
Protecting behavioral research subjects

"Each is the proper guardian of his own health, whether bodily, or mental and spiritual," wrote John Stuart Mill. That might seem logical and agreeable enough to most observers, but the concept of such freedoms becomes increasingly complex and muddled in the area of research on human beings, particularly on those institutionalized for emotional difficulties.

Today, behavioral research with patients is fairly widespread at mental institutions throughout the United States. About one of five National Institute of Mental Health-supported research projects involves inpatient populations, according to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. NIMH spends more than \$60 million a year on research grants, and the Veterans Administration spends more than \$6 million for behavioral research. Projects typically involve comparisons of various therapy approaches that may or may not include drug administration.

The question of consent, as well as the nature of the research itself, is especially touchy with institutionalized, emotionally disturbed persons "because they are considered mentally infirm," says a recently completed commission report on research involving such institutionalized patients. The report and its recommendations have been forwarded to HEW Secretary Joseph A. Califano for incorporation into any future research regulations developed by HEW.

Recommendations for regulation of behavioral research on institutionalized persons include the following: The research would not interfere with the patient's health care; patients must give informed consent, and those who cannot should not be involved in research unless it is relevant to their condition; and no one should be involved in research over his or her objection unless the research involves a therapy not otherwise available and the subject's participation is specifically authorized by "a court of competent jurisdiction."

In addition, the commission recommends that research projects be approved only after a review board has determined the appropriateness and quality of the procedures, facilities and researchers; that, if applicable, previous studies have been completed on animals, tissue or cells; that good reason exists for using institutionalized persons; that the person's privacy is maintained; and that any risks of harm or discomfort are minimized.

In cases where a patient is "able to understand and make a free choice," but incapable of completing a formal, informed consent procedure, the patient may "assent" to his or her participation in a project, but only if that project presents no

more than minimal risk and may be of "direct benefit" to the subject.

In a survey of current behavioral research procedures for the commission, University of Michigan investigators have found that most projects present "very low" risk probabilities to subjects. However, in interviews with 33 subjects, the researchers found that about one-fourth of them reported "unexpected difficulties" — including side effects, physical discomfort and emotional problems — and felt they did not have enough information about the project. On the other hand, more than two-thirds said they benefited from participation in the research. □

Psychologists and urban affluence

It may be socially acceptable these days for people to openly frequent their friendly, neighborhood shrink (there's even a New York talk show host who holds his therapy sessions on the air). But unless that neighborhood is fairly affluent, well-populated or near a university, chances are the availability of psychologists, psychiatrists and social workers will offer rather lean pickings to the prospective client.

In a "human ecological analysis" of the geographic distribution of mental health caregivers in the United States, researchers at Johns Hopkins University and the American Psychological Association correlated characteristics of states and cities with the abundance of service-giving psychologists, psychiatrists and social workers. The study itself is termed "a first try at a more analytic treatment of the geographic distribution of psychologists" (the survey's primary target group), and is judged "successful" by its authors, James M. Richards Jr. of the Johns Hopkins School of Health Services and Gary D. Gottfredson of APA.

The results, if not overly surprising, are enlightening: "When number relative to population is considered, psychologists are concentrated in affluent, urban states and in university towns," according to Richards and Gottfredson. "The same pattern was obtained for all the groups providing mental health services. No evidence was obtained that any of these groups is distributed in a way offering special advantages for serving groups such as poor, black, or rural people, who appear to need better access to mental health services."

The researchers surveyed all 50 states and the District of Columbia, plus 916 cities and unincorporated areas with populations of 25,000 or more in the 1970

census. States were rated on five measures: emphasis on large-scale agriculture, population size, affluence-urbanization, white predominance and emphasis on specialized (high income) agriculture. Ratings of cities included measures of population, affluence, white predominance and emphasis on higher education.

Across the board, the professional caregivers tend to settle in highly populated, urban, high-income areas and to avoid rural, agricultural areas of lower income. In addition, two-thirds to three-fourths of all the mental health professionals were located in the surveyed cities, compared with only 45 percent of the general population and 65 percent of physicians in general. The researchers indicated some surprise at the extent of such city concentration but add that the finding "is consistent with earlier studies indicating that when health professionals choose practice sites, they consider the quality of the social and cultural environment, the availability of colleagues and the quality of educational facilities for children."

And though there was no significant correlation with predominantly white areas, the results indicate that "all of these groups tend to be concentrated in relatively wealthy cities." Most important, "there is no evidence that any of these groups are distributed in a way that offers special advantages for meeting the needs of black people, poor people, etc., for mental health services."

The implications of these findings are particularly significant to the question of third-party insurance coverage (which some psychologists have been advocating for years) either privately or through any proposed form of national health insurance. Based on the results, say the researchers, "professions like psychology that are seeking to obtain such reimbursement should make their case mainly on grounds other than overall geographic distribution."

Nicholas A. Cummings, president-elect of APA, notes that the distribution of psychologists "follows closely the distribution of physicians, attorneys ... of the professions in general. There *are* underserved areas," he said in an interview. "But to use that as an argument against insurance coverage for psychologists is wrong — there is a crying need."

Statistics from California's Medi-Cal program (similar to Medicaid in other states) indicate that the poor utilize outpatient psychological services at a rate three times greater than the national average in urban areas, says Cummings. "There is no reimbursement in most poor areas now," he notes. If there were such coverage, in the form of national health insurance or other public funding arrangements, more services would be available to the poor, Cummings says. "Psychologists will go where the reimbursement is." □