Assessing treatment efficacy in acute aphasia: paradoxes, presumptions, problems and principles

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#### **Abstract**

It is paradoxical that most studies that have examined the efficacy of aphasia rehabilitation have involved patients with stable, chronic aphasia, while most clinicians treat patients whose aphasia is of much shorter duration and often more dynamic. Extending the results of treatment efficacy studies with chronic patients to acute patients requires that two essential presumptions be made: (1) a method that works with chronic patients will in fact work with acute patients; (2) the method is equally appropriate for both chronic and acute patients. These presumptions and problems that may arise when assessing treatment efficacy in acutely aphasic patients are discussed. Principles that may guide future studies are enumerated.

#### Introduction

Time post-onset is widely recognized as an important factor when considering the performances of persons with aphasia. The brain's ameliorative responses to insult generally result in improved performance during the acute recovery period. Indeed, clinicians often cite short time post-onset as a positive prognostic factor, and many have advocated early treatment in part to 'take advantage' of spontaneous recovery.

When reviewing the aphasia treatment literature, one finds that most studies fall into two categories with respect to their treatment of time post-onset. The first category is composed mainly of earlier group studies in which time post-onset was reported in aggregate terms (e.g. Basso et al. 1979, Sarno et al. 1970) and case reports in which little or no information was provided regarding the duration of the subjects' aphasia (e.g. Berman and Peele 1967, Helm-Estabrooks et al. 1982, Sparks et al. 1974). Studies comprising the second category generally began to appear in the late 1970s. For the most part, these are studies that employed single-subject experimental designs (Herson and Barlow 1976, McReynolds and Kearns 1983). The introduction of these designs brought about a more systematic treatment of time post-onset in treatment efficacy research. Because single-subject

designs essentially require stable baseline performances, clinical researchers began routinely to use subjects who were several months, even years, post-onset. Using chronically aphasic subjects, whose 'natural' recovery had plateaued, provided researchers with the stable baselines that the experimental designs demanded.

Most treatment efficacy studies reported in the past decade which have demonstrated adequate experimental controls to identify specific treatment effects have employed chronically aphasic subjects. However, a few studies (e.g. Linebaugh et al. 1996, Murray and Holland, 1995, Warren et al. 1987) have successfully examined treatment efficacy in patients with acute aphasia. For the purposes of this paper, acute will refer to the period extending up to 3 months postonset; chronic will refer to all times post-onset beyond 3 months. While some may wish to extend the acute period beyond 3 months, we have selected this cut-off point based on the preponderance of evidence indicating that most spontaneous recovery occurs within the first 3 months post-onset (Kertesz and McCabe 1977, Mazzoni et al. 1992). We discuss several issues pertaining to the assessment of treatment efficacy in acute aphasia. In particular, we examine certain paradoxes that exist and presumptions that have been made in the assessment of treatment efficacy. In addition, selected problems that may arise in the assessment of treatment efficacy in acutely aphasic patients and principles that may guide future research are considered.

#### **Paradoxes**

Scrutinizing the aphasia treatment efficacy literature in the context of contemporary clinical practice reveals two important paradoxes. The first paradox is that while most speech-language treatment conducted in rehabilitation facilities is provided to acutely aphasic patients, most recent treatment efficacy studies have recruited chronically aphasic patients as subjects. As noted above, this was done in order to facilitate obtaining the stable baselines required by single-subject experimental designs. In most cases, the subjects have been at least 12 months post-onset of aphasia, and in many studies the subjects are several years post-onset (e.g. Doyle et al. 1987, Hillis 1991, Marshall et al. 1990, Raymer et al. 1993, Thompson et al. 1997). In contrast, the patients actually receiving treatment generally are of significantly shorter times post-onset and are behaviourally more variable. The literature is nearly devoid of studies with adequate experimental controls that demonstrate the efficacy of a specific treatment with both acute and chronic patients.

A second paradox involves the way in which one views spontaneous recovery. While the precise mechanisms by which performance improves in the aftermath of stroke and other insults to the brain are not clearly understood, the improvement itself has been well documented (Kertesz and McCabe 1977, Mazzoni et al. 1992, Vignolo 1964). Importantly, this improvement may result from both physiological restitution of neural processing and patients' discovery of compensatory strategies. It is a process that may continue for 3 months, 6 months, or perhaps even longer (Kertesz and McCabe 1977).

