

## From Psychiatrist-Researcher to Psychiatrist and Researcher: Heinz Lehmann

Maureen Muldoon PhD

Associate Professor, Faculty of Arts and Social Science

University of Windsor, Canada.

### ABSTRACT

Critics offer a number of objections against the use of physical restraints in psychiatric care. The objections typically cite the difficulty in reconciling this treatment with trends towards increasing respect for patient autonomy and dignity. Critics also question whether the efficacy of such treatments have been adequately studied, risks have been properly identified, and so on. Although we should take these concerns seriously, they must be set against the sometimes ambiguous nature of the caregiver's obligations, as well as the perceived sophistication of alternative treatments. Restraint-use necessarily involves medical paternalism, and there are institutional safeguards that should continually be reexamined in light of what we learn about patient care. Still, were we to deny caregivers the authority to restrain their patients we might create ethical problems at least as great as those that restraint-use is said to create. By the late 1960s, Lehmann had changed his practices in conducting research with human subjects and he was able to articulate explicitly his understanding of the ethical requirements of human subject research. This paper explores how his responsibilities to treat his patients, not only as patients but as research subjects, were challenged during his early career.

**Key Words:** Heinz Lehmann; history of research ethics; psychiatrist-researcher.

The formulation of research ethics in the early 21st century has grown from the Nuremberg Code (1947) and the *Declaration of Helsinki* (1964). In the early part of the twentieth century, the use of human subjects in research was governed largely by the conscience of the physician-researcher. The anti-vivisectionist movement (Lederer, 1995), the beginning of the regulation of drugs and controlled trials (Glass & Lemmens, 2002; Curran 1967), the horrific accounts of the Nazi experimentation, the revelations of research violations in the United States described by Henry Beecher (1966) challenged the practices of these physician-researchers.

Even though much has been written on the history of human experimentation, there has been little attention focused on physician (psychiatrist) perspectives on the conduct of ethical research. In the 1950s and 1960s, the physician-researchers struggled among themselves to determine what constituted sound research methodology, research integrity, and the ethical use of subjects (Latimer & Newman, 1963). The discourses by the psychiatrist-researchers were both supportive of and resistant to the developments of research ethics. They helped to shape the understanding of what constitutes the ethical conduct of research as they both cared for and conducted research with their patient-subjects. Research with human subjects has had an impact on both the public trust and on the authority of the physician. According to Rothman (1991), prior to the middle of the 1970's, decisions regarding the treatment of the patient were made solely and independently by the physician at the bedside. After that time, the authority of the physician in decision-making became subject to review by others, such as ethics committees, lawyers, legislators and administrators. These strangers at the bedside have transformed medical decision-making. This change took place because of the issues associated with the real conflict of interest inherent in the dual role of the physician-researchers raised by both the public and other professionals. (Rothman, 1991).

This paper examines the practices and views of Dr. Heinz Lehmann, a psychiatrist, during the decades between 1940 until 1970. It was during this time that the dual roles of the physician-researcher became separate and distinct.

### Heinz Edgar Lehmann, Psychiatrist-Researcher, Psychopharmacologist

Heinz Edgar Lehman was born in Germany in 1911 and received his medical training there. Under the Nazi law, Lehman was classified as a "non-Aryan." As a result, he immigrated to Canada in 1937 and became a naturalized Canadian citizen in 1948. Upon arriving in Canada, Lehman joined the medical staff at the Verdun Protestant Hospital, which was renamed the Douglas Hospital in 1965. He was appointed Clinical Director in 1947 and he served as Chair of the Department of Psychiatry at McGill University from 1971 to 1974.

Lehmann's reputation grew as a clinician, researcher, and teacher. He was fluent in German, French and English, and was, therefore,

able to keep up-to-date with the psychiatric literature from Europe. Lehmann was actively engaged in a variety of different projects. His ability to read scientific publications from France, for example, enabled him to learn about the development and use of the drug, chlorpromazine, also known as Largactil, in the treatment of schizophrenia in 1953 (Cahn, 2001). He also determined that the drug, imipramine, was therapeutically beneficial for the treatment of depression. Lehmann (1958) described the new field of psychopharmacology as a complex interdisciplinary blend of pharmacology, psychology and Psychiatry. Lehmann's publications and professional activities were not limited to Canada but were shared with the international research community, especially in the United States. He is widely remembered as a physician who was humane and caring to his patients. He died in 1999.

