Response to NICE 10 year surveillance (2017) – Chronic fatigue syndrome/myalgic encephalomyelitis

Invest in ME Research has submitted a response to the Natioanl Institutefor Health and Care Excellence (NICE) after the request for comments on the **NICE guideline on CG53 Chronic fatigue syndrome/myalgic encephalomyelitis: diagnosis and management Surveillance proposal** consultation document.

The eight thousand word + content are documented here for ease of access and printing.

Our official reply is at this address - https://tinyurl.com/ydexpd8m

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NICE Question 1:

Do you agree with the proposal not to update the guideline?

Invest in ME Research Response: NO

Invest in ME Comments on Question 1:

1. Background:

In order to comment on the recommendation by NICE not to update the NICE guideline on Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis (CFS/ME) it is not sufficient merely to look for new evidence which has come about in recent years - one necessarily needs to look back on the original guidelines to understand what a failing they were and what they missed.
To comment on why a review of the guidelines is required it is necessary to repeat that the original guidelines were at fault and that they were rejected almost unanimously by the patient community.

We use some of the comments from our original submission and from our later review in 2013 in the following points –

- The original NICE guideline put forward a psychosocial model for ME and promoted CBT and GET as the options for management. The biological model with evidence of inflammatory, immune, oxidative and nitrostative pathways as key areas was ignored. This was heavily criticised.

- The AGREE Instrument (Appraisal of Guidelines Research and Evaluation Instrument) with which NICE is obliged to comply in the formulation of all its Guidelines is specific: "The health benefits, side effects and risks should be considered when formulating the recommendations".

- NICE failed to conform to the AGREE Instrument which requires that NICE is obliged to give equal weight to three main sources of data: "evidence-based" medicine, usually deemed to be random controlled trials (RCTs); the opinion and experience of physicians with expertise in the area, and the opinion and experience of the patient group for whom the Guideline is intended.

- NICE did not abide by the European AGREE standards which govern guideline development.

- Invest in ME rejected the original NICE guidelines as unfit and has recommended them to be updated/rewritten.

- Invest in ME concluded that the basis of the NICE Guidelines was in viewing as broad a section of fatigue states as possible, where high quality biomedical research into ME was ignored. Essential research showing the multi-system nature of ME was not considered or discussed.

- NICE exhibited a bias toward promoting a predetermined one-size fits all approach to ME by continually highlighting CBT and GET therapies despite widespread derision from ME patients.

- The original NICE guidelines left both healthcare professionals and patients in a state where they became, and have become, of little use to anybody – neither to patients nor to healthcare staff. Patients were dissatisfied with the guidelines. Doctors were afraid to venture outside of the NICE guidelines in case they were taken to the GMC by individuals and groups with vested interests in perpetuating the myths about ME being a behavioural disorder.

- There was almost universal condemnation of the guidelines by patients, patient support groups, most ME charities and even healthcare providers.

- Over twenty internationally renowned ME/CFS experts provided Statements in support of the Claimants" case for the Judicial Review of the National Institute for Health and Clinical Excellence (NICE) Clinical Guideline on "CFS/ME" that was brought by ME/CFS sufferers [Statements of Concern about CBT/GET provided for the High Court Judicial Review of February 2009

http://www.investinme.org/Article-361%20Statements%20of%20Concern%20CBT-GET%20JR%20Feb09.shtml]

We believe these comments are still valid today.
No evidence has been produced to contradict these statements.

So, before even beginning to analyse the Surveillance proposal consultation document, one must state categorically that the NICE guidelines were already on very shaky ground and that cannot be ignored.

It was no small matter that the very population for whom the NICE guidelines were supposedly intending to benefit were, instead, forced to take NICE to a Judicial Review, such was the dissatisfaction with the guidelines and it was plain for all to see that patients were not listened to.

Recommendations not to update NICE guidelines must first reflect on whether the existing Guidelines are valid – and they for the most part are not.

It was Professor Mark Baker, director of NICE in 2014, who said in a Forward-ME meeting (http://www.forward-me.org.uk/25th%20June%202014.htm)

" Turning to the ME/CFS Guideline specifically, the Professor said that it did not meet our needs and it did not meet theirs (NICE's) either. ".

Professor Baker had been in post for two years at that time)

Regarding the Surveillance proposal consultation document –

2. NICE states that

   - The NICE Board sets our strategic priorities and policies, but the day to day decision-making is the responsibility of our Senior Management Team (SMT).

Therefore, it would be worthwhile to note from the outset that accountability must remain then with these staff and functions. Should any patient be affected deleteriously by the guidance in NICE then these people in NICE must be made accountable.

Going forward then any harm coming to patients by these guidelines and from any decision not to update them must be seen to be caused by the NICE Board and SMT and accountability must be taken by those members.

3. NICE states –
"NICE is committed to involving patients, carers, service users and the public in the development of its guidance and other products. By involving the very people for whom

the guidance will be relevant, we put the needs and preferences of patients, carers, service users and the public at the heart of our work."
[https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PPIP-leaflet-1.pdf]

Were there any patients, carers, service users and the public involved in the current surveillance team?

4. From reviewing the Surveillance proposal consultation document we believe NICE is already displaying its predisposing bias in favour of the Biopsychosocial (BPS) lobby and therapies – something which we believe undermines this whole Surveillance proposal consultation process and requires independent scrutiny.