For the clinician, spontaneous recovery is an ally, a resource to, perhaps, be harnessed and directed. For the clinical researcher, however, spontaneous recovery is a potential saboteur, one that may confound the interpretation of results and obscure a viable treatment effect. It must be planned for in designing treatment experiments and it must be accounted for in analysing and interpreting results. In

short, spontaneous recovery must be an important focus of maintaining experimental control in studies of treatment efficacy in acute aphasia.

## Presumptions

In the context of standard service delivery practices; that is, that speech-language rehabilitation is more commonly provided to acutely than to chronically aphasic patients, consumers of efficacy studies that used chronic subjects are asked to make two important presumptions. First, they are asked to presume that a treatment approach that is efficacious with chronic patients will be similarly efficacious with acute patients. Unfortunately, this presumption has no empirical support. As was stated above, no well-controlled study has been conducted in which a particular treatment has been shown to be efficacious for patients with both acute and chronic aphasia. Treatments that have been shown to be efficacious with chronic patients await demonstration of their efficacy with acute patients.

The second presumption that consumers of the treatment efficacy literature are asked to make is more fundamental to the clinical enterprise. They are asked to presume that a treatment that is appropriate for chronic patients is likewise appropriate for acute patients. Most of the treatments that have been shown to be efficacious with chronically aphasic patients involve so-called model-based treatments; that is, the treatment is directed toward a specific 'locus of impairment' (e.g. lexical retrieval, syntactic decoding or formulation, orthographic to phonologic conversion) within a model of neurolinguistic processing (Byng 1994, Shapiro and Thompson 1994). Identification of the locus of impairment requires that the patient's responses be sufficiently consistent to justify targeting of the process in treatment. Generally, acutely aphasic patients are regarded as being more variable in their responding than are chronic patients. While no direct comparison of response variability between acute and chronic patients has been reported, several studies have attested to the variability of responding in acute patients (Horner and Rothi 1981, Linebaugh et al. 1995). If acutely aphasic patients are indeed more variable than chronic patients, then treatments that engage a wider range of processing impairments may be more appropriate for acute patients and those that focus on a specific processing impairment may be more appropriate for chronic patients. Furthermore, the brain of the patient in acute recovery may be more amenable to treatments that foster reorganization and restoration of function (Keefe 1995) than are the brains of chronic patients. Perhaps, treatment for acute patients should be based on theories of rehabilitation that consider restoration of function, whereas intervention for chronic patients should focus on developing compensations for residual deficits and functional disabilities (Gonzalez Rothi 1991). Of course, until tested in empirically valid methods, these assertions themselves are no more than presumptions to be made in planning treatment.

#### **Problems**

Many potential problems confront the clinical scientist seeking to assess the efficacy of treatments with acutely aphasic patients. Three particular problems will be discussed as a means of illustrating the difficulties one might encounter. The data that are reported are from a recent study that assessed the efficacy of a combined pre-stimulation-cueing hierarchy treatment for anomia. The treatment and the experimental design are described in the Appendix.

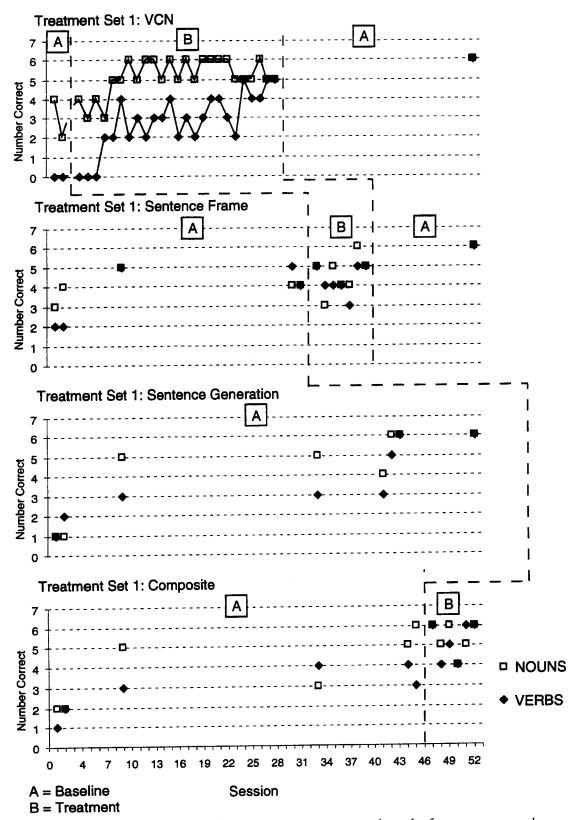


Figure 1. Subject Y. D.'s performances on treatment set 1 on the four treatment tasks.

