EVIDENCE OF EFFICACY?

Margaret Williams 10th March 2008

The document "Deliberate Deceit or Inexcusable Ignorance?" (available online at http://www.meactionuk.org.uk/Deliberate_deceit.htm) noted some of the evidence about the lack of efficacy of cognitive behavioural therapy (CBT) which the National Institute for Health and Clinical Excellence chose to ignore when recommending CBT as the primary intervention for "CFS/ME" (Chronic Fatigue Syndrome /Myalgic Encephalomyelitis) in its Guideline published in August 2007. In the case of "CFS/ME", CBT also includes graded exercise therapy or GET).

Under the rules governing the production of its Guidelines, NICE is required to give equal weight to three main categories of evidence: (i) random controlled trials / non-random controlled trials (ii) expert evidence (a source of concern, since the "experts" are chosen by NICE itself and seem to be carefully selected so that the desired outcome will be achieved, with clinicians who have a life-time's experience in a disorder being rejected in favour of those who set and underpin Government "policy") and (iii) patient / user experience and expertise (another source of concern, given the mounting evidence that NICE does not always give equal weighting to patients' evidence).

It seems that any evidence, no matter how substantial, that does not come within these categories can be disregarded with impunity.

In its management recommendations for "CFS/ME", NICE has subscribed to the unsubstantiated views of the Wessely School, who study patients with chronic "fatigue", not ME, but then claim their studies include patients with ME. Wessely and his likeminded colleagues have established their position as Government advisers on "CFS/ME" and Wessely has stated openly that patients with ME/CFS are fooling themselves by refusing to accept that their illness is psychosomatic; he is on record as stating: "These patients are generally viewed as an unavoidable, untreatable and unattractive burden" (BJHM 1994:51:8:421-427).

ME has been classified by the World Health Organisation as a neurological disease since 1969, but Wessely's on-the-record intention is to re-classify "CFS/ME" as a somatisation disorder, to the extent that he ignores the body of knowledge known to other (non-psychiatrist) clinicians and researchers working in the field of ME/CFS, thereby raising once again the question that has been publicly asked many times: at what point will that body of scientific knowledge be so great that it will be considered serious professional misconduct to pretend that it does not exist?

Not only has NICE ignored the biomedical evidence relevant to the disorder under review, but it has also ignored the evidence of expert clinical psychologists experienced in the delivery of CBT who know that it is of little proven efficacy.

Such machinations would appear to invalidate the whole exercise.

In the case of ME/CFS there is credible evidence from over 3,000 patients that CBT/GET is not effective and -- more worryingly – that it may be actively harmful; moreover, there is a substantial body of evidence from experienced clinical psychologists themselves that CBT simply does not merit the acclaim afford to it by NICE. This evidence was available to NICE before the production of its Guideline on "CFS/ME" but seems to have been ignored.

The evidence quoted below is not a blanket condemnation of clinical psychology as a whole, nor of those clinical psychologists who employ objective neurocognitive testing to investigate dysfunctional brain pathways: the regime recommended by NICE is quite different and aims to change the "attitudes" and "beliefs" of patients suffering from a classified organic disorder so that they accept it is a somatisation disorder (when such is not the case, and for which there can be no justification).

Quite apart from the contents of the website "Articles Critical of Psychiatry" (http://www.uea.ac.uk/~wp276/article.htm), senior clinical psychologists of impeccable integrity have for years expressed their concerns about various aspects of CBT, noting the relationship between the exercise of coercive social and economic power (i.e. state control) and the people (i.e. patients) who are controlled by those wielding such power, and noting also the role that socio-economic power plays in maintaining people's distress (see, for example, "Social Power and Psychological Distress" by David Smail available at http://www.davidsmail.freeuk.com).

Some of these concerns about the efficacy of psychotherapy in general and about CBT in particular (and about what they deem to be the inappropriate reliance on it by NICE) are set out below.

As long ago as 1988, in an article titled "Psychotherapy: deliverance or disablement?", David Smail wrote:

"A recent working party of the British Psychological Society quoted with approval in its report on psychotherapy a definition of the latter as an:

'informed and planful (sic) application of techniques derived from established psychological principles by persons qualified through training and experience to understand these principles and to apply these techniques with the intention of assisting individuals to modify those personal characteristics as feelings, values, attitudes and behaviours as are judged to be maladaptive or maladjusted'.

