

UK Council for Psychotherapy

# NICE under scrutiny

the impact of the National Institute for Health and Clinical Excellence guidelines on the provision of psychotherapy in the UK

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## Executive Summary

This paper examines the negative consequences for patients of their inability to access the full range of psychotherapies due to a combination of NICE's approach to mental health and the implementation of its guidance through Improving Access to Psychological Therapies (IAPT).

NICE's methodology has been inappropriately applied to psychotherapy in that:

- It adheres to an overly medicalised perspective on emotional distress
- It has not consulted with the full range of relevant professional psychotherapy groups and psychotherapy research experts in the field
- It treats psychotherapy as if it were a drug for research purposes when a more appropriate metaphor might be therapy as a dialogue
- It uses an inflexible hierarchy of evidence which its own Chairman has criticised.

The relevance of the assumptions which underpin NICE's preferred research method for all psychological therapies, randomised control trials (RCTS), is questioned.

The case is made for NICE to adopt a pluralist approach to research methodologies in order that research using methodologies better suited to psychotherapy can be admitted for consideration in creating guidelines.

While NICE recognises many of the issues raised concerning its methodology, it is *acting* as though they don't exist by only recommending those therapies which can provide a very narrow type of evidence.

The case is examined that the current process works in favour of some therapies (eg CBT(Cognitive Behavioural Therapy)) and puts others at an unreasonable disadvantage, with the result that the choice of therapies available on the NHS is diminishing at a time when the government has stated it is committed to increasing choice. Researchers tend to favour the psychotherapy they themselves practice.

The Department of Health is called on to intervene as a matter of urgency prior to NICE's Guidance Development Group review in December 2011 so that the matters raised in this paper might be considered in the review.

# Contents

<b>Introduction</b>	4	2.4.3 Specific limitations and constraints of RCTs	16
<b>The NICE approach to setting guidelines</b>	5	(i) How far are RCT results generalisable?	17
2.1 Acting as if experiences of mental distress are medial 'conditions' which can be 'diagnosed'	6	(ii) The allegiance effect	17
2.2 Who is selected to sit on GDGs?	8	(iii) The lack of consistency in what's used as a 'control therapy'	18
2.3 Psychological therapies: drug-like 'interventions' or 'dialogues'?	9	(iv) The cost	18
2.4 Randomised Control Trials (RCTs) – a critique in terms of psychotherapy research	12	<b>Alternative approaches to research</b>	19
2.4.1 RCTs – a brief explanation	13	3.1 Practice-based evidence	19
2.4.2 The big questions	13	3.2 Alternative quantitative methods: clinical outcomes for routine evaluation (CORE)	20
Is it possible to produce unbiased knowledge?	13	3.3 Qualitative research methodologies	21
Is it possible to compare therapies based on different theories using RCTs?	14	<b>Conclusion</b>	22
Simple vs complex systems: bike or butterfly?	15	<b>References</b>	23
Therapist skills/operations vs presence	15		
Standardised vs unique	15		

## Introduction

This paper scrutinises NICE's current process for producing the national guidance upon which psychological therapies should be recommended by doctors and provided by the National Health Service (NHS). It also seeks to demonstrate how the implementation of these guidelines is leading to a dramatic reduction in choice – choice that service users actually want. This comes at a time when the coalition government has explicitly said in their 2010 NHS white paper that they will have 'more choice and control' (DoH, 2010:1).

We start by considering how NICE's clinical-guideline production process has been applied to issues of mental health and go on to raise serious questions about the 'one size fits all' approach that has been adopted. In treating issues of mental health for research purposes as if they are the same as those of physical health, it is explained how NICE is effectively excluding the majority of existing psychological therapies (which do not operate from this standpoint) from being seriously considered for inclusion in its recommendations.

## The NICE approach to setting guidelines

NICE stands for the National Institute for Health and Clinical Excellence. It aims to 'provide guidance, set quality standards and manage a national database to improve people's health and prevent and treat ill health' (NICE, 2010: About Nice, para1) and as part of this work it creates 'Clinical practice guidelines [which] are "systematically developed statements that assist clinicians and patients in making decisions about appropriate treatment for specific conditions"' (NICE, 2009: 11-12).

Initially, NICE (2004) worked with a broad definition of what constituted mental health in recognition of the 'contested' nature of the concepts of mental health and mental illness and the 'myriad' factors which create poor mental health. The language and research approach used in formulating the most recent guidelines, however, is firmly embedded within the model of biological medicine (or biomedical model) which underpins the rest of NICE's work for the NHS. This model assumes that:

- patient experiences (**symptoms**) are
- indicative of underlying **conditions** which
- need to be **diagnosed** in order for
- an appropriate **treatment** to be prescribed.

While NICE (2009:632) openly recognises the dangers of "'medicalising" distress by adopting minor depression as a discrete diagnosis', it does not apply the same logic to the field as a whole and to how it might therefore go about achieving its goals in a more appropriate way. The

relevant question, therefore, is how does the biomedical approach to issues of mental health play out in NICE's process and result in less choice for patients?

To create a clinical guideline for use within the NHS, NICE:

- Selects a 'condition' on which to issue guidelines about treatment options
- Creates a guideline development group (GDG), composed of representatives of all the 'relevant professional groups' (AGREE, 2001: criteria 4)
- Defines what 'clinical review questions' (agreed by the GDG) will be explored in relation to that condition
- Examines research conducted on 'interventions' for participants who have been 'diagnosed' with the 'condition' giving primacy to those studies which have used a Randomised Control Trial (RCT) because in NICE's (2009a:46) hierarchy of evidence (in which types of research evidence are ranked according to the perceived validity of their findings) this is the research methodology of choice for 'other' medical interventions.