## Problem 1. Strong overall recovery

In some instances, enthusiasm for an apparent treatment effect must be tempered in the context of a strong overall recovery. Patient Y. D. was a 50-year-old woman who entered the treatment protocol at 3 weeks post-onset. Her Western Aphasia

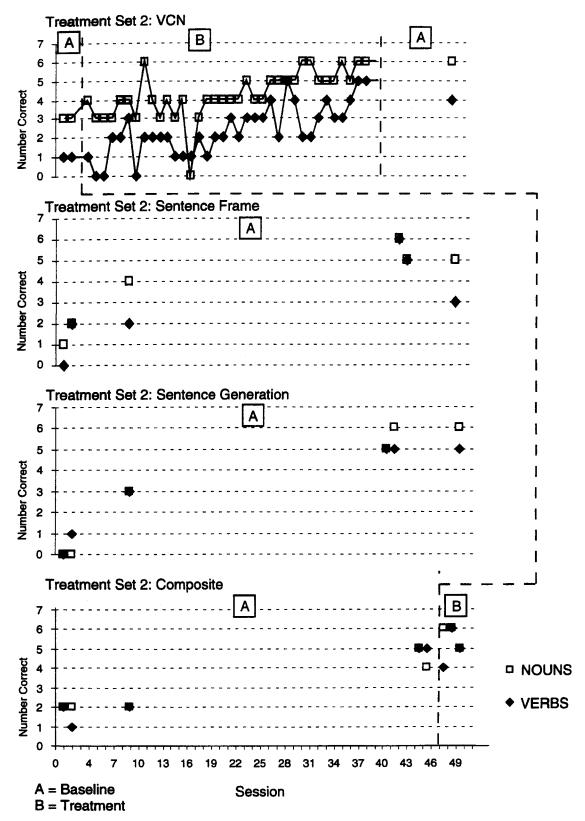


Figure 2. Subject Y. D.'s performances on treatment set 2 on the four treatment tasks.

Battery (WAB) (Kertesz 1982) Aphasia Quotient (AQ) at entry was 57. Her aphasia was classified as Wernicke, and she presented with particular impairments in word retrieval and auditory comprehension. Figures 1–3 display results of the intervention. Comparison of the results for treatment sets 1 and 2 with those for the

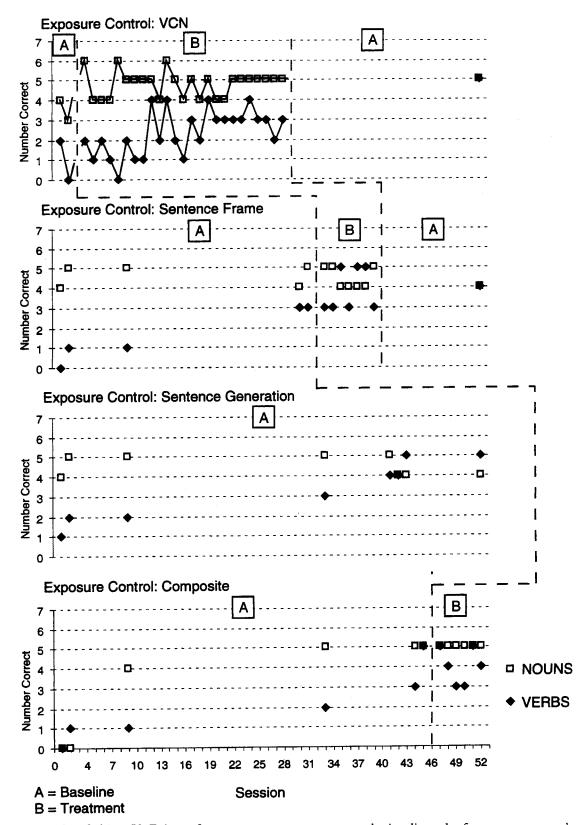


Figure 3. Subject Y. D.'s performances on exposure control stimuli on the four treatment tasks.

