

Wilful Ignorance?

Margaret Williams 28th August 2021

ADDENDUM:

In this article I stated about the 15 patient surveys/retractions of GET to which I referred that: "It is understood that none of these surveys was considered or discussed by the GDG". This information came directly from a senior person involved with NICE.

I am now informed that I was incorrect to state this, as some (but not all) of them were discussed by the GDG.

What appears to remain the case is that the damage caused as a result of GET was not properly recognised and accepted by the NICE hierarchy, in other words, that the weight of the evidence of harm recorded in those surveys/comments was not fully recognised.

I apologise unreservedly if this was not made clear.

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The "pausing" of the release of the revised NICE Guideline for ME/CFS is not the fault of the Guideline Development Group (GDG): for the avoidance of doubt, the GDG has no executive powers; it is merely advisory and it is the members of NICE's own hierarchy who are the ultimate decision-makers about what a Guideline contains and when it is released. The NICE hierarchy works with the National Guideline Centre (NGC), which is hosted by The Royal College of Physicians (<https://www.rcplondon.ac.uk/about-us/what-we-do/national-guideline-centre-ngc>).

Just nine hours before the release was due, aware of the threatened refusal to implement the revised Guideline by The Royal College of Physicians and The Royal College of Paediatrics and Child Health (now apparently joined by The Royal College of General Practitioners), NICE "paused" the release. In doing so, NICE failed to comply with its statutory obligations by succumbing to the egregious bullying of these Royal Colleges (some of whose members have gone on record stating that they were not consulted over their Colleges' refusal to implement the revised Guideline).

In order to avoid a class legal action, the Medical Royal Colleges are surely obligated to consider the ever-increasing extent of what has been known for decades about the potential harm of incremental aerobic graded exercise therapy (GET) for people with the neuroimmune disease ME/CFS (as distinct from those with chronic "fatigue" who were included in their clinical trials by proponents of the psychogenic model because they insist that there is no need for sub-grouping), the sheer extent of which evidence they appear to be wilfully ignorant.

From the year 2000 onwards, surveys of thousands of patients carried out by UK ME/CFS charities have shown unequivocally that GET can be harmful <https://www.margaretwilliams.me/2010/notes-re-get.pdf> (pp 6 ff).

The empirical evidence continues to mount that GET can result in high rates of adverse effects, for example:

(i) in 2012 the ME Association carried out another survey of 1,428 respondents. The most significant change was observed in those who had received GET used on the basis that there is no underlying physical cause and that patients are ill because of inactivity and deconditioning, with 59% reporting that their illness had become even more severe. As a result of this survey, in 2015 the ME Association concluded that GET *“cannot be regarded as a safe and effective form of treatment for the majority of people with ME/CFS....The fact that many people, including those who consider themselves severely affected, are being referred to specialist services for an intervention that makes them worse or much worse is clearly unacceptable and in many cases dangerous. GET should therefore be withdrawn by NICE and from NHS specialist services...for everyone who has a diagnosis of ME/CFS”*.

(ii) in 2019 Forward-ME’s survey of 2,274 participants’ experience of directive (as opposed to supportive) cognitive behavioural therapy (CBT) and GET (analysed by Professor Helen Dawes and her team of Oxford Brookes University) found that 67.1% reported a deterioration in physical health as a result of GET. These results were submitted to NICE <https://www.mereseach.org.uk/wp-content/uploads/2019/04/Amended-Final-Consolidated-Report.pdf>.

However, although the results may have been *“well-received by the Chairman of the Guideline Development Group”*, it is understood that none of these surveys was considered or discussed by the GDG, its remit being only to consider randomised controlled trials (RCTs) of CBT and GET and in particular, the PACE trial; furthermore, the final assessment of the “evidence” was undertaken by NICE’s permanent staff, not by the GDG.

Despite strenuous efforts to find in favour of GET, the NICE hierarchy was compelled to admit that the quality of the RCT evidence was *“low”* or *“very low”*; indeed, twenty years ago the systematic review of GET interventions produced by the Centre for Reviews and Dissemination at York found that the *“transient gains”* may be *“illusory”* (Whiting P, Bagnall A-M et al; JAMA 2001;286:1360-1368).

In the intervening twenty years, there are still no good quality RCTs showing GET to be beneficial.

