

Illustrations of the NICE Guideline Development Group's failure to adhere to the Guidelines Development Manual

Margaret Williams

8th November 2008

The following illustrations come from the version of the Manual used during the production of CG53. The Manual consists of 89 pages, so the following quotations are merely illustrative.

Section 1 of the Manual states: *"The advice in this document draws on international guideline development methodology and is based on internationally accepted criteria of quality, as articulated by the AGREE Instrument"*.

The Manual states at **Section 2: Scoping the Guideline**: *"Guideline topics are selected by the Department of Health and the Welsh Assembly Government, which identify the main areas to be covered by the Guideline in a specific remit. This remit is then translated into the scope document for the Guideline. Preparing the scope is the first stage in developing a Guideline, and it determines the shape of future work. The scope is drafted by the NCCs, consulted upon, and signed off by the Institute"*.

The remit from the DoH states: *"The Department of Health and Welsh Assembly Government asked the Institute: To prepare for the NHS in England and Wales, guidance on the assessment, diagnosis, management of adjustment and coping, symptom management, and the use of rehabilitation strategies geared towards optimising functioning and achieving greater independence for adults and children of CFS/ME"*.

From the Manual, it is clear that a remit is turned into a "scope" that is drafted by the National Collaborating Centre in conjunction with NICE, and is "signed off" by NICE before the work begins on producing a Guideline.

As far as CG53 is concerned, there appears to be a mismatch between the original remit and the scope that NICE / National Collaborating Centre officials produced: somewhere along the line, the remit has been modified to enable the pre-determined outcome to be achieved (namely, the blanket recommendation of CBT and GET as the primary management intervention: the scope states that *"specific interventions covered by the Guideline will include return to education and/or employment"* and will include *"graded exercise therapy and psychological therapies (including cognitive behavioural therapy)"*. Thus the decision to recommend CBT/GET was clearly made before the disorder in question had been identified or defined by the GDG and before the GDG had considered the suitability of such recommendations.

Section 2.2.1 of the Manual states: *“Considering the remit: The remit received by the Institute from the DH/Welsh Assembly Government forms the basis of the scope, and **all areas specified by the remit are normally addressed in the scope.**”*

As the remit states that the Guideline should provide **guidance on the assessment and diagnosis** of the disorder in question, there has clearly been a departure from required procedure as set out in the Manual, firstly by NICE / NCC officials in the disingenuous crafting of the scope, and secondly by the GDG in its restrictive interpretation of the already-restricted scope, because the published Guideline CG53 does neither.

The remit further states that guidance should be provided on **symptom management**, yet the GDG failed to encompass the symptomatology of ME/CFS and was dismissive about cardinal symptoms, stating on the CG53 website (in their comments on Stakeholders’ submissions) that they did not consider individual symptoms of the disorder. For example, the GDG states: *“The symptoms listed are those that will assist the clinician in identifying the condition. The GDG were concerned that if there were a comprehensive list, serious symptoms would not be investigated and treated promptly as there was a risk they would be regarded as ‘normal’ for a person with CFS/ME”; “the evidence does not enable us to specify which patients with which symptoms will benefit from each programme”* (yet the GDG recommended a “one size fits all” regime); *“one of the aims of the guideline is to raise awareness of presenting symptoms”* (yet key symptoms are excluded, and the GDG specifically advise that cardiovascular or respiratory or neurological symptoms mean that the person cannot have ME/CFS, which is perverse, since these are key symptoms commonly seen in ME/CFS. This amounts to a serious failure of procedure); *“the guideline does not address the management of individual symptoms”; “the Guideline Development Group did not have the time to write a guideline on each symptom”* (so how can the Guideline aid diagnosis if it did not have time to list the symptoms by which the disorder can be identified)?

It is illogical and a failure to fulfil the remit not to include well-documented symptoms of the disorder in question.

Section 2.3.2 of the Manual states: *“The Chair of the Guideline Review Panel (GRP) is expected to comment on whether the scope falls within the remit”*. In the case of CG53, there seems to have been a failure by the Chair of the GRP (Professor Mike Drummond) to ensure adherence to the procedures set out in the Manual, because the scope failed to capture all the issues included in the remit.

The scope itself states: *“The Institute’s clinical guidelines will support the implementation of National Service Frameworks in those aspects of care where a framework has been published”*. ME/CFS is included as a neurological disorder in the NSF, yet the NICE Guideline does not accept that ME/CFS is a neurological disorder, so there is a clear breach of procedure in this important respect. CG53 does not support the aspects of care as set out in the NSF for people with the long-term neurological condition ME/CFS. The long-term conditions model requires *“disease-specific care management”*

which involves providing people who have complex long-term conditions with “*responsive, specialist services using disease-specific protocols*”. CG53 makes no mention of this requirement in its management recommendations.