Four main problems with this approach in developing guidelines for issues of mental health are now examined.

## 2.1 Acting as if experiences of mental distress are medical 'conditions' which can be 'diagnosed'

Psychotherapists have been aware for many years of the important distinctions to be made between the:

- a) biomedical model as it is practiced in medicine
- b) medical model in psychotherapy
- c) non-medical model approach to issues of mental distress which places a greater importance on the role of *psychosocial* causes.

The medical model in psychotherapy (b) is essentially an analogy, 'a descriptive schema borrowed from the practice of medicine and superimposed on the practice of psychotherapy' (Elkins, 2009:67-71). Many believe, as Elkins summarises, that 'the superimposition of this model uses medical terms to describe what is essentially an interpersonal process that has almost nothing to do with medicine.'

A growing number of practitioners see the continued use of this analogy as problematic because it has led many to believe that there actually is a biological basis to mental health issues. Most now understand that, as one commentator has put it, 'For all the talk about neurotransmitters, hormones and the brain, psychiatric emotional disorders are the same moods we call emotional distress coincident with something else that seems to justify intervention. It is not biological pathology' (Mirowsky, 2007:301).

Alongside many others writing about the social causes of mental distress (Mirowsky and Ross, 2003, Horwitz 2002, Bentall 2004), Pilgrim et al (2009) summarise the strong interdisciplinary case for the importance of personal relationships in both the creation and amelioration of mental health problems. In line with the call for the widespread adoption of a biopsychosocial model for understanding such experiences (Engel, 1977), they do not suggest that biology does not play a part, but that that part is a subordinate one.

No one doubts that issues of mental and emotional health can have biological *consequences*, but few subscribe to the idea of there being direct biological *causes* for them. As the British Association for Counselling and Psychotherapy (BACP) recently stated in a recent response to the Health Professions Council (HPC) on the issue of regulation, 'The medical model used in and by the HPC and expressed in this consultation in the Standards of Proficiency is questioned and rejected by BACP on behalf of its members. There is evidence from our members that many who work as psychotherapists eschew the medical model' (Aldridge, 2010:2).

As even NICE (2009:628) recognises: 'Despite considerable work on the aetiology of depression including neurobiological, genetic and psychological studies, no reliable classificatory system has emerged that links either to the underlying aetiology or has proven strongly predictive of response to treatment' in addition to the fact that 'The construction of "depression" as a clinical condition is contested amongst GPs (Chew-

Graham et al., 2000; May et al., 2004; Pilgrim and Dowrick, 2006)' (NICE, 2009:99-100).

In its guideline on depression, however, while there are several pages devoted to discussing 'The Disorder' (NICE, 2009:17), NICE does not define what it means by a 'condition' and there appears to be no recognition of the *consequences* of the position it is taking up in this central debate by working with depression as though it is a medical 'condition'. By doing this, it is argued that NICE's approach is inherently flawed: because NICE believes in mental health 'conditions', they logically also have to believe in 'diagnosis' and 'treatment'. As one psychiatrist commented 'By using inappropriate disease analogies, we have been hoisted by our own petard' (Kingdon and Young, 2007:286).

As Mirowsky and Ross (2003:31) state, 'A person is diseased or not. The disease is malaria or not, cholera or not.... A language of categories fits some realities better than others. It fits the reality of psychological problems poorly.' As categorisation is at the heart of diagnosis, this gives rise to a significant problem – NICE bases all of its guidelines on evidence gathered around patients who have been 'diagnosed' with the relevant 'condition'.

For depression, NICE (2009:17-18) acknowledges that 'Distinguishing the mood changes between clinically significant degrees of depression (for example, major depression) and those occurring "normally" remains problematic and it is best to consider the symptoms of depression as

occurring on a continuum of severity (Lewinsohn et al., 2000).'

Bentall (2009: para 4) highlights that research has shown that 'psychiatric diagnoses are poor predictors of response to treatment, giving little indication of which patients will respond to which drugs. They are therefore hardly more meaningful than star signs – another diagnostic system that is supposed to tell us something about ourselves and what will happen in the future, and which is widely embraced despite no evidence of its usefulness.'

While the use of diagnoses in terms of the medical model in psychotherapy (b) is common in psychoanalytic schools, Hoffman (2009) highlights the ambiguity about the classification of patients by personality types at the heart of the Psychodynamic Diagnostic Manual (PDM Task Force 2006:29) which suggests that while there might be an initial usefulness in considering such types, 'the person's individuality eventually becomes more impressive than his or her conformity with an abstraction.'

In summary, it appears that a significant proportion of psychotherapists, researchers and doctors do not believe diagnoses of mental health 'conditions' are appropriate or helpful, in fact, quite the reverse. Even the Guideline Development Group (GDG) for Depression (NICE, 2009:23-24) 'considered it important to acknowledge the uncertainty inherent in our current understanding of depression and its classification, and that assuming a false categorical certainty is likely to be unhelpful and, even worse, damaging.'

Despite these factors, NICE followed its process of only seriously considering research evidence conducted using participants with depression as a firm 'diagnosis' (eg NICE, 2009:262). If stakeholders in the field do not recognise the use of diagnoses then inevitably this stance is going to reduce the amount and type of research evidence available to NICE.

## 2.2 Who is selected to sit on GDGs?

The second issue with how NICE implements its approach surrounds the composition of GDGs which play a vital role in the development of its recommendations: 'The exact composition of the GDG should be tailored to the topic covered by the clinical guideline. It should reflect the range of stakeholders and groups whose professional activities or care will be covered by the guideline' (NICE, 2009a:29).