"In my view, this is far from accurate as a definition of what actually happens in psychotherapy, but serves its purpose in suggesting a view which many therapists are only too happy for the population at large to believe". (In: Gavin & Susan Fairbairn (eds). Ethical Issues In Caring. Aldershott: Avebury, 1988).

In 1999, David Smail wrote "<u>Patients' Powers and the Impotence of Psychotherapy</u>" (Universities Psychotherapy Association, Review No: 7: 35-42) in which he said:

"Psychotherapy has no account to offer which is both rigorous and coherent of how it brings about change in its clients.

"What are we trying to change? Since all the therapist has in front of him or her is the client, the effort has usually been to change clients themselves in some way or other. If the therapy 'works', then no one enquires too closely into why it works and just assumes that it was indeed the therapeutic technique. However, when, as is so often, it doesn't work, then questions have to be asked.

"Now an element of irritation with recalcitrant clients starts to creep in, and there may be talk of 'resistance' or 'dependency needs', etc. What clients need to do is 'assume responsibility' for change.

"The therapeutic process constitutes a kind of invitation to individuals to exercise their will appropriately. If they don't, then that must be because of their own ulterior motives (the kind of therapeutic recalcitrance alluded to above) for which therapists can't reasonably be held to account.

"To be credible as a therapeutic undertaking, psychotherapy must lay claim to powers which will bring about change in its clients.

"If we're going to analyse anything, it should be the ways in which the environment damages the people who consult us.

"This radical shift in perspective from the person to the environment immediately renders irrelevant some of the most vexed questions of traditional clinical approaches. For example, concepts such as 'resistance', 'lack of motivation', 'inadequate personality', 'dependence', and so on may be translated into much less morally loaded considerations".

In 2001 Smail wrote "<u>The Impossibility of Specifying 'Good' Psychotherapy</u>" (see Clinical Psychology 2001:7:14-18; first presented at the Universities Psychotherapy Association Annual Conference, University of Surrey, November 1999):

"The focus, of course, is mainly on the procedure, not nearly so much on the people who carry it out. (There is a) considerable body of evidence -- arguably the only consistently persuasive evidence-- that it is the personal characteristics of therapists rather than

therapeutic technique which achieve such improvement as can be identified in the field.

"Why do we cling so tenaciously to a view of psychotherapy which is not only counter to our own experience but also in fact unsupported by the vast bulk of the research literature?

"The short but inescapable answer to this question is: because it is in our interests to do so.

"It is in the interests of a society which causes immense damage to huge sections of its population to represent that damage as the consequence of essentially individual psychological aberration, in principle curable through therapeutic intervention.

"In modern times, truth is the servant of interest. Indeed, in so-called 'postmodern' times, the distinction between truth and interest becomes obliterated: truth becomes an entirely pragmatic concept, knowledge becomes indistinguishable from power.

"In fact, we haven't really got a clue as to what constitutes good psychotherapy because we steadfastly refuse to pose it in the appropriate way.

"Psychotherapy is not appreciably more effective than any other approach to emotional distress; technique has virtually nothing to do with such success as therapy does enjoy (and) the personal characteristics of therapists are more important to outcome than any theoretical allegiance; that training of practitioners is largely irrelevant and untrained volunteers can often do just as well or better.

"We cannot possibly even begin to attempt a definition of good psychotherapy without first radically revising our assumptions about psychotherapy itself".

In 2006, Smail wrote "<u>Is Clinical Psychology Selling its Soul (Again)?</u>" (Clinical Psychology Forum: 2006:168:17-20):

"Trailing along for most of its career as a minor profession in the shadow of medicine, clinical psychology has often been tempted to sacrifice integrity to expediency.

"Since we cannot afford to discover that such treatment doesn't work, critical thought, genuine empirical enquiry and scientific detachment no longer figure seriously in our discourse.

"We found ourselves, following the Thatcherite counter-revolution, facing new masters. These were no longer clinicians, but business people looking to set up health services as profitable enterprises in which clinical activities are strictly supervised and controlled to conform to managerial aims.

"It is thus not surprising that many clinical psychologists overlook such notions as 'evidence-based practice'. In fact there is no reliable evidence base for much of what we do.

"It is even less surprising that many of us should react with excitement to the advice of Lord Richard Layard that clinical psychologist numbers should be dramatically increased in order to help deliver 'therapy for all on the NHS'. Layard's view was, after all, conceived within the Prime Minister's Strategy Unit.