### Lehmann as Psychiatrist-Researcher

Robert A. Cleghorn (1984) observes that systematic developments in psychiatry appeared later than in modern medicine which witnessed significant discoveries in the 18th century. In psychiatry, various treatments were tried from antiquity to the 1930s, but significant therapeutic benefits were not realized until the early 1940s. It was during this time that Lehmann first experimented on his patients (Lehmann & Ban, 1997). He injected oil of turpentine into the abdominal wall of a woman with schizophrenia. This treatment produced a large abscess along with a fever. It had already been known that psychotic patients became more lucid when they had a high fever. Lehmann and his colleague, Thomas Ban (1997), explained that the physiopathology of dementia praecox/schizophrenia was unknown at that time. They added that there had been many attempts at the physical or pharmacological treatment of schizophrenia. Other psychiatrist-researchers conducted trials using cocaine, manganese, castor oil, injection of animal blood, and sulphur in oil. Lehmann admitted that these early efforts at treatment were painful, but that in some cases partial remissions were produced for short periods (Lehmann & Ban, 1997). Lehmann's recollections of these early trial and error attempts at treatment made no reference to procuring consent from the patient or guardian or an assessment of risk and benefit (Healy, 1996). His intention was to find an effective way to treat his schizophrenic patients. He was acting as the psychiatrist-researcher on behalf of his patient-subjects. The dual roles were combined as he sought the best way to treat his patients.

Shorter (1997) and Healy (2002) have documented the early history of the drug, chlorpromazine, in great depth. Henri Laborit, was experimenting with a form of anesthesia. He asked Rhone-Poulenc, a pharmaceutical company, to create a drug that minimized the antihistamine effect but increased the sedative effects. This drug was called chlorpromazine. It produced a strange effect which was described as a "chemical lobotomy." Three French psychiatrists, named Delay, Deniker and Harl wrote a paper about this drug in 1952. In 1953, Dr. Ruth Koeppel-Kajander, a young woman psychiatrist, first used chlorpromazine with her patients in London Ontario. In November of that year, at a psychiatric meeting near Toronto, she reported on the effects of the drug (Shorter, 1997). Lehmann recounts how he first experimented with chlorpromazine during this time. His paper describing the efficacy of chlorpromazine based on this research was the first to be published in North America (Healy, 1998). He remembered inviting the first resident physician that he met, G. E. Hanrahan,

to start research on a new drug (Lehmann & Hanrahan, 1954). Lehmann and Hanrahan asked some nurses to serve as volunteers before giving any drugs to their patients. Many nurses were willing to participate. He compared the reactions of the nurses on chlorpromazine to nurses who were given secobarbital, a commonly used drug with known effects. Chlorpromazine made the nurse's sleepy and some fainted from orthostatic hypotension. Lehmann and Hanrahan admitted to being frightened by this reaction. When the nurses awoke, they were asked to complete some tests. It was found that the nurses who had been given chlorpromazine performed better than those who had taken secobarbital. The patients who were then tested included those suffering from schizophrenia, depression and organic dementia. Lehman said "we didn't know who to give it to...We just chose 70, and we did them all simultaneously, within one or two months (Healy, 1996, p.161).

Lehmann remembered that there no institutional or regulatory oversight for the research. It was the researcher himself who determined whether his actions were responsible. Lehmann said, "The only thing I had to ask myself was, was the thing reasonable, was it worthwhile and was it responsible?" (Healy, 1996, p. 160 ). He was uncertain whether he had obtained consent from his patients or guardians. He remarked that the families of the patients were always very happy about anything that was done because few effective treatments for the patients were available in those days (Healy, 1996, p.160). Lehmann's comments reflected the freedom that was accorded to psychiatrist-researchers at this time. The design of the research seemed to be little more than a treatment decision. There was, however, the belief that the research had the potential to offer some therapeutic benefit to the patients. He ordered chlorpromazine as a treatment for his patient-subjects in the same way as he would have prescribed a more commonly used drug at that time.

### Separation of the Role of Psychiatrist and Researcher

The increased awareness of the *Nuremberg Code*, the human rights movement during the 1960s, the revelations of the abuse of human subjects made known by Henry Beecher and the developments in the regulation of research with humans were influences that contributed to a clearer distinction between the role of the psychiatrist and researcher. Some psychiatrist-researchers in North America during the 1950s were critical of any proposed rules or principles put forward to guide clinical research (Ayd, 1967). These researchers feared that codes could lead "to the imposition of restrictive regulation by authorities outside the medical profession" or that they may "dilute existent controls within the profession." (Latimer & Newman, 1963, p. 115). They held to the belief that codes cannot substitute for the integrity of the individual investigator. However, both the *Nuremberg Code* and the *Declaration of Helsinki* did have a definitive impact on changing the ethos of research with human subjects.