exposure control stimuli indicates that Y. D.'s performances on treated stimuli improved to a greater extent than did her performance on the untreated stimuli. For treatment set 1, she reached criterion on the visual confrontation naming (VCN) task after 25 sessions, the sentence frame (SF) task after seven sessions,

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	Entry	Exit
Western Aphasia Battery		
AQ (100) <sup>a</sup>	57	89-2
Object naming (60)	37	54
Auditory word	50	60
recognition (60)		
Sequential	23	76
commands (80)		
Repetition (100)	70	91
PPVT (175)	105	111
BNT (60)	13	24
FCP-Speaking (70)		
SLP	25	<b>4</b> 6

Table 1. Standard test results for subject Y.D. at entry to and exit from the treatment protocol

generalized to criterion for the sentence generation (SG) task, and reached criterion on the composite task after six sessions. For treatment set 2, she reached criterion on the VCN task after 36 sessions, generalized to criterion for the SF and SG tasks, and reached criterion on the composite task after three sessions. While her performance on the exposure control stimuli improved, she failed to reach criterion level performance on any of the four tasks. However, comparison of Y. D.'s performances on standard measures at entry to and exit from the protocol (see table 1) reveals a strong overall recovery; her AQ increased to 89.2 and her sequential commands score increased to 76/80. This, combined with her improved performance on the exposure control stimuli, requires that we be cautious in our interpretation of the treatment effect.

## Problem 2. 'Runaway' generalization

L. C. was a 67-year-old man who presented with anomic aphasia with an AQ of 88.4. His primary impairment was in word retrieval. While at 8 months post-onset L. C. is beyond our cut-off point for acute aphasia, his data are reported here because his performance on the treatment protocol well illustrates a pattern that may be observed in acute patients.

Figures 4–6 display his performances on the three stimulus sets. As can be seen, his performance on nouns was very good at baseline, but his verb production was significantly impaired. L. C. reached criterion on the VCN task for treatment sets 1 and 2 after four and five sessions, respectively. His performance immediately generalized to criterion level on the SF, SG, and composite tasks for both treatment sets. His performance on the exposure control stimuli improved to near criterion level on all four tasks. Thus, experimental control could not be demonstrated clearly and a potentially powerful treatment effect is obscured.

#### Problem 3. When to continue, when to terminate

Acutely aphasic patients in a comprehensive rehabilitation programme face great demands on their physical and cognitive endurance. Thus decisions regarding which patients to enter into a protocol, when to continue treatment, and when to

<sup>&</sup>lt;sup>a</sup> Maximum score.

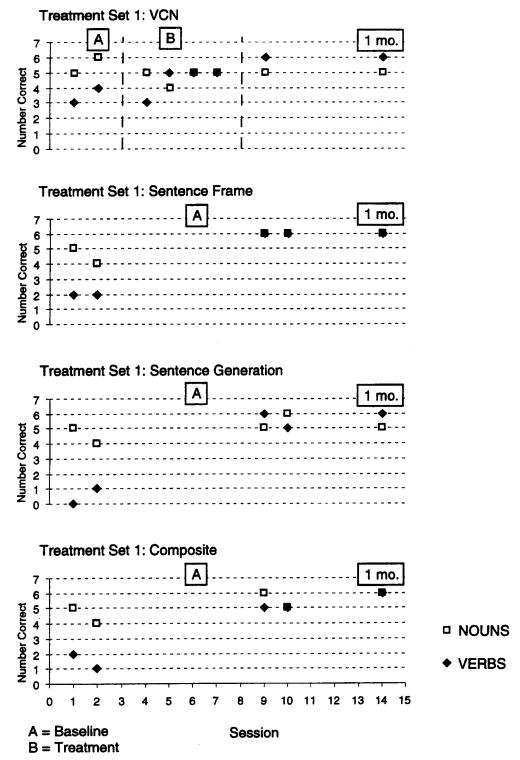


Figure 4. Subject L. C.'s performances on treatment set 1 on the four treatment tasks.

