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Response to the NICE clinical guideline on depression

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The National Institute for Health and Clinical Excellence (NICE) this year updated the NICE clinical guideline for the treatment of depression in adults. The British Psychoanalytic Council, Association for Psychoanalytic Psychotherapy in the NHS, Anna Freud Centre, and Tavistock and Portman NHS Foundation Trust as a group contributed to the consultation, cautiously welcoming the draft, but disagreed with the way that NICE had assembled its evidence, favouring CBT at the expense of other psychological therapies.

Summary

- The NICE Guideline on Depression in Adults makes clear the complex nature of depression and its clinical and social importance.
- It highlights the important role of psychological therapies in the treatment of depressive disorders.
- It recognises the importance of maintaining a plurality of treatment and not withdrawing established psychotherapies.
- The scope of the guideline is limited by a narrow, undifferentiated and simplistic conception of depression. It unhelpfully restricts itself to randomised controlled trials, and excludes naturalistic trials despite their advantages in assessing psychotherapeutic treatments and treatments in the real world.
- The evidence of the lasting effects of long-term psychotherapy in depression is not reviewed despite the evidence that depression is frequently chronic or recurring and the evidence of the limited effect of short-term treatments.
- The guideline fails to consider the importance of individual patient preferences or different types of depression, leading to restrictive and misleading one-size-fits-all recommendations.
- The evidence presented, in keeping with the scientific literature, demonstrates equivalence between Cognitive Behavioural, Interpersonal, and Short Term Psychodynamic Psychotherapies.
- The guideline misleads by recommending CBT based on the number of studies supporting it.
- CBT for depression provided through the Improving Access to Psychological Therapies services has not to date shown itself more effective or acceptable to patients in the real world than non-CBT therapies.
- There is an urgent need for well-funded trials to explore if those who do not respond to CBT can benefit from other forms of treatment including psychodynamic psychotherapy and the extent to which long-term treatments have superior outcomes in the medium or long-term.

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. It publishes guidance which aims to ensure that the promotion of good health and patient care in local health communities is in line with the best available evidence of effectiveness and cost effectiveness.

In 2004 NICE published *Clinical Guideline 23 on Depression: management of depression in primary and secondary care*, as a full guideline and a condensed NICE clinical guideline (NICE, 2004). NICE has published a separate guideline on *Depression in Children and Young People* (NICE 2005). Further guidelines on *Depression in Chronic Health Problems and Anxiety and Depression* are in progress.

As part of a planned updating process in February 2009 NICE published draft revisions of the full guideline (NICE, 2009a) and condensed clinical guideline (NICE, 2009b). NICE has now published its partial update, Clinical Guideline 90 (NICE 2009c, d, e).

The revision rightly emphasises the complex nature of depression and its importance, highlighting the central importance of psychological therapies in the treatment of depressive disorders:

- That depression is a 'heterogeneous group of related disorders' (NICE 2009c, p13)
- That 'incomplete recovery and relapse are common' (p15).
- That when depression persists or recurs after treatment it is important to consider which 'psychosocial factors may be preventing recovery' (p16)
- That 'the impact [of depression] on social and occupational functioning, physical health and mortality is substantial' (p17).
- 'Emotional, motivational and cognitive effects substantially reduce a person's ability to work effectively, with losses in personal and family income as well as lost contribution to society in tax revenues and employment skills. Wider social effects include: greater dependence upon welfare and benefits with loss of self-esteem and self-confidence; social impairments, including reduced ability to communicate and sustain relationships during the illness with knock-on effects after an episode; and longer term impairment in social functioning, especially for those who have chronic or recurrent disorders' (p17).
- 'Depressive illness causes a greater decrement in health state than the major chronic physical illnesses angina, arthritis, asthma, and diabetes' (p17)
- 'Nearly two-thirds of [suicides] occur in depressed people' (p17).
- 'Marital and family relationships are frequently negatively affected, and parental depression may lead to neglect of children and significant disturbances in children' (p17).
- That depression has important social origins (p18).
- That subthreshold depression is of great importance (p18).
- 'Early life experiences such as a poor parent–child relationship, marital discord and divorce, neglect, physical abuse and sexual abuse almost certainly increase a person's vulnerability to depression in later life (p21).
- 'Personality traits such as 'neuroticism' also increase the risk of depression when faced with stressful life events' (p21).
- 'The role of current social circumstances in increasing the risk of depression, such as poverty, homelessness, unemployment and chronic physical or mental illness cannot be doubted even from a brief examination of the epidemiology of depression… social vulnerability factors for depression in

women in Camberwell, South-East London, included: having three or more children under the age of 14 years living at home; not having a confiding relationship with another person; and having no paid employment outside the home. Lack of a confiding relationship appears to be a strong risk factor for depression' (p21).

- 'Less than half of treated patients achieved full remission and sustain it over a period of 2 years following treatment' (p142).