The scope places apparent emphasis on “*correct diagnosis*”, on “*the process of assessment*” and on the “*clinical case definition*”. Despite the apparent emphasis on these key issues, CG53 is in breach of required procedure in that no guidance is provided in CG53 to assist clinicians on “*correct diagnosis*”, nor on the “*process of assessment*”, and CG53 does not even include the internationally accepted “*clinical case definition*”. Instead, the GDG has concocted its own “case definition” which bears no relationship to the international case definition (the 2003 Canadian case definition).

Not to identify and define the disorder in question is in clear breach of required procedure, since there can be no correct diagnosis or appropriate clinical management of an undefined disorder.

Section 2.2.2 of the Manual states: “***Preliminary search of literature (stage-one search):*** *A broad preliminary search of the literature is important to obtain an overview of the issues likely to be covered by the guideline – the clinical need and the clinical management of the condition – and to help define key areas*”. In the case of CG53, no such overview of the issues was carried out.

Section 3.1.1 of the Manual states: “***Details should be provided about how the proposed constituency of the GDG relates to the subject area of the Guideline and to stakeholders. There should be some explanation of how the members will be selected***”. In the case of CG53, the “constituency of the GDG” did not relate to the neurological disease ME/CFS, but only to medically unexplained chronic fatigue.

Section 4 of the Manual is entitled “***Forming and running a GDG***”. It states: “***Convening an effective GDG is one of the most important stages in producing a guideline. Membership needs to (comprise) clinicians (both content-area specialists and generalists). Its exact composition needs to be tailored to the topic covered by the Guideline***”. There was an unequivocal failure of procedure in CG53, because “**content-area specialists**” were deliberately excluded from the GDG and the Guideline was not “**tailored to the topic covered by the Guideline**” at all (as confirmed by GDG member Dr Fred Nye, who is on record stating that the GDG was directed to “*adopt the inclusive approach*” which included “*people who are merely tired*” (J Inf 2007:55:6:569-571).

Section 4.1.1 of the Manual states under “**Key roles and functions of the group leader**”: “*The group leader (in this case Professor Richard Baker) needs relevant background knowledge, including in-depth knowledge of the topics to be covered*”, but Professor Baker had no experience or knowledge of ME/CFS (as confirmed at paragraph 15 of the WS of Professor Peter Littlejohns).

The Manual states that another key role of the group leader is to ensure that the group has relevant information. Professor Baker failed to ensure that the GDG had the necessary

information about ME/CFS. The GDG ignored over 4,000 peer-reviewed papers on the disorder that the Guideline purported to be addressing.

The Manual continues: *“The group leader is expected to have a good understanding of the guideline topic and is likely to be a clinician. Clinical knowledge is advantageous in understanding the scope of the guideline”*. Professor Baker works two days a week as a part-time GP and had no prior “clinical knowledge” about the disorder in question. He did not therefore have the required “good understanding of the guideline topic”.

In respect of the professional members of the GDG, the Manual states: *“Professional members should be representative of the healthcare workers involved in the care of patients affected by the guideline topic”*. There was a clear breach of procedure in this respect, since the “healthcare workers” including consultant physicians who specialise in treating ME/CFS patients were deliberately excluded from the GDG.

Instead, people with no knowledge or experience of ME/CFS patients were specifically chosen, all of whom could be relied upon to support the Wessely School psychosocial model of the disorder.

For example, one of the GDG members was Dr Alastair Santhouse who is a consultant liaison psychiatrist at the same London & South Maudsley NHS Trust as Wessely. In 2005, Wessely wrote a Foreword for Santhouse (*“Fatigue as a Window to the Brain”*; Psychological Medicine 2005:35(12)). Santhouse is on record as asserting: *“Psychiatry is the noblest branch of medicine”* and states of himself: *“At times I am carried away by the nobility of my calling”* (BMJ 2008:337:a2331). He is on record as stating that psychiatry is not helping enough people with depression, anxiety, conversion disorders and somatoform disorders (doi:10.1136/bmj.a2262). Santhouse has co-authored with Nigel Blackwood who also works at The Institute of Psychiatry with Wessely. Blackwood is keen on “emotional processing” and has co-authored with Richard Bentall, Professor of Experimental Psychology who, together with GDG member Dr Fred Nye, authored papers on CBT/GET for “CFS/ME” and is in receipt of an MRC grant of £824,129 for research to encourage “exercise” in “CFS/ME” patients (*“Patient education to encourage graded exercise in CFS”*; B J Psychiat 2004:184:142-146). It may also be noted that Alastair Santhouse (known to his friends as Al Santhouse) sponsored Simon Wessely’s cycle ride to Paris in 2007, as did Trudie Chalder, Alison Wearden and Peter White (all of whom have strongly influenced the NICE Guideline), which seems to indicate an effective closed-circuit network.