terminate treatment are especially important. Two cases will be used to demonstrate this issue. R. A. was a 52-year-old man who entered the treatment protocol at 2 weeks post-onset. His aphasia was classified as transcortical sensory with notable impairments in auditory comprehension and word retrieval; his initial AQ was 60.8. R. A.'s participation was terminated after only 11 sessions because of minimal improvement. This decision was based in large measure on the failure of his error responses to move toward the target. However, as can be seen in figures 7–9, 3

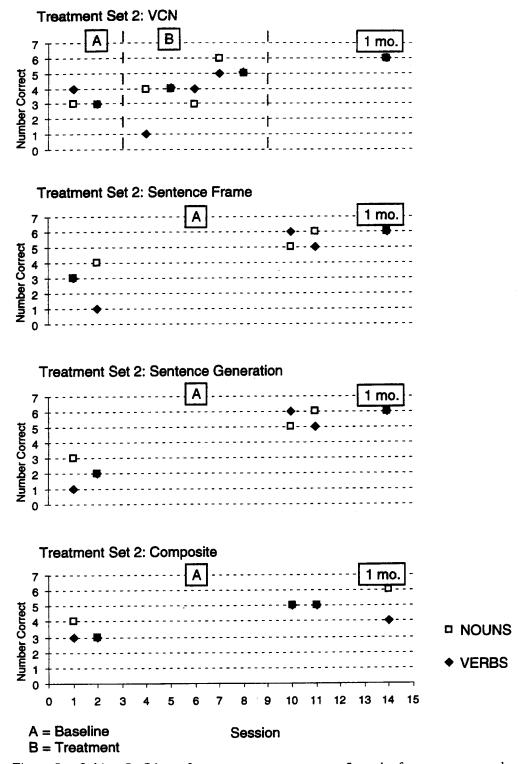


Figure 5. Subject L. C.'s performances on treatment set 2 on the four treatment tasks.

months later his performances approached criterion level on all four tasks. These results invite speculation as to whether or not the specific treatment was terminated prematurely or if a different treatment would have yielded better results. One also might ask if R. A.'s improvement might have been faster and his outcome more favourable if treatment had been continued or if a different treatment had been employed. Finally, the question arises as to whether or not treatment is appropriate for all patients immediately post-onset.

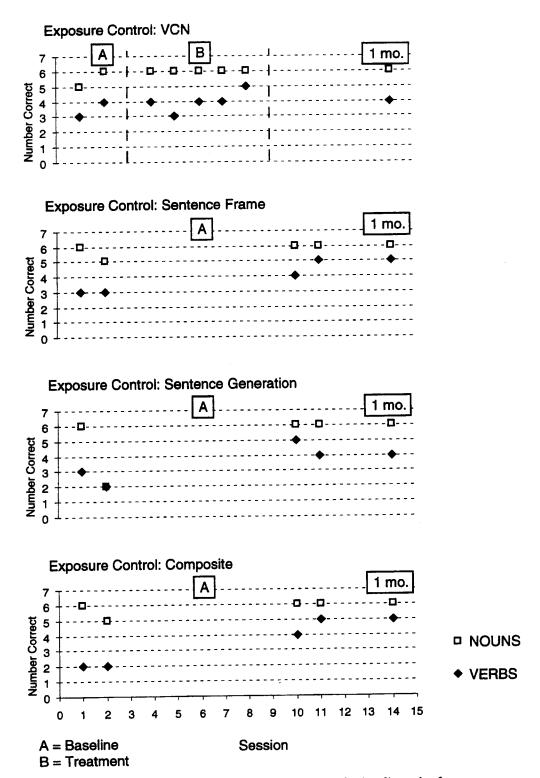


Figure 6. Subject L. C.'s performances on exposure control stimuli on the four treatment tasks.