The guideline emphasises the complex nature of treatment decisions and the limitations of the evidence base for the psychotherapeutic treatment of depression,

- ...symptom counting ... and ... symptom severity rating scales by themselves should not be used to make the diagnosis, although they can be an aid in assessing severity and response to treatment. (p19).
- That making 'a diagnosis of depression does not automatically imply a specific treatment' (p20)
- That 'it is also common for depressed people to a have co-morbid psychiatric diagnosis, such as anxiety, social phobia, panic and various personality disorders, and physical co-morbidity' (p20), to which one should add substance misuse
- 'Choice of treatment is a complex process and involves negotiation and discussion with patients, and, given the current limited knowledge about what factors are associated with better antidepressant or psychotherapy response, most decisions will rely upon clinical judgement and patient preference until we have further research evidence. Trials of treatment in unclear cases may be warranted but the uncertainty needs to be discussed with the patient and benefits from treatment carefully monitored' (p20).
- That 'guidelines are not a substitute for professional knowledge and clinical judgement' and that 'there will always be some people and situations for which clinical guideline recommendations are not readily applicable. This guideline does not, therefore, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual, in consultation with the person with depression or their carer' (p9), and that 'a good therapeutic relationship is at times as important as the specific treatments offered' (p10).

The guideline recognises the importance of maintaining a plurality of treatment and not withdrawing established psychotherapies:

- 'Where established therapies are not recommended, this does not necessarily mean that the withdrawal of provision from the NHS is endorsed but may suggest the need for further research to establish their effectiveness or otherwise' (p142).

However, the guideline and its proposed implementation through IAPT centres have been criticised by third sector mental health providers, psychoanalytic practitioners, and CBT researchers, as being flawed and unworkable. The Mental Health Providers Forum (MHPF 2009), for example, representing 36 third sector mental health providers, shared our concerns about the methodologies and limited range of studies used by NICE.

Misrepresentation of results

The guidelines recommend that high intensity psychological treatment for moderate depression should be CBT or IPT (or in some circumstances behavioural activation or behavioural couples therapy). If antidepressants, CBT, IPT, behavioural activation or behavioural couples therapy have been declined then the guideline allows that:

'short-term psychodynamic psychotherapy might still be considered... but that the limited evidence should be drawn to the attention of the healthcare professional [sic].' (NICE 2009c p249-250).

In the the Quick Reference Guide clinicians are instructed to:

'Discuss with the person the uncertainty of the effectiveness of counselling and psychodynamic psychotherapy in treating depression.' (NICE 2009e p16)

The evidence presented in the Full Guidance demonstrates 'no clinically important differences' between cognitive behavioural therapy, interpersonal psychotherapy, short-term psychodynamic psychotherapy and brief supportive counselling, behavioural activation or GP treatment as usual. (NICE, 2009c, Full Guidance p199-200).

'**The evidence indicates no clinically important differences for the comparison of CBT with short-term psychodynamic psychotherapy in decreasing depression** (BDI at endpoint SMD -0.35; 95% CI -1.30, 0.61) **or with Gestalt psychotherapy** (BDI at endpoint SMD 0.17; 95%-0.56, 0.91). **From this evidence it is not possible to draw any clear conclusions about the relative efficacy of the treatments**.' (p198-199)

'**Again, there were no clinically important differences between CBT and IPT** (BDI at endpoint 0.21; 95% CI -0.01, 0.41; HRSD at endpoint 0.13; 95% CI -0.06, 0.32). **This evidence although limited suggests that IPT might be as effective as CBT in the treatment of depression**.' (p198)

'**There were no clinically important differences identified between CBT and behavioural activation** (BDI at endpoint 0.34; 95% CI -0.26, 0.95; HRSD at endpoint -0.03; 95% CI -0.62, 0.57). **From this evidence it is not possible to draw any clear conclusions about the relative efficacy of the treatments**.' (p198)

'**Three trials reported in the previous guideline included a comparison between CBT in primary care versus usual GP care**. The studies varied in duration: Freeman2002 consisted of 16 sessions over a 5-month period, Scott1992 was of 16-week duration and Scott1997 was of 6 weeks. **In terms of leaving the study early due to any reason, the evidence suggests that there is a higher risk for discontinuation in those in the CBT (primary care) group** (RR 1.54; 95% CI 0.97 to 2.46). The evidence here is difficult to interpret as many patients in GP care may have been in receipt of anti-depressants and the duration of treatment was shorter than that typical of CBT. **At end of treatment self-report depression scores** SMD 0.01 (-0.83 to 0.85) **were not significantly different as were clinician rated depression scores** SMD -0.33 95% CI (-0.74 to 0.08).' (p199)

It is important to note that the evidence base for STPP is extensive, far more extensive than the limited number of studies included in NICE's review of the evidence, but that many trials of STPP were excluded on questionable grounds (see below).

In this respect the analysis is consistent with other large meta-analyses. E.g. Cuijpers *et al*. (2008) analysed 53 RCTs and concluded that all short-term psychological therapies were equally efficacious with the exception of IPT, which was marginally

more efficient and non-directive supportive treatment was marginally less effective. The authors concluded that there was no large difference in the efficiency between the major psychotherapies for mild to moderate depression. The authors also reviewed earlier comparisons of CBT and other short-term psychotherapies and found no evidence of difference after controlling of investigator allegiance. The guideline cites Elkin (1989) as also finding no difference between CBT and IPT, however this is a misrepresentation, the study reported that 'Comparing each of the psychotherapies with the placebo plus clinical management condition, there was limited evidence of the specific effectiveness of interpersonal psychotherapy and none for cognitive behavior [sic] therapy.' (p971). However other studies do report finding no evidence of differences between different short-term psychotherapies: Wampold *et al*. (1997), Robinson *et al*. (1990), Churchill *et al*. (2001) found that less severely affected individuals (self-selected patients and volunteers) appeared to benefit more from CBT, but that among the more severely affected (individuals attending psychiatric outpatients and the more severely depressed) there was no difference between groups.

