British Journal of Psychiatry (1994), **165**, 4–8

Editorial

Clinically Relevant Outcome Research in Individual Psychotherapy

New models guide the researcher and clinician

KENNETH I. HOWARD, DAVID E. ORLINSKY and ROBERT J. LUEGER

How can we design relevant psychotherapy research? The answer must be shaped by the objectives and potential consumers of such research. For over 40 years, "does psychotherapy work?" (Eysenck, 1952) held the attention of psychotherapy researchers, and randomised clinical trial methodology seemed the most appropriate empirical option for answering this question. There are now well over 500 studies that attest to the efficacy of psychotherapy (see Smith *et al*, 1980; Shapiro & Shapiro, 1982; Lipsey & Wilson, 1993, for meta-analytic research summaries); it seems that psychotherapy is one of the best documented medical interventions in history. But the conclusion that psychotherapy "works" is akin to finding that antibiotics "work". We are left with the daunting task of determining which of the wide variety of treatments (psychotherapies, antibiotics) are appropriate for which variety of illnesses (psychopathologies, infections). Morris Parloff (1982) warned us of this need for specificity in his classic article, "Bambi meets Godzilla", but our preoccupation with documenting the efficacy of psychotherapy has only recently abated enough to mount empirical studies of such specificity.

In order for the findings of specificity-oriented psychotherapy outcome research to be relevant to the practitioner, patients, therapists, therapies, and treatment settings must be representative of some specified populations and outcome measures must be clinically relevant. The individual clinician must decide the extent to which research findings are based on samples, procedures, and measures that are applicable to his or her own clinical practice. We present here some theoretical models for the guidance of outcome research, and briefly describe some of our own recent work in this area.

Currently, clinical trial methodology is the 'official' model for this outcome research; it is most useful for addressing questions regarding the sufficiency of an intervention: "Can this treatment produce this desirable effect in this type of patient?" However, five problems arise when this methodology is applied to patient populations. Firstly, the process of random assignment in itself militates against generalisability, as it does not represent the process through which patients enter and persevere in treatment. Secondly, because of the multitude of uncontrolled, potentially causally relevant, independent variables, the sample size in a particular study is never sufficient to ensure that random assignment will equate groups with regard to possible confounds. Thus, even when groups are randomly 'equated' and significant outcome differences between them are obtained, we cannot be sure that these differences were a result of the causal influence of the selected independent variables. Thirdly, when within-cell variation exceeds measurement error, there are reliable differences among patients within treatments; that is, some patients are responding differently to the same treatment (Lyons & Howard, 1991). Fourthly, although patients may be randomly assigned to treatment conditions, therapists almost never are, with the result that outcome findings reflect therapist-by-treatment packages in which therapist characteristics are neither well controlled nor well described. Typically, this research design does not permit the attribution of outcome findings to treatment effects alone. Finally, in conducting research with patients it is virtually impossible to avoid missing data (attrition) because patients routinely fail to provide complete information at all data points and to complete treatment regimens as defined by the investigator. Missing data, therefore, always compromises random assignment, often reducing the clinical trial to the status of a poorly designed quasi-experiment.

Another approach would be to standardise a treatment and determine the type of patient who responds well to it (Howard *et al*, 1993). This systematic exploratory approach would entail a self-correcting learning model that continuously incorporates the response to treatment of new patients in order to clearly determine the relevant patient group. It is unlikely, however, that we could ever standardise a treatment in such a way that it could be delivered in the same way by the same therapist across patients, by different therapists, or in different settings.

Meaningful research

Clinical research has to be judged ultimately on the basis of its informativeness. It is self-defeating to espouse a methodology that we must

always fail to properly implement and be forced to move (apologetically) to *post hoc*, secondary analyses to make sense of our data. Instead, we recommend the adoption of a more systematic exploratory methodology and a greater emphasis on the generalisability and the constructive replication of findings. This entails more explicit attention to quasi-experimental methods and to the design of studies in a manner that allows us to evaluate the most plausible threats to internal and external validity.

This systematic exploratory, quasi-naturalistic approach is an outgrowth of the case study method. A sophisticated case-based approach that is useful for building theory and is sufficient to address potential threats to internal validity has been outlined by Kazdin (1981). This case method entails the systematic use of objective data, continuous assessment, a model of problem stability, diverse and heterogeneous samples of patients, and clear evidence of an effect that can be measured for its magnitude and used to modify treatment processes. A case-based method that realises all of these features can address a variety of potential confounds. But how are we to systematically describe these cases?