GDG member Dr Richard Grunewald is a consultant neurologist, but he does not accept that ME/CFS is a neurological disorder and has a published track record asserting that “CFS/ME” is a behavioural disorder.

GDG member Dr Julia Smedley is an Occupational Physician at Southampton University Hospital NHS Trust and Senior Lecturer at the MRC Epidemiology Unit. Her clinical background is in general medicine and her main interest is in occupational risks to healthcare workers. Her publications include “A survey of the delivery and uptake of

influenza vaccine among healthcare workers” (Occup Med 2002:52:271-276); “Respiratory illness in agricultural workers” (Occup Med 2002:52:451-459); “Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity and health service use among residents” (BMJ 2006:333:1241) and “Influenza immunisation: attitudes and beliefs of UK healthcare workers” (Occup Environ Med 2007:64:223-227). Wessely School psychiatrist Professor Michael Sharpe is very active in the world of Occupational Health and Insurance Medicine and his views permeate the world of Occupational Medicine (i.e. that ME is a “*pseudo-disease*” that can be “*cured*” by CBT and that ME sufferers who “*refuse to accept the stigma of mental illness remain the undeserving sick of our society and health service*”).

GDG member Dr Philip Wood (known as “Phil Wood”) has been a consultant immunologist at Leeds since January 2002. His main interest is in adult and paediatric allergy, but he has an interest in “chronic fatigue” (note: this is not the same as ME/CFS). He has published one study on allergic disease in children (Eur J Pediatr 2005;164:741-747). He is a clinician in the Leeds & West Yorkshire CFS/ME Service, whose 2008 booklet “Goal Setting” says the following: “*CFS/ME is a diagnosis that does not fit under one specific medical speciality. Complex referrals may be seen initially by a physician and liaison psychiatrist. Unfavourable prognosis is associated with prolonged duration of symptoms (and) untreated beliefs around the need for purely physical treatment. The Leeds & West Yorkshire CFS/ME Service finds that if the practitioner can demonstrate why a diagnosis has been made, then that patient will start to engage in taking some responsibility in managing the effects of CFS/ME. The Leeds & West Yorkshire CFS/ME Service has three components: 1) Medical assessment by Dr Philip Wood; 2) Biopsychosocial assessment and considerations of interventions in liaison psychiatry led by Dr Hiroko Akagi and 3) Therapy Services, led by Sue Pemberton, occupational therapist. We all need goals to move forward in our lives. Without specific goals we can feel demotivated. This can have an impact on how we feel about ourselves. Setting and working towards a goal releases energy. How do you feel when you have no goals? The therapist within the team will help you with goal setting*”. The “Useful Books” list contains only books by Wessely School members (Trudie Chalder’s “Coping with Chronic Fatigue”, which has nothing to do with ME/CFS; “Overcoming Chronic Fatigue” by Trudie Chalder & Mary Burgess; and a book by psychiatrist Michael Sharpe, co-authored by Frankie Campling, a Wessely School supporter). Bearing in mind that many ME/CFS sufferers are professional people, such a superficial approach is an affront to their intelligence and cannot help people deal with vertigo, cardiomyopathy, pancreatitis, dysautonomia, adrenal insufficiency or vasculitis, all of which are well-documented key features of ME/CFS.

None of these GDG “experts” has anything to offer people with ME/CFS, but everything to offer the pre-determined agenda of the NICE Guideline CG53 to recommend CBT/GET across the nation. None of them is a “*disease-specific*” expert as required in the Manual, but no expert dissenting voices were permitted to be GDG members. The result is the recommendation of inappropriate behaviour-modifying interventions for people with a serious multi-system disorder who are unable to benefit from the recommended interventions.

The Manual further states: “GDG members are expected to read all relevant documentation”. In this case the GDG ignored over 4,000 peer-reviewed papers on the disorder that the Guideline purported to be addressing.

Section 4.1.2.1 of the Manual is clear: “Professional members should be asked to declare interests *before* a firm offer is made”. In the case of CG53, this either did not happen at all, or else the Chairman of the GDG (Professor Richard Baker) failed in his duty to adhere to the Manual by permitting so many people with obvious vested interests to be members of the GDG.

At **section 4.2.1** the Manual states: “The declaration of interest form should be completed before any decision about the involvement of an individual is taken. The group leader should determine whether these interests are significant. If it is considered that an interest is significant in that it could impair the individual’s objectivity throughout the development of a guideline, he or she should not be invited to join the group”. How can holding the position of Chief Medical Officer to not one, but to two, medical insurance companies that are ruthless in their intention not to accept ME/CFS as a neurological disorder not automatically have excluded Dr William Hamilton from being a member of the GDG? Instead, evidence has been obtained that he was head-hunted to be on the GDG precisely because of his published papers in which he asserts that CFS/ME is a behavioural disorder.