The evidence reviewed by NICE provides support for the 'equivalence paradox' that different short-term psychotherapies are equally effective, at a global level and in the short-term, in a range of neurotic conditions. The equivalence paradox has survived over thirty years (Cuijpers et al. 2008) and has recently been confirmed in a large outcome study in the NHS (Stiles et al 2008).

In moving from evidence to recommendations (section 8.9.8) the final guideline (NICE 2009c) states 'With 46 studies, cognitive behavioural therapies have the largest evidence base' (p245). Later this becomes: 'CBT has the best evidence base for efficacy but it is not effective for everyone' (p253). In commenting on the decision to withdraw the previous recommendation for psychodynamic therapy, the draft guideline comments that the decision 'was influenced by contextual changes in the NHS including the significant increase in evidenced based psychological interventions [guided self help and CBT] made available through the IAPT [Improving Access to Psychological Therapies] programme' (NICE 2009a, p196); this comment is dropped from the final version.

It is important not to confound number of trials with what the trials show. The purpose of systematic reviews is to carefully weigh up what the evidence actually shows, not simply count the trials and go with the most voluminous evidence. Evidence based recommendations should be based on what the trials show, not the number of trials.

That the Guideline Development Group was influenced to drop the recommendation for psychodynamic psychotherapy on the grounds of the greater availability of guided self help and CBT through IAPT reveals circular thinking (we'll recommend it because it's available) and a disregard for scientific evidence that should have no place in an evidence based guideline.

Saying that the evidence is limited, or uncertain, after a partial review of the evidence (see below), and a review that nonetheless found 'no clinically important differences', is misleading.

Through 'vote counting', misrepresenting the data, and circular thinking, recommendations are made which will be widely misinterpreted as showing that CBT and IPT are superior treatments, whereas in reality the guideline demonstrates 'no clinically important differences' between the short-term psychological therapies reviewed.

The problem of considering depression as a unitary disorder

Given that the complexity of depression has been thoroughly recognised in the preamble to the guideline it is inconsistent that the guideline goes on to treat depression as if it were a single homogeneous condition, distinguished only by degrees of severity, with the diagnosis based on symptom counts, and ignores the importance of social origins, co-morbidity, psychosocial factors that may prevent recovery, relationship difficulties or effects on children. The guideline does not adequately distinguish between depression as a symptom, syndrome, or the spectrum of neurotic and personality difficulties and disorders (McQueen in press).

The validity of the diagnosis of depression as a unitary concept is not supported by epidemiology, phenomenology or genetics (Cole *et al*. 2008). Depression and related neurotic conditions; generalised anxiety disorder and obsessive-compulsive disorder do not occur independently of each other. They do not have their own particular aetiology. They do not respond only to specific treatments acting on pathological processes specific to the presumed disorder. And they commonly change over time, with the features of depression, anxiety, phobic or obsessive-compulsive disorders alternating (Goldberg & Goodyer, 2005, Tyrer, 1985; Tyrer *et al*. 2003; Taylor, 2008). Most patients with clinically significant depression meet the criteria for several different symptom-based diagnoses and have to cope with many additional suboptimal functions of the personality (Westen *et al*, 2004). Only a minority satisfy the criteria of only one diagnosis: patients meeting criteria for major depressive disorder are nine times more likely than chance to meet the criteria for other conditions (Angst & Dobler-Mikola, 1984); 50–90% of patients with Axis I conditions also meet the criteria for other Axis I or Axis II disorders (Westen *et al*, 2004). A large epidemiological study found that 72.1% of a community sample of adults with depression had co-morbid axis I or II disorders; 59.2% had anxiety disorders, 24.0% had substance use disorders, and 30.0% had impulse control disorders (Kessler *et al*. 1993). Others have reported that 48% of those with depression have generalised anxiety disorder (GAD), and 72% of those with GAD have depression (Moffitt *et al*. 2007).

It follows from the lack of differentiation of depressive disorders in the guidance that there is no recognition that CBT may be counterproductive in some sub-types of depression (Casement, 2009). Personality disorders have been found to have a negative prognostic impact on depressive disorders (Gunderson *et al*, 2004; Shea *et al*, 1990). For example, the rate of remission of Mood Disorder is significantly reduced by co-occurring Borderline Personality Disorder (BPD) (Gunderson *et al*, 2004). Improvements in BPD will be more often followed by improvements in the Mood Disorder. For this reason it is recommended that clinicians should primarily treat the personality disorder (Gunderson *et al*, 2004).

Despite the recognition of the importance of diverse aetiological factors in the preamble (p20), these are lacking from the treatment guidance. An understanding of developmental psychopathology should inform the understanding and treatment of depression in adults (e.g., the special edition of Development and Psychopathology, 1992, vol. 4). For some (perhaps many) individuals presenting with feelings of unhappiness, unworthiness, and so on, there is a need to promote

development *through* the maladaptive relationships and emotional difficulties with which they present (Balint, 1968; McQueen *et al*, 2008; Hall & Marzillier 2009).

Patients with depression who have experienced early relational trauma have differential responses to treatment for depression (Nemeroff *et al*, 2003) (and molecular and functional brain changes (McGowan *et al*, 2009). CBT and antidepressants may have at best limited contributions in this regard but the recommendations overlook these factors.