How does NICE decide who should be part of a GDG? In the introduction to the guidelines on Depression (NICE, 2009:12), it states that: 'the methodology used here reflects current international understanding on the appropriate practice for guideline development (AGREE: Appraisal of Guidelines for Research and Evaluation Instrument)<sup>1</sup> This framework contains the requirement that, in terms of 'Stakeholder Involvement', 'The GDG should include individuals from all the relevant professional groups' (AGREE, 2001: criteria 4).

However, according to NICE (2009:14), the GDG for depression, 'included two people with depression and a carer, and professionals from psychiatry, clinical psychology, general practice, nursing and psychiatric

pharmacy, with psychotherapists being notable by their absence in this list.

An overall analysis (see Table 1 overleaf) of the composition of the GDGs which produced the clinical guidelines on Anxiety (NICE, 2004a), Depression in Adults (NICE, 2009) and Schizophrenia (NICE, 2009b), reveals that:

- Just 6.7% of GDG members were psychological therapists
- 33% of GDG members were representatives of the medical profession
- 36% were staff from the National Collaborating Centre for Mental Health (NCCMH) led by a partnership between the Royal College of Psychiatrists and the British Psychological Society's Centre for Outcomes Research and Effectiveness (NICE, 2009:13)

Perhaps not unsurprisingly the composition seems to reflect the underlying assumption that the presenting issues of service users are of a medical nature. Of the GDGs analysed there was only *one* nominated representative of a counselling or psychotherapy member organisation specifically listed in the published guideline (a 'BACP Lead Advisor' on the Anxiety GDG).

Psychological therapists appear to have been regarded as one homogenous professional group who are largely interchangeable and it is questioned whether any consideration was given to the importance

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<sup>1</sup> It is worth noting that AGREE is an 'integrated research programme currently funded by the BIOMED-2 Programme of the European Union' (AGREE, 2001: Introduction), which in EU terminology area 2 is devoted to 'research on biomedical technology and engineering'.

of the difference between their ways of working in terms of their representation. The one psychoanalytic psychotherapist on the GDG for depression (but who was not mentioned in their description of it) noted 'there are 5 CBT specialists represented on the group' (Clarke, 2008).

Given how vital the issue of GDG composition is: 'Where evidence is lacking, the guidelines incorporate statements and recommendations based upon the consensus statements developed by the GDG' (NICE,

2009:12) it is questioned whether NICE has lived up to its intention to ensure they include 'individuals from all the relevant professional groups' (AGREE, 2001: criteria 4).

In addition, Mollon (2008:10) has argued that 'many clinical psychologists within the British Psychological Society (BPS), committed to research along CBT lines, have been closely involved in developing the NICE guidelines (some of which are co-published by the BPS)'. As such, this points to the necessary awareness that the development of the NICE guidelines has not taken place in a political vacuum and factors including the researcher allegiance effect (Luborsky et al., 1999) and the selection of research methodologies which are best suited to establishing the efficacy of CBT have been of issue (as discussed later).

In summary, the impetus to the development of Empirically Supported/ Validated Treatment standards is arguably far more economic, political and interest driven, than it is scientific (Beutler, 1998: Hubble et al., 1999)' (Bohart and House, 2008:189).

### 2.3 Psychological therapies: drug-like 'interventions' or 'dialogues'?

The third issue with NICE's approach is that it relies on the assumption that work undertaken in a psychotherapeutic relationship constitutes a treatment or 'intervention'. Again, NICE does not specifically define what it means by this clearly important term: 'the type of evidence that will be most relevant depend[s] on whether the review questions are about

Table 1

Category	Schizophrenia		Anxiety		Depression		Total	
	No	% of GDG	No	% of GDG	No	% of GDG	No	% of GDG
NCCMH staff	8	30.8	2	14.3	17	48.6	27	36
Health Economists	1	3.8	1	7.1	3	8.6	5	6.7
GPs/nurses/ pharmacists	2	7.7	4	28.6	5	14.3	11	<b>14.7</b>
Psychiatry affiliated	8	30.8	3	21.4	3	8.6	14	<b>18.7</b>
Clinical psychologists	2	7.7	1	7.1	2	5.7	5	6.7
Service users/carers	3	11.5	2	14.3	3	8.6	8	10.7
psychological therapists	2	7.7	1	7.1	2	5.7	5	<b>6.7</b>
Total	26	100	14	100	35	100	75	100

interventions, diagnosis, prognosis, patient experience, service delivery or cost-effectiveness' (Dillon and Timms, 2010:1).

In the Guideline Manual the only apparently relevant definition is for an 'interventional procedure': 'Any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or a body cavity, or using electromagnetic radiation (which includes X-rays, lasers, gamma-rays and ultraviolet light)' (NICE, 2009a: 243). While the ears and mouth are indeed bodily cavities, this definition is clearly inappropriate for the endeavour of psychotherapy. It does, however, fit with the idea of psychotherapy as being equivalent to a *drug*.

This approach, it is argued, 'implicitly subscribe[s] to an investigative paradigm that we will call the drug metaphor. Rooted in the broader medical model of psychological disorder and its treatment, this paradigm views psychotherapy as comprising active ingredients, supplied by the therapist to the client, along with a variety of fillers and scene-setting features' (Stiles and Shapiro, 1989:522).

If psychotherapy shouldn't be seen as a drug-like intervention, how *should* it be seen? For some commentators, 'to call what therapists do in their work "interventions" fundamentally misrepresents it in ways that distort the human, experienced meaning of it for both therapist and client.' Bohart and House (2008:195-6) go on to propose that 'in contrast to the idea that the therapist is 'treating' a 'disorder', therapy becomes a co-created dialogue between two (or more) intelligent, living, embodied beings. The guiding metaphor for this approach is

therefore *conversation* and *dialogue*', taking place in the context of an interpersonal relationship. 'Psychotherapy is conceived of, above all, as a *practice*' (see also Heaton, 2010).

In some parts of the guideline on depression NICE is clearly aware of the importance of the relationship between client and therapist: 'Indeed, the importance of organising care in order to support and encourage a good therapeutic relationship is at times as important as the specific treatments offered' (NICE, 2009:12-13).

The idea that therapy is first and foremost relational has been used to explain why in so many studies outcomes are broadly the same regardless of the theoretical frameworks of the therapists involved. Being in relationship is regarded as one of a number of factors common to all types of therapy. This idea is also known as the 'dodo bird' effect<sup>2</sup>, the term first coined by Rosenzweig (1936). While NICE are dismissive of 'dodo bird' findings, they give no basis for this dismissal (NICE, 2009:165). As Pilgrim et al (2009:244) summarise, however, 'extensive and repeated research on the link between process and outcome has demonstrated that the quality of the relationship consistently predicts outcome, independent of the espoused model or condition being treated.'

However, DuRubeis et al (2005:174) have challenged research findings stating there is no significant difference in outcomes between different psychotherapies, as well as the assertion that there is a statistical relation between the therapeutic alliance (when taken as a

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<sup>2</sup> Based on the in Lewis Carroll's *Alice's Adventures in Wonderland* (1865), at a certain point a number of characters become wet. In order to dry themselves, the Dodo decided to issue a competition. Everyone was to run around the lake until they were dry. Nobody cared to measure how far each person had run, nor how long. When they asked the Dodo who had won, he thought long and hard and then said 'Everybody has won and all must have prizes.'

common factor) and outcome, concluding that the specific effects of psychotherapies 'may be substantially stronger than is widely believed.' Both Castonguay (2005) and Craighead et al (2005) agree that specific elements of psychotherapies are important but only *in combination* with the strong therapeutic alliance which DuRubeis et al (2005) play down, while Wampold (2005:194) strongly contests DuRubeis et al's (2005) reasoning. It is possible that it is what the therapist *believes* to be important that is at issue here and maybe therefore be part of (as discussed later) the researcher allegiance effect.

The relative importance of specific therapeutic approaches (therapy as drug metaphor) versus dialogue-in-relationship is a complex question that, when it comes to research, NICE appears to treat it as if it has already been resolved. As the ongoing debate testifies there is still considerable uncertainty as to how to interpret the findings that exist, and, as such, there is the case that NICE should not only *allow* evidence appropriate to therapy as dialogue, it should also *pay heed* to it.

For example, while service user views were well represented in the NICE guideline on depression, when it came to making treatment recommendations their preferences were discounted in favour of RCT evidence. This is explicitly acknowledged; 'There was a strong feeling within the service user and carer topic group that [this] highlights the reasons why many people opt for private therapy; that psychological treatment offered by the NHS in the form of CBT does not go far enough in addressing the trauma experienced in childhood. The study by Ridge

and Ziebland (2006) confirms the opinions of the topic group and the testimony from the personal accounts that people with "deep and complex problems felt the need for longer term therapy"'(NICE, 2009:90).

The report goes on to say, however, that 'The service user and carer topic group do acknowledge, however, that as there has been little research into the efficacy of long-term psychodynamic therapy, it cannot be recommended as a course of treatment in this guideline.' The GDG considered that studies such as that conducted by Leichsenring and Rabung (2008) which demonstrated the efficacy of long term psychodynamic therapy for complex mental disorders had an insufficient focus on depression as a diagnosis and so discounted it. They also stated that 'in the Knekt and colleagues' (2008) study of short- and long-term psychodynamic versions of solution-focused psychotherapy outpatients with mood or anxiety disorders *only 65.8%* had recurrent episodes of major depressive disorder' (emphasis added, NICE, 2009:162), and so again discounted it. Interestingly, they went on to comment in relation to the Knekt et al study that 'it is difficult to determine whether or not the long-term benefits associated with psychodynamic psychotherapy resulted specifically from the therapy or the prolonged contact with the therapist during that time'. It appears that having dismissed the 'dodo bird' effect they then invoke it as a possible explanation for the apparent efficacy of a particular therapy.

Shedler's (2010) comprehensive review of the available evidence for psychodynamic therapy, unconstrained by a focus on a single

diagnosis (while still arguably coming from within the medical model in psychotherapy), concludes that ‘the available evidence indicates that effect sizes for psychodynamic therapies are as large as those reported for other treatments that have been actively promoted as “empirically supported” and “evidence based”’ (Shedler, 2010:107).

While there is considerable personal testimony in the guideline, therefore, it appears that NICE disregards it in order to adhere to a potentially flawed commitment to RCT evidence focused on particular ‘diagnoses’ above all other.

#### **Why does this debate matter?**

If it is accepted that psychotherapy’s positive effects are the result of a combination of specific therapeutic actions *and/or* the quality of the therapeutic relationship, then other kinds of research evidence need to be reconsidered when forming guidelines, with the probable impact of widening patient choice.

#### **2.4 Randomised Control Trials (RCTs) – a critique in terms of psychotherapy research**

The architect of the RCT said that ‘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, 1965:108). While NICE recognises that there are problems with RCTs, especially for psychological therapies, it is suggested that GDGs have acted as if they

are ‘the only way’ when it comes to making their recommendations for treatment. This has had, and is still having, serious consequences for the range of therapies available to patients both within and increasingly outside the NHS, as training institutions gear up to produce therapists who can deliver ‘NICE-approved’ treatments.

