

Ludwik Fleck: On Medical Experiments on Human Beings

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Abstract

Ludwik Fleck's article, 'On medical experiments on human beings' was published in 1948 in the main Polish medical journal; it was destined for general practitioners. Fleck was prisoner in the concentration camp Buchenwald, where he witnessed Nazi murderous 'experiments' on the camp's inmates; he testified about these experiments in the Nuremberg Trial of Nazi doctors. This article, and Tadeusz Kielanowski's comment on Fleck text, stress, however, that an exclusive focus on the – hopefully rare – criminal activities of doctors may be misleading. It is important to prevent the numerous ethical transgressions of 'normal' medical science and routine clinical practice.

Keywords

clinical trials, experiments on humans, informed consent, bioethics

Medicine is grounded in empirical knowledge.¹ Not only its progress but also the standardization of drugs, and even the education of students, rely

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on performance of complex experiments. Studies of nutrition and metabolism, specific physiological problems, endocrinology, clinical pathology, therapeutics, hygiene, toxicology, and many other issues depend on the possibility of experimenting on humans.

What is a surgical technique tried for the first time, if not an experiment on a human being? And since every medical act takes place in unique conditions, one can argue that every such an act is “performed for the first time.” The same is true for the use of drugs. “L’expérience n’est au fond qu’une observation provoquée” (Claude Bernard).² Is the surveillance of symptoms of heart disease after the administration of extract of digitalis, or of those of intestinal pathology after application of a diet, an observation or an experiment? We should also remember that sometimes it is necessary to conduct an experiment, such as a skin test or a blood test, in order to make a diagnosis.

These are well-known elements of medical practice managed in everyday life without major misunderstanding. It would not have been necessary to dwell on these issues, were there not new developments in medicine. Recently, the need to conduct experiments on human beings has increased greatly, partly because scientists are reaching the limit of what is possible to study in laboratory animals and partly because when the questions investigated become more complex, it becomes increasingly important to take into consideration the differences between animals and humans. Finally, because of the steady increase in the number of questions that have to be studied through experiments on humans: investigations of the efficacy of work in specific conditions, of nutritional needs (deficiency pathologies), of the functioning of the human organism at great heights (aviation); tests of new vaccines or of the mechanism of action of new pharmacological preparations. Careful and slow investigation of these issues through observation of already existing conditions cannot be reconciled with present-day needs and with the pace of today’s life.

Nearly every issue of a foreign scientific journal describes systematic experiments on human beings. I have discovered that between April and September 1947, the journal *Science* published five series of such experiments: infection of volunteers with common cold virus cultivated in eggs, study of coproantibodies in immunized volunteers, research on the level of ascorbic acid in the blood, investigation of the effects of low atmospheric pressures, and research on nutrition in well-defined conditions.³ In some cases, scientists have conducted large-scale experiments on human beings. In Elgin State Hospital, Illinois, researchers observed, over three years, the effects of a diet poor in thiamin and riboflavin on thirty-six people: “A special building housed the patients and very satisfactory facilities were provided for continuous supervision and rigid control of diets.”⁴

Selected research areas, such as the study of food poisoning, are grounded in tests made on humans: “some years ago, Dolman worked with strains of staphylococci that produced potent hemolysins, dermatoxins, and lethal toxins but did not produce illness in 42 volunteers on 110 occasions. A strain that he received from Dr. E. O. Jordan, however, yielded a filtrate of which 2 ml caused severe gastro-intestinal disturbance in 9 volunteers, and a lesser degree of disturbance in 4 others” (Dack 1943).⁵

The growing frequency of experiments on humans provokes further thoughts. In the near future, new, remarkable developments will appear. After blood transfusion will come organ grafts and then genetic manipulations. Even the “surgery of the soul” is no longer a mere fantasy.⁶ Is it not time now to think about the possibility of abuses? About the prevention of clearly useless, brutal, or criminal experiments? Nazi Germany provided dramatic examples of transgressions. In many cases, these were merely sadistic crimes with clearly sexual undertones, but some among these activities showed at least a superficial similarity to scientific experiments.

Some reactions to Nazi medical crimes indicate that it is not always possible to rely on physicians’ moral instincts and their capacity to evaluate what is acceptable and what is unacceptable for a researcher. An English doctor, who works in the London School of Hygiene and Tropical Medicine, published a letter in *The Lