

Response to NICE Committee

12th January 2010

Dear Mr Middleton,

I urge you to consider following Sir Ian Kennedy's second part of his very considered recommendation number 25 regarding recognising innovative psychological therapies.

Merely responding that you already have a 'Guide for the Methods of Technological Appraisal' does not do justice to his recommendation. He considered that gold standard RCTs were better suited for drug treatments, rather than new psychological therapies. He suggested that you consider new methodologies that may be better suited to recognising innovative psychological treatments, methodologies which were not in existence when the original NICE 'Guide for the Methods of Technological Appraisal' were written, and I believe have hence not been adequately considered, especially in this context. I would urge you to follow his recommendation and at the very least consider a systematic approach to evidence regarding psychological therapies, including the place of RCTs and non-experimental evidence, as this is extremely important to our profession.

I have outlined below some of the main arguments, as follows:

1. Some of the difficulties of NICE guidelines regarding new psychological therapies
2. Examples of new methodology that is suited to psychological therapy
3. Some of the potential benefits of establishing an alternative methodology (in addition to RCTs) for recognising psychological therapies.
4. How these newer methodologies could fit into the NICE framework
5. Issue of randomisation
6. Recommendation

1. Some difficulties of NICE guidelines regarding new psychological therapies

- a.** RCTs are very costly, and in this climate it is imperative to consider less expensive alternatives
- b.** RCTs are inaccessible to most therapists who may have developed innovative therapies. Firstly, they would not have access to funding like

pharmaceutical or manufacturing companies. Secondly, they will be employed and would not be free to leave their post to be part of an RCT. Thirdly, the source of referrals for most clinicians does not lend itself to randomisation, which would require an academic institution or a large clinic.

c. RCTs generally have relatively small sample sizes for psychological treatments

d. RCTs require controls (ie waiting list controls) for every study, which could be considered to be ethically difficult to keep some clients waiting for treatment (eg those with high suicidal ideation)

e. As a result of the current system, most new therapies just call themselves a variant of CBT to be acceptable and used. Many second and third generation CBT bears very little resemblance to CBT on which NICE guidelines are based! Consequently service purchasers and service users may mistakenly assume that the treatment they are receiving is NICE approved. This practice could almost be considered to be unethical. While NICE guidelines are excellent and very highly regarded, the current system may undermine NICE in this field, which would be most unfortunate!

f. Because of the newer forms of CBT, Improved Access to Psychological Therapy (IAPT) has had to stipulate that their therapists are IAPT trained CBT therapists, to ensure that they adhere to the NICE guidelines. As a result almost all the experienced CBT therapists who actually teach the IAPT CBT courses would not be eligible to work in IAPT themselves!

h. Because NICE does not have a rigorous but accessible route for recognising new psychological therapies, new psychological therapies are likely to continue to call themselves a variant of CBT to be acceptable, or else remain true to their roots and struggle as an unrecognised therapy.

One colleague was told that they needed to have about £300,000.00 in order to fund a trial that would gain NICE approval (out of the league of any therapist's salary). Another colleague told me that it took her 8 years to do an RCT with an academic institution for her innovation in therapy. As you can see, this is obviously out of the reach of an individual health practitioner and clearly the confusion and mess that is happening in the world of psychological therapy is a sign that the current system for recognising new therapies is not working very well!

While RCTs need to be kept as are an strong and rigorous methodology, if there is now an alternative new methodology that is equally rigorous, producing the same type of high quality reliable results, and that is more accessible. NICE does need to consider approving an alternate route that is equivalent to RCTs to evaluate the effectiveness of new psychological therapies!

2. Examples of new methodology that is suited to psychological therapy

Rigorous Practice-Based Evidence (RPBE)

Briefly, this involves evaluating every client in every session, using standardised questionnaires, often more than one at each session. This means that pre and post data will be available for every participant, even those who do not complete treatment. The results can be compared to the results of RCTs using the same questionnaires, existing benchmarks (for 'practice as usual'), or sophisticated 'matched controls' could be relatively easily created using existing data. The use of more than one questionnaire every session, or triangulation, provides more confidence in the results. Many therapists in many different sites can be part of one study.

Mapping

This is not as crucial as the above, but does involve drawing out the similarities between the new therapy and proven psychological techniques from both a practical and a theoretical level. This may also help to identify what aspect of the treatment is critical to change. Mapping by itself would not be sufficient to demonstrate the effectiveness of a treatment, and would need to be done in conjunction with rigorous testing. However, mapping may fall under the guise of 'expert evidence' and as such I will not refer to mapping again in this email, but will focus instead on RPBE.