According to NICE’s current Guidelines Manual (NICE, 2009a:39-46) which all GDGs rely on: ‘Although there are a number of difficulties with the use of RCTs in the evaluation of interventions in mental health, the RCT remains the most important method for establishing treatment efficacy.’ Yet the Chairman of NICE, Sir Michael Rawlins (2008:31) has said that ‘To regard the randomised controlled trial as the gold standard is unsustainable.’

It is also worth noting that NICE only seek to establish *efficacy*, ie ‘the measurable effects of specific interventions’ (Nathan et al, 2000: 964-5), rather than *effectiveness*, whether treatments are feasible and have measurable beneficial effects across broad populations and in real-world settings.’

The following questions are now considered: What difficulties do NICE acknowledge with RCTs? What are the other main criticisms levelled at RCTs which NICE has not acknowledged? Why does NICE still rely so heavily on RCTs?

### 2.4.1 RCTs – a brief explanation

First of all, what is meant by a randomised control trial? A report by Clark (2006:1) for the Department of Health stated that: 'The gold standard for determining clinical effectiveness is the RCT in which the treatment to be evaluated is compared with various control conditions. Patients are randomly allocated to the treatment under investigation or the control conditions in order to ensure that any difference in outcome is not due to patient characteristics.' This approach is founded on a broadly positivist approach to science.

When NICE was set up in 1999, it assumed that the hierarchy of evidence it applies for medical interventions applies equally well to the field of mental health and hence to emotional distress. These procedures were therefore 'derived from experimental science by clinical researchers with the objective of separating the effects of the therapy per se from changes that may result from other factors' (Schmitt Freire, 2006:324) – the psychotherapy-as-drug metaphor. 'The "treatment" then is the independent variable, which is applied to the "dependent variable" – *the client* (or the client's "disorder"), the goal being to "operationalise" the treatment clearly and unambiguously' (Bohart and House, 2008:193) through the use of treatment manuals.

In the mass of literature on this subject there are two main types of problems highlighted with this methodology:

- First, there are big questions raised about the basic assumptions

made by RCT proponents in terms of how knowledge can be produced and how that fits (or doesn't) with the underlying nature of some psychological therapies.

- Second, there are a range of specific limitations and constraints of RCT methodology.

### 2.4.2 The Big Questions

#### Is it possible to produce unbiased knowledge?

As one researcher puts it, 'It is now well established in the philosophy of science that there are no pure facts but only facts as couched in one conceptual system or another. There are no pure observations but rather observations couched in a theory-laden vocabulary' (Schmitt Freire, 2006:327).

One way of making sense of this is to consider that we are witnessing a 'paradigm war' (Kuhn, 1962) in which two fundamentally different ways of viewing both the endeavour of psychotherapy and research into it, are clashing. From the post-positivist view of science, the RCT is *not* a neutral experimental work. In fact, it has been argued that behaviourist theories of therapy share some common assumptions and characteristics with RCTs (Bohart and House, 2008; Westen et al, 2004; Chambless and Ollendick, 2000; Goldfried and Wolfe, 1998; Kendall et al, 1999; Nathan et al, 2000; Loewenthal, 2011) and that this could explain why they have found such a degree of success using this research methodology

in becoming empirically supported treatments. An example is the idea that therapy can act specifically on certain symptoms. (While the case can also be made that symptom removal is a goal of psychoanalytic therapy, as Shedler (2010:100) puts it ‘Successful treatment should not only relieve symptoms...but also foster the positive presence of psychological capacities and resources.’)

So not only is it argued that it is not possible to produce unbiased research, it is claimed that this research methodology is more likely to suit those therapies with which it shares a theoretical paradigm. This is not to say that RCTs can never be valid, but that they are not generally valid – “the assumptions...apply to some instances but not others”. (Westen et al, 2004:632-3).

**Is it possible to compare therapies based on different theories using RCTs?**

A logical extension of this is that RCTs cannot be used to compare therapies based on behaviourist and non-behaviourist theories of psychological change ‘Because...terms in very different theories cannot share the same meaning...Terms such as *therapy*, therapeutic relationship and psychological problem have very different meanings and conditions of applicability. Accordingly, these are incommensurable theories’ (Schmitt Freire, 2006: 329-30). Essentially it is argued that behaviourist and non-behaviourist theories are fundamentally so different they require different approaches to research them. As we

have already seen, for a large number of therapists, therapy should be regarded more as a dialogue than a drug.

To summarise the differences between these paradigms in terms of what is given primacy:

Therapy as ‘drug’	Therapy as ‘dialogue’
<ul style="list-style-type: none"> <li>Simple system (the universe as giant clock made up of discrete parts)</li> </ul>	<ul style="list-style-type: none"> <li>Complex adaptive system (quantum theory view - interconnectedness, holism)</li> </ul>
<ul style="list-style-type: none"> <li>General to all individuals</li> </ul>	<ul style="list-style-type: none"> <li>Responsive to the individual</li> </ul>
<ul style="list-style-type: none"> <li>Therapist skills/operations</li> </ul>	<ul style="list-style-type: none"> <li>Therapist presence</li> </ul>
<ul style="list-style-type: none"> <li>Standard manualised approach</li> </ul>	<ul style="list-style-type: none"> <li>Unique, professional judgement used based on broad relational principles</li> </ul>
<ul style="list-style-type: none"> <li>Universal truth</li> </ul>	<ul style="list-style-type: none"> <li>Local truths</li> </ul>
<ul style="list-style-type: none"> <li>Intervention</li> </ul>	<ul style="list-style-type: none"> <li>Conversation and self-healing</li> </ul>
<ul style="list-style-type: none"> <li>Therapist led</li> </ul>	<ul style="list-style-type: none"> <li>Client led</li> </ul>
<ul style="list-style-type: none"> <li>Treatment (originates outside the relationship)</li> </ul>	<ul style="list-style-type: none"> <li>Practice (originates from within the relationship)</li> </ul>

Expanding on some of these points of difference:

**Simple vs complex systems: bike or butterfly?**

The positivist view of the world is one which sees all psychological therapy as a *simple* rather than *complex* system; it's like the difference between a bike and a butterfly – you can dismantle a bike to see how it works, optimise its parts and put it back together again. The argument here is that it is not possible to do the same thing with a butterfly and that to treat one as the other is to mistake its essential nature.