Individuals with a weaker sense of their own subjectivity, such as those who have received a diagnosis of borderline personality disorder, find it harder to compare the validity of their own perceptions of the way their mind works with the explanations and models that a 'mind expert' (clinician) offers. Both cognitively based and dynamically orientated therapies can give ready-made answers and provide illusory stability by inducing a process of pseudo-mentalisation in which the patient takes on the explanations without question and makes them his/her own. Conversely, both types of perspective can be summarily and angrily dismissed as overly simplistic and patronising, which in turn fuels a sense of abandonment, feelings of isolation and desperation (Fonagy & Bateman, 2006). Without reference to these potential complexities the guideline may inadvertently encourage simplistic formulations for treatment.

A single disorder guideline for depression is clinically artificial and of questionable clinical use.

The need for guidelines on the treatment of mixed disorders

In clinical practice most treatment-seeking patients with 'depression' have comorbid neurotic disorders, personality disorders, and or substance misuse. This, coupled with the questionable utility of depression as a unitary diagnosis, suggests the need for research and guidelines on how to treat the actual patients that seek treatment, with a range of complexity, comorbidity and aetiologically diverse conditions that feature depression. Trials using patients with 'pure' depression, or depression without comorbidity are unrepresentative and less unwell than patients with comorbidity, these patients are likely to have better outcomes because of their less severe conditions consequently trials with patients with 'pure' depression risk overstating the benefits of treatment.

The guideline refers to several systematic reviews and meta-analyses which show both that STPP is effective for mixed and common mental disorders, and that there is no evidence for superiority of either CBT or STPP (Abbas, 2002, 2006; Abbas et al, 2006; Cuijpers et al, 2008; Knekt et al, 2004, 2008a, 2008b; Leichsenring, 2005; Leichsenring et al, 2004), but then excludes them from consideration because they do not deal with pure depression. A further government sponsored systematic review of brief psychotherapy for depression that also found no evidence of superiority (Churchill *et al*, 2001) was not included.

However looking at 'common mental disorders' has greater validity and gives a better indication of effectiveness than studies with high homogeneity but which do not reflect the complexity of patients encountered in primary l*et al*one secondary care. (Leichsenring, 2004; Black, 1996; Geddes, 2009; Bagshaw & Bellomo, 2008; Grossman & MacKenzie, 2005; Blair, 2004).

We note inconsistency in that the guideline includes health economic studies for computerised CBT in mixed anxiety and depression (NICE 2009c p158). This makes the decision to exclude such mixed studies from the clinical review in the case of dynamic therapies more questionable.

The importance of patient preference and choice as opposed to imposition of stepped care

Patient preferences and strength of preference have been shown to have a significant influence on whether patients take up treatment and complete it (Raue *et al*, 2009). Raue *et al*, (2009) argue on the basis of the importance of strong preferences that if a patient has a strong treatment preference they should be offered that treatment so as to reduce non-take up and discontinuation.

The 'stepped care' model proposed is unproven as a method of providing psychological therapies, (Bower *et al* 2005). In practice stepped care does not appear to function well, at the Doncaster Improving Access to Psychological Therapies (IAPT) pilot site where the stepped care protocol was applied 47% of patients dropped out before the second appointment (Clark *et al*, 2008, p12-13). This will be discussed further below when considering the evaluation of IAPT.

Individual factors – Tailoring treatment: The Guideline does not address the primary clinical goal of deriving a formulation explaining the predisposing, precipitating, perpetuating and protective factors that give rise to the form of depression in that individual patient and choosing treatment which reflects careful tailoring of treatment towards what is specific to the individual patient and the issues the patient feels are relevant. This cannot be addressed based on the restricted types of evidence admitted by the Guideline Development Group.

These are commonplace diagnostic challenges for clinicians. The Guideline (p 8) stresses that guidelines are not a substitute for professional knowledge and clinical

judgement. However, the political reality is that they do shape management practice in a way that often precludes the application of clinical judgement (e.g., in determining what treatments are not available – see IAPT below).

The guideline limits patient choice by offering only restricted options; antidepressant drugs or CBT, IPT, or possibly behavioural couples therapy and that psychodynamic psychotherapy should only be available after 'failing' or refusing other treatments. This is not evidence based or respectful of patient choice.

Limitations of a short-term perspective on a chronic disorder

Short-term trials for a chronic disorder: The guideline recognises that 'Less than half of treated patients achieved full remission and sustain it over a period of 2 years following treatment' (p142). However the majority of studies reviewed only have short follow up periods, which give little indication as to how the treatment may affect relapse rates. The range of follow up periods among the trials of CBT ranged from 2 months to 24 months. Among the trials of STPP the range was 3 months to 48 months.

The guideline states that 'for patients in remission who did not relapse during follow-up, it was assumed that no further additional treatment or mental health care resources beyond the 6-month maintenance period were required' (p232). This lacks credibility given the long-term and relapsing nature of depression after short-term treatments.

This reliance on short term trials resulted in the economic analyses being based on only six months of follow up: when cost modelling 'a time horizon of 15 months was chosen to reflect the available comparative clinical evidence. This included 3 months of the initial therapy, followed by 6 months maintenance therapy and 6 months follow-up' (p230). It is questionable how useful this short-term analysis is in evaluating treatments of a long-term disorder.