A. S., a 73-year-old woman, presented with Wernicke aphasia with an AQ of 49.9. Her particular impairments were in auditory comprehension, word retrieval, and repetition. A. S. was continued in the protocol even though she required 50 sessions to reach criterion on the VCN task for treatment set 2. She subsequently reached criterion level on the SF, SG, and composite tasks in seven, 11, and eight sessions, respectively. She never reached criterion level on the VCN task for

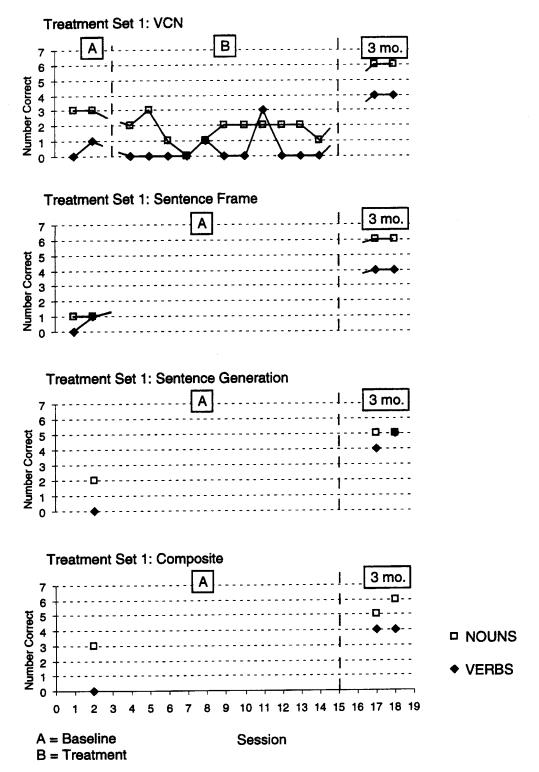


Figure 7. Subject R. A.'s performances on treatment set 1 on the four treatment tasks.

treatment set 1. Nevertheless, her object naming (Western Aphasia Battery, Kertesz 1982), cookie theft description (Boston Diagnostic Aphasia Examination, Goodglass and Kaplan 1983), and functional speaking rating (Functional Communication Profile, Sarno 1969) all improved. Comparing A. S.'s response to treatment with that of R. A. raises important questions regarding optimal timing for specific interventions for specific patients. It seems possible that A. S. might

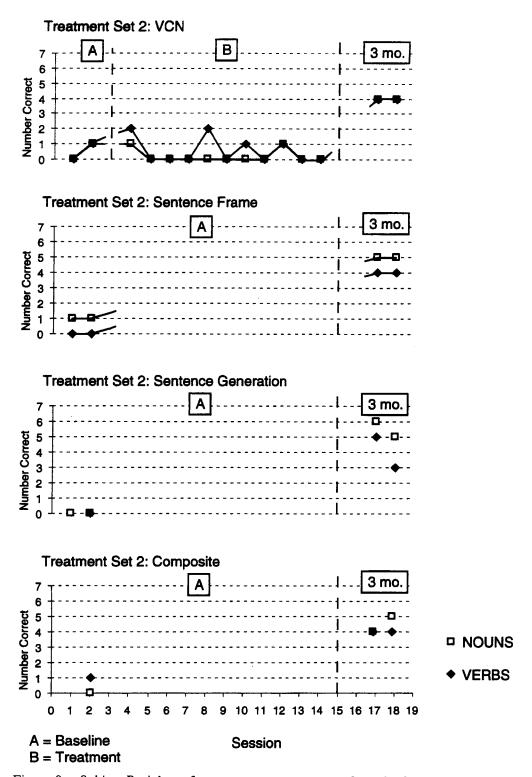


Figure 8. Subject R. A.'s performances on treatment set 2 on the four treatment tasks.

have been better served if the treatment protocol had been modified or perhaps if direct treatment of her anomia had been deferred. Determining the optimal time to implement particular treatment approaches requires precise delineation of patients' impairments and strengths, careful monitoring of their ongoing responses to treatment, and multiple replications of the treatment study across subjects in which initiation of the treatment is deferred for some patients.