In contrast to the idea of treatment being applied to a disordered part of a person, for many non-behavioural approaches 'the therapeutic relationship is an interpersonal and dialogical process and a complex holistic phenomenon that cannot be dismantled into component, linear causal parts' (Schmitt Freire 2006:328).

**Therapist skills/operations vs presence**

In the drug metaphor the therapist is seen as applying a set of therapeutic ingredients to a patient with a specific condition in order to relieve specific symptoms. However, some such as Rowland (2007:28), stress the importance of the relational: 'Psychological therapies are by definition relational therapies. The therapeutic alliance between therapist and patient is an important influencing variable in terms of outcome; it tends to be best captured by qualitative research and case studies.' Bohart and House (2008:195) go on to contend that: 'With client-centred therapy in particular, it is the "being" of the therapist and client in indissoluble relationship which is assumed to be therapeutic, and not specific

"therapist operations" skills or programmatic interventions... Therapy "works" through the interrelational *presence* of the therapist, rather than through specific technological, or skill-based operations.' There is some similarity here with the growing importance of relational psychoanalysis (Mitchell, 1988).

**Standardised vs unique**

One of the key assumptions of the RCT methodology is that the 'treatment' can be standardised in order to attempt to eliminate the impact of the therapist – this is usually done by manualising the approach to be taken – specifically stating what the therapist should do and ideally when. 'Manualisation represents an attempt to specify the ingredients of a particular therapy, analogous to purifying the ingredients in a pill (Luborsky and DeRubeis, 1984; Waskow, 1984' (Stiles and Shapiro, 1989:522).

There are two fundamental issues with the attempt to manualise non-behaviourist approaches to therapy:

- (i) *Therapy as dialogue*, by its nature it is 'inherently unpredictable' (Bohart and House, 2008:195).
- (ii) To manualise implies that the role of the therapist can be encompassed within a set of prescriptive instructions, that there is no significant level of professional *judgement* involved in deciding how to respond to each unique individual client. As Hoffman, (2009:1054) quotes from Bohart, O'Hara, and Leitner (1998:145) 'The therapist is a disciplined improvisational artist, not a manual-driven technician'.

Westen et al (2004:638) have pointed out 'The extent to which a treatment requires a competent clinical decision maker who must decide how and where to intervene on the basis of principles (even principles carefully delineated in a manual) is the extent to which that treatment will not be able to come under experimental control.... This places a premium on development of treatment packages that minimise clinical judgment because such treatments are the only ones that allow researchers to draw firm causal conclusions.'

An alternative strategy to an overt paradigm war is put forward by Fonagy (2002:58) as cited by Hoffman (2009:1057-8), 'It needs to be recognised that objections to research will not win the day. It is unlikely that the prevailing view that places controlled studies at the top of the hierarchy of evidence will change, *no matter what the strength of opposing arguments* [emphasis added] ... The best strategy available to us is to collect all the data available rather than enter an epistemological debate amongst ourselves' regardless of any concerns the researcher may have about its appropriateness.

However, Fonagy's statement gives credence to the notion that two competing paradigms are battling it out and helps contextualise the decision by researchers such as Lemma, Target and Fonagy (2010:342) to design hybrid manualised 'treatments' such as Dynamic Interpersonal Therapy (DIT). This is part of the trend which sees 'a reversal of means and ends...taking place' (Westen et al, 2004:638) whereby there is an increasing use of 'treatment manuals' beyond the lab and so what started

as an attempt to operationalise therapy in order to attempt to measure it, is now becoming the 'defining features of the treatments themselves'. Rather than such research *informing* practice, it is now *dictating* it.

While NICE (2009:639) fully recognises the role of practitioner judgement for GPs, it is argued that by treating therapy as a drug rather than a dialogical practice, NICE does not accord the same recognition to psychotherapists. In fact, NICE is effectively *removing* the option of GPs and patients to exercise their judgement in choosing from amongst a range of 'treatments' as increasingly only 'NICE approved' manualised treatments are available for selection. It is recognised that issues of cost-effectiveness are clearly important and an idea that is seen to be gathering momentum is that of the utilisation of personal mental health budgets, similar to those in operation in social care (DoH, 2010a). It can be argued, however, that there will be little point giving such control to service users if there are no real choices left to be made.

Having considered the most fundamental issue as to whether to use RCTs at all for the non-behavioural therapies we now turn to a brief overview of some specific issues that have been raised concerning the detail of their use.

#### **2.4.3 Specific limitations and constraints of RCTs**

Four issues are selected for a brief discussion in order to demonstrate that there is considerable debate about how far RCTs can be relied upon even amongst those who use them.

**(i) How far are RCT results generalisable?**

As the Chairman of NICE has noted: 'Randomised controlled trials may not necessarily be generalisable to the circumstances beyond the population that has been studied' (Rawlins, 2008:11).

Essentially, while in drug trials the RCT experimental conditions closely approximate clinical reality, it is argued that in 'psychotherapy RCTs the conditions created represent a substantial deviation from usual psychotherapy clinical practice conditions' (Mottram 2000:1).

