

## **Informed Consent in Aphasia Research: Myth or Reality?**

Aura Kagan and Mikael D. Z. Kimelman

Does the nature of aphasia preclude the ability to make informed decisions about participating in clinical research? We suggest that for many aphasic adults, capacity for decision making is often masked by the language problem, especially in cases of severe aphasia.

The Aphasia Centre-North York serves over 200 adults with chronic aphasia. Over the past 16 years, the Centre has developed methods of training conversation partners which allow aphasic individuals the opportunity to converse and reveal their competence in discussions of complex topics (Kagan, *in press*; Kagan & Gailey, 1993). Observers have expressed surprise at the level of competence revealed by aphasic adults when these methods are used in conjunction with specially designed materials combining pictographs and large text in a carefully organized visual framework.

Our preliminary exploration began with a routine request by the second author for access to aphasic subjects. The proposal included a standard informed consent form approved by the Office of Research Services at the University of Toronto (Appendix A). In line with the philosophy of the Aphasia Centre, Kagan was asked to redesign the standard text-based form to increase the accessibility of the informed consent process. Questions arising from our preliminary experience with this modified form, and the associated process of obtaining informed consent, constitute the basis for this paper.

### **BACKGROUND**

Discussion of communication disorders is conspicuously absent from the literature on informed consent. Subgroups for whom special pro-

tection and guidelines are considered include the institutionalized, those with cognitive disorders, and the elderly (American College of Physicians, 1989; Kaye, Lawton, & Kaye, 1990; Sachs & Cassel, 1990).

Metz and Folkins (1985), in one of the few articles discussing ethics in speech-language pathology research, remind us that the risk in our field is not related so much to procedures as to the way in which investigators communicate (or fail to communicate) with their subjects. In a profession dedicated to communication, this is ironic.

As clinical researchers in aphasia, we have a vested interest in obtaining consent from potential subjects, but do we protect their interests? In contrast to the general research community's increasing interest in patients' rights (American College of Physicians, 1989; Jonas, 1970; Sachs & Cassel, 1990), researchers in our field have not made such rights a priority.

It is important to distinguish between those individuals for whom competence itself is in question and those for whom competence is masked. Our belief is that many people with aphasia fall into the latter category. In other words, they do have the capacity to make informed decisions or at least to participate in the decision-making process. However, traditional methods of obtaining consent may not always allow this capacity to be revealed. This is especially true in cases of severe aphasia.

## DISCUSSION

### Proxy/Surrogate Decision Making

*Should significant others routinely be asked to provide proxy consent for adults with aphasia?*

According to Sachs and Cassel (1990), physicians recognize that proxy decision-makers serve because of a "de facto" determination regarding individuals' impaired ability to make decisions. Is this the message that we, as aphasiologists, want to be sending to aphasic individuals and their families?

In a disturbing study described by Warren et al. (1986), proxies who gave consent were questioned. A number of consents were given although the proxy believed that the cognitively impaired person would probably not have given consent if he or she had full decision-making capacity. In addition, a small number of surrogates gave consent even though they would not have participated in the project them-

selves. Studies such as these indicate that the decision to use proxy judgments should be considered carefully. Therefore, we began by asking 50 individuals with varying degrees of aphasia how they felt about proxies making decisions on their behalf.

Over half of those surveyed, including those with severe aphasia, say "No" to proxy decision making (see Table 1). The figure increases to 66% when we include those who trust their own spouse, but feel that the principle of proxy decision making is generally wrong for aphasic individuals. Only 14% gave an unequivocal "Yes." The question of proxy decision making engendered emotional responses from the aphasic individuals we surveyed, as exemplified in the following dialogue:

Marg (a woman with moderate aphasia, 19<sup>1</sup>/<sub>2</sub> years postonset): A long time . . . I'm strong-willed person, very happy, but . . . get on the show . . . and the person . . . Marg [pointing to herself] is a person. . . . Jim [pointing to another aphasic individual] is a person too!

Interviewer: So you think the person should be making decisions about themselves?

Marg: That's right! That's right!

## Accessibility

*Do we provide our aphasic subjects with information in an accessible format?*

Alexander (1988) distinguished between global incompetence in decision-making and what he termed operational incompetence where compensation is possible through the use of different modalities. We believe that, in the context of obtaining informed consent, many adults with aphasia could shift from the global to the operational category if we helped them compensate by providing information in an accessible format. This would also minimize the possibility of implicit coercion.