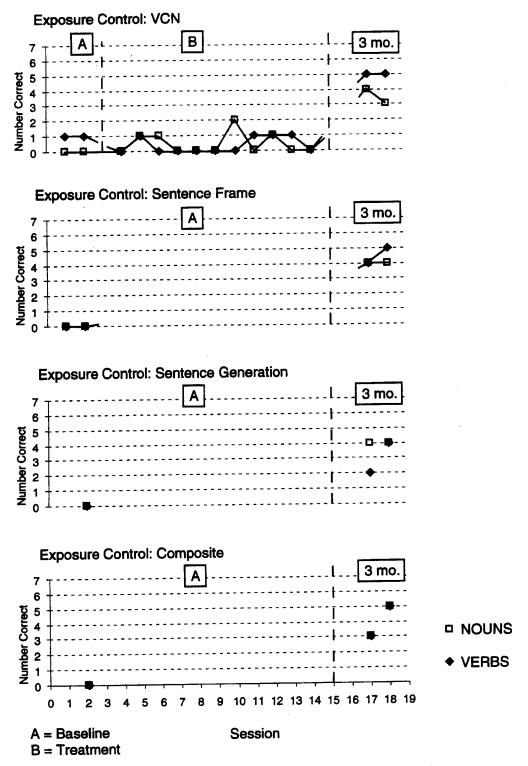


Figure 9. Subject R. A.'s performances on exposure control stimuli on the four treatment tasks.

## **Principles**

It is essential that researchers interested in determining which treatment approaches best serve the aphasic population directly examine the efficacy of specific treatments with individuals with acute aphasia. This presents a particular challenge, because the experimental protocols that are used must enable researchers to differentiate

specific treatment effects from spontaneous recovery and the effects of concurrently provided treatments. We offer the following principles to guide such investigations.

- (1) Base the treatments to be examined on a theory of treatment that is consistent with expectations for persons who are in the early stages of recovery from brain injury. Byng and colleagues (Byng and Black 1995, Byng et al. 1994) have called for clear explications of the theories of rehabilitation that underlie specific treatment approaches. If the occurrence of spontaneous recovery in acutely aphasic patients is taken as a suggestion that these individuals' brains are more amenable to treatments designed to promote restoration or reorganization of neural processing (Gonzalez Rothi 1991) than are those of chronic patients, then such treatments should be the focus of efficacy studies with acutely aphasic patients. This, of course, does not preclude the assessment of the efficacy of other types of treatment with these patients. In particular, some clinical investigators may wish to examine the efficacy of interventions designed to develop strategies that aphasic patients can use to compensate for functional disabilities as they evolve through the acute phase of recovery.
- (2) Employ standard measures of aphasia severity in order to monitor subjects' overall improvement. As demonstrated by patient Y. D. discussed above, many patients show marked improvement in both treated and untreated language domains during acute recovery. It is important to have a measure(s) of overall recovery (e.g. WAB, PICA) in order to legitimately evaluate treatment effects. However, some caution is advised, because little is known about the effects of repeated administration on patients' performances on most standard tests of aphasia.
- (3) Employ a multiple baseline design that permits the monitoring of subjects' performances on untreated stimuli on the treatment tasks. While treatment may legitimately focus on training specific, personalized functional responses and behaviours, treatments that yield improved performances on untrained responses are more powerful and cost effective.
- (4) Directly measure generalization of performance on treated stimuli to subsequent levels of a task continuum. Frequently, target responses must be trained through a series of successively more complex tasks in order to take them from the patient's initial level of performance to functional use in natural communication situations. Stimulus generalization to more complex, untrained tasks is an important metric of treatment efficacy.
- (5) In order to obtain valid assessments of generalization and maintenance, employ criterion-based, rather than time-based, experimental designs. Criteria for acceptable levels of performance may be operationalized in several ways (e.g. level of acquisition, maintenance of performance, response and/or stimulus generalization). While little empirical evidence exists about what constitute adequate criteria to achieve maintenance and generalization of treatment effects, nevertheless, experimental designs that train target behaviours to a predetermined level of performance appear to provide a more valid assessment of treatment efficacy than designs that train for a prescribed number of sessions or stimulus presentations. Time-based protocols may be of benefit, however, in view of reimbursement practices that are based on number of treatment sessions.

