J Forensic Sci, Jul. 1974, Vol. 19, No. 3

*J. A. Perper,*[1] *M.D., LL.B., M.Sc.*

# Medical Experimentation on Captive Populations in the United States

Medical experimentation on humans is generally subjected to detailed ethical and legal limitations and safeguards. These safeguards should be even more stringent and more meticulously followed when captive populations are used. The narrow definition of captive population includes inmates of prisons and correctional institutions, and patients in psychiatric institutions and hospitals for the mentally retarded. The broader definition also includes children and fetuses whose medical destinies are under the nearly complete control of parents or legal guardians.

## Medical Experimentation on Prison Populations

In the United States, drug companies, usually acting through physicians with access to prisons, have had little difficulty testing their products on volunteering inmates. Research projects on cancer, leukemia, and infectious disease—some funded by the Federal government—have also been conducted on volunteering prisoners. Objections have been raised about the scientific value and reliability of such experiments performed on antisocial individuals with high rates of drug addiction, hepatitis, etc, who conceivably may wish to sabotage the investigations [*1*]. However, most medical scientists view prisons as almost ideal places for human experimentation, considering the large reservoir of healthy volunteers, the tightly controlled environmental conditions, and the practically inescapable supervision.

The first reported experimental study on human prisoners in the United States was conducted by Colonel R. P. Strong in 1904 [*2*] and has been followed by many others. After the second World War, the numbers of studies increased considerably, so that at the present time many thousands of prisoners are subjects of medical research (complete data on the total number of prisoners involved are not available). A study of one large prison system in Michigan revealed that from 1964 to 1968 close to 11,000 prisoners were subjects of medical research, consisting mainly of medication trials for pharmaceutical companies [*3*].

The pertinent questions to be asked in relation to medical experimentation on prisoners are:

1. For what reasons do prisoners enter experimentation?
2. Is consent free and informed?
3. Are the experiments potentially or actually detrimental to their health?

Presented at the 3rd World Congress on Medical Law, Ghent, Belgium, 19–23 Aug. 1973. Received for publication 17 Sept. 1973; revised manuscript received 14 Dec. 1973; accepted for publication 20 Dec. 1973.

[1] Chief forensic pathologist, Allegheny County Coroner's Office; clinical assistant professor of pathology, School of Medicine, associate professor of epidemiology, School of Public Health, University of Pittsburgh; and adjunct professor of law and deputy director, Institute of Forensic Sciences, Duquesne University School of Law.

There is no doubt that prisoners are attracted to participate mainly because of material advantages in the form of financial compensation or increased prison privileges. Even small sums of money paid as compensation for participating in medical experiments appear relatively large when compared with the pay offered for regular prison jobs.

Some studies have indicated that the motivation of prisoners volunteering for the experiments is markedly similar to that of free volunteers [*2,4*]. In addition to financial compensation and hope for reduction of the sentence or parole, these include the seeking of medical attention or advice, the escape from boredom, and the search for adventure or risk-taking situations.

Unfortunately, the frequency of the various motivations is not listed. Even if the motivations are similar in both populations, their intensity in inmates may be so markedly altered by the prison milieu as to push them to accept unreasonable risks.

Some studies have shown that monetary compensation or other financial advantages are the overwhelming consideration [*1*]. In many prisons the sanitary conditions and the medical care are so poor that the experimental setup, despite its inconveniences, offers to the volunteers a much safer and more comfortable environment. In order to prevent being dropped from a prolonged experiment and encountering financial loss, prisoners may go to great lengths and withstand considerable personal suffering to conceal serious side effects of drugs or disease.

Some of the experiments have seriously endangered the health of many inmates. Fatalities have also occurred. Besides experimental trials on drugs, prison populations have been subjected to dangerous pathophysiological investigations, some performed recklessly. In 1964 a program of plasmapheresis by the Southern Food and Drug Administration was interrupted after an outbreak of hepatitis occurred in 376 prisoners, with three deaths. The outbreak was traced to extremely poor injection techniques [*1*].

Despite the vociferous opposition by inmates to reduction of large-scale experiments and to the corresponding reduction in income, serious considerations should be given to more stringent medicolegal control of scientific investigation on prisoners.

While it is questioned that the consents of inmates are really free, the damage by experimentation is in many instances very real. These risks should be fully evaluated by a highly qualified medical committee before such ventures are allowed. In 1964 Michigan's Department of Corrections established a Research Protocol Review Commission, composed of five physicians and specialists in various areas related to prospectual studies. It approves experiments on human volunteers in prisons only if the participating prisoners are fully informed, in lay terms, of the risks involved and are allowed to withdraw at any time. The Commission recommended the appointment of a special advisory committee consisting of representatives of the Michigan Department of Corrections and the deans of the local medical schools. It seems that it would be better from the ethical point of view if the Review Commission included local medical general practitioners and at least a representative of the community at large.