Henry Beecher (1966) wrote an influential article entitled, "Ethics and Clinical Research" in which he examined numerous research studies involving human subject research and exposed the use of dubious ethical practices. One psychopharmacologist, Lawrence Kolb, admitted that in the quest to pursue research as a "Holy Grail" he was not surprised that the principles of the *Nuremberg Code* were ignored or forgotten and that it was "impossible to conclude

that this group has a record of consideration superior to that of clinical investigators at large.” (Kolb, 1967, p. 326)

In 1963, after the thalidomide tragedy (Lemmens and Bouchard, 2002), changes were introduced to the *Food and Drug Act* in Canada. Similar changes were made in the United States to evaluate drugs on the market (Glass and Lemmens, 1999). The legal standard for informed consent for research in Canada was established by the *Halushka v. The University of Saskatchewan* (1965). In this case, the physician-researchers were found to have failed to tell the subject that the drug was a new anesthetic, and involved risk. This legal standard for disclosure was similar to changes in the United States regarding consent requirements. In the United States, regulation of human subject research was under the authority of two federal agencies (Curran, 1967). The National Institutes of Health (NIH) provided financial support to research projects and the Food and Drug Administration (FDA) regulated new drugs. The NIH was reluctant to impose regulations on researchers regarding issues of patient safety and rights. In 1965, it was announced by the National Advisory Council to the NIH that “guidelines would be prepared to require ‘prior review’ of the judgment of principal investigators concerning the welfare of human beings.” (Curran, 1967, p. 141). These guidelines addressed the welfare and rights of the subject, required informed consent of the subject and included an assessment of risks and potential benefits of the research.

In 1962, amendments were made to the *Federal Food, Drug and Cosmetic Act*, referred to as Public Law 87 or the *Kefauver-Harris Amendments*. The U.S. Senate required that a researcher must obtain the consent of the subject prior to receiving an experimental drug. Lehmann elaborated on the difficulties of the informed consent issue for his patient-subjects. He clarified the dilemma posed by the new regulations. Lehmann explained:

It is difficult to conceive how this law could be meaningfully applied to most psychotic patients. The majority of them would probably be better off if no attempts were made to explain to them that they were participating in an experiment. Many of them would not be in a condition to properly understand the information they would be given by the investigator. On the other hand, the legal acceptability of the commonly used practice to have a representative of the patient, for instance, a member of the family, sign consent for him, has been seriously questioned. (Lehmann, 1967, p. 915)

He went on to say that even if the investigator thought that it was in the best interest of the patient not to be informed of his or her participation in the trial, this professional judgment would likely not be recognized by the courts. The role of psychiatrist and the role of the psychiatrist as a researcher were now distinct with different responsibilities to the patients or human research subject respectively.

#### **Lehmann’s View of the Ethics of Research with Human Subjects in 1967**

Lehmann (1967) was able to clearly explain the ethical dimensions of human subject research involved in clinical trials. He knew the language of philosophy and he could distinguish different types of normative ethical arguments. He identified medical ethics as deontological, or principle-based. He attributed the principles put

forward by Claude Bernard (1865), as the as the basis of all modern codes regulating research with humans. Lehmann recounted Bernard’s principles as:

experiments involving humans be undertaken only when needed information cannot be procured by other means, that the experiments be carried out in a methodical manner, that the voluntary consent of the subject be obtained, that any experiment that causes the subject distress be discontinued and the whole experimental plan be abandoned if the patient so desires.” (Lehmann, 1967, p. 950)

He identified the spirit of Bernard’s principles as requiring the researcher to protect the subject from serious bodily harm, unnecessary physical and mental suffering and injury to the subject’s dignity. He was able to list the professional codes that covered investigations on human subjects. He acknowledged the impact of the *Nuremberg Code*, and the *Declaration of Helsinki*. He stressed as well that the investigator must be satisfied that there is ethical justification for the experiment before any research begins. He elaborated on the topics of safety, recruitment of subjects, informed consent, use of placebos, the tensions between scientific rigor and clinical concern, the disposition to conduct research on oneself and family, harm/benefit ratio and the value of ethical review committees.

#### **Safety**

Lehmann (1967) acknowledged the need for animal studies prior to testing a drug on humans. He noted the difficulties in determining whether there have been sufficient results from animal studies as well as problems in interpreting such studies. He stated that it remains the responsibility of the psychiatrist-researcher to decide whether a new drug is safe or not

#### **Finding Volunteers and Obtaining Informed Consent**

Lehmann (1967) agreed with the “four rights of a human subject” (as cited by Shimkin, (1967), p. 217): informed consent, volunteer participation, peer review, and recourse to religious and other counsel. Lehmann was concerned that some anxious and hypochondrial patients who should not be given too much information in their own interest. He feared that the subject’s sickness might their motivation to participate. For healthy volunteers, he thought that money was the best way to obtain the best subjects. He made an exception for prisoners as volunteers for research with psychotropic drugs because of the problem with pathological personality types.