"Richard Layard, we should remember, is an academic economist as well as New Labour peer, and acknowledged in his 2005 talk that 'I probably know less about mental health than anyone' in his audience. But then mental health is only indirectly his concern – much more important is reducing the number of those claiming state benefits.

"Layard seems to have dispelled any doubts his ignorance of mental health matters may have caused him by placing his reliance on the productions of the National Institute for Health and Clinical Excellence (NICE): their guidelines are downloadable from their website, as is their more recent advice on 'computerized cognitive behaviour therapy'.

"Layard concludes from his self-confessedly untutored examination of the NICE guidelines that the number of clinical psychologists should be doubled, operating from, and leading, psychological treatment centres set up country-wide on a 'hub-and-spoke basis'.

"The staff would operate under clear NICE guidelines relating to number of sessions, and patient progress would be monitored using a standard national system of recording completed at the beginning of each session (Layard 2005, p4).

"There is no doubt that the NICE guidelines come down heavily on the side of CBT.

"The kind of bureaucratized 'science' peddled by NICE is exactly the kind of thing a healthy and independent clinical psychology would criticize, not endorse.

"In many ways the guidelines make somewhat numbing reading, since they appear to wipe out almost everything the copious research into psychotherapy in the twentieth century seemed to establish about the uncertainty of the therapeutic enterprise.

"In their way they're masterpieces of pseudo-scientific bureaucracy.

"Their method is to proceed via a kind of algorithm of treatment recommendations, with the recommendations in turn being scrupulously backed up by recitation of the 'evidence base' that has been identified for them.

"What is striking about the evidence base is its near total reliance on mechanized research methodology together with a near total indifference to the actual content of the research.

"A kind of unholy alliance is built up involving the Cochrane Library and various limiting methodological requirements concerning control groups, double-blind trials, etc., which results in the virtually automatic churning out of 'results' that inevitably support the relative superiority of CBT.

"None of the factors that one had always taken as being important (in psychological therapies) receive any real consideration or influence the NICE evaluation of the so-called evidence.

"Huge reliance is placed on self-report questionnaires to indicate improvement or otherwise. Reflecting a total faith in mechanization, 'measurement' is everywhere and meaning nowhere; questions concerning reliability are mostly taken for granted while validity is on the whole simply not considered.

"This is in fact a strangely unhinged, make-believe world in which entirely hypothetical constructs are taken as pointing to valid entities in the real world.

"The NICE version of things may not be valid or remotely true, but it is certainly useful in enabling the central control and direction of professional activity, whether in research or practice. As you can imagine, it's also not uninteresting to those practitioners who stand to gain from its undisputed rule".

Smail quotes Roth and Stirling, who think that Layard may be a bit too enthusiastic about what CBT can achieve ('...there is a real risk that the efficacy of CBT is being over-sold'):

"The government will only be persuaded to move on the basis of hard-headed arguments, because this is—at the end of the day—an exercise in transfer of costs between departments, justified by a projection that this will be a cost-neutral exercise with major social benefit. It is for this reason that the rationale of offering evidence-based treatments of known efficacy is pragmatic, even if not completely consonant with clinical opinion (Roth & Stirling 2005, p 48).

"What all this amounts to is that we have lost any semblance—indeed any pretence—of pursuing scientific inquiry (into) what is true.

"This is almost classic in its near-phobic avoidance of considering anything that could possibly be construed as speaking the truth".

As noted above, this cogent and compelling evidence was certainly available to NICE in the year preceding the publication of its Guideline on "CFS/ME", but -- as with all the evidence that did not comply with current "policy" – it was ignored by NICE.

Another credible voice from within the discipline of Clinical Psychology that was also ignored by NICE is that of Craig Newnes. Newnes trained at the Boston Psychoanalytical Institute. His first Supervisor was Dr Dorothy Rowe. He has over 30 years experience and is Psychological Therapies Director for Shropshire Community and Mental Health Trust. He is editor of The Journal of Critical Psychology, Counselling and Psychotherapy and Clinical Psychology Forum, the practice journal of the Division of Clinical Psychology. He is Chair of the British Psychological Society's Psychotherapy Section. He has a life-time commitment to the NHS and is an outspoken critic of the hypocrisy, self interest, confusion and downright lies which characterise so much of the practise of psychiatry and psychology.