The selection of inmate volunteers must be careful to reduce or eliminate overt or covert pressures from prison authorities to enter the experiments. In the Michigan prison system, the prospective volunteers learn of the experiments only through posted announcements. In order to apply for volunteer participation they must request and fill out proper forms [*3*].

**Experimentation on the Mentally Retarded and Children**

Experiments on institutionalized mentally ill or retarded people are frequent. Such experiments are usually not comprehended by the human subjects who are "volunteered"

rather than volunteers. No clear legal guidelines have yet been formulated to cover this problem. Since the capacity of suffering may not be related to I.Q., experimentation on the mentally disabled should be undertaken only after careful determination of the risks, the amount of discomfort likely to be produced, and the possible benefit to be gained. Some of the experiments on these subjects exposed them to serious diseases. In a New York institution for mentally retarded children, patients were purposefully fed or injected material contaminated with viral hepatitis [5]. Similar dangers may affect children even when the consent of parents or other legal guardians is secured properly. Responsible legal spokesmen have fully supported the position of the United States Supreme Court that, "Parents may be free to become martyrs themselves, but it does not follow that they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make the choice for themselves (*Prince v. Massachusetts*, 321 US 159 at 170, 1944)" [6]. In such instances it would be fit and proper to start experimentation only after specific judicial approval has been secured following ordinary or special hearing procedures.

In 1949 the World Medical Association adopted the following policy in its International Code of Medical Ethics:

> Under no circumstances is a doctor permitted to do anything that would weaken the physical or mental resistance of a human being except from strictly therapeutic or prophylactic indications imposed in the interest of his patient.

This wording would seem to exclude completely children and the mentally retarded as subjects of any study lacking direct therapeutic value. It may well be that the "no circumstances" clause is too sweeping to be firmly respected and followed. However, it seems that very painful experiments or those involving a distinct possibility of body damage or serious complications should be completely barred on mentally incompetent populations in the absence of significant direct benefit. From a pure legal viewpoint, Curran and Beecher indicate that a strict interpretation of the so-called "informed consent" clause of the Nurenberg code, "that the person involved should have legal capacity to give consent," could outlaw all experimentation on children or the mentally retarded [7].

In 1966 the American Medical Association (AMA) Ethical Guidelines for Clinical Investigation appeared to relax the rules on experimentation on children by requiring only that: "I. The nature of the investigation is such that mentally competent adults would not be suitable subjects. II. Consent in writing is given by a legally authorized representative of the subject under circumstances in which an informed adult would reasonably be expected to volunteer himself or his child." In 1969 these requirements were made stricter, affirming that: "a parent, for example, may have no authority to expose his child to risk except for the child's own benefit." This is actually a more stringent position than the one presently held by the American courts. In children above 14 and able to understand the risks involved in the experiment the courts have sanctioned experimental medical procedures exclusively benefitting human beings other than the subjects, providing that informed consent has been secured from both the child and his legal guardian [8].

### Medical Investigation on Fetuses

The problem of investigations on fetuses is more complicated, including consideration of gestational age, development of central nervous system, viability, reason for abortion or termination of pregnancy, therapeutic promise of the project, etc. In England an advisory Group on the Use of Fetuses and Fetal Material for Research was instituted in

1970 [9]. This group formulated a code of practice which permitted research only on nonviable or so-called pre-viable fetuses, defined as fetuses under 20 weeks of gestation and weighing less than 300 g. According to these guidelines, a research project is not allowed to provide any monetary compensation for the fetal material, and the decision whether fetal material is to be used must rest with the medical attendant at birth and not with the researcher. Giving the mother drugs toxic to the fetus is also forbidden even if termination of pregnancy is contemplated [10].

## Discussion

As the ethical concepts on medical experimentation on humans in general and on captive populations in particular are crystallized, they should be embodied formally in laws. At the present time the House of Representatives and the Senate of the United States are seriously considering the regulation of human experimentation. In the meantime, it has been suggested that unethical studies should be rejected by responsible editors of scientific publications in order to discourage repetition of such activities. It is now the formal requirement of the Committee on Editorial Policy of the Council of Biology Editors that editors must screen reports submitted for publication from an ethical point of view and make certain that the experimentation was performed accordingly [11].

## Conclusion

In conclusion it is suggested that medical experimentation on a captive population should be more effectively controlled medically and legally, in order to spare our less fortunate fellow human beings the suffering from unethical scientific investigation.

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Coroner's Office, Allegheny County
542 Fourth Ave.
Pittsburgh, Pa. 15219