Other research confirms the need to take a long-term perspective on depression: In clinically significant depression the natural course of the condition is often prolonged, relapsing or recurrent (Surtees & Barkley, 1994). After a first episode of depression only 50% remain free from depression over 23 years of follow up. The figure would be lower if it included cases with recurrent depression (Eaton *et al*, 2008). Ninety

percent of people having three episodes of depression will experience recurrences (Gelder *et al*, 2001). At one year follow-up about 60% of those treated with drugs still meet criteria for caseness (Goldberg *et al*, 1998).

Some evidence exists which suggests that in the longer term psychodynamic psychotherapies may lead to late improvements; e.g. Snyder *et al*, (1991) found large differences in four-year follow-up data regarding marital status and marital accord for 59 couples receiving either behavioural (BMT) or insight-oriented (IOMT) marital therapy in a controlled outcome study. Although no significant group differences had been observed between the 2 treatment conditions at either termination or 6-month follow-up, by 4-year follow-up a significantly higher percentage of BMT couples had experienced divorce (38% for BMT couples compared with 3% for IOMT couples).

Erosion of benefits of CBT: Recent government-sponsored research into the long-term effects of CBT used in the treatment of anxiety found that the positive effects of CBT identified in the original trials were eroded over a period of two years. No evidence was found for an association between more intensive therapy and more enduring effects of CBT. The cost-effectiveness analysis showed no advantages of CBT over non-CBT (Durham *et al*, 2005).

Short-term psychotherapies have large effect sizes in the short term, comparable to or greater than medication, and depressed individuals treated with short-term psychotherapy are likely to 'recover' from depression after receiving psychotherapy. However even after receiving short-term psychotherapy for depression, individuals still have considerably lower mood and considerably more depressive symptoms than does the general population. Robinson et al (1990) compared studies of short-term psychotherapy for depression and found that before treatment depressed subjects scored on average 21.8 on the Beck Depression Inventory (BDI), after treatment the average BDI score was 11.8, however in the general population (matched for age and gender) the mean BDI score was 7.0, and in the population free of mental health difficulties the mean BDI score was 4.9.

Long Term Psychotherapy: Given that depression is recurrent or chronic in the majority of individuals and the limitations of short-term treatments it is surprising that there is no consideration in the guideline of the role of long term psychotherapy. Especially given that there is a considerable evidence base for long term psychotherapy. Short-term psychotherapy is sufficiently effective for most subjects suffering from acute distress, but insufficient for a considerable proportion of patients with chronic mental disorders or personality disorders. According to Kopta *et al* (1994), (p.1014, Figure 2), about 70% of the patients with acute distress were rated as clinically significantly improved after 25 sessions. For patients with chronic distress, this was true for about 60%. However, for patients with characterological distress, i.e., personality disorders, the same data suggest that after 25 sessions only slightly more than 40% of the patients are clinically significantly improved. More than 52 sessions are required for about 50% of these patients to be clinically significantly improved. Perry *et al* (1999) estimated the length of treatment necessary for patients with personality disorder to no longer meet the full criteria for a

personality disorder (recovery). According to these estimates, 50% of patients with personality disorder would recover by 1.3 years or 92 sessions, and 75% by 2.2 years or about 216 sessions (Perry *et al*, 8, p. 1318). According to these data, the majority of patients with acute distress benefit significantly from short-term psychotherapy, whereas for patients with chronic distress and personality disorders, short-term psychotherapy is not sufficient. This is true of psychodynamic therapy, and of psychotherapeutic approaches that are usually short-term, such as CBT (Linehan *et al*, 2006; Linehan *et al*, 1994; Giesen-Bloo *et al*, 2006).

There is good evidence that long term psychodynamic psychotherapy has superior results to short term psychotherapy in patients with complex, or co-morbid disorders. These results are clinically and statistically significant, both in RCTs (Leichsenring & Rabung, 2008) (Knekt *et al*, 2008) and observational studies (Knekt *et al*. 2004, 2008a, 2008b; de Maat *et al*, 2009) with no difference between observational studies and RCTs (Leichsenring & Rabung, 2009). Long-term psychodynamic psychotherapy produces enduring changes in personality functioning (Bond & Perry, 2004; de Maat *et al*, 2009; Fonagy, 1999; Clarkin *et al*, 2007). It is regrettable the updated guideline has dropped a previous recommendation for consideration of long-term psychodynamic psychotherapy, and risks removing provision for those patients who may need this treatment, as well as unjustifiably restricting patient choice.

The need to consider effectiveness and observational trials alongside RCTs and efficacy trials

Randomised Control Trials and observational studies: 'RCTs are simply experimental tools used to test hypotheses — they are not well designed to assess clinical effectiveness' (McAllister-Williams, 2008, p67). RCTs face particular problems in assessing complex interventions where there may be multiple 'active ingredients' and patient preferences may influence outcome (MRC, 2000). It is widely disputed that RCTs represent the highest form of evidence for psychotherapy. In psychotherapy particularly randomisation may reduce the validity of the intervention. Naturalistic studies may be a more valid means of assessing the effectiveness of psychotherapy in the real world (Leichsenring, 2004). Randomized clinical trials test a somewhat artificial treatment in an artificially controlled setting with atypical patients, so they have reduced generalisability to the real world of mental health care delivery (Ablon & Jones, 2002; Bagshaw & Bellomo, 2008; Black, 1996; Blair, 2004; Geddes, 2009; Grossman & MacKenzie, 2005).