As early as the first page NICE refer to a study of internet-based cognitive behavioural therapy in children and young adults. This study has already been heavily criticised by patients as flawed research.
A very strange choice of an example for ME guidelines – if one assumes that NICE is really being objective.

5. NICE states –
"Evidence consistent with, or not deemed to impact, current recommendations was found in the following areas: general principles of care; presentation; diagnosis; general management strategies after diagnosis; referral to specialist CFS/ME care; specialist CFS/ME care; review and ongoing management; and key principles of care for people with severe CFS/ME."

We find this implausible.

The USA Institutes of Medicine (IOM) report, the NIH P2P report, the revelations regarding the flawed PACE trial - all have affected diagnosis, ongoing management, specialist care, referrals.

6. NICE states -
"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."

The current NICE guidelines require Post Exertional Malaise (PEM) as a core symptom which is correct.
But then they make "physical or mental exertion makes symptoms worse" as one of the optional symptoms. This does not make sense.

The IOM report called for the use of Oxford criteria to be dropped – which the PACE Trial and many other CBT and GET studies have used.

This therefore undermines completely the reasoning not to update the already flawed NICE guidelines and the dependency on PACE to prove anything.

NICE must take note of IOM, NIH, AHRQ and CDC decisions.
Not to do so would be negligent.

The NICE board is directly accountable for any decision not to remove CBT and GET from recommendations and this must be taken into account by any future damage caused by NICE recommendations.

7. NICE have not publicised who the "Topic Experts" used in the Surveillance proposal consultation process were.

This information must be publicised.

To do otherwise will reinforce the view that the Surveillance proposal consultation document has been solely influenced by the viewpoints from BPS supporters.

It is also not correct for NICE to decide itself who these Topic Experts are without the public being able to know and comment.

Under 1.5 Who is involved in this document it states -

"When developing guidelines, NICE involves people who might be affected by the guideline recommendations in a collaborative and transparent way."

Why has this not been performed for this review which is important for patients?
Why are patients or patient groups not involved?
We do not accept that NICE has been transparent.
This calls into question the validity of this document.

8. NICE need to downgrade CBT and GET just as USA has done.

The 'definitive' PACE trial long-term outcome did not show any benefit and scientists from around the world have called for its retraction or re-evaluation.

The CDC has updated their website about ME/CFS to use the 2015 Institute of Medicine report and has removed Graded Exercise Therapy (GET) and Cognitive Behavioural Therapy (CBT) from its recommendations https://www.cdc.gov/me-cfs/about/index.html.

The USA Agency for Healthcare Research and Quality (AHRQ) also downgraded CBT and GET.

The USA CDC is not recommending CBT/GET so UK guidelines are at odds with both NIH and CDC recommendations.
(https://www.cdc.gov/me-cfs/treatment/index.html; https://www.nih.gov/mecfs/about-mecfs; https://www.ncbi.nlm.nih.gov/books/NBK379582/)

9. The CBT described by NICE for CBT is not the same supportive CBT as for other chronic illnesses.

CBT developed for CFS/ME is directive and based on the premise that CFS/ME is perpetuated by wrong illness beliefs and inactivity leading to deconditioning.

CBT for CFS/ME is aimed at "addressing any over-vigilance to symptoms.

This sort of CBT is not prescribed to other chronic illnesses and it should not be recommended for CFS/ME.
Cancer patients, for example, are told to monitor and report their symptoms, not ignore them.

As such, this is dangerous and NICE stating the opposite should mean that the NICE board and the NICE Senior Management Team must be answerable in court for any damage made to patients who carry out this advice.
NICE will be accountable if it ignores the advice to withdraw this unsound recommendation.
NICE would be negligent.

10. NICE states
"The experts also gave their thoughts on the current status of diagnostic criteria in NICE guideline CG53 and elsewhere, in light of these reports. Their comments included:
The HHS Chronic Fatigue Syndrome
Advisory Committee state: 'A priority should be placed on developing biomarkers and diagnostic tests... research has neglected many of the biological factors underlying ME/CFS'. Whereas in the UK there may be increasing acceptance of CFS/ME in the umbrella of functional neurological disorders."

This comment above is far beyond NICE's remit and takes it into dangerous and uncalled for areas which will be opposed by ME patients.

NICE states that the UK considers CFS/ME as a functional (i.e. nothing wrong pathophysiologically) neurological disorder whereas US considers it neurological.

NICE is part of the Department of Health (DoH) – a department that always confirms that ME is neurological.

How is it possible that NICE accept this statement for UK when numerous government health departments including Department of Health have constantly reassured that they consider ME as a neurological disorder, no mention of functional?

NICE cannot disregard the WHO and the UK government's official position on ME being a neurological disease.

The WHO ICD-1O lists Postviral Fatigue Syndrome and ME in G93.3 (CFS indexed to it) and the current Beta ICD-11 draft also has Postviral fatigue syndrome, ME and CFS under "Other disorders of the nervous system".

Functional Neurological Symptom Disorders have their own classification and there is no mention of PVFS, ME or CFS in that category.

UK" Functional neurological symptom disorder (FNsD) is a condition in which patients experience neurological symptoms such as weakness, movement disorders, sensory symptoms and blackouts. The brain of a patient with functional neurological symptom disorder is structurally normal, but functions incorrectly."