#### **The Use of Placebo**

Lehmann (1967) acknowledged the controversy of using a placebo as a control in a clinical research. If a treatment was known to be effective, it was not defensible to deprive the patient of that treatment. It is the decision of the investigator, however, as to whether a placebo-controlled study was necessary to establish the effectiveness of the treatment for a pathological condition.

#### **Scientific Rigor versus Clinical Concern**

Lehmann (1967) also describes what he considers a conflict of interest for the researcher-psychiatrist in following scientific

procedure (statistics). In order to avoid bias, the statistician would require a patient who experienced an adverse reaction on a prior occasion to remain in the study. The researcher-psychiatrist would have to decide whether to act as a clinician or as an investigator. Lehmann clearly distinguishes the roles of physician and that of researcher.

### Reciprocity as a Criterion

Some investigators believed that an experiment should first be performed on an investigator before the participation of human subjects. If an investigator would not participate because of the possible risks, then, the investigation would be suspect. (Lehmann, 1967)

### The Benefit/Harm Ratio

Lehmann (1967) held that the research must respect the rights of the human individual within human experimentation. He affirmed the moral demand to alleviate human suffering and the need to determine the ratio of possible harm to possible benefit.

### The Creation of Review Committees

At this time, committees were being created in hospitals and universities to review the legal and ethical aspects of the controlled clinical trial. These committees regularly consisted of both physicians and lay people. Lehmann was open to this review process. He stated "the formation of these committees can be considered a favourable development since they serve to provide an objective view point, a balanced perspective and also share the responsibility for each clinical investigation. (Lehmann, 1967, p. 956) He acknowledged the problems that arose for the investigator when the controlled clinical study was reviewed by numerous committees, each with different requirements and time-frames. He advised investigators to endure the inconveniences of increased paper work and review committees.

By this point in Lehmann's professional life, the dual role of psychiatrist-researcher was separated in a definitive way. His deep understanding of the issues are expressed in his considerations of benefit /harm ratio to the subject, conflict of interest of the psychiatrist-researcher, the challenges of informed consent with the psychiatric population, the limitations of placebo use and the value of review committees. The psychiatrist-researchers would have to decide whether they were acting as a physician or as a researcher. Lehmann not only came to understand the specific obligations of the psychiatrist in the role of researcher, but was also willing to talk about these issues among his colleagues.

### Conclusion

When Lehmann first began his career, the roles of the psychiatrist-researchers were inseparable. New treatments were tried out with the hope that they would offer some benefit to the patient. Psychiatrist-researchers appealed to their conscience as a guide for ethical decision-making in the treatment and conduct of research with their patients. This decision-making responsibility was tied to the personal integrity of the psychiatrist-researcher.

Many subsequent events intervened to affect this situation: the

*Nuremberg Code* and the *Helsinki Declaration*, new regulations in the United States and Canada, the patient rights and consumer rights movement, the increasing concern regarding malpractice suits, Beecher's revelation of abuses, the creation of committees to review research, to name a few. The psychiatrist-researchers responded in a gradual and measured way. There were drugs now that made a real difference to their patients' well-being and to society at large. By 1967, there were regulations in the United States that specified the requirement for informed consent. Changing public expectations as well as regulatory and legal developments led to the gradual separation of the role of the researcher from that of the physician-psychiatrist. For the early psychopharmacologists, however, this separation of the roles did not come immediately or easily. The requirements for informed consent presented challenges for the psychiatrist-researcher that other medical researchers did not face. There was a perplexity as to how and when they were supposed to get consent from their mentally ill patients.

Was it possible for Lehmann who had begun practicing medicine in the 1930's and who had worked in the dual role of psychiatrist-researcher to change his understanding of what he was doing in two distinct roles, each with its own set of obligations? When Lehmann read about the drug, chlorpromazine, he was quick and eager to experiment with it in the hope that it might help his patients. His engagement in the discourses on research ethics in the late 1960's might have stemmed from his openness to new ways of doing things and his enduring commitment to serve the interests of his mentally ill patients. The fact that he wrote about ethical issues in psychiatric research after the 1960's, suggests that even though the psychiatrist role and the researcher role had become distinct for him, the importance of research and the importance of offering effective psychiatric care for his patients remained as an enduring aspect of his world view. It was the conduct required by each of the roles that had changed.

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**Address for Correspondence:**

*Dr. Maureen Muldoon  
History, CHN G123  
Faculty of Arts and Social Science  
University of Windsor  
Windsor, Ontario N9B 3P4*

**Email:** [mhmul@uwindsor.ca](mailto:mhmul@uwindsor.ca)

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