A model of relevant patient presenting characteristics

The DSM–III–R diagnostic system (American Psychiatric Association, 1987) has not been very useful for categorising patients, it being more or less arbitrary and seemingly ever changing. Also, most clinicians are unwilling or unable to obtain the required training or to spend the time necessary to arrive at a reliable and valid diagnosis for a patient. Therapists are usually confronted by a patient who is quite upset – anxious, frustrated, depressed – and must deal directly with this presentation. At this level, what do we need to assess?

Based on extensive literature reviews (Orlinsky & Howard, 1978, 1986), we have developed a conception of some important psychological characteristics that have an impact on the patient's utilisation of individual psychotherapy. This model is comprised of three categories of variables: psychopathology (presenting symptoms or syndromes), pathology-proneness (psychological vulnerabilities), and life stress. *Psychopathology* refers to the manifest psychiatric symptomatology of the patient. It is concerned with the types and intensity of distressing experiences and behaviours. The concept of *pathology-proneness* refers to the fact that all people are vulnerable to some extent, meaning that there are some life situations with which each of us would have difficulty coping. Some people have relatively pervasive psychological and behavioural vulnerabilities or deficits that make it difficult for them to cope with the challenges and stresses of a wide variety of life situations. This proneness to psychopathology may stem from severe emotional conflicts or inevitable limitations of adaptive resources, from maladaptive social attitudes or dysfunctional cognitions, and so on, and these in turn may be based on hereditary, developmental, or situational factors. In the context of a person's actual resources and vulnerabilities, current *environmental stress* may overwhelm his or her social supports and coping capacities and, thus, trigger manifest psychopathology and the need for therapeutic intervention.

In assessing a patient's condition it is important to measure the kind and severity of symptoms, the kind and pervasiveness of vulnerabilities, and the likely recurrence of the environmental stressors.

The dosage and phase models

The dosage model of psychotherapeutic effectiveness (Howard *et al*, 1986) demonstrated a lawful linear relationship between the log of the number of sessions and the normalised probability of patient improvement. The dose–response function was shown to differ for different syndromes of pathology (e.g. borderlines require a higher treatment dose than do depressives). Subsequent work (Horowitz *et al*, 1988; Howard *et al*, 1993; Howard *et al*, in press; Kopta *et al*, in press) has provided evidence of the differential responsiveness of various symptoms and syndromes to psychotherapy.

The dosage model gave rise to the following three-phase conception of psychotherapy (see Howard *et al*, 1993).

Remoralisation. Some patients are so beset by problems that they become demoralised, feeling at their "wit's end". This experience is so pervasive and intense that the patient's ability to mobilise personal coping resources is severely disrupted. This state responds to a variety of interventions – medication, vacation, emotional support – and will usually abate following a few sessions of supportive or crisis oriented psychotherapy (Frank, 1973; Frank & Frank, 1991). For some patients, this reduction of distress will allow them to mobilise their own coping resources, leading to resolution of current life problems. Other patients move on to a second phase of therapy.

Remediation. A second phase of therapy is focused on remediation of the patient's symptoms that have led them to seek professional help. (Some patients

begin therapy in phase two, i.e. they seek help before the emergence of immobilising distress.) Treatment is concerned with refocusing the patient's coping skills to bring symptomatic relief. This phase usually lasts three or four months (about 16 sessions), but it can vary depending on the symptoms. At this point many patients terminate treatment, but some will find that their problem(s) have been encountered repeatedly in their lives (e.g. instability in employment, problematic interpersonal relationships) and are probably the result of long-standing behaviour patterns (habits, character) that are maladaptive and/or hinder the achievement of life goals (e.g. finding a satisfying career, forming a long-lasting intimate relationship). These patients will move on to the third phase.

Rehabilitation. A third phase focuses on unlearning maladaptive, long-standing behaviour patterns, learning to prevent them, and rehabilitation. This phase of therapy may last many months or years, depending on the accessibility and malleability of these maladaptive patterns, and on the treatment model applied.