An example of this is the debate surrounding the selection of participants. As NICE (2009:637) states: 'The evidence base for treatments considered in this guideline is based primarily on RCTs in which standardised criteria have been used to determine entry into the trial. Patients seen clinically are rarely assessed using standardised criteria reinforcing the need to be circumspect about an over-rigid extrapolation from RCTs to clinical practice.'

It has been suggested that there are several ways in which this selection does not mirror reality:

- Many psychotherapy clients choose their therapists, 'entering a kind of treatment they actively sought with a therapist they screened and chose' (Seligman, 1995:967).
- Clients typically have multiple problems, an issue also known as 'co-morbidity' (Seligman, 1995). There remains a live debate in terms of how significant this latter issue is (Westen et al., 2004; Stirman et al., 2005).

It is contended that while NICE has recognised that there are problems, it is *not* taking any corrective action for them with potentially fundamental consequences for the future of provision.

**(ii) The allegiance effect**

This refers to the finding that 'researchers show a marked tendency to find evidence which supports their own orientation' Luborsky et al (2003) (also see Winter et al., 2010). A review by the Department of Health (2001) including an allegiance examination of its own work, found that CBT practitioners, like others, were most likely to favour their own approach and least likely to consider the possibility of the utility of other approaches. This reinforces the findings review which found that researcher allegiance accounted for *over two-thirds* of the variance found in outcomes. (Luborsky et al (2003), cited in Cooper (2008)).

On this basis, Westen et al (2004) estimated that the findings of a comparative trial can be predicted by reference solely to the researcher's therapeutic orientation. Cooper goes on to argue that considering 'much of the empirical support for cognitive and behavioural therapies comes from cognitively and behaviourally-aligned researchers, some fundamental questions are raised about its validity' (Cooper, 2008:2). Cooper's argument does not suggest a deliberate bias, but instead one which is unintentional or even structural.

**(iii) The lack of consistency in what's used as a 'control therapy'**

According to Cooper (2008:3), examples of this include where the 'supportive counselling' group established to compare the efficacy of CBT

for clients experiencing first episode psychosis (Haddock et al., 2006) was provided by 'five research therapists who had been trained in CBT and [who] were supervised by experienced cognitive behavioural therapists.' Cooper argues that, 'from a cynical standpoint... what most of the comparative research shows is the cognitive behavioural therapists bring about more improvements on cognitive behavioural indicators of change when they practice in the way that they are trained in, committed to and believe in; as opposed to practising in a way that they are neither fully trained in nor committed to, nor think will be effective.'

**(iv) The cost**

It is also widely recognised that RCTs are, as the Chairman of NICE (Rawlins, 2008:31) puts it 'becoming outrageously expensive' to run in terms of 'money, time and energy' and he has called for changes to be made to some of the drivers of this.

The use of RCTs in establishing psychotherapeutic efficacy is a trend in the UK which has mirrored developments in the US. In response to criticism however, the American Psychological Association (APA) launched the 'Criteria for Evaluating Treatment Guidelines' (APA, 2002) which includes an acknowledgement of the value of alternative research methods and 'a de-emphasis on RCTs as the gold standard in psychotherapy outcome research' (Schmitt-Friere, 2006). This was further reinforced in 2006 by the APA's publication of the new 'Policy Statement on Evidence-Based Practice in Psychology' (APA, 2006) recognising the contribution to evidence based practice of multiple research designs and methods.

In the UK meanwhile, while individual NICE GDGs (such as the one for depression) recognise that there are criticisms of the use of RCTs for psychological therapies, they state that: 'It is beyond the scope of this chapter to discuss the RCT in detail and its role in evaluating psychosocial treatments. RCTs are explored and critiqued in detail elsewhere (Westen et al., 2004; Stirman et al., 2005; De Los Reyes and Kazdin, 2008; Kazdin, 2008; Rawlins, 2008)' (NICE, 2009:159-60).'

It is noted that NICE is next due to review its Guideline Development Manual in December 2011 (2009a:18). As individual GDGs appear to see the re-evaluation of the use of RCTs as beyond their remit, it is suggested that this review should be brought forward and used to urgently reconsider NICE's use of hierarchies of evidence in full consultation with *all* relevant stakeholders. As the current Chairman of NICE has stated, 'Hierarchies attempt to replace judgement with an over-simplistic – pseudo-quantitative – approach to the assessment of the totality of the available evidence. Decision-makers need to incorporate judgement as part of their appraisal of the evidence in reaching their conclusions. Hierarchies should be replaced by embracing a pluralistic approach to evidence' (Rawlins, 2008:55).

Finally other methods of research advocated as part of a more pluralistic approach are considered.

## Alternative approaches to research

### 3.1 Practice-based evidence

NICE's approach aims to lead to evidence-based practice: 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individuals' (Sackett et al., 1997:2). As has been argued, however, it is what constitutes such evidence that is at issue. While RCTs can be useful when considered as one method amongst many, and when used appropriately for the type of question being researched, an alternative source of evidence is *practice-based evidence*, defined as 'good-quality data from routine practice' (Margison, 2000:124). A UKCP report (2006) summarises the arguments in favour of this and suggests that "it gives a voice to practitioners and service users, recognising that they have firsthand knowledge and experience of what works and alternatively both what needs to change, and how it may change (Ryan, P. and Morgan, S. 2004)" (Thomas et al., 2006:5).

While practice-based evidence research aims to be no less rigorous than evidence-based practice in 'Using practice as a natural laboratory' (Westen et al, 2004: 656), the primary difference, it is suggested, between the two approaches is the degree of focus on the experiences of service users and providers in comparison to externally set criteria of assessment. Where typically researcher lead 'efficacy studies [RCTs] emphasise internal validity and replicability; [practitioner lead] effectiveness studies emphasise external validity and generalizability' (Nathan et al., 2000:965).