3. Some of the potential benefits of establishing an alternative methodology (in addition to RCTs) for recognising psychological therapies.

Rigorous practice-based evidence (as used by IAPT and HGIPRN)

- cheaper
- any therapist would be able to access this methodology
- consequently accessible to many therapists in many settings
- potentially much larger sample sizes would be available
- relatively easy to create sophisticated a matched control database that would not require a new control group for every new study
- treatment control groups may be more credible than control groups in some RCTs for psychological therapy, as they would be believed by the therapist
- could easily compare the new therapy to valid treatments and existing RCTs (eg compare CBT and waiting list control to new therapy)

- treatment is done in naturalistic settings, which increases external reliability
- pre and post treatment data would be available for all participants in the study, including drop outs (those who do not complete treatment), leaving no attrition bias
- use of multiple therapists in multiple settings can help to control for extraneous variables, particularly in similar effect sizes are found using the same questionnaires in all the treatment settings

Establishing a recognised alternative route to RCTs in getting new psychological therapies approved

- NICE recognition of an alternative route for approval that is seen to be as robust in its conclusions as RCTs for psychological therapy is important in facilitating a change
- new therapies will not need to call themselves a variant of CBT in order to be used
- new versions of CBT are also more likely to be evaluated (as it is more accessible), and these results can be compared to existing CBT RCT studies to clarify the effectiveness of subtypes of CBT
- new therapies are more likely to be rigorously evaluated earlier
- also allows for continuous evaluation of new therapies, as well as existing services, which will strengthen the reliability of the conclusions
- much more rigorous evaluation is likely to be undertaken, producing very high sample sizes for psychological treatment
- NHS can be more involved in evaluating new psychological treatments, as cost is not prohibitive

4. How these newer methodologies could fit into the NICE framework

The new rigorous practice-based evidence (RPBE) could be considered to be a combination of a disconnected network and perhaps a meta-analysis, and comparing these to RCTs or a mixed treatment comparison (MTC). This has not been adequately considered by NICE. Indeed, with reference to a disconnected network, NICE (2008) states "There is the possibility of using non-randomised evidence to span discontinuities but this is beyond the scope of any published methodology." In addition, while NICE produced a 'Briefing paper for methods review workshop on evidence synthesis (indirect and MTCs)', issues and questions were raised but no final conclusion on the use of this methodology appeared to be reached in NICE's 2008 update.

New psychological therapies in a RPBE would be considered as a '**disconnected network**', because they may not have any previous

treatment trials due to their expense and lack of accessibility to psychologists and therapists who do not work in academic institutions.

RPBE could be considered to be like a **meta-analysis** using multiple therapists at multiple sites all in one study. NICE's 2008 guidelines state that a "synthesis of outcome data through meta-analysis is appropriate provided there is sufficient relevant and valid data that uses measures of outcome that are comparable" (5.4.2) For example, the Human Givens Institute Practice Research Network (HGIPRN) has collected data on over 1300 patients with over 46 therapists using the same treatment technique in sites across the England, Scotland, Wales and Northern Ireland. This data includes pre and post data on all patients, including 'drop outs' (those who did not complete treatment) and would be traditionally 'left out' of traditional RCTs. Another example of this methodology being widely used is in the Improved Access to Psychological (IAPT) services that have been rolled out by the government across the UK. Many CBT therapists over multiple sites have collected data on every patient that they see, including those who drop out of treatment. While the IAPT is not using new psychological techniques, it demonstrates that this methodology can be used widely and relatively easily with psychological treatment, and by therapists in real clinical settings (as opposed to more traditional treatment trials). It also demonstrates that using this methodology can generate very high sample sizes for psychological studies.

Because RPBE uses standardised questionnaires, the results can be relatively easily compared to **mixed treatment comparators (MTCs)**. The MTCs would be primarily based on RCTs, whose results would have been based on randomisation. The MTCs would include waiting list control groups, as well as legitimate treatment controls (in that the therapists believe that their therapy will be effective, as opposed to 'sham' treatment control groups). As a result, this could reduce the cost, and be ethically more acceptable (in that they do not require additional patients to be deprived of treatment for a time in order to be part of the 'waiting list' control group). To make this methodology more sophisticated, it would be relatively easy to create an ever-expanding data base of 'matched controls' in which data from the RPBE could be randomly matched for age, gender, etc to the control groups. The MTCs could also be compared to benchmarks for the standardised questionnaire, such as Clinical Outcomes in Routine Evaluation (CORE), which is used widely across the UK, and could be used as a 'treatment as normal', although this database is not very accurate and may only include as few as 36% of patients actually seen in some cases, and as such would not be a good comparator for the purposes of NICE, in my opinion.

5. Issue of randomisation

The issue of randomisation is extremely important in helping to demonstrate that treatment effects are likely to be as a result of the treatment and not other extraneous variables. In fact this is so important that NICE considers RCTs, and especially meta-analysis that include RCTs to be the 'gold standard' in evidence.

I would argue that in RPBE, treatment effects can also be demonstrated to be as a result of the treatment and not other extraneous variables, and hence can be considered to be equivalent to randomisation in indicating the causality of the treatment in producing the treatment effects. For example, if over 46 therapists over multiple sites, population groups, and referral routes all demonstrate a similar treatment effect on standardised questionnaires, and that effect is equivalent to treatment in RCTs and significantly greater than controls using the same questionnaires, the treatment effect cannot be due to a therapist effect, or due to the colour of paint on the walls of the building, or another random artifact. Demographic data and 'pre' the scores on the standardised questionnaire can indicate whether the sample is representative and similar to the samples of other studies. If necessary, the results can also be statistically adjusted to account for a non-representative sample, but with large sample sizes, the sample is likely to be representative, as the current examples of this methodology demonstrate. Thus, if many therapists on many sites, with many different referral routes all demonstrate similar significant treatment effects on standardised questionnaires that are equivalent to those found in RCTs, particularly if the demographic information and initial scores on the questionnaires are statistically controlled for, it is extremely unlikely that these effects can be attributed to anything other than the effect of the treatment. The larger the sample size in a RPBE, the more powerful the effects!

When considering this issue, it is also important to consider randomisation in RCTs for psychological therapies. Due to the nature of psychological therapy, sample sizes in RCTs tend to be relatively small compared to drug treatment trials, often around 30 per group. However, with smaller sample sizes being common, there is also a higher risk in these RCTs that the sample may still be biased in spite of randomisation. In addition, the selection criteria that is required in an RCT, which makes the results very specific, may also bias the overall sample, so that it may not have as many complex or co-morbid cases, or may have to filter out those in higher risk of suicide due to the waiting list control, or may exclude patients who may not respond well to psychological treatment, all of which may not make the sample of the RCT representative of patients who are actually treated in clinics. RPBE by definition is more likely to be representative, especially if there are high number of those referred are not excluded and are accepted

for treatment. Thus, it is possible that the selection process prior to randomisation may bias the sample by definition. The high sample sizes that are possibly in RPBE make the sample more likely to be representative, and therefore dramatically reduce the potential bias in the sample. Studies that accept a higher proportion of the referrals, like some RPBE studies, are also less likely to bias the sample in a way that may inflate the treatment effect.

In addition, treatment 'drop outs', or attrition bias, may also end up biasing the sample to favor the treatment. This may end up countering the effects of randomisation especially if there are a relatively high number of drop outs in a study. In fact, the results of the RPBE demonstrate that the treatment effects are much higher for those who complete treatment compared to those who drop out. Even though patients might be randomly allocated before treatment starts, this does not guarantee that the drop out rates will also be randomised, and indeed it may be that people who are not particularly suited to the therapy disproportionately drop out. Thus, the final sample on which the results are based, may be actually a biased sample that can negate some of the effects of the original randomisation! This is rarely considered in RCTs. Because data on drop outs in RPBE is available, the impact of drop outs biasing the sample and the results is controlled for, and could produce more accurate and valid results.

Randomisation is therefore not required to demonstrate causality when there are sufficiently large sample sizes, multiple therapists and multiple sites. Sample selection and drop outs in RCT can counter or weaken the effects of randomisation in demonstrating that the treatment effects are due to therapy alone and not other artifacts. The larger sample size, accounting for all drop outs, and the use of multiple therapist in multiple locations in RPBE help to strengthen the validity of the conclusion that the treatment effects are due to the therapy and not some other cause. Thus, both RCTs and RPBE have their strengths and weaknesses, but in spite of this both methodologies can indicate causality and hence the effectiveness of a psychological treatment.

6. Recommendation

I would urge that NICE consider RPBE as an alternate route, while maintaining the traditional RCT, for new psychological therapies to be recognised. Obviously, the greater the sample size, and the more therapists and sites that are used, the more powerful the results. In fact, with large numbers, and given that data is also available for 'drop outs' (which is not traditionally available in RCTs), it may be that some RPBEs may be more powerful than a RCT and are actually equivalent to a meta-analysis. Given the impact on our profession, it is extremely important that NICE does

seriously consider newer methodologies for recognising psychological therapies.

I have been invited to speak at the British Psychological Society's Annual Conference this year, entitled "An exciting new era for practice-based evidence!"

Please do not hesitate to contact me if you have any queries.

Kind regards

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