Our own work (Howard *et al*, 1993) has demonstrated that these phases are sequentially dependent: remoralisation → remediation → rehabilitation. To the extent that these phases are distinct, they imply different treatment goals and, thus, the selection of different outcome variables. Also, different interventions will be appropriate for different phases of therapy; certain tasks may have to be accomplished before others can be undertaken; and different therapeutic processes may characterise each phase. Remoralisation might be accomplished through the use of encouragement and empathic listening; remediation with the use of interpretations or clarifications; assertiveness training may be useful for rehabilitation.

The Northwestern/Chicago psychotherapy research programme

The example presented is a quasi-naturalistic (i.e. systematic case-tracking) study of psychotherapy in which we do not directly interfere with the treatment episode of any patient, assign patients to therapists, limit the number of sessions, or tell therapists how to conduct their sessions. We do have unknowable indirect impact since patients and therapists know that they are participating in research, have consented to this participation, and complete research questionnaires that inquire about the treatment and its effects. We have tried to make all of this treatment-syntonic and 'user friendly' by designing and selecting methods that have face validity for all involved, in the context of the goals and procedures of individual psychotherapy.

Most importantly, our selection of assessments is theory-based. In accordance with the dose–response model, we assess outcome regularly throughout the course of treatment. The selection of outcome measures is based on our phase model of psychotherapy. Remoralisation is monitored by a measure of subjective well-being and shows a quick response to treatment. Remediation is monitored by a measure of psychiatric symptoms and responds more gradually, once remoralisation is accomplished. Rehabilitation is monitored by a measure of life functioning and responds even more gradually, once remediation has been accomplished. Scores on these three scales are combined into a Mental Health Index. We also include the patient's assessment of the quality of the therapeutic bond (relationship) and clinician-based ratings of the patient's condition on seven dimensions of functioning, combining the latter into a Clinical Assessment Index.

The major advantage is that, in addition to having demonstrated an orderly pattern of response to treatment for these variables, we have developed a system for clinical feedback regarding the status and progress of each case (Howard *et al*, 1992). Using scores on the Mental Health Index (MHI), the Clinical Assessment Index (CAI), the Therapeutic Bond (TB) and the component scores from these indices, we can produce a report which depicts the course of therapy for a patient. This feedback can be used in supervision and case management, as well as in making treatment decisions. We have thus translated the clinical relevance of research from a general conceptual issue into a practical clinical application.

The following are two illustrative cases from our study.

A success

This patient was a single man in his late 20s. He was employed full time in a job appropriate for his education. He presented for treatment complaining of panic attacks, crying spells, restlessness and inability to make decisions, and stated that his goal was to "... overcome my feelings of worthlessness ..." His diagnosis based on the Structured Clinical Interview for DSM–III–R (SCID: Spitzer *et al*, 1988) was major depression.

Therapy was conducted by a married, female, clinical psychology predoctoral intern. Her therapeutic orientation was eclectic psychodynamic with an emphasis on object relations and self-psychology. She had previously seen only 6 – 10 patients in individual psychotherapy.

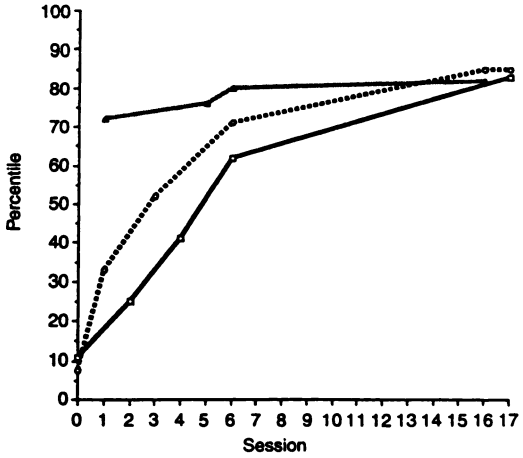

Fig. 1 A treatment success (-□-, MHI; ●●●○●●●, CAI; ■■■ TB).

Figure 1 shows the course of therapy for this patient. The therapeutic bond was higher than average. By the end of this 17 session treatment, from both the perspective of the therapist (CAI) and the patient (MHI), the patient was seen as functioning in the normal range (a percentile score above 83) at termination.

A failure

This patient was a young, single woman, well educated and appropriately employed. At intake, she complained of depression, inability to concentrate, teeth grinding, migraine headaches, and being unable to work. She had had two previous psychiatric treatments and was treated with antidepressants and anti-anxiety medications. Her intake diagnosis, based on the SCID, was major depression.