So while the US priority is to find biomarkers and diagnostic tests the UK (with NICE) is trying to brush this off by placing CFS/ME under an umbrella of FND and treat it with CBT and GET as there is nothing wrong biologically, they say.

This statement has to be withdrawn.

This seems, again, to have been heavily influenced by the BPS lobby – which makes us again wonder what the real agenda is of NICE and who were the NICE-selected Topic Experts.

It may be so that a FOI act will be required to reveal the identities of the Topic Experts, who chose them and what links they have to insurance companies and/or other organisations or individuals which have vested interests in perpetuating a view of ME being a behavioural disorder.

11. The dismissal by NICE of the AHRQ's finding of a lack of evidence once Oxford is excluded is negligent.

(Post-exertional Malaise being hallmark of CFS/ME yet research based on Oxford criteria that do not require PEM are being considered)

NICE guidelines state post-exertional malaise and/or fatigue is required but then it says "physical or mental exertion make symptoms worse" is optional.
PEM by CCC, ME-ICC, and IOM definitions includes symptom exacerbation following exertion.

So NICE either does not know what PEM is or else does not take it seriously either.
This is negligence by NICE.
NICE must be made accountable for any damages caused from this negligence.

12. NICE makes a point about shared decision making with regard to the guidelines - but this does not apply to patients with work-related insurance coverage as insurance companies demand patients go through CBT/GET regimes (and NICE recommends these) before getting their payments.

As patients do not get better undergoing these therapies there is often a long and distressing process to fight the injustice.

Again NICE must be accountable for damages, and costs, relating to the burden brought on to patients by this erroneous and negligent recommendation.

13. NICE should withdraw evidence of CBT/GET and not sit on the fence by saying that it does not do so "and none of the papers reporting on the PACE trial have been retracted".

There is no point in NICE stating that none of the papers have been retracted. This is an establishment attempt to stop real debate and is so disingenuous of NICE.
That is passing on the responsibility and NICE reviewers should have enough scientific expertise to make the decision on the evidence base of CBT/GET themselves.

QMUL spent £200k+ trying to stop PACE data being made available to the public.
The Lancet has its own failings that it should be dealing with.
We know that the editor of the Lancet is not responsible – refusing to engage and discuss despite multiple attempts to force retraction and failing to answer this charity's letters [http://www.investinme.org/IIMER-Newslet-1511-01.shtml].
We make this point to enforce the view that NICE cannot base decisions on the flawed editorial policies of journals who have their own reasons for failing to listen to academic and patient opinion demanding the retraction of their papers.

14. As the NHS is in financial trouble then it would be far more beneficial for the patients and the NHS if honest and up-to-date information about the disease was given, help with information about education and work provided and monitoring of patients regularly to avoid missing other illnesses that may hide in this population.

Psychological supportive services should be provided only to those who really need them.
It is a misuse of scarce funding to force CBT and GET – failed therapies which have no evidence base – on to patients who do not want them.

NICE is imprudent in wasting scarce financial resources.

This is a matter for the government to act upon.

15. NICE state that
" Peer-reviewed study reports were assessed by abstract."

For such an important document as this Surveillance proposal consultation it is not good enough to rely on reading abstracts only as they do not reveal methodological flaws and peer reviewing has been shown to be inadequate in the "gold standard" PACE trial for example.

This is a major failing that should invalidate the Surveillance proposal consultation document.

16. The NICE document states – regarding the PACE Trial –

"The authors have responded to these criticisms in an FAQ, and have re-analysed the main outcome measures according to the original protocol with similar results to those in the primary PACE results paper i.e. reduced fatigue and increased physical function. However, many commentators continue to dispute the PACE trial findings."
This should be changed to "many informed and knowledgeable commentators.".

Reanalysis by Matthees et al states -

> "This re-analysis demonstrates that the previously reported recovery rates were inflated by an average of **four-fold**."

http://www.virology.ws/wp-content/uploads/2016/09/preliminary-analysis.pdf

This is significant enough to make it mandatory for NICE to remove all references to the PACE Trial for any judgement to be made.

NICE cannot use PACE for anything other than to reject its previous guidelines comments. Continuing to use PACE Trial references to justify the bias inherent in this document will make the Surveillance proposal consultation document invalid and a further review process will be required.
It is negligent of NICE not to remove PACE Trial data for purposes of this Surveillance proposal consultation.

17. NICE seems to accept Cochrane reviews without question.
Yet the Cochrane reviewers such as Dr Larun have conflicts of interest as they have co-authored with the investigators of the papers they are reviewing.
https://jcoynester.wordpress.com/2016/03/20/why-the-cochrane-collaboration-needs-to-clean-up-conflicts-of-interest/

This is unacceptable.
The Cochrane CFS/ME reviews are not considered to be unbiased.
Cochrane is not a safe choice and is not independent
NICE must hand over the review to an independent body.
We do not consider NICE to be independent.
We do not consider Cochrane, as it has been seen so far with regard to ME, to be either independent or unbiased.

18. Under **Summary of evidence from surveillance**
In Q-01 and Q02 it states
"Provide information on returning to work or education"
How is this possible?

With its welfare reforms the current government has been determined to take this out of the doctor's hands and give to corporate parasites who are made responsible for determining work and benefits yet have no knowledge of the condition].