Section 5 of the Manual deals with “Developing Clinical Guidelines” and is clear that the GDG needs to identify “clinically relevant evidence”. The section on “Patient Population” says: “Which patients or population of patients are we interested in? How can they best be described? Are there subgroups that need to be considered? What is really important for the patient?”. With CG53, there was a failure of procedure in all these respects because none of these Manual requirements was complied with. The GDG actually stated that it found no evidence for subgroups (even though the international literature is replete with such evidence).

Section 6 of the Manual entitled “Identifying the evidence” states: “It is important to ensure that this process is as thorough and unbiased as possible. Searching should focus on locating the best evidence from all relevant sources –potentially, this involves extensive work. The evidence used by the GDG will come from two main sources: searches of electronic databases by the technical staff at the NCC (and) via stakeholder organisations that are invited to submit relevant information”. This identifies a serious failure of procedure, because although an extensive amount of relevant evidence was submitted by stakeholders, it was comprehensively ignored by the GDG.

Section 11 of the Manual lays down the requirement for the GDG to establish what are the most important characteristics of the patient group to be studied; CG53 entirely failed in this respect.

Section 14 of the Manual is entitled Consultation and dealing with stakeholders' comments and is unequivocal: *“Consultation with stakeholders is an integral part of the NICE guideline development process. Comments received from stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important they are addressed appropriately. The following key points should be taken into account when responding to comments. 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”*. There has been justified outrage at the GDG's dismissal of stakeholders' comments as biased.

The Manual states: *“The members of the NICE editorial team are experienced medical editors/writers, but they are not medically qualified or clinically experienced. It is therefore crucial that the guideline developers take responsibility for ensuring that the documents are clinically correct”*. The GDG must take full responsibility for the final Guideline. In the case of CG53, the GDG failed to observe numerous fundamental matters of procedure.

It is accepted that the Systematic Review of the literature on management of “CFS” was (and remains) in large measure limited to the Wessely School studies of CBT/GET. It is because the Wessely School has commandeered the research funding, to the exclusion of other disciplines, that there is no RCT evidence-base of other successful interventions. It does not mean that there is no evidence of other interventions being clinically helpful, only that there is no RCT evidence due to the absence of funding for non-psychologically based approaches.

As the Chairman of NICE, Professor Sir Michael Rawlins, acknowledged at his 2008 Harveian Oration, randomised controlled trials (RCTs), 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, hierarchies themselves are illusory tools for assessing evidence. **RCTs should be replaced by a diversity of approaches that involve analysing the totality of the evidence-base.**

This means that the NICE Guideline CG53 which relied exclusively on RCT evidence (most of it publicly acknowledged to be methodologically flawed) failed the very patients for whom the Guideline was intended.

Finally, the Spring / Summer 2008 issue of Liaison News (the Newsletter of the Liaison Faculty of the Royal College of Psychiatrists) makes interesting reading: *“The final presentation of the day was from Simon Wessley (sic) who gave a fascinating overview of his work on chronic fatigue syndrome. He described his early involvement seeing patients at Queens Square, followed by work defining the condition, and then setting up effective clinical trials culminating in the dissemination of the NICE guidelines. He brought the conference down to earth, however, with a glimpse of the downside of this journey – the*

vitriolic response of a small but very vocal group of patients which brought the requirement for a wider adoption of the biopsychosocial approach into sharp focus!"
<http://www.rcpsych.ac.uk/pdf/Faculty%20Newsletter%20July%202008.pdf>

From this issue of Liaison News, it may be deduced that Wessely did change the case definition; that he did “set up” the clinical trials (which have not been clinically effective, as he himself has publicly acknowledged: “*It should be kept in mind that many CFS patients, in specialised treatment centres and the wider world, do not benefit from these interventions*” -- Psychol Med 2006;36: (7):895-900), and that his intransigent belief that ME/CFS is a behavioural disorder did influence the NICE Guideline.

It may also be deduced that Wessely exults in what he perceives as his victory (i.e. his input into the NICE Guideline, the publication of which he seems to regard as the culmination of his efforts, despite the fact that he was not a member of the GDG). He seems to think that the Guideline has dealt a blow to those who oppose his beliefs, in that their voice has “*brought the requirement for a wider adoption of the biopsychosocial approach into sharp focus*”. In other words, the more that ME/CFS patients object, the greater the need for them to be silenced. In reality, those patients whom he wishes to silence show more acuity than Wessely in understanding that chronic fatigue is a symptom and not a disease.

Many concerned people had hoped that the GDG was seeking the best way of helping a substantial number of seriously ill members of society. It seems clear that the GDG members have simply become the tool of the wilfully blind and powerful financial interests.

Unless the NICE Guideline’s flawed procedures are exposed, the consequent potential abuse of patients with ME/CFS will continue.