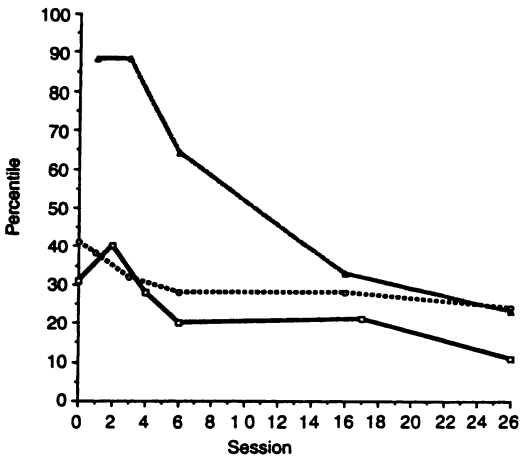

Fig. 2 A treatment failure (-□-, MHI; ●●●○●●●, CAI; ■■■ TB).

The therapist was a young, married, male clinical psychology predoctoral intern. He described his therapeutic orientation as "interpersonal–psychodynamic". He had previously seen over 40 patients.

Figure 2 shows the course of therapy for this patient. The therapeutic bond was somewhat unstable and deteriorating. From both the perspective of the therapist (CAI) and the patient (MHI), the patient's condition worsened over treatment.

Since this was a research project with other goals, neither of these therapists received any feedback on the course of their treatments. But it is clear that such feedback would have provided valuable information for the failure case, and confirmation of progress for the success case.

Conclusion

The time-honoured approach to clinical research is the randomised clinical trial. For this to be informative to a practitioner or policy maker, the study sample must represent a patient population identifiable to the practitioner and main effects must be unambiguous. Regarding the first, attrition and subject recruitment criteria (e.g. the use of structured diagnostic interviews) provide unavoidable barriers to generalisation; the second, overlap of outcome distributions (i.e. some patients in the poor treatment having better outcomes than some patients in the better treatment) (Howard *et al*, in press) and within-cell variation that exceeds measurement error (Lyons & Howard, 1991), as well as unknown therapist-by-treatment confounds, compromise the application of research findings. So this approach seems fruitless in terms of clinical relevance.

Convincing clinicians that psychotherapy research has a practical value is a daunting challenge (see Talley *et al*, 1994). Numerous authors have discussed the disjuncture between research and practice (Cohen *et al*, 1986; Strupp, 1989; Whiston & Sexton, 1993). Strupp perhaps said it best: "Although I have greatly profited from the investigation of others, nothing is as convincing as one's own experience" (Strupp, 1989, p. 717). The key to impacting clinician's experience is to provide information relevant to the current case in treatment.

The approach that we have taken is to develop a theoretical framework – the dosage and phase models – operationalise and test the concepts, and develop a system for feedback to the clinician about the course of a single treatment (see Kazdin, 1993, for a similar approach) which can be viewed at several levels. Our experience is that therapists

welcome this feedback and that it enhances the treatment of a specific case.

Acknowledgements

This is a condensed, modified version of a paper presented at the Research Meeting of the Mental Health Foundation held at Balliol College, Oxford, September, 1993 (Howard *et al*, in press). This work was partially supported by grants RO1 MH42901 and KO5 MH00924 from the National Institute of Mental Health. We are grateful for the clinical work of Cori Hillmann and the statistical work of Bruce Briscoe.

References

AMERICAN PSYCHIATRIC ASSOCIATION (1987) *Diagnostic and Statistical Manual of Mental Disorders* (3rd edn, revised) (DSM-III-R). Washington, DC: APA.

COHEN, L. H., SARGENT, M. M. & SECHREST, L. B. (1986) Use of psychotherapy research by professional psychologists. *American Psychologist*, **41**, 198–206.

EYSENCK, H. J. (1952) The effects of psychotherapy: An evaluation. *Journal of Consulting Psychology*, **16**, 319–324.

FRANK, J. D. (1973) *Persuasion and Healing*. Baltimore: Johns Hopkins University Press.

—— & FRANK, J. B. (1991) *Persuasion and Healing: A Comparative Study of Psychotherapy*. Baltimore: Johns Hopkins University Press.

HOROWITZ, L. M., ROSENBERG, S. E., BAER, B. A., *et al* (1988) Inventory of interpersonal problems: psychometric properties and clinical applications. *Journal of Consulting and Clinical Psychology*, **56**, 885–892.

HOWARD, K. I., BRILL, P. L., LUEGER, R. J., *et al* (1992) *Integra Outpatient Tracking Assessment: Psychometric Properties*. Radnor, PA: Integra.

——, KOPTA, S. M., KRAUSE, M. S., *et al* (1986) The dose-effect relationship in psychotherapy. *American Psychologist*, **41**, 159–164.

——, KRAUSE, M. S. & LYONS, J. (1993) When clinical trials fail: a guide for disaggregation. In *Psychotherapy and Counseling in the Treatment of Drug Abuse* (eds L. S. Onken & J. D. Blaine). Washington, DC: National Institute of Drug Abuse.

——, —— & VESSEY, J. T. (1994) Analysis of clinical trial data: the problem of outcome overlap. *Psychotherapy*, **30**, 546–553.

——, LUEGER, R., MALING, M., *et al* (1993) A phase model of psychotherapy: causal mediation of outcome. *Journal of Consulting and Clinical Psychology*, **61**, 678–685.

——, ORLINSKY, D. E. & LUEGER, R. J. (in press) The design of clinically relevant outcome research: some considerations and an example. In *Research Foundations for Psychotherapy Series* (eds M. Aveline & D. Shapiro). Chichester: John Wiley.

KAZDIN, A. E. (1981) Drawing valid inferences from case studies. *Journal of Consulting and Clinical Psychology*, **49**, 183–192.

—— (1993) Evaluation in clinical practice: clinically sensitive and systematic methods of treatment delivery. *Behavior Therapy*, **24**, 11–45.

KOPTA, S. M., HOWARD, K. I., LOWRY, J., *et al* (in press) The psychotherapy dosage model and clinical significance: A comparison of treatment response rates over time for psychological symptoms. *Journal of Clinical and Consulting Psychology*.

LIPSEY, M. W. & WILSON, D. B. (1993) The efficacy of psychological, educational, and behavioral treatment: confirmation from meta-analysis. *American Psychologist*, **48**, 1181–1209.

LYONS, J. & HOWARD, K. I. (1991) Main effects analysis in clinical research: statistical guidelines for disaggregating treatment groups. *Journal of Consulting and Clinical Psychology*, **59**, 745–748.

ORLINSKY, D. E. & HOWARD, K. I. (1978) The relation of process to outcome in psychotherapy. In *Handbook of Psychotherapy and Behavior Change* (2nd edn) (eds S. L. Garfield & A. E. Bergin), pp. 283–329. New York: John Wiley.

—— & —— (1986) Process and outcome in psychotherapy. In *Handbook of Psychotherapy and Behavior Change* (3rd edn) (eds S. L. Garfield & A. E. Bergin), pp. 311–381. New York: John Wiley.

PARLOFF, M. B. (1982) Psychotherapy research evidence and reimbursement decisions: Bambi meets Godzilla. *American Journal of Psychiatry*, **139**, 718–727.

SHAPIRO, D. A. & SHAPIRO, D. (1982) Meta-analysis of comparative therapy outcome studies: a replication and refinement. *Psychological Bulletin*, **92**, 581–604.

SMITH, M. L., GLASS, G. V. & MILLER, T. I. (1980) *The Benefits of Psychotherapy*. Baltimore: Johns Hopkins University Press.

SPITZER, R. L., WILLIAMS, J. B. W., GIBBON, M., *et al* (1988) *Structured Clinical Interview for DSM-III-R*. Washington, DC: American Psychiatric Press.

STRUPP, H. H. (1989) Psychotherapy: can the practitioner learn from the researcher? *American Psychologist*, **44**, 717–724.

TALLEY, F., BUTLER, S. & STRUPP, H. (eds) (1994) *Research Findings and Clinical Practice: Bridging the Chasm*. New York: Basic Books.

WHISTON, S. C. & SEXTON, T. L. (1993) An overview of psychotherapy outcome research: implications for practice. *Professional Psychology: Research and Practice*, **24**, 43–51.

K. I. Howard, PhD, Northwestern University, Illinois; **D. E. Orlinsky**, PhD, University of Chicago, Illinois; **R. J. Lueger**, PhD, Marquette University

Correspondence: Dr K. I. Howard, Department of Psychology, Northwestern University, 2029 Sheridan Road, Evanston, Illinois 60208-2710, USA

(First received December 1993, final revision January 1994, accepted January 1994)