- (6) Include an ecologically valid functional outcome measure among the measures of generalization to be employed. The ultimate goal of aphasia treatment is improved functional communication. While some treatments are aimed at developing behaviours and skills that are precursors to functional change, those treatments that most deserve a place in the clinician's armamentarium are those that include the necessary steps to achieve enhanced functional communication. Thus, measures that reliably predict patients' performances in natural communicative situations should be included in experimental protocols.
- (7) In view of the demands on patients in comprehensive rehabilitation programmes, multiple probes are an acceptable alternative to continuous probes (McReynolds and Kearns 1983, p. 207). Multiple probe designs represent a compromise in that they do not expose patients to probe stimuli with the same intensity as trained stimuli. This compromise can be mitigated in part by including a set of 'exposure control' stimuli that are presented and probed as frequently as trained stimuli (see Appendix) while using periodic probes for stimuli across baselines.
- (8) In making decisions regarding continuation or termination of an experimental treatment protocol, consider both general prognostic factors and changes in the 'magnitude of inaccuracy' of subjects' responses. Patients' overall prognoses may in part guide efficacy researchers' decisions regarding continuation of the treatment under investigation, but the primary factor should be progress toward and acquisition of target behaviours.
- (9) In planning replications across subjects, randomly assign some patients for deferred treatment on the specific aspect of language performance addressed by the experimental treatment. Deferring implementation of the treatment under investigation will provide potentially valuable information about natural recovery of the aspect of communicative performance being addressed and optimal timing for the treatment.
- (10) Examine the efficacy of treatments that have worked with chronic patients directly with acute patients. Decisions regarding which treatments to implement at what times post-onset of aphasia should be based on empirical investigations, not presumptions.

## Acknowledgement

Work presented in this manuscript was supported by a grant from the US Public Health Service, NIDCD No DC01782. The authors express their appreciation to the persons with aphasia who participated in our research.

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## **Appendix**

### The treatment

The treatment was a combination of pre-stimulation and response contingent cueing hierarchy approaches that have been demonstrated to be efficacious individually. The treatment programme was composed of four tasks that placed increasing cognitive-linguistic demands on patients and required successively more complex responses. The first task, visual confrontation naming, required the patient to produce either a target noun or a verb that commonly occurs with one of the nouns. Each treatment trial was initiated with the clinician presenting a semantic pre-stimulation (e.g. dishes: 'Point to the ones you clean after eating'; wash: 'Which one shows how you clean dishes') and the patient's pointing to the one of four pictures that matched the pre-stimulation. If the patient pointed to an incorrect picture, the following cues were presented sequentially until the patient pointed to the target picture: (1) repeat the pre-stimulation; (2) gestural cue; (3) point to the correct picture while repeating the pre-stimulation. Once the target picture was identified, it was presented in isolation and the patient attempted to produce the target noun or verb. If an error response was produced, the following cues were presented sequentially until the target word was produced: (1) sentence completion; (2) first phoneme; (3) imitation. In the second task, sentence frame, a picture depicting one of the noun-verb combinations was presented along with a sentence frame (e.g. dishes/wash: He's \_\_\_\_ the \_\_\_\_; broom/sweep: She's with a \_\_\_\_\_). In the third task, sentence generation, the pictures used in the sentence frame task were presented, but without the sentence frame. In both the sentence frame and sentence generation tasks, patients were required to produce the target noun and verb. In the fourth task, composite, two of the pictures were presented, and the patient was required to produce a response containing both target nouns and verbs. Criterion level for all four tasks was accurate production of five of the six target nouns and five of the six target verbs on two successive probes.

# Experimental design

Three sets of target words were used. Each set was composed of 10 nouns and 10 verbs, each of which was highly associated with one of the nouns. The nouns in each set were selected from two semantic categories (Battig and Montague 1969) and the frequencies of occurrence of the words in each set were approximately equivalent (Francis and Kucera 1982). In each set, six of the nouns and verbs were designated as treatment stimuli; the remaining four nouns and verbs were used to assess response generalization. For each patient entered in the treatment protocol, one of the word sets (treatment set 1) was treated once per day, one set (treatment set 2) was treated twice per day, and the third set (exposure control) was presented twice daily but with no pre-stimulation or contingent cueing. Inclusion of the

exposure control set provided a means of differentiating the effects of the specific treatment protocol being examined from the effects of concurrent treatments and

spontaneous recovery.

The experimental design involved multiple probes across the four levels of the treatment protocol. All 30 nouns and verbs were probed daily at the current treatment level under baseline conditions. They were probed across all levels of the protocol whenever a set reached criterion level.