

Ethical Considerations in Clinical Research

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The nature of clinical research is such that audiologists often shift roles as clinician and researcher. These role changes present unique ethical questions that impact the consumer with hearing impairment. With the current emphasis on consumers in this country, audiologists must ensure that their research and clinical practice are commensurate with the highest ethical codes. This paper is intended to address some of the ethical issues surrounding clinical research.

Given the mood of consumers in this country, no issue today may be of greater interest than professional ethics. From the presidency to health care providers, the ethics of clinical practice, service delivery, and research appear to be of utmost concern. Certainly, the press has focused attention on numerous ethical scandals, for example, the HIV research conducted at the National Institutes of Health (NIH). Although research in rehabilitative audiology may not present life threatening consequences, it is imperative, nonetheless, that the ethical standards in this area be as high as in any other health care enterprise. And although such organizations as the American Speech-Language-Hearing Association and the American Academy of Audiology have developed Codes of Ethics, the issues involved in professional ethics are complex and dynamic (Resnick, 1993). Therefore, this paper will address some basic ethical issues to consider when conducting research with consumers who are hearing-impaired.

Many of the principles to be discussed are mandated by the U.S. Department of Health and Human Services (Levine, 1986). In addition, most large institutions have Institutional Review Boards for the purpose of protecting human subjects. However, other issues are not so straightforward and require judgement

on the part of the researcher. With this background in mind, this paper is intended to stimulate thought about the ethical issues surrounding clinical research.

THE DISTINCTION BETWEEN RESEARCH AND EVALUATION/TREATMENT

Because of the nature of clinical settings and the need for profit, research data are often collected from patients being seen for routine evaluation and treatment. When patients meet subject selection criteria, they may be included in ongoing research studies. This is in direct contrast to settings where subjects are recruited actively to participate in a research study. Given this scenario, both the audiologist and the consumer who is hearing impaired take on dual roles. The role of the audiologist shifts from "clinician" to "researcher" and that of the consumer shifts from "patient" to "subject."

This role change must be questioned with regard to its impact on charges for clinical services. Should the "patient" who is now a "subject" be charged for services? Is this patient/subject being given tests that are part of a research protocol that are not necessarily part of the routine evaluation battery? Is the ultimate goal of treatment the pursuit of better patient outcome? Or is the ultimate goal the pursuit of answers to a research question?

Assistance with these questions might be provided by the work of Barlow, Hayes, and Nelson (1984). These authors suggest that the goal of research is to develop better organized statements of relations between events while the goal of treatment is to improve patient functioning. In their purest forms, research and treatment goals are easy to distinguish. However, for clinician/researchers, the goals can be easily mixed. Table 1 illustrates how these goals may be prioritized among four different activities. In treatment evaluation, the primary goal is patient outcome; the clinician/researcher is interested in the efficacy of the treatment as a secondary goal. Conversely, in treatment research the goal

Table 1
The Distinction Between Treatment, Treatment Evaluation,
Treatment Research, and Research

Goals	Pure Treatment	Treatment Evaluation	Treatment Research	Pure Research
Pursuit of better organized scientific statements	None	Secondary	Primary	Primary
Pursuit of better client outcome	Primary	Primary	Secondary	None

Note. Adapted from *The Scientist Practitioner* by D. Barlow, S. Hayes, and R. Nelson, 1984. New York: Pergamon Press, Inc.

is better organized scientific statements with a secondary hope for patient improvement (Barlow et al., 1984).

Examining these goals should provide guidance for the clinician with regard to the fee for service. Making judgements about fees for services using these guidelines protects the patient/subject while simultaneously maintaining the integrity of the clinician/researcher.

THREATS TO INFORMED CONSENT

The first tenet of conducting clinical research involves informed consent. Principle I of the Nuremberg Code states that "the voluntary consent of the human subject is absolutely essential" (Levine, 1986, p. 98). In order for the consent of the subject to be considered valid, the subject must be legally competent, informed, and comprehending of the procedure. Furthermore, the consent must be voluntary. Clearly, the purpose of informed consent is to preserve respect for the individual by allowing the subject to make free choices. Informed consent has both legal and ethical bases and has been the subject of volumes of legal writing and decisions (Grady & Wallston, 1988; Levine, 1986).

Certainly, obtaining informed consent is a necessity before embarking on any clinical research involving human subjects. However, there are many possible threats to informed consent. The following discussion includes a few of the most common.

Deception

Deception in research can take several forms. Perhaps the most common is involving people in research without their knowledge or consent. Grady and Wallston (1988) suggest that informed consent is not necessary if anonymity is maintained (i.e., the subjects' names are not known) or if the patient's experience in the program is not changed in any way (e.g., given different evaluation or treatment). They suggest, however, that the majority of the time subjects should know they are in a study and informed consent should be obtained.

Giving misleading information about the purpose of the study is another common form of deception. It is not necessary to provide the hypothesis of the study to subjects because this has the potential to bias them. However, it is generally accepted practice to inform subjects about the purpose of the study. This is often done on the consent form that subjects sign. Giving a verbal explanation as well can remove any hint of subject deception and potentially will increase the subject's understanding.