The guideline development group would do well to heed the advice of NICE's own chair Michael Rawlins, who has criticised the 'undeserved pedestal' that RCTs occupy (Rawlins, 2009) and quotes Bradford Hill, the architect of the RCT: 'Any belief that the controlled trial is the only way would mean not that the pendulum had swung too far but that it had come right off the hook' (Hill, 1965).

RCTs test what happens at the level of populations, not individuals. They are based on a statistical abstraction of what happens in the 'population' with that diagnosis. RCTs only apply to individuals in a probabilistic way, that is in so far as one can extrapolate from the hypothetical statistical population to the concrete individual with his or her

idiosyncrasies and individual history. Individuals all differ from the population mean, and therefore respond differently from the 'average' (McQueen, 2009).

CBT, IPT and psychodynamic psychotherapy have all already proved their efficacy in RCTs. It is therefore appropriate that the guideline consider effectiveness and naturalistic studies to assess how well these psychotherapies function in the real world of NHS practice, with patients who in the majority have complex and co-morbid conditions.

In any case it has been shown empirically that high quality observational studies which use observational control groups do not systematically differ to RCTs in general medical conditions (Concato *et al*, 2000) and in trials of long-term psychotherapy (Leichsenring & Rabung, 2009).

Both CBT and STPP have demonstrated efficacy in RCTs as reviewed in the draft Full Guidance, however once efficacy is proven evidence of effectiveness is required. Several reviews that confirm the effectiveness of STPP in RCTs in real world mixed settings exist (Abbas, 2002; Abbas, 2006; Abbas *et al*, 2006; Cuijpers *et al*, 2008; Knekt *et al*, 2004, 2008a, 2008b; Leichsenring, 2005; Leichsenring *et al*, 2004). However they were excluded because of their clinical heterogeneity (NICE 2009a, p145-146), precisely the attribute required for establishing effectiveness in the real world.

The results of two (non randomised) observational outcomes studies of psychotherapy in the real world of the NHS, highly relevant for this guideline, and again showing similar effectiveness of different short-term psychotherapies, were not included (Stiles et al 2006, 2008).

Other issues

Use of the term evidence based: Section 6.1.2 states that 'for a therapy to become evidence based it typically passes through several phases of treatment development' and then goes on to argue, via an hourglass metaphor, a set of normative stages in the development of a new treatment (p125). Whilst this may describe some aspects of the development of CBT, there is no scientific justification for this prescription. It is unscientific and misleading to assert that only treatments that have evolved through these stages are evidence based. Any treatment that has evidence of effectiveness is, in a straightforward sense, evidence based, even if some of the mechanisms of the treatment remain obscure or debated. This is the case for many pharmacological treatments and physical treatments such as ECT. Indeed this is also the case for CBT; see for example Jones *et al*, (1993).

The repeated labelling of CBT as evidence based and psychodynamic psychotherapy as not is unscientific, devalues the meaning of the terms and amounts to little more than spin.

Branding of psychotherapies: There is no discussion of the empirical separation of the different 'brands' of psychotherapy compared in the guideline, which has been shown to be limited (Ablon & Jones, 1998). Specifically there is no mention of the important work of the NIMH treatment of depression collaborative research program demonstrating 'that cognitive behavior [sic] therapists occasionally used psychodynamic strategies and that it was these techniques that were responsible for promoting patient change' (Jones *et al*, 1993) and that relying on brand names of therapy can be misleading and that patient in-session characteristics were far more important correlates of outcome than treatment type (Ablon & Jones, 2002).

Health Economic Evidence review and considerations: The restriction to only consider studies of cost effectiveness conducted in the UK is scientifically unjustified, overly restrictive and leads to the exclusion of many important studies e.g. Abbas (2002, 2003, 2006).

Improving Access to Psychological Therapies

There is a close relationship between the NICE guidance on depression, with its enthusiastic endorsement of CBT and the IAPT initiative. IAPT evolved out of *The depression report: A new deal for depression and anxiety disorders* (Centre for Economic Performance, 2006), sometimes referred to the Layard report, after its principle author, the economist Richard Layard. It is important to note, however, IAPT is intended to be an evolving programme.

The economic rationale behind the depression report was to get people on long-term sickness benefits with depression and anxiety off benefits and back into work, through short courses of CBT. The Depression Report made ambitious claims for the efficacy of CBT in depression and anxiety: 'The typical short-term success rate for CBT is about 50 per cent.' And 'After recovery, people who suffered from anxiety are unlikely to relapse.' (p6) These claims need to be seen in the context of translating from trials to real world settings where epidemiological evidence tells us co-morbid presentations will prove to be the norm in IAPT.. The economic analysis advanced in the Depression Report was that treating those on sickness benefits for depression and anxiety with CBT would lead to some of those numbers returning to work so that the cost of the service would be 'fully offset, of course, by rapid savings to the Department of Work and Pensions and HM Revenue & Customs.' (p11)

A stated aim of IAPT is to implement NICE guidance for depression (and anxiety). It is therefore relevant to consider briefly the results of the Initial Evaluation of the Two Demonstration Sites for the pilot phase CBT service models for IAPT (Clark *et al*, 2008).

At Doncaster GPs were asked to refer patients with at least moderate depression 'except those with a history of repeated treatment failure, psychotic features, personality disorder, primary drug/alcohol problems, or significant risk.' And 'all patients with GAD [generalised anxiety disorder] panic disorder (with or without agoraphobia), simple phobias, social phobia, and health anxiety, except those with significant suicide risk or who have failed to respond to at least 3 interventions' (p5).

It was found that 47% dropped out before the second session (p12-13). Fifty three percent were described as 'treated' after 2 or more sessions, however the methodology (in NICE's terms) is of poor quality, ignoring those who drop out of treatment (it is a 'survivor analysis' and is therefore biased toward selecting good outcomes and inflating effect sizes) there is no intention to treat or sensitivity analyses, and as such the results may be not be attributable to the effect of the interventions, rather they may be a result of drop out. The tools used for diagnosis and monitoring therapy (the nine item Patient Health Questionnaire (PHQ) and seven item Generalized Anxiety Disorder Questionnaire (GAD)) are screening tools, neither are designed or validated as diagnostic tools or for measuring treatment response, which limits comparability of outcomes.

NICE recommendations for the stepped care management of depression indicate that patients who fail to respond at step 2 care should be offered a move to step 3 where 'CBT is the psychological treatment of choice' but therapists could also 'consider interpersonal psychotherapy (IPT) if the patient expresses a preference for it or you think the patient may benefit from it'. Interpersonal therapy was not available in Doncaster IAPT so there was no choice. Of the 1603 that had any of the step 2 interventions, 34 also had step 3 CBT, while 1569 did not. This gives a step-up rate of 2.1%. There is no investigation of why 98% did not progress to individual CBT, but it is possible that some of these patients may have been disaffected by what they received and disengaged. If so, it represents a wasted opportunity.

It is reported that out of the 4451 referrals to the Doncaster IAPT over 13 months 66 people per month were referred on to the various PCT counselling services (p.16). This gives a referral rate to counselling of 19% (13x66/4451). It is interesting to compare the step up rate of 2.1% to stage 3 CBT at Doncaster with the 19% of referred patients who were referred on to PCT counselling services. Although it is recognised that referral on to counselling is a form of stepping-up, albeit one outside of the stepped care protocol recommended by NICE, the figures for referrals to counselling are not presented as part of the overall step-up rate. These figures suggest that step 3 CBT may be less well suited to the needs of the patients referred to IAPT than counselling provided through the PCT counselling services.

Psychological outcomes at Doncaster were based on verbal answers to the GAD and PHQ at the start of each session given to the case manager. Based on this the authors concluded that 56% had recovered by the time they left the system. It is important to note that this is a post treatment assessment and a survivor analysis and is therefore biased toward good outcomes.

A follow up survey was conducted at three months after the end of treatment. The

response rate was low at 51%. The authors claim that 50% were still 'recovered', but given the low response rate this figure must be treated with caution. At follow up employment figures showed a net increase in benefit receipts of 2.4%. There was an increase of numbers going to work of only 1 person (out of 452 responders) that was matched by a reduction of one among those receiving statutory sick pay (SSP). The total number with jobs (i.e. employed whether or not on SSP) remained constant. Again it is worth noting that this is a 'survivor analysis' and may inflate good outcomes, which 2nd-phase IAPT services might then struggle to replicate.

The Newham site differed in that it saw a broader range of common mental health conditions and the data was presented differently. Here 33% dropped out before the second session. Nonetheless it is claimed based on answers given by patients to their case managers on the PHQ and GAD that 55% had recovered after two or more sessions.

Among people who concluded treatment and attended 2 or more sessions, the net increase of people at work corresponded to 10% of the treated population. This increase came mainly from reducing numbers receiving Statutory Sick Pay (a decrease of 6%), and a decrease in numbers in the 'other' category (not employed, and not receiving benefits or SSP) of 4%. However this was pre to post treatment, not to follow up, looking at the figures differently SSP fell from 10 to 2 post treatment, out of 72 with jobs pre treatment. The number with jobs (SSP and at work) rose from 67 to 72 = 5/135 =3.7%. However given that 33% dropped out, these results also need to be treated cautiously.

The response rate to the three-month follow up study at Newham was 36% (60 responses), which is very low. At follow up the authors claim that 42% remained 'recovered', however given the very low response rate it is difficult to attach meaning to this. With regard to employment in the follow-up survey, there was a net increase in numbers employed of three. The net drop in benefit receipt was one. There was a net increase in numbers receiving Statutory Sick Pay of two. Again the results should not be attributed to the effects of the interventions without caution as a result of drop out and the low response rate.

It is too early to say whether IAPT is going to fulfil the expectations set out in the Depression Report. The challenges outlined above illustrate the difference between efficacy studies, as used in the Depression Report, and effectiveness studies such as the review of the outcomes from the IAPT pilot sites.

IAPT will be most likely to meet these challenges and achieve good outcomes if it can gain widespread support among psychotherapy practitioners. But the perception, at least, amongst many non-CBT practitioners, and some CBT practitioners, is that NICE and IAPT are combining to systematically devalue all other approaches.