The NICE guidelines have done nothing to help with this.

19. NICE states -
". Healthcare professionals responsible for caring for people with CFS/ME should have appropriate skills and expertise in the condition."
How is this possible?
There is no specialism in CFS/ME thanks to NHS policies and this is a false view painted by NICE.
NICE has to take some responsibility for no expertise in CFS/ME being developed due to NICE's faulty beliefs about this disease.

20. NICE state that –
1.1.3.2 Every person diagnosed with CFS/ME should be offered: information about the illness (see section 1.1.2) acceptance and understanding assistance negotiating the healthcare, benefits and social care systems assistance with occupational activities including work and education if appropriate (see section 1.4.5).

1.1.3.3 An individualised management plan should be developed with the person with CFS/ME, and their carers if appropriate. The plan should be reviewed and changes documented at each contact. It should include:
relevant symptoms and history
plans for care and treatment, including managing setbacks/relapses information and support needs
any education, training or employment support needs
details of the healthcare professionals involved in care and their contact details.

and then states
Surveillance decision

This review question should not be updated.

Yet despite all these fine words none of this happens for a person with CFS/ME.
NICE guidelines are ineffectual.

21. NICE states -
". It was concluded that physicians could improve diagnosis and treatment of CFS/ME through insight from the experiences of people with CFS/ME."

This shows the hypocrisy of NICE – or rather of those influences who control what NICE promote.

Before NICE has stated the rights of the patient.
Then NICE states that "GPs should explore the patient's illness beliefs before referral"
Then NICE state that "physicians could improve diagnosis and treatment of CFS/ME through insight from the experiences of people with CFS/ME. "

Patients do not want CBT or GET – yet NICE is so compromised by the BPS influences that you make quite contradictory remarks.

NICE also state –

> "The authors concluded that GPs should explore the patient's illness beliefs before referral to maximise patient engagement in therapy."

And

> "During the 3-year surveillance review, a qualitative study concluded that GPs could elicit and explore patients' CFS/ME beliefs before referral to specialist care."

This is totally bogus.
Are there any other conditions where these sort of questions are asked before patients get a referral to a specialist? Does this have to happen if it does not happen for MS, cancer, dementia and other diseases?
We think not.

Does NICE not think that the patients should also ask the GP's illness beliefs about ME?

Perhaps NICE can add that to their recommendations.

22. NICE state
"Some issues were raised around consent to treatment. NICE guideline CG53 includes the sections 'Your responsibility' and 'Patient-centred care' which explain in detail the considerations that healthcare professionals should make when implementing the guideline, including fully involving patients and carers in decision-making, providing appropriate information, and that the guideline is not mandatory."
One of the few points we agree with NICE.

We believe this statement should be at the start of the NICE guidelines (in its current form) – marked clearly and boldly in a disclaimer box – for all to see before reading further -

The recommendations in this guideline are not mandatory.

23. It strikes us that throughout the document that the "topic Expert" ought to be the patient.

Did any patients take part in this review?

24. NICE states -

"An educational programme was developed whereby CFS/ME continuing education materials were distributed to healthcare professionals at conferences."

Does NICE evaluate the education being provided?
If not then why not?

Invest in ME Research has held 12 International Biomedical Research Conferences on ME and 7 International Biomedical Research Colloquiums but despite invitations each year none of the UK health authorities have accepted an invitation to attend these.

However, the US NIH and CDC representatives have attended and found them useful.

25. NICE states -
Post-exertional malaise (PEM) is a required symptom for NICE diagnosis but strangely "physical or mental exertion makes symptoms worse" is optional yet NICE accepts qualitative research papers for its review that do not require PEM , namely Oxford Criteria which have now been rejected by US health authorities.

NICE dismiss criticism of use of the Oxford criteria – obviously because in doing so it would invalidate the NICE pre-determined decision not to update the original guidelines.

All research references based on Oxford criteria need to be removed from the Surveillance proposal consultation document

26. If NICE say CFS/ME (their term) is now considered FND then why are CFS patients still banned from donating blood even if they are recovered?

NICE cannot even define recovery in the context of CFS/ME it seems.
"CFS : Post Viral Fatigue Syndrome
I am sorry but unfortunately, we cannot accept a donation if you have this condition or if you have previously had the condition even if you are now recovered."
https://my.blood.co.uk/knowledgebase/Index/C

27. NICE are deliberately waiting for additional studies from known BPS protagonists and for the flawed PACE Trial to be incorporated into Cochrane so that they can then update the guideline based on these totally false and flawed views.

Yet NICE do not consider the current Phase III multi-centre placebo controlled rituximab trial almost finishing in Norway.

One would be cynical to believe that NICE were deliberately attempting to force through a BPS agenda for CFS/ME guidelines ahead of the possible good results coming from the Norwegian Phase III rituximab trial.
We are cynical.

We believe this is an establishment effort to falsify the view of CFS/ME and use bogus, chronologically dependent information to skew a decision on CFS/ME which will avoid taking into account the Norwegian trial results.

This should be publicised.

It makes the NICE Board and SMT to be acting in an immoral and corrupt way, if true, and is therefore negligent. If true, this will need further investigation and scrutiny by parliament.

28. Asking for removal of GET from the NICE guidelines is not enough.
CBT needs to be removed for the reasons stated above.

29. NICE states -
"A qualitative study described the development of an epidemiological case definition to distinguish CFS/ME from other chronic fatiguing conditions. However, it was not clear from an assessment of the abstract if diagnostic validity and reliability were tested."

Why did not the Topic Expert reviewers check the full paper?

Surely it is important for NICE to be more accurate. This is shoddy work from NICE and calls into question the competence of the Topic Experts that NICE themselves selected.

30. NICE states -
"The comments regarding the need for the Oxford criteria to be retired do not impact directly on the guideline because it recommends a different diagnostic approach than the Oxford criteria."

The evidence for CBT and GET that NICE currently recommend rely on studies that used Oxford Criteria which are broader than the current NICE Criteria so the decent thing to do the same as the US AHQR and downgrade CBT and GET.
Even the CDC website has removed CBT and GET from its pages.

31. NICE states –

"The experts also gave their thoughts on the current status of diagnostic criteria in NICE guideline CG53"
And
"There are no gold standards by which one set of criteria can be said to be better or worse than any other. "

Yet did not Professor Peter Littlejohns, NICE Clinical and Public Health Director, state the following after patients took NICE to a judicial review –
"The 2007 guideline was welcomed by patient groups as an important opportunity to change the previous situation for the better, helping ensure that everyone with CFS/ME has access to care appropriate for the individual. **Today's decision means that the NICE guideline is the gold standard for best practice in managing CFS/ME".**

NICE contradicting itself again.

32. NICE states –
"The comments regarding the need for the Oxford criteria to be retired do not impact directly on the guideline because it recommends a different diagnostic approach than the Oxford criteria. In terms of NICE excluding studies using Oxford criteria from evidence reviews for the guideline, as one of the topic experts stated: broadly defined diagnostic criteria in the NICE guideline (which was supported by almost all stakeholders during scoping) allow the inclusion of the vast majority of people with CFS/ME, and a corollary of this was that it allowed the inclusion of the majority of trials, which have typically used broad diagnostic criteria. Further, topic experts had no concerns about the inclusion criteria of trials in CFS, and it was also noted by topic experts that there is no gold standard definition of chronic fatigue syndrome."

This is madness.

All researchers are stating at our Colloquiums that Oxford criteria and the broad range of less stringent criteria inhibit research.
We do not wish to have "..the inclusion of the majority of trials, which have typically used broad diagnostic criteria." For guidelines for CFS/ME. It is completely negligent and pointless to do this.

33. Recently this from Professor James Baraniuk of Georgetown University Medical School, Washington, USA
http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1353578?journalCode=rftg20&

" **Results:** The Oxford criteria designated CFS in 25.5% of 2004 males and 19.9% of 1954 females. Based on quadrant analysis, 85% of Oxford-defined cases were inappropriately classified as CFS. Fukuda criteria identified CFS in 2.3% of males and 1.8% of females." The Oxford criteria were untenable because they inappropriately selected healthy subjects with mild fatigue and CIF and mislabeled them as CFS."
This says it all.
CIF stands for Chronic Idiopathic Fatigue.

NICE may say this was not available to them.
Well it is known to NICE now!

And this only strengthens the argument to remove all research based on Oxford criteria – a case which was already strong before the Surveillance proposal consultation but is now overwhelming.
NICE must withdraw all research referencing or based on Oxford criteria.
To do otherwise would be negligent.

34. NICE states -

"Topic expert feedback Topic experts highlighted evidence on maternal anxiety and depression associated with chronic disabling fatigue in adolescents 13 years old[55]. This evidence has been summarised in the 10 year surveillance summary section."

Why is this research being discussed by NICE topic experts as it not about CFS or ME but chronic fatigue which can be caused by almost anything?

It needs to be removed.

35. NICE states -
"People with CFS/ME have reported pacing to be helpful in self-managing CFS/ME. However, healthcare professionals should advise people with CFS/ME that, at present, there is insufficient research evidence on the benefits or harm of pacing."

Was the PACE trial supposed to study pacing (Adaptive Pacing) as one of the arms?
If NICE can state that CBT and GET are beneficial and without harm then surely the form of pacing that was studied in the "gold standard" PACE trial would show the same?

There is no evidence of benefits or harms of sleep hygiene for CFS/ME either but NICE gives advice on sleep!!

36. NICE states -
"The therapist should adhere closely to empirically grounded therapy protocols."

Here again we need to point out that the often made remark that CBT is used in other chronic illnesses such as heart disease, diabetes, cancer etc. but these are supportive CBT therapies not the directive ones as in CFS/ME.

37. Page 26
"Undertake an activity analysis to ensure that the person with CFS/ME is not in a 'boom and bust' cycle before they increase the time spent in exercise."

There is no evidence that CFS/ME patients are "in boom and bust" cycles.

38. Page 32
"Trials using Oxford criteria were eligible when developing NICE guideline CG53, and topic experts had no concerns about the inclusion criteria of trials in CFS. It was also noted by topic experts that there is no gold standard definition of chronic fatigue syndrome."

NICE guidelines require Post-Exertional Malaise (PEM) as a key symptom in CFS/ME yet it accepts research using Oxford Criteria that do not require PEM as reliable evidence. How can this be scientific?

39. Pages 29 to 36 seem to accept evidence for CBT and GET uncritically. Instead of going through the flaws of these reviews we would like to refer to a submission sent to us by a supporter Graham McPhee.

Graham has emphasised that any implication that CBT or GET are actually treatments for CFS/ME causes real harm to a large number of patients, creating false expectations in members of the medical profession, government bodies, employers or insurance companies, badly affecting the way that they are treated.

Here are Graham's points which we would like to put forward -

- You were written to in 2012 to draw your attention to an analysis of the PACE trial on the use of Cognitive Behaviour Therapy etc. on CFS/ME. A small group of us with scientific backgrounds had major concerns about the methodology, analysis and conclusions of this trial, but you explained that your advice was based mainly upon peer-reviewed studies rather than individual comments.

- Due to the persistent difficulties in obtaining the data, it has taken a long time to be able to produce such an analysis, but there are now a number of peer-reviewed articles that clearly demonstrate the failure of CBT and GET to produce any measurable improvement in the functioning of patients with CFS/ME.

- 'PACE-gate': when clinical trial evidence meets open data access
http://journals.sagepub.com/doi/full/10.1177/1359105316675213

- PACE trial claims of recovery are not justified by the data
http://www.tandfonline.com/doi/pdf/10.1080/21641846.2017.1299358

- Can patients with CFS really recover…
http://www.tandfonline.com/doi/abs/10.1080/21641846.2017.1259724?journalCode=rftg20

- Do graded activity therapies cause harm in CFS
http://journals.sagepub.com/doi/full/10.1177/1359105317697323

- CBT and objective assessments in CFS
http://journals.sagepub.com/doi/abs/10.1177/1359105317707215

- The existing inclusion of CBT as a possible treatment for CFS/ME continues to cause great problems in the patient community due to the false expectations that this engenders, amongst the medical profession, insurance companies, government agencies and employers.

- The situation is utterly different from the way in which CBT is considered as possibly helping some patients to cope with conditions such as heart disease: the difference between being considered an effective treatment and being offered as support for a condition is of major importance in the real world.

- As for GET, it is clear that the risks of this approach causing harm is far too great. The evidence to suggest it is safe is far too weak, and the results from large-scale surveys of patients clearly indicate major concerns.

- As a mathematician who has studied both statistics and experimental psychology, I find it astounding that NICE continues to put forward CBT and GET as potential treatments for CFS/ME on the basis of studies which would be decried were they to support acupuncture or homeopathy:

- a reliance on subjective responses to unblinded treatment would never be tolerated in alternative medicine – how can they retain any respect here?

- You finally have some peer-reviewed evidence showing that these therapies are neither curative nor treatments for CFS/ME: is it not time that your advice reflected that position?

40. The CBT prescribed by NICE for CFS/ME is not the same supportive CBT as for other chronic illnesses. CBT developed for CFS/ME is based on the premise that CFS/ME is perpetuated by wrong illness beliefs inactivity and fear avoidance leading to deconditioning. CBT for CFS/ME encourages patients to ignore their symptoms and keep on going even if they have set backs. This sort of CBT is not prescribed for other chronic illnesses.

41. NICE states -
"Topic experts highlighted the qualitative study on the SMILE trial which reports on the experience of service users (patients and parents/carers) for children with CFS/ME."

This study has never been published so why does NICE even mention this?
Another flaw in the NICE Surveillance proposal consultation.

Lightning Process practitioners have been reported to the Advertising Standards Agency several times. An unregulated, unaccountable pyramid business has no place in treatment of people with ME.

It was unethical to expose children to this in a study in the first place.

Including this is a shameful act by NICE and their so-called "Topic Experts" – and brings yet again into doubt the make-up of these NICE selected persons who are controlling the future of people with ME in the UK.

42. Nice states
"It was considered appropriate to wait for more evidence before adding a definition of recovery to the guideline."

We find this statement astonishing as the current NICE guideline states "Most people with CFS/ME will improve over time and some people will recover and be able to resume work and normal activities."

More appalling statements by NICE.

43. NICE state –

In **RR – 03 What is the prevalence and incidence of CFS/ME in different populations?**

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

The Deputy Chief Medical Officer of England admitted that the CMO does not know the prevalence of ME in UK and that no figures are kept. See http://www.investinme.org/IIME-Newslet-1701-01.shtml
Therefore, this decision is incorrect as no prevalence and incidence figures exist.
It surely also show another failing in NICE as we are nowhere nearer to understanding the scale of the problem. The NICE guidelines have done nothing to help in this area.

44. There are serious implications for children implicit in the document.
It is interesting that NICE document in their surveillance-review-proposal a link to How effective is FITNET-NHS for children and young adults with CFS/ME?
NICE gives prominence to FITNET, an un-blinded trial that does not even require NICE criteria (post-exertional malaise optional unlike NICE), yet makes no mention of the Norwegian Phase III multicentre double blinded, placebo controlled rituximab trial that is going to be published in 2018.

The FITNET trial appears to be on chronic fatigue not ME (or CFS/ME).
FITNET is a study already ridiculed by patient groups. It indicates already to us that NICE exhibits bias toward a BPS approach to ME.

45. At a meeting organised by Invest in ME with Dr Martin McShane, Director of Domain Two, NHS Commissioning Board, was presented with evidence of families of ME patients being prosecuted due to their children having ME and the healthcare staff dealing with the cases not understanding the disease process sufficiently. This is far from uncommon.

Dr McShane stated that he understood the family's anger and said he would feel exactly the same if he was in their situation. He expressed his apologies and acknowledged the need to balance the system to ensure that situations such as this would not occur and that a major task was to alleviate stress for patient and carer.

He said he heard what the parents were saying .

This means that the NICE guidelines have failed as the guidelines still allow this intolerable situation to occur. We need to address the major flaw in the NICE guidelines – namely its bias toward promoting a predetermined one-size fits all approach to ME by continually highlighting CBT and GET therapies despite widespread derision from ME patients. 5] http://www.investinme.org/IIME-Newslet-1303-04.shtml

This was in March 2013 – many years after the NICE guidelines were created and with

ample chance for the NICE guidelines to have "worked" if there was seen to be any use for them.

This clearly demonstrates that the NICE guidelines have failed as the guidelines still allow this intolerable situation to occur.
We need to address the major flaw in the NICE guidelines – namely its bias toward promoting a predetermined one-size fits all approach to ME by continually highlighting CBT and GET therapies despite widespread derision from ME patients.

46. The PACE trial as well as any of the other CBT/GET trials for CFS/ME are unblinded with subjective outcomes making them worthless. NICE would not accept drugs on that kind of evidence.

47. As NICE seem so fond of merely reading abstracts then we would like to use the following abstract from Emeritus Professor Jonathan Edwards of UCL to point out the inadequacies of the PACE Trial in this paper, one that your "Topic Experts" so conveniently ignored –

PACE team response shows a disregard for the principles of science
http://journals.sagepub.com/doi/full/10.1177/1359105317700886

> "The PACE trial of cognitive behavioural therapy and graded exercise therapy for chronic fatigue syndrome/myalgic encephalomyelitis has raised serious questions about research methodology. An editorial article by Geraghty gives a fair account of the problems involved, if anything understating the case. The response by White et al. fails to address the key design flaw, of an unblinded study with subjective outcome measures, apparently demonstrating a lack of understanding of basic trial design requirements. The failure of the academic community to recognise the weakness of trials of this type suggests that a major overhaul of quality control is needed."

The paper concludes –

> "White et al. (PACE PI) conclude that they stand firmly by the findings of the PACE trial, presumably because of their inability to understand its basic flaws. As has been suggested by others, the flaws are so egregious that it would serve well in an undergraduate textbook as an object lesson in how not to design a trial. Its flaws may have only been widely appreciated recently simply because those involved in trial design in other disciplines were unaware of its existence. Now that they are aware, there appears to be near unanimity. The patients have been aware of the problems for several years, and all credit to them for their detailed analyses. In my experience, most of the people with a deep understanding of the scientific questions associated with CFS/ME are patients or carers. To suggest that when these people voice their opinions they are doing a disservice to their peers seems to me inexcusable."

48. In 2013, at the 8th Invest in ME Research International ME Conference, Dr Clare Gerada (chair of Royal College of GPs) stated that GPs knew very little about ME. This was six years after the NICE guidelines were published, proving that the NICE guidelines had not been useful and doctors were still uninformed about this disease.

Therefore, to leave the current outdated and unusable NICE guidelines for ME for another period, just sitting on the shelf with no updates reflecting the current poor education regarding ME and without any knowledge of the biomedical research performed/about to be performed, would effectively mean that no clinical guidelines for ME will have been reviewed for 15 years.
That is unacceptable.

This would show not only contempt for the patients and families suffering from the effects of this disease – it would also show gross incompetence and negligence by NICE.

Patients are currently being misdiagnosed, mistreated and healthcare staff are being mis-informed and the current unsatisfactory status cannot be left for another generation.

GPs are left in a situation where their patients have rejected NICE, they do not understand enough about the disease, they are not familiar with the real effects and consequences of ME or of the possible research producing data.

49. The PACE trial demonstrably proved that CBT and GET (the primary treatment recommendations of the NICE guidelines) do not work.

Many articles have proven the PACE Trial to show that CBT and GET do not benefit ME patients and do not back up the original NICE guidelines' recommendations.

NICE guidelines should be updated to reflect recent evidence that the recommended therapies in the existing guidelines (CBT and GET) do not lead to objective improvements in physical activity –

or they should be rewritten in the next couple of years as more biomedical research evidence is likely to be published - but certainly not based on FITNET and PACE.

NICE Question 2:

Do you agree with the proposal to remove the guideline from the static list?

Invest in ME Research Response: YES

Invest in ME Comments on Question 2:

1. Yes.

But not because of the dubious and cynical reasons given by NICE.
It is good that the guideline will be off the static list but the reasons stated make it even clearer that the guidelines probably need a complete rewrite that exclude research based on Oxford Criteria and all references to the PACE Trial.

2. You have used two reasons for taking it off the static list.

One is PACE – something you forever claim never influenced the original guidelines but now say it does – despite all of the unbiased and informed academic world documenting the flaws in that study and recommending that it should be dismissed completely.

The other is FITNET – another contrived establishment set up to produce policy-based evidence which has not real use in the real world.

Yet NICE quite blatantly – and negligently – avoid mentioning the Phase III multi-centre, placebo controlled rituximab trial in Norway.

