past, cognitive behavior therapy (CBT) and a graded exercise therapy (GET) were recommended as treatments. However, these recommendations were based on studies that included patients with other fatiguing conditions. Because of the hallmark intolerance to exertion of CFS/ME, exercise may actually worsen the health of those living with this disease. Currently, there are no FDA approved treatments for CFS/ME."*** In May 2017, the CDC also followed this with a statement [68] that said: ***"Today, CDC recognizes the 25th anniversary of International Awareness Day for CFS/ME and Fibromyalgia. We continue to promote understanding of CFS/ME by: Supporting one of the largest-ever studies of CFS/ME. Seven CFS/ME doctors are identifying major health problems and symptoms of patients with CFS/ME. This will help us develop better and easier ways to diagnose and treat CFS/ME. Early findings contributed to a 2015 report by the Institute of Medicine's Committee on CFS/ME and have been recently published."*** More recently, on or around 8th July 2017, the CDC updated its website, having removed all references to GET [69] and made a statement [70] that demonstrates clearly that the CDC do not consider there to be any existing treatments for ME/CFS:

67 https://pbs.twimg.com/media/DA7LnGPW0AA3C66.jpg:large
68 https://blogs.cdc.gov/publichealthmatters/2017/05/me-cfs/
69 https://www.cdc.gov/me-cfs/
70 https://www.cdc.gov/me-cfs/treatment/index.html

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			"There is no cure or approved treatment for myalgic encephalomyelitis/chronic fatigue syndrome (CFS/ME)." On this date, the CDC also promoted the use of the IOM diagnostic criteria for the diagnosis of CFS/ME [71]. There are a number of disparities between the UK and US in the diagnosis and management of CFS/ME but I think the GET example is evidence enough to demonstrate that there are significant differences to warrant an acknowledgement in the NICE guidance that there is no consensus and a large disparity between authoritative members of the UN regarding treatment and management of CFS/ME and the harms associated with treatment. In particular, whilst the CDC/IOM identify the biological nature and needs of patients, the UK fails not only to include any reference to biological causation but to dismiss the IOM report out of hand. NICE favour a handful of very subjective and questionable RCT's over 9000 biomedical papers. This is clear psychiatric bias and discrimination against those with a physical illness and disability. The pre-trial mass media promotion of the FitNET-NHS trial as a cure for 2/3rds of children is the latest continuation of mass media brainwashing of a plethora of professionals and the public. This can only serve to incite yet more prejudice against those with a physical disability, that responds very differently to exertion than most other illnesses. Exertion scientists warn, causes harm; that there's a physical block in the metabolism of aerobic energy. Yet NICE guidance encourages planned increases aerobic exercise! The inequality is exacerbated by psychiatric refusal to acknowledge cardinal symptoms or extreme symptoms that may exist. The weakening of diagnostic criteria (by omitting key features of ME) results in a cohort of sufferers that includes subjects that may not have CFS/ME. This makes researchers conclude that CFS/ME is less severe than a more accurately

[71] https://www.cdc.gov/me-cfs/symptoms-diagnosis/diagnosis.html

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
			selected cohort might indicate. Indeed, it seems that sufferers with more with extreme symptoms are then denied a diagnosis, as it is claimed that CFS/ME cannot become so severe, and this results in the severe patients being denied appropriate care. The continuation of the psychiatric bias in the UK directly denies patients their legal and legitimate rights to biomedical progress by putting a roadblock in the way of biomedical science and any possibility of a cure or treatments to alleviate patient's suffering. The following quotes clearly demonstrate the appalling prejudice that exists in the UK as observed by other major territories: **"In the UK, CFS is an exceedingly dangerous term.", Dr Byron Hyde.** [72] **"the protocols in England are totally barbaric!", Prof. Ron Davis".** [73] The UK urgently need to remove the importance of bio-psychosocial intervention and bias and embrace the plethora of biomedical science for its citizens in order to bring equality to patients. <u>Conclusion</u> Given that NICE are a public body with an exemplary function, it has a duty to protect the citizens of the UK and in particular people with disabilities. The UK ratified the UNCRPD (08-06-2009) & UNCRPD Optional Protocol (07-08-2009) [74] meaning they will protect persons with disabilities, in this case people with ME/CFS. **This document states: "*States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability*.",** UNCRPD - Article 25: Health [75].

[72] https://www.healthrising.org/blog/2017/05/23/doctors-hyde-amy-browns-m-e-enterovirus-story/
[73] http://forums.phoenixrising.me/index.php?threads/bbc-interview-with-ron-davis.51891/page-5
[74] http://www.un.org/disabilities/documents/2016/Map/DESA-Enable_4496R6_May16.jpg
[75] http://www.un.org/disabilities/documents/convention/convention_accessible_pdf.pdf

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			By only making available coping strategies for people with ME/CFS and not acknowledging the current biomedical research available in the world, NICE withholds this right to the highest attainable standard of health. If NICE does not recognize the opposing views on the benefits and risks of harm from GET and does not refrain from biased recommendations and from informing the public that there is no consensus on treatment they are bringing patients in danger and are in violation of **Article 15 - Freedom from torture or cruel, inhuman or degrading treatment or punishment and Article 25 - Health** [76] which says health services should be designed to minimize and prevent further disabilities, including among children and older persons. As the NICE guidelines confirm treatment recommendations need free and informed consent of the person concerned, Article 3 in the NICE Charter on Human Rights [77], but in reality there are actual consequences. NICE need to acknowledge that by necessity, coping with the illness may require extended periods of isolation; that the treatments recommended by NICE are experimental and may or may not cause harm and that adults and children alike should be free to refuse such experimental treatments without risk of false allegations being made against them; harms and false allegations that have to date, driven fear of the NHS and other professionals, into families who are faced by them. Also stated in Article 25 (d)(f) [78] persons with disabilities are entitled to the same standard of quality care as others. NICE therefore is obliged to incorporate awareness of rights of persons with disabilities so people with ME/CFS can access the same standard of quality care as to others. This asks for training and promulgation of ethical standards for public and private health care so patients can be treated with dignity, autonomy and have their needs taking seriously.

[76] http://www.un.org/disabilities/documents/convention/convention_accessible_pdf.pdf
[77] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN
[78] http://www.un.org/disabilities/documents/convention/convention_accessible_pdf.pdf

ID	Questions	Overall response yes / no	Comments Please insert each new comment in a new row
			Discriminatory denial of health care or health services without recognizing the risks of harm brought on by recommended treatment or false allegations is a violation of the rights of persons with disabilities. Therefore, NICE needs to review the current guidelines, not only in light of the international advances made in the scientific understanding of the disease, but also to ensure persons with disabilities are met with respect and dignity, and are protected from treatment that causes further harm.

Please email this form to: surveillance@nice.org.uk

Closing date: 9am, 24 July 2017

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NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, if NICE's reasonable opinion is that the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.