The literature makes ethical requirements quite clear. Metz and Folkins (1985) wrote that informed consent documents need to be written in language understandable to the subject. According to Sachs and Cassel (1990), studies consistently show that for the normal population, consent forms generally require at least a college education to read and comprehend, with many having readability requirements at the postgraduate level. Should we be using the same forms for aphasic

**Table 1. Aphasic Adults' Responses to the Question: "Is Consent by Proxy OK in Aphasia Research?"**

	<i>Severe Aphasia (n = 14)</i>	<i>Moderate Aphasia (n = 23)</i>	<i>Mild Aphasia (n = 13)</i>	<i>Overall (n = 50)</i>
OK	2	—	5	7 (14%)
OK for me, but not for all (i.e., I trust my spouse)	1	5	—	6 (12%)
Not OK	6	14	7	27 (54%)
Unsure	5	4	1	10 (20%)

individuals? Our preliminary observations indicate that when we use standard consent forms, we cannot always be sure that our aphasic subjects really know or understand what they are agreeing to do, as illustrated in the following example:

The research assistant read and paraphrased the standard written consent form for Doris, a severely aphasic woman, 2½ years postonset. Doris followed along, interacting appropriately. For example, she pointed to sections of the written text and made affirmative vocalizations. She willingly signed the form. Both authors observed the entire interview and felt that Doris did demonstrate comprehension—until the research assistant attempted to verify comprehension of some of the key points. It was clear that Doris did *not* understand that the project would not benefit her personally and that she would not learn to speak better by participating. More explanation, in a different format, was required.

Doris exhibited one type of masking effect where appropriate pragmatics can mask the degree of language impairment. More commonly, however, the language disorder itself masks competence or decision-making capacity.

To circumvent at least some of the masking of competence, we developed a modified version of the traditional written consent form. We identified critical elements of the original form and depicted them using a carefully organized combination of pictographs, large text, and symbols (see Appendix B). It should be noted that this form is only one part of the *process* of informed consent. Skill and training are needed to use the form as a basis for dialogue. The researcher must supplement material with techniques such as additional writing or drawing, highlighting of crucial elements, and constant comprehension

verification in more than one modality. (*Note:* The pictographic consent form was reviewed and accepted by The University of Toronto.)

The idea of adapting the way that material is presented to facilitate comprehension is not new. For example, Tymchuk, Ouslander, and Rader (1986) improved consent comprehension in older subjects through the use of storybook formats and pictures. We want to emphasize that our particular adaptation of the consent form is not being presented as the ideal. We are, however, suggesting that some form of adaptation is necessary.

From our survey of aphasic adults, it seems that they agree (see Table 2). Seventy-six percent indicated a strong preference for the adapted form, with an additional 8% indicating that they would like access to both adapted and standard written versions. For example, when we presented both versions of the consent form and asked which was preferred, one adult with aphasia, pointing to the adapted version and pounding the table for emphasis, said slowly and deliberately, "this . . . is . . . sensational!" Most subjects who were presented with both forms wanted to take the adapted form home for further discussion with their families. It is also interesting to note the high proportion of those with mild aphasia who preferred the adapted form.

## Comprehension Verification

*Whatever the format, should we routinely verify understanding before allowing subjects to sign the consent form?*

Some aphasic subjects readily acknowledge that they do not understand the consent form, but others, for a variety of possible reasons, may not do this or may not realize that they have misunderstood. Based

**Table 2. Aphasic Adults' Responses to the Question: "Which of the Two Consent Forms Do You Prefer—the Written or Pictographic?"**

	<i>Severe Aphasia (n = 14)</i>	<i>Moderate Aphasia (n = 23)</i>	<i>Mild Aphasia (n = 13)</i>	<i>Overall (n = 50)</i>
Pictographic	11	21	6	38 (76%)
Written	2	1	4	7 (14%)
Both	1	—	3	4 (8%)
Unsure	—	1	—	1 (2%)

on studies using elderly subjects, Miller and Willner (1974) called for a two-part consent form that would include a questionnaire to test comprehension and recall.

Our experience thus far indicates that verification of comprehension is crucial, but, in order to circumvent memory problems, we feel that this should be done on-line, immediately after each critical element has been explained. This makes it more likely that we are testing comprehension rather than recall.