3. The reason NICE have made the Surveillance proposal consultation is to avoid having to examine the results of a possibly positive rituximab trial. In your world where you try to avoid doing anything it will be quite convenient to keep this away from being reviewed for another five years so that nothing happens.

If this is true it shows that NICE is a very suspect organisation that needs to be investigated.
This means the CEO and the whole board are culpable and it should be the objective of every ME organisation to make NICE accountable.

NICE Question 3:

Do you have any comments on areas excluded from the scope of the guideline?

Invest in ME Research Response: YES

Invest in ME Comments on Question 3:

Taxonomy

We pointed this out when we reviewed the original NICE guidelines, and in the 2010 response to the consultation process.
NICE have not listened or taken any action and continue to maintain and perpetuate the terminological mess around ME.

The name is myalgic encephalomyelitis – not encephalopathy.

As we noted in our response to the NICE guidelines the terminology may be crucial in dealing with ME, especially as GPs, paediatricians, other healthcare personnel and the media use different terms.

Dr. B. Saraceno of the WHO clarified the classification in writing on October 16, 2001 - "Post-viral fatigue syndrome remains under the diseases of nervous system as G93.3. Benign myalgic encephalomyelitis is included within this category."
Benign myalgic encephalomyelitis (ME) and post viral fatigue syndrome (PVFS) are classified under WHO classification ICD 10 G93.3 and chronic fatigue syndrome (CFS) is listed in the tabular index.

We would prefer to use the term ME for the illness but also recognise that ME/CFS is used widely, as in the Canadian Consensus Criteria. CFS/ME is used in the NICE documents.

The UK government supports this definition of ME as a neurological illness and therefore subscribes and endorses the name of myalgic encephalomyelitis.
Myalgic encephalomyelitis must be used by NICE to describe ME.

The original NICE standards on terminology were extremely poor and unprofessional and this continues.

It is a cynical move to attempt to try to make ME into something far more nebulous.

As we have stated CBT and GET must be dropped as recommendations for treatment of ME.

The NHS is currently wasting a huge amount of funds in giving these failed therapies to ME patients which are either useless, or deleterious to the health of ME patients.
More importantly these therapies are rejected by patients and, at a time where the NHS needs all the funding it can get, there is no sense in wasting resources or funds like this.

We need to do things differently.

NICE's remit - "Our aim is to drive and enable excellence across the health and social care system"
What does NICE plan for the future?

Patients are already against the existing NICE guidelines and demand change – is your proposal to leave it in such an unsatisfactory state of affairs – with misinformed healthcare staff pitted against patients?

It is not helpful to include yet more flawed research using broad criteria.

Of course, this all keeps people occupied – another delaying tactic of government agencies.

On the NICE website it is stated that NICE guidelines help health and social care professionals to:

1. prevent ill health
2. promote and protect good health
3. improve the quality of care and services
4. adapt and provide health and social care services.

These guidelines and the predetermined NICE decision not to review them mean that, for ME patients, none of these are met.

NICE will now be guilty of maintaining ill health, is responsible for not promoting and protecting good health, is doing nothing to improve the quality of care and services, and is in no way adapting or providing health and social care services.

The NICE board and CEO are complicit in this and any harm done to ME patients by continuing to promote CBT and GET as therapies for ME will necessitate that the NICE board should be made accountable, especially as NICE have been forewarned of the dangers.

The USA IOM report conducted a full literature review for its report in 2015. Yet NICE did not see fit to build upon that and use it.

Instead it used its own selected, unidentified "Topic Experts" to cherry-pick research abstracts to satisfy an agenda to bias the ME guidelines.

To leave the current outdated and unusable NICE guidelines for ME for a number of years with no updates reflecting the current poor education regarding ME and without any knowledge of the biomedical research performed/about to be performed, would effectively mean that no clinical guidelines for ME will have been brought up to date for up to 17 years.

That would be unacceptable.

NICE Question 4:

Do you have any comments on equalities issues?

Invest in ME Research Response: YES

Invest in ME Comments on Question 4:

1. By ignoring the recent IOM, NIH, AHRQ and CDC decisions to remove CBT and GET from their recommendations and stipulate that the Oxford criteria and research using those criteria need to be abandoned then NICE are negligent.
Healthcare staff in this country will not be aware of the mounting evidence accumulated by the US organisations or their decisions if NICE ignore this recent evidence.
This will therefore harm patients.

2. NICE has not given adequate time for a charity such as Invest in ME Research to respond.
This is quite a cynical act by NICE.

Knowing that patients have reduced capability to analyse, and charities such as Invest in ME Research who do not have salaried staff able to concentrate on only one thing, then NICE expect that they will have less to answer.

This inequality deserves investigation as you certainly have given far more time to an anonymous group of "Topic Experts" – whom, it seems, are heavily biased toward the BPS view of ME.
As such this is discrimination.

3. The composition of your "Topic Expert" group cannot be determined.
It is a group appointed by NICE to oversee NICE's work.
This surely is not correct and needs scrutiny by an independent body.

We do not trust NICE to investigate this themselves but feel we have to make this point.

The Surveillance proposal consultation document is clearly grossly biased toward a BPS view of ME and unrepresentative of patient views on the disease from which they, not NICE, suffer daily.

Go to NICE Consultation Review web page

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