In an article in The Guardian (Brainwashed: 10th January 2002), Newnes was trenchant: "The truth is that, unlike all other doctors, psychiatrists do not do physical tests to confirm their diagnoses".

Indeed so; furthermore, in the case of ME/CFS it is Wessely School psychiatrists who have advised Government that no tests should be performed to confirm the diagnosis (in the 1996 Joint Royal Colleges' Report), thereby safeguarding their own beliefs about the nature of the disorder, since appropriate testing in other countries has yielded firm evidence that ME/CFS is not a somatistaion disorder. As Dr Derek Enlander (an ME patients' advocate and Physician-in-Waiting to the UK Royal Family when they visit New York) pointed out on 9th March 2008 to the Dean of the Royal Society of Medicine: "There is enough physical evidence over the past fifty years to show that this is a primary physical problem" (Co-Cure:10th March 2008).

Newnes continued: "We are also well aware of the massive conflicts of interest involved in studies that do finally appear in the official literature. Effective Health Care concluded: 'Most relevant trials are undertaken by those with clear pecuniary interest in the results'".

Again, this applies in ME/CFS, where the management regime recommended by NICE was formulated by Wessely School psychiatrists, Wessely himself being on the Board of the commercial company that is now delivering such regimes within the NHS.

In his paper "The implausibility of researching and regulating psychotherapy" (available at http://www.davidsmail.freeuk.com/implausibility.doc), Newnes says:

"Psychotherapy can neither be researched nor internally regulated outside the bounds of self interest.

"Even the concept of "outcome", so beloved by researchers, is nonsense.

"It just isn't possible to exclude all human variables. Computerized Cognitive Behaviour Therapy attempts to do just that, as if all potential clients are reasonably au fait with computer technology. We have no idea of what the outcome of such an encounter might be.

"Some of the less publicized research should not slip by us. For example, Eysenck (1952) surveyed nineteen reports on the results of psychotherapy (just over 7,000 patients). He went on to suggest that two thirds of people in distress amenable to psychotherapy spontaneously recover; about the same proportion who are said to benefit. A key finding was brushed under the carpet - in addition to a small percentage of clients claiming spectacular success for therapy, roughly the same proportion (5%) felt a lot worse. Many killed themselves.

"(CBT) is championed in the Layard report as a good way to get people back to work and off State benefit. Research into CBT is upheld as of the most sophisticated type and clearly indicative of success. I shall limit myself to critiquing one aspect of the research favoured by Government Quangoes of the Layard type. The critique is based, again, on the way self interest is revealed within the preferred methodology.

"Layard's report leans on the Department of Health's (2001) previous document, Treatment Choice in Psychological Therapies and Counselling. This earlier document categorises research based evidence as follows: meta-analysis, randomized controlled studies (RCTs), controlled studies, quasi-experimental studies, descriptive studies and "expert committee report on clinical experience". The first two, meta-analysis and RCTS, are regarded as the strongest guides to recommending State or insurance-based funding for therapy. It is possible to criticise such a hierarchy of approved methodology from virtually any perspective; recipient report is simply not mentioned (and) only vast academic and frequently drug company sponsored institutions can carry out meta-analysis or RCTs.

"The next part of the process, the expert consensus, is the supreme folly.

"The Layard panel manages to neglect a huge range of psychotherapy research.

"Layard and his colleagues don't address such awkwardness because the Report isn't about people feeling better. It's about claiming to get people back to work and off benefits.

"Therapists in Layard's brave new world become an arm of the state-serving bourgeoisie in a far more explicit way than before. In effect, they are paid by the State to make sure people remain cogs in the machine".

The quotations above come, not from any of the army of newly-recruited "therapists" who are being crash-trained to deliver production-line programmes that are dictated by current "policy", but from the work of experienced and distinguished Clinical

Psychologists, so it is disturbing that agencies such as NICE and the Medical Research Council so persistently ignore their wisdom.

In relation to ME/CFS, this persistent disregarding of the evidence by official bodies seems to permeate UK Departments of State and their agencies like a massive tectonic fault-line and it represents the difference between sound science based on objective evidence and the speculations of certain psychiatrists who, despite the weight of the scientific evidence, have become increasingly remote from the realities of the disorder. Undoubtedly, further activity along this fault-line will lead to legal challenges to both the NICE Guideline and individuals who persist in denying the validity of the biological evidence.