The Social Care Institute for Excellence (SCIE), which is to be merged with NICE, recognises the importance of practice-based evidence and is a signatory to the Salisbury Statement (SPRING, 2009:2) which advocates its development and use, particularly at a time 'when there are increasing doubts about the adequacy of scientific knowledge as a sole basis for improving practice'.

As summarised in a UKCP report (Thomas et al., 2007) there are an increasing number of examples of researchers and clinicians coming together to form collaborative Practice Research Networks (PRNs) which are regarded by advocates as offering 'an alternative to traditional clinical studies' (Smith et al., 2005: 285). One such is being modelled by the Pennsylvania Psychological Association Practice Research Network (PPAPRN). Castonguay et al (2010:328) describe their Network as being based on an active collaboration between researchers and clinicians in the development of clinically relevant studies that are at the same time scientifically rigorous.' 'This practice based study investigated 1,500 events described by clients and therapists as being particularly helpful or hindering in their psychotherapy' (Castonguay, 2010:337-8) and involved a mix of therapists aligned to CBT, humanistic and psychodynamic therapies.

This approach, while having limitations, appears to offer three primary contributions:

- (i) It provides knowledge about the process of change.

- (ii) It illustrates how the process of data collection can be immediately relevant to clinical work thereby demonstrating the possibility of a simultaneous and seamless integration of science and practice.
- (iii) It provides evidence of the feasibility of a long-term collaboration between clinicians (Castonguay, 2010:343).

### **3.2 Alternative quantitative methods: Clinical Outcomes for Routine Evaluation (CORE)**

The CORE Outcome Measure (OM) (Evans et al., 2000) can be seen as an alternative quantitative method to RCTs. According to Aveline (2006:19-20) this is 'one of the most promising' of several 'reliable, relevant and sensitive psychometric systems for routine use' which have been developed to monitor psychotherapeutic outcomes at both an individual and service level.

CORE is a 34-item self-report questionnaire completed by clients, usually pre and post therapy, that assesses four domains:

- well-being
- functioning
- risk
- current problems/symptoms.

This client measure is complemented by a clinician completed 'Therapy Assessment Form' and 'End of Therapy' form. In its use by an IAPT pilot

site, research findings were that 'the CORE System of evaluation is useful in demonstrating reliable and clinical change as well as contextualising a client's difficulties at point of intake and discharge' (Rao et al., 2010). In a voluntary sector psychodynamic counselling service, Winter et al (2003:266) found 'clinically as well as statistically significant' evidence pointing to the 'effectiveness of the psychodynamic counselling service provided'. Again, using CORE, Stiles et al (2006:555), surveyed over 1,300 service users of Cognitive Behavioural, Person-Centred and Psychodynamic therapies, and found in agreement 'with previous findings, that theoretically different approaches tend to have equivalent outcomes.'

As it stands, research utilising the CORE-OM is discounted in favour of RCTs in the NICE hierarchy of evidence and has thus not informed the creation of its guidelines on the provision of psychological therapy. IAPT (2010:4) is, however, prepared to use 'patient-reported outcome measures' to assess the success or otherwise of those same 'NICE approved treatments' (albeit ones that are focused on particular 'conditions' such as PHQ9, GAD7 (IAPT, 2010: Appendix D)).

While not without its own methodological issues, the CORE-OM arguably offers a rigorous and yet practice-based alternative to an RCT paradigm and shows that there are alternative strategies which merit consideration as part of a more pluralist approach to evidence that would broaden the research base for psychotherapy.

### 3.3 Qualitative research methodologies

If it is to be taken that RCTs may provide only one perspective on the efficacy of psychotherapeutic treatment, an alternative is to advance the case for psychological therapy research which embraces non-RCT, relational methodologies in an inclusive paradigm, (even within a mixed-method approach) – an argument supported by many (McLeod 2001, 2003; Schmitt Freire, 2006; Bohart and House, 2008; Margison 2000; Marshall and Rossman, 2006).

Qualitative researchers 'tend to be concerned with the quality and texture of experience, rather than the identification of cause-effect relationships' (Willig, 2008:8). McLeod (2000:118) considers available qualitative research studies such as Howe (1989) and argues that 'the link between intervention and outcome is established through descriptive accounts given by therapy participants.' He also recognises the need to feed into policy debates and suggests that 'there exist techniques in qualitative methodology...that would allow the reliability of statements about clinically significant change to be built on inter-observer consensus' (McLeod, 2000:122).

The range of possible qualitative methodologies is too broad to detail here (see for example Willig, 2008; McLeod, 2000, 2001 and 2003; Loewenthal and Winter, 2006), but it is argued that 'The stage is set by growing dissatisfaction with drug-metaphor process outcome research, for novel and important contributions by clinician-researchers using

alternative, discovery-oriented methodologies' (Stiles and Shapiro, 1989:539).

## Conclusion

While NICE recognise some of the shortcomings of its process, because of its reliance on a biomedical approach to issues of mental health and its refusal to take non-RCT evidence into serious consideration when making its recommendations, its actions, in combination with IAPT, are *leading to a serious reduction in patient choice in the NHS*.

It is recommended therefore that NICE should act on its own stated doubts over the appropriateness and reliability of its method and open

up its process to a more pluralist approach to what constitutes evidence in the same way that the APA has done in the USA. In addition to the scheduled review of its Guideline Manual due to start in December 2011, the expansion of NICE's remit to include Social Care represents a further opportunity for such a review to take place. Indeed if it is not reviewed then this raises the question of how NICE can be held to account for the serious impact of its work on patient choice.

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