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IN THE LITERATURE

Questioning the Voluntary Nature of Informed Consent

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Are voluntary informed consents truly *voluntary*? How well informed are individuals recruited for clinical trials of their choices to refuse participation or withdraw at any time during the study? Clinical researchers have an obligation to abide by codes of ethics that protect the interests of human research subjects and are under careful evaluation by Institutional Review Boards to fulfill that obligation. Drs Robert M. Nelson and Jon F. Merz, however, argue in their recent *Medical Care* article, "Voluntariness of Consent for Research: An Empirical and Conceptual Review,"[1] that despite all the emphasis placed on the importance of voluntariness in clinical trials, various recruitment and consent practices may undermine the possibility of informed voluntary consent.

Nelson and Merz describe *voluntariness* as "an exercise of free will or choice—an act being done volitionally or with intent and deliberateness, and one that is free from coercion and undue influence."[2] After reviewing the relevant literature, the authors conclude that the scarcity of information specifically addressing voluntariness in research studies reflects a lack of a coherent model or adequate tool for measuring voluntariness in informed consents. This lack of a measuring standard compromises the researcher's ability to ensure the voluntary nature of the patient's consent to participate. The authors investigate the voluntariness issue by exploring characteristics of potential research subjects and behaviors of clinical researchers in the research setting.

Nelson and Merz cite diminished cognitive or other capacities, socioeconomic status, disease status, and the patient's family position as factors that may constrain prospective research subjects' ability to make voluntary decisions. They describe the elderly, children, prisoners, minorities, and those with low income and little education as populations most vulnerable to undue influence and coercion by the researcher's behavior and the practices of recruitment and consent. These populations are considered vulnerable despite their practical reasons for desiring to enroll in the clinical trials, which range from, "altruism, a sense of duty to others, the chance for personal medical benefits, financial gain, and trust in the health care provider."[3]

Physicians are ethically and legally bound to protect the best interest of their patients. While the clinical researcher may believe that participating in the study is in the best interest of the patient, Nelson and Merz question researchers' ability to

"look out" for their patients' interest, believing that certain researcher behaviors can persuade, manipulate, or coerce potential research subjects. The authors demand further exploration of the physician's role as a researcher and the possible impact of the physician's role on voluntariness.

The clinical researcher's status as a physician alone may carry strong influence in swaying the decision to participate. The authors consider patient "trust" as "power" physicians have over their patients. Such trust can be problematic in that it may be used (unconsciously or not) to persuade or manipulate.

Manipulation, according to Nelson and Merz, "seeks to influence a person's decision through altering the available choices or the perception of those choices."[4] The study identified three forms of manipulation: manipulating options, manipulating information, or psychological manipulation. For instance, researchers may withhold information about all the treatment options available in the clinical trial except for the one trial option they want the subject to enroll in.

Coercion, on the other hand, involves the use of credible threat or harm to force participation. A result of coercive researcher behavior, for instance, may be the patient's fear of loss of health care benefits or of retribution for refusing to participate. Individuals with the age-, socioeconomic-, and cognitive-characteristics mentioned above may be vulnerable to such a threat of harm that could be resisted under other circumstances or by other people.

Nelson and Merz do recognize the gray areas in determining whether "trust" (or power) creates undue influence. They also admit that there is a fine line between what is appropriate influence and what is inappropriate or coercive influence. They contend that while defining and determining the fine lines are difficult, these tasks can be accomplished with further study of the characteristics of potential research participants and behaviors of clinical researchers. They offer prescriptive solutions to addressing voluntariness, recommending, first, that careful attention be given to the content of and process by which information is relayed to potential research subjects. Nelson and Merz conclude that the evident lack of empirical measures for voluntariness calls for a reasonable public policy that will hold researchers accountable by placing on them the burden of proof to demonstrate the absence of undue influence or coercion.

Questions for Discussion

1. Do you think that any decision is made completely voluntarily?
2. Provide your own definition of "voluntariness."
3. Do you agree with Nelson and Merz that a standard measurement for voluntariness is feasible? Is it necessary?
4. What factors would you consider when crafting a "reasonable" public policy to determine the voluntariness of research subjects, as suggested by Nelson and Merz?

References

1. Nelson RM, Merz JF. Voluntariness of consent for research: an empirical and conceptual review. *Med Care*. 2002;40(Suppl):V69-V80.
2. Nelson, Merz. V-69.
3. Nelson, Merz. V-70.
4. Nelson, Merz. V-73.

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