The risks presented by uncritical enthusiasm of proponents of CBT and/or IAPT have led to concern among practitioners of CBT themselves. Writing in *The Psychologist*, Marzillier and Hall (2009) respond to IAPT:

> 'there is one major drawback – it won't work.' 'when the dust settles and it is realised that CBT is not the panacea it has been made out to be, there may well be a backlash against all psychological therapies.' 'Those with mild to moderate problems are the ones who will respond best to CBT or a similar therapy. Only a minority of those with more serious and complex problems – who are likely to be

those on long-term incapacity benefit – will benefit from that approach alone, and many will need something different from short-term, specific treatments designed to alleviate symptoms.' 'What concerns us with the Layard analysis is the way this complexity has been glossed over to arrive at general conclusions that seem superficially plausible but in reality are not. The attraction may be that at last the value of psychological therapy is recognised and serious money made available for it. But if the basis for this expansion is flawed, there will be trouble ahead. If the equations do not work, there may well be a backlash as the new breed of psychological therapists fails to deliver what it promises and the cost savings predicted by Layard do not materialise.' 'The worry of the IAPT programmes is that people are being trained to work in one particular way (as CBT therapists) with the result that managers think this is the only way. Put crudely, the message is that most mental health problems will be 'solved' if we train enough [CBT] therapists. This should be exposed for the nonsense it is.' 'We reject the one-size-fits-all, techniques-driven approach in favour of the virtues of initial psychological assessment, careful formulation and offering patients a range of options, amongst which therapy, CBT or otherwise, is just one.'

It is worth quoting these not to fuel concern or take sides in the argument, since any judgements about IAPT are premature, but to draw attention to increased risks from mutually reinforcing assumptions in the NICE guideline. If **assumed** superiority of CBT, not supported by evidence, were to prevent redesign or experiment with second and third phase IAPT models, this would stifle further development and innovation.

Summary and conclusion

The revision of the NICE guideline on the treatment of depression is to be welcomed for making clear the complex nature of depression and its importance. It rightly highlights the central importance of psychological therapies in the treatment of depressive disorders and their effectiveness. However the guideline limits its utility to patients and clinicians by restricting itself to a narrow, undifferentiated and simplistic conception of depression. It also unhelpfully restricts itself purely to randomised controlled trials, and excludes naturalistic trials despite their clear advantages in assessing psychotherapeutic treatments and treatments in the real world. The evidence for the lasting effects of long-term psychotherapy in depression is not reviewed despite the mass of evidence presented that depression is frequently chronic or recurring and the evidence of the limited effect of short-term treatments. Furthermore the economic analyses are based entirely on short-term models. There is insufficient consideration of importance of individual patient preferences or different types or aetiologies of depression, leading to restrictive one-size-fits-all recommendations, with attendant implementation risks.

The 2004 NICE guidelines for depression and 2004 NICE guidelines for anxiety with their recommendations for CBT contributed in part to the development of the Depression Report and Improving Access to Psychological Therapies. The first-phase IAPT model has not yet been shown to be any more effective or acceptable to patients in the real world than existing services but NICE's new guidance risks reinforcing an untested assumption, stifling improved patient care and restricting patient choice through overly-crude or coercive implementation.

Notwithstanding this, **the evidence presented, in keeping with the bulk of the scientific literature, finds 'no clinically important differences' between Cognitive Behavioural Therapy, Interpersonal Psychotherapy, Short Term Psychodynamic Psychotherapy and Brief Supportive Counselling**. Having excluded much evidence for the effectiveness of STPP and Counselling the 2009 guideline recommends CBT and IPT as its preferred treatment options on the basis, not of superiority, but on the fact that there were more trials demonstrating efficacy. In principle, then, this leaves an open door for IAPT to evolve and test a broader range of service models.

One should ask what sort of evidence would be necessary to reliably conclude that one form of psychotherapy is superior to another. The answer should include replicated studies, consistently showing a clinically relevant advantage of one treatment over another, long follow-up periods, different methodologies, and data showing effectiveness in real world settings. The data we have currently, including from IAPT, points strongly **against** any reliable conclusion favouring CBT or IPT over other therapies.

We have few studies by research groups demonstrating equipoise (for an exception see Stiles et al 2008). Investigator allegiance, the motivation of research groups to 'prove' their own brand of therapy to be best, has been shown to introduce large biases (Luborsky *et al*. 1999).

By wording recommendations in a way, which may be misinterpreted as showing CBT and IPT are superior 'evidence-based' treatments, NICE risks devaluing science, as well as undermining the credibility of its guideline.

Patients with depression treated with CBT or IPT often have positive but limited initial responses followed by high rates of recurrence. It is essential, and in the interest of patients, that all treatment options for depression are fully explored. Indications are that longer-term psychodynamic psychotherapy may have superior and more lasting effects for some patients. There is an urgent need for well-funded trials to explore if those who do not respond to CBT can benefit from other forms of treatment including psychodynamic psychotherapy and the extent to which long-term treatments have superior outcomes in the medium or long-term.

There is a need for future NICE guidelines that are adapted to the differing types and aetiologies of depression and the differing priorities of individual patients. They should cover long-term psychotherapies and consider the range of types of evidence required to assess the effectiveness of psychotherapy in the real world. It is essential that guidelines are based on systematic reviews of the evidence and not simple counting of trials. They should impartially present the evidence as it is. It remains to be seen what the published guideline will say and, more importantly perhaps, how IAPT evolves its 2nd and 3rd phase service models to continue the task both of implementing NICE's guidelines **and** achieving good outcomes for all IAPT's patients – including the 50% who fail to recover having had NICE's preferred treatments.

Acknowledgements

I would like to thank Peter Hobson, David Taylor, Alessandra Lemma, Nick Midgley, Mary Target, Paul St John Smith and Peter Fonagy for their help and suggestions.

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Published by
The British Psychoanalytic Council
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19-23 Wedmore Street
London N19 4RU
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