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More Illustrations of GDG's failure of procedure in CG53

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1. **Selection of GDG:**

In NICE's response to Stakeholders' comments (in the General Table, which is one of seven Tables), the GDG states:

"b. Selection of GDG members:

The GDG was convened on the basis of NICE methodology in which stakeholder organisations were asked to nominate patient and professional members. In accord with the NICE technical manual in effect in 2005, **stakeholders registered in at the time of the request (20 April 2005) were invited to complete the pro-forma detailing the evidence that they wished to submit. This was reviewed against the scope".**

This clearly indicates that only those stakeholders who could be relied upon to support the pre-determined agenda (as set out in the final scope) were permitted to be GDG members --- anyone who intended to present evidence that did not support the pre-determined agenda was excluded from the GDG (including disease-specific experts). This demonstrates bias and contravenes the Guideline Development Manual.

2. re: **requirement for SECOND consultation on draft Guideline:**

At page 307 in "General comments from stakeholders" at: "Issue 3. NICE Manual" - the GDG state:

"Please note that this guideline started before the publication of the NICE Manual in April 2006 **and is based on the previous edition".**

In the 2005 edition the Guideline developers are there instructed to:
"…Write the first consultation draft of the guideline
... Consult and respond to stakeholders' comments ... Review in light of stakeholders' comments
... Prepare second consultation draft of guideline ...
…Consult and respond to stakeholders' comments ... Review in light of stakeholders' comments ...
…Prepare final guideline .... Review and update within an agreed timeframe".

The second consultation was dropped without informing stakeholders as required.

It was not only the public, charities and MPs calling for another consultation.

Such was the confusion, the College of Occupational Therapists also voiced their concern: “Due to the number of comments raised, we would like to suggest that a further draft is circulated to stakeholders for consultation prior to its publication.”

The GDG merely responded: “Noted”.

They seemed to display regular intolerance to critical thinking as they reacted to the consultation process, refusing to engage or respond adequately and appropriately throughout the entire exercise.

3. **GDG's required response to stakeholders' comments:**

Under “Principles of responding to stakeholders’ comments” developers are instructed: “How to respond":

“• Each comment must be acknowledged and answered as fully and as factually as possible. It is important to acknowledge that each point has been seen and has been understood. Some comments may be presented as general commentary, but they should still be noted.

• If changes are made to the document, this must be made clear in the response. If no changes have been made, it should be made clear why this was not thought necessary.

• For comments made on draft guidelines:

– responses and changes must be made with the agreement of the whole GDG, preferably through a meeting. This meeting needs to be arranged early in the process to ensure that GDG members will be available

– any subsequent changes to guideline documents need to be reflected in each version, and an audit trail of changes must be maintained".

Reacting to critical comment by the Association of British Neurologists over the total irrelevancy of an unproven hypotheses by Wessely et al. from a 1999 Lancet article they referenced and sought to promulgate (ie. that ME doesn't exist and that CFS is a heterogeneous term for a functional [behavioural] somatoform disorder which includes premenstrual tension etc) the Guideline Development Group were provoked into clarifying their psychosomatic view of “CFS”:

"This paragraph does not reflect any opinion published in the literature but rather summarises the consensus view of the GDG".

The Association of British Neurologists had submitted the following to the GDG: *"This paragraph deals with a publication (Wessely et al, Lancet 1999) which was published as a HYPOTHESIS and which remains to be proven. However, the GDG seems to have taken it as a matter of fact. This particular paragraph, being only a hypothesis, is totally irrelevant for the purpose of a dedicated guideline on CFS/ME".*

The paragraph in question stated: " *CFS has been described as part of a broader condition that includes a range of related disorders including fibromyalgia, irritable bowel syndrome, chronic pain, pelvic pain, temporomandibular joint dysfunction and atypical facial pain. The subdivision of this broader condition into several different entities is thought to be due to the specialisation of secondary-care medicine and the predominating symptom at time of presentation e.g. fibromyalgia in rheumatology and irritable bowel syndrome in gastroenterology. However, the predominating symptom can change over time causing uncertainty for the patient and diagnostician leading to further tensions and distress. The original clinical diagnosis of CFS becomes irritable bowel syndrome because bowel symptoms predominate over fatigue despite the same illness and disability experience."*

It continued: "*Terminology used by doctors such as 'functional syndrome' and 'medically unexplained symptoms' are part of common usage in clinical practice today. The terms have arisen to describe non-conventional diseases and are intended to validate CFS and overlapping conditions to help improve patient care and research into the disorder. Although the term 'functional' has been found to be more acceptable with patients than terms such as 'psychosomatic' or 'medically unexplained', some terminology has become derogatory with use. For some patients and health professionals, the functional concept and all associated terminology are deemed unacceptable. The 'mental or physical' condition debate predominates in the clinical encounter undermining the doctor patient relationship .. etc*." (CFS/ME: full guideline DRAFT September 2006 Page 134).

<u>Angered by further accusations about this section, the GDG then claimed the reverse</u>: "*The views of a few members of the GDG did not dominate the guideline. Great care was taken during development to ensure all views were identified and a balanced guideline produced. Specifically, the GDG does not state that MM/CFS [sic] is a behavioural disorder, a psychiatric illness, a somatic/functional disorder, an illness belief, depression or anxiety disorder."*

"We have recognised that CFS/ME is a physical illness"

"Consensus was used, and a recommendation that CFS/ME should be recognised as a physical illness has been made"

Repeatedly the GDG mislead stakeholders making it up to suit themselves:

"Any physical illness has a psycho-social aspect to its management. The Guideline Development Group did not promulgate a psychosocial theory for the causes."