Recently, the United States and other governments as well as major health care organisations have withdrawn GET and CBT as the treatment of choice for patients with ME/CFS <https://www.mayoclinicproceedings.org/action/showPdf?pii=S0025-6196%2821%2900513-9>

Given the paucity of the RCT evidence of the effectiveness and safety of GET, it is important to recall what the-then Chairman of NICE, Professor Sir Michael Rawlins, acknowledged in his 2008 Harveian Oration held at The Royal College of Physicians: he was clear that randomised controlled trials, long regarded as the *“gold standard”* of evidence, have been put on an undeserved pedestal in the hierarchy of evidence. As the Royal College of Physicians’ Press Release stated at the time, **RCTs should be replaced by a diversity of approaches that involve analysing the totality of the evidence-base.**

Given the stated position of The Royal College of Physicians about the need to analyse the “totality” of the evidence, on what rational grounds can the existing evidence of harm induced by GET for people with ME/CFS not be taken into consideration by these Royal Colleges?

The current President of the RCP, Professor Andrew Goddard, is on record stating that the Royal College’s ME/CFS experts confirm the benefits of GET. Those “experts” are thought to include Dr Alastair Miller whose views are being promoted by the Science Media Centre in its press release of 17th August 2021 and Dr Gabrielle Murphy, both of whom are well-known staunch advocates of GET.

It is notable that, when questioned by a senior NHS Consultant Physician about the long-term benefits of GET, Dr Miller conceded that he did not know; he said he saw patients only once and did not do follow-ups, so the question arises as to how he can confidently confirm the alleged benefits.

This brings to mind the disturbing article on 26th August 2021 in The Independent by Jane Dalton entitled “*NHS mental health experts pressurised to exaggerate success rates, expert claims: ‘Actual human experience was secondary to creating data that would shore up the evidence base for the model to guarantee further investments’, says one*”

<https://www.independent.co.uk/news/health/nhs-therapists-patients-manipulate-data-b1908629.html>

The intransigence of some members of these Medical Royal Colleges in not accepting the now-substantive evidence contra-indicating GET for people with ME/CFS is likely to result in the perpetuation of significant iatrogenic harm, a fact which some clinicians appear to disregard with impunity.

Physicians are notoriously slow to accept change (“ME/CFS: Past, present and future”; William Weir and Nigel Speight: *Healthcare* 2021:9(8):984 <https://www.mdpi.com/2227-9032/9/8/984>); the article is sobering because it shows that dogma, not science, rules the roost in UK medicine.

What it behoves all physicians not to disregard is the fact that in 2015 there was a change of UK law relating to informed consent and medical negligence. Anyone found guilty of breaking the law acquires a criminal record. Such a record would surely impact a clinician’s professional insurance and their right to practise medicine.

However, since the change in UK law in 2015, all NHS staff are required by law to comply with the up-dated UK Law on Consent. The long-held Bolam case-law principle held that a doctor would not be negligent if information/treatment given to a patient was compatible with a reasonable body of medical opinion <https://www.medicolegal-partners.com/2019/07/11/bolam-to-montgomery/>

The Bolam principle was replaced in 2015 by the Montgomery case-law, which states: “*The doctor is under a duty to take reasonable care to ensure that the patient is aware of **any material risks** involved in **any recommended treatments**” (emphasis added). This means that the law now requires patients to be fully informed of all material risks involved in any treatment; the information provided must not be limited to the views of just some doctors, nor indeed to government Guidelines. Doctors’ ignorance of the law is no excuse and the law applies to all medical personnel, not just to doctors (Full UK Supreme Court Judgement,*

UK Supreme Court documentation on Montgomery (Appellant) v Lanarkshire Health Board (Respondent) Case ID UKSC 2013/0136, 11th March 2015 <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>).

Despite the lack of reliable RCTs, the *“totality of the evidence-base”* includes not only decades of substantive and professionally analysed evidence of the adverse effects of GET for ME/CFS patients but also the publication of over 9,000 expert articles showing the biomedical basis of ME/CFS.

This means that physicians who prescribe GET are now at risk of legal action being brought against them. By continuing to promote GET for people with ME/CFS, the Royal College of Physicians is irresponsibly going back on its own words (which still stand) and is not only putting sick people with a life-wrecking neuroimmune disease at risk of becoming bed-bound and requiring tube-feeding but also its own members at risk of losing their licence to practice medicine.

Ignorance, particularly wilful ignorance, is no defence in law.