Some researchers choose to explain the true purpose of the study at its conclusion. This is called debriefing (Grady & Wallston, 1988). At this point, the results of the study can be explained to the subject if desired. Furthermore, when subjects sign the consent form, they can be told that this information will be available to them upon completion of the study.

The issue of deception in research is important from an ethical standpoint.

Perhaps equally important, deception of the subject can undermine the credibility of the professional, not only as a researcher, but as a clinician.

Coercion

Coercion of subjects can be subtle or overt. Although the clinical researcher may not feel that he/she has the authority to require that the patients participate in research, the patients may feel subtle pressure. Furthermore, patients may feel they have little or no ability to refuse. They may think erroneously that clinical services are contingent on their agreement to participate in a research project.

Clinical researchers must assure patients that they have the right to refuse participation in a research project without jeopardizing their care or their professional relationship. Furthermore, it must be made clear that the subject may refuse participation initially or at any time during the project. Although withdrawal of the subject may jeopardize the research project, the subject's right to self-determination is an important part of informed consent (Grady & Wallston, 1988).

Inducements

Another form of coercion is offering incentives or inducements to patients to participate in a research project. This is a common practice which can be mutually beneficial to the clinical researcher and the patient/subject. Free audiological evaluations are typical inducements that are provided in return for participating in audiological research. This is not considered coercion unless the inducement is so strong that the person is unlikely to resist when he/she otherwise would not have participated (Grady & Wallston, 1988).

Money or unaffordable health care are often used as inducements to attract people with minimal incomes or those who typically could not afford the clinical services. Ethical practice does not dictate that inducements cannot be offered. Rather, the clinical researcher must be aware of the extent to which certain populations are especially vulnerable to inducements (Grady & Wallston, 1988). Whether and how to use inducements is not an easily decided issue. For example, the patient who could not afford rehabilitative services may choose to participate in a treatment study. Is inclusion of this subject unethical? Can it be justified that the subject is receiving a treatment that he/she may not have been able to afford without participation in the research study?

Technical Language

Another common threat to informed consent is the use of technical jargon. It includes the use of language that lay people cannot understand either because it is too technical or worded at too high a level for the average person. This consists of not only audiological jargon but also technical and legal jargon. Often, its presence may result purely from oversight on the part of the clinical researcher and may make understanding an informed consent form difficult for the subject.

Unfortunately, subjects may sign an informed consent form without fully comprehending the procedures for a variety of reasons (eagerness to participate in the project, a desire to please the researcher, etc.). Therefore, the clinical researcher should evaluate the reading level of the consent form or ask a lay person to check for readability. Many simple readability formulas are available, some in software form (e.g., Gram•mat•ik 5, 1992).

SPECIAL ISSUES IN HEALTH CARE SETTINGS

Some ethical issues are specific to health care settings. These issues arise from the dual roles of the consumer as patient/subject and the audiologist as clinician/researcher.

Capacity to Make Choices

Patients may have diminished capacity to make informed choices, particularly if they are ill or have cognitive problems. If a patient's ability to decide is compromised in any way, then the manner in which the information is presented to the patient should be modified so that the patient understands. If this can not be done, then the patient should not be asked to participate in the research study. This may be true particularly in conducting research with elderly individuals with diminished cognitive abilities or with residents of long term care facilities.

Provider-Patient Relationship

The distinction between researcher and health care professional easily can be obscured. If the subject provides information regarding his/her audiological status during the course of the research project, that information is confidential and must be confined to the research (Levine, 1986). Therefore, even if the researcher is also the subject's audiologist, the two roles must be separated. This ethical consideration primarily involves information management rather than the provision of clinical services in conjunction with research.

Confidentiality is an essential component of the provider-patient relationship. Confidentiality refers to a mode of management of private information (Levine, 1986) that also must be maintained during clinical research. Maintaining confidentiality shows respect for the patient/subject and strengthens the role of the clinician/researcher.

Withholding Benefits From Control Groups

Use of a control group is common practice in research design. However, it presents a particularly difficult issue in health care that impacts on rehabilitative audiology. One ethical "rule of thumb" states that in no case should the control group receive less than the standard health care. That is, subjects cannot be denied the benefits they would receive ordinarily if they were not in a research study. This does not mean that the hypothesized benefits of an experimental treatment cannot be withheld. Some ethicists suggest that when the researcher

is convinced that the experimental treatment is beneficial, it can be provided to the control group after the research has been completed (Grady & Wallston, 1988).

CONCLUSIONS

A few of the basic ethical issues facing clinical researchers have been highlighted. Audiologists who consider themselves to be ethical practitioners and researchers nonetheless must be aware of changes in the current ethical climate. Politicians, lawyers, clergy, health care providers, and researchers are being examined daily regarding their ethical practices. This questioning is now perceived as a right of the media and the population at large. Audiologists cannot ignore the impact of this scrutiny on their professional conduct. With the current emphasis on consumers, audiologists must be certain that their research practices and procedures are commensurate with the highest ethical codes.

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