The truth was otherwise:

"I have stayed to the end, hoping that I could try and make even a small difference, I came to the belief that this was futile, a while ago, but I still tried, ***the final straw came when the group voted to remove that ME/CFS is a physical illness, the inclusion of this was vital for both patients and doctors, and its removal will do more harm, with more doctors continuing the erroneous belief that this is a psycho-somatic/mental health issue*****"** (Tanya Harrison (patient representative) letter of resignation from GDG dated 16th July 2007 to Professor Richard Baker).

4. **The number of patient representatives on the GDG**

In its Guideline on Epilepsy (The Diagnosis and Management of the Epilepsies in Adults and Children, October 2004), there were FOUR patient representatives all nominated by charities and the GDG and GDG co-optees for the Epilepsy Guideline consisted of 27 members, including people nominated by the Royal Colleges and by epilepsy charities. The GDG consisted of 13 members and the co-optees numbered 14 and consisted of disease-specific experts.

This is in stark contrast to CG53, which had NO representative from the patients' charities and NO representative from the Royal Colleges on the GDG itself. CG53 did not have a single disease-specific expert as co-optee. The co-optees consisted of a nurse, a paediatrician and a liaison psychiatrist, as well as lay person Jill Moss, founder of the children's charity AYME. Thus only one ME charity (a children's charity) was represented, whilst all the other ME charities, including the other, longer-established childrens' charity, were excluded.

It is the case that in the 2004 Report of the RCPCH on "CFS", Jill Moss was listed on page 11 as "Dr Jill Moss"; she is a former special needs teacher but was awarded an honorary doctorate for educational services (ie nothing to do with medical issues) by the Open University (where her husband had worked for some years). In the Report, she is listed next to Dr Nigel Speight and other clinicians who are legitimately entitled to use the title "Dr", but for her to do so is misleading and in no way represented an association with the Royal College of Paediatrics and Child Health.

The presence of Jill Moss is notable, since her presence effectively gave two voices to the children's charity AYME, since paediatrician Dr Esther Crawley was on the GDG and is also AYME's Medical Adviser. This is significant, because it gave two votes in support of CBT and GET whilst excluding the charities who opposed CBT/GET.

For the record, the key principle behind the Epilepsy Guideline were that the Guideline should: "*consider ALL the issues that are important in the diagnosis, treatment and management of epilepsy in children and adults"*. Such was not the case in CG53.

5. **Acknowledgement of the contesting paradigms of ME/CFS**

The GDG dismissed the importance of the contesting paradigms of ME/CFS v "CFS/ME" by stating (Issue 4: 8.2): "*It is doubtful whether this discussion would be helpful"*. It would certainly have been helpful to patients with ME/CFS, but their needs were repeatedly ignored by the GDG. There is no justification for the GDG's statement: "*The research on biomarkers and brain-imaging reviewed by the GDG was unconvincing and we did not find any research avenue in this field which merited special attention"*, since there is a wealth of such evidence.

When stakeholders pointed out that *"ME has many more symptoms which require managing than simply 'excessive fatigue' "*, the GDG's response was *"This is not directly relevant to the diagnosis and management of CFS/ME".*

When stakeholders also pointed out that: "*Research has shown that there is very little, if any, deterioration in muscle function as a consequence of rest"*, the GDG's response was: "*This is not directly relevant to the diagnosis and management of CFS/ME".*

Furthermore, the GDG also decided that the post-viral issue in ME/CFS that was included in the draft Guideline was irrelevant: *"We have removed the recommendation on post-viral management (as it is) outside the scope of this guideline".* Had this important issue been retained in the final Guideline, it would have militated against the blanket recommendation for psychotherapy for everyone with "CFS/ME". The GDG actually assert that whilst epidemics do occur, they are "*rare events"*. Because the GDG intentionally did not consider the totality of the evidence-base, they expediently ignored the fact that, up to 1990, there were 63 documented epidemics (The Clinical and Scientific Basis of ME/CFS, ed. Hyde, Goldstein & Levine, 1992: chapter 16, pp 176-186).

6. **The status of the GDG members**

Stakeholders (BRAME) responded to the GDG's assertion that the result of patients' surveys were subject to bias so could safely be ignored: "*You ask patients, carers, and medical professionals who work with ME patients, to fill in a questionnaire, and then infer that the results are biased. So are we to assume that NICE, and the majority of the GDG, did not agree with incorporating the results into the Guideline? If bias is reflecting the facts and reality of the illness, and the impact it has on patients' lives, then why do you always accept without question the bias towards CBT and GET by the psychiatric / psychological school of thought. Our feedback is that the patient voice and experience has once again been ignored".* NICE's reply was: "*We have taken the results into*

consideration". This was later denied on the basis that patients' surveys carried out by ME/CFS charities were biased.

The GDG actually stated: "*Professional members (of the GDG)* ***do not need to be experts but have an interest in CFS/ME"***. This needs to be compared with the list of disease-specific experts who were on the Epilepsy GDG.