Therefore, as part of our consent form, we included a series of questions in pictured and simple written format to determine understanding of key issues (see Appendix B). The following example illustrates how the modified consent form and process was used to ensure verification of comprehension:

A research assistant presented the modified form to Jules, a man with global aphasia who was 3 years postonset. On-line comprehension verification revealed that Jules did not understand all issues (e.g., the one relating to therapy vs. research). The assistant had to reexplain the issues several times and reverify comprehension before asking Jules to sign the form. Jules took a long time to respond yes or no to verification questions, but when he did, his response was definite and consistent. The modified form provided a useful basis for the verification process.

## **Research Versus Treatment**

*Do aphasic subjects agree to participate in research because they think that it is treatment?*

We agree with M. T. Sarno (personal communication, 1992) that this question represents a crucial ethical issue in aphasia research. Our view is supported by studies (cited by Sachs & Cassel, 1990) on the attitudes of nursing home residents to research. These studies reveal that a major difference between individuals who agreed, versus those who refused to participate, was whether they perceived that the study would help them directly. Information on this topic, while typically required in all written consent forms, is not always stressed or made clear.

## **CONCLUSION**

Based on our preliminary observations, we believe that (1) the use of proxy decision-makers should be avoided if possible; (2) consent information should be given to potential aphasic subjects in a comprehen-

sible format that enables independent decision-making, or at least more active participation; (3) on-line verification of comprehension should become standard procedure when obtaining informed consent; and (4) the distinction between research and treatment *must* be made clear to potential subjects.

Many questions were not addressed in this paper. For example, how do we weigh the benefits and costs of this time-consuming process? What are the implications for obtaining consent to medical treatment when the patient is severely aphasic? Do we do enough to get assent from aphasic adults when we cannot obtain legal consent? Have the mechanics (i.e., the consent form) become more important than the process of dialogue with the subject? Are researchers concerned that giving too much information might deter potential subjects, and is this question appropriate? Do we use the consent process to protect ourselves as researchers or to genuinely inform our subjects?

In terms of protecting ourselves as professionals, the precedent-setting case *Reibl v. Hughes* (1980) decided by the Supreme Court of Canada may be of interest. Before *Reibl*, legal decisions were made on the basis of what the reasonable physician should tell a patient. After *Reibl*, the question became, What would the reasonable lay person expect to be told? What most professionals routinely do to obtain consent would probably fall into the *reasonable researcher* category, but what about the *reasonable aphasic adult*? Rozovsky and Rozovsky (1984), in a scathing critique of the current use of consent forms within clinical contexts, commented that generic forms with their lists of warnings and risks almost always impede genuine dialogue. They explained that consent is a communication process and suggested that genuine informed consent requires a more dynamic dialogue or process. We feel that, in both research and clinical contexts, forms adapted specifically for aphasic adults will facilitate the type of process described by Rozovsky and Rozovsky (1984).

As Weisstub (1990) pointed out, the issue of decision-making capacity cannot be discussed in purely scientific terms, but must also reflect the sociolegal and cultural context. The way in which we conduct research may be far more important than the research results we obtain.

Let us also remember that a slower progress in the conquest of disease would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having. (Jonas, 1970, p. 28)

## ACKNOWLEDGMENTS

The authors wish to acknowledge the contribution of staff at the Aphasia Centre-North York, in particular, that of Joanne Winckel, M.H.Sc.

## REFERENCES

- Alexander, M. P. (1988). Clinical determination of mental competence: A theory and retrospective study. *Archives of Neurology*, 45, 23-26.
- American College of Physicians. (1989). Cognitively impaired subjects (position paper). *Annals of Internal Medicine*, 111(10), 843-848.
- Jonas, H. (1970). Philosophical reflections on experimenting with human subjects. In P. A. Freund (Ed.), *Experimentation with human subjects*. New York: George Braziller.
- Kagan, A. (in press). Revealing the competence of aphasic adults through conversation. *Topics in Stroke Rehabilitation*, 2(1).
- Kagan, A., & Gailey, G. F. (1993). Functional is not enough: Training conversation partners for aphasic adults. In A. L. Holland & M. Forbes (Eds.), *World perspectives on aphasia*. San Diego: Singular Publishing Group.
- Kaye, J. M., Lawton, P., & Kaye, D. (1990). Attitudes of elderly people about clinical research on aging. *The Gerontologist*, 30, 100-106.
- Metz, D. E., & Folkins, J. W. (1985, March). Protection of human subjects in speech and hearing research. *ASHA*, pp. 25-29.
- Miller, R., & Willner, H. S. (1974). The two-part consent form: A suggestion for promoting free and informed consent. *New England Journal of Medicine*, 290, 964-966.
- Reibl v. Hughes, 2 S.C.R. 880 (1980).
- Rozovsky, L. A., & Rozovsky, F. A. (1984, November). Why consent forms should be phased out. *Canadian Doctor*, pp. 18-22.
- Sachs, G. A., & Cassel, C. K. (1990). Biomedical research involving older human subjects. *Law, Medicine & Health Care*, 18(3), 234-243.
- Tymchuk, A. J., Ouslander, J. G., & Rader, N. (1986). Informing the elderly: A comparison of four methods. *Journal of the American Geriatric Society*, 34, 818-822.
- Warren, J. W., Sobal, J., Tenney, J. H., Damron, D., Levenson, S., DeForge, B. R., & Muncie, H. L. J. (1986). Informed consent by proxy: An issue in research with elderly patients. *New England Journal of Medicine*, 315, 1124-1128.
- Weisstub, D. N. (1990). *Enquiry on mental competence*. Toronto: North Ontario Ministry of Health.



## **APPENDIX A: A SECTION OF THE STANDARD, WRITTEN CONSENT FORM**

Graduate Department of Speech Pathology

FACULTY OF MEDICINE  
UNIVERSITY OF TORONTO  
88 College Street  
Toronto, Ontario, Canada M5G1L4  
Telephone (416) 978-2770  
Fax (416) 978-1596

### **INFORMED CONSENT**

**PARTICIPANT:** \_\_\_\_\_

**PROJECT TITLE:** Studies of Acoustic and Attentional Influences on Auditory Comprehension in Aphasia

**PRINCIPAL INVESTIGATOR:** Mikael D. Z. Kimelman, Ph.D.  
Assistant Professor  
(416) 978-8332

#### **PROJECT INFORMATION**

**PROJECT OBJECTIVES:** This project is designed to investigate how people with aphasia process information that they hear. Of specific interest is how words in sentences and paragraphs are understood.














**POTENTIAL BENEFITS:** I understand that this project is for research purposes. I should not expect to gain any therapeutic benefit from participating in this study. The procedures in no way constitute any form of treatment.

**LOCATION:** This project is being carried out in multiple locations including the Graduate Department of Speech Pathology at the University of Toronto and at the Aphasia Centre.

**PROCEDURES:** Each person will participate in two sessions within 3 weeks. Each session will last from 2 to 4 hours. The amount of time per session will depend on the individual and his or her need for rest breaks, which will be given whenever necessary. Additional sessions will be scheduled if required. At the first session, hearing will be screened and speech-language tests of speaking, listening, reading, and writing will be administered. Then a series of short stories will be presented via tape recorder. Yes/no questions will be asked immediately following each story. At the second session, additional speech-language tasks and short stories with accompanying questions will be presented.

Portions of each session may be video- and/or audio-recorded. Each participant has the right to review any of the recorded material. The recordings are made so the data can be analyzed at a later time and for archiving. Unless other arrangements are made (i.e., agree under separate consent to tapes to be used for teaching purposes) all recordings will be saved for a period of five years or until all analyses are complete when they will be erased.

## APPENDIX B: SECTIONS OF THE ADAPTED CONSENT FORM

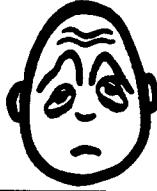
<p>what</p> 	→ Can I Expect?				
<p>POTENTIAL BENEFITS:</p> <ul style="list-style-type: none"><li>—This will help research!</li><li>—This is not therapy.</li><li>—You will not get better by being in this study.</li></ul>					
<p>_____</p> <p><i>Will this help research?</i></p>	<table border="0"><tr><td style="text-align: center;"> Yes</td><td style="text-align: center;">_____</td><td style="text-align: center;"> No</td><td style="text-align: center;">_____</td></tr></table>	 Yes	_____	 No	_____
 Yes	_____	 No	_____		
<p><i>Will this help you?</i></p>	<table border="0"><tr><td style="text-align: center;"> Yes</td><td style="text-align: center;">_____</td><td style="text-align: center;"> No</td><td style="text-align: center;">_____</td></tr></table>	 Yes	_____	 No	_____
 Yes	_____	 No	_____		

4) **HOW OFTEN?** 2 Xs

**Session 1**

**Session 2**

**tired**



**BUT**

If you get tired  
we will stop and  
start again on  
another day.

**stop**



3) **HOW LONG?**



**Session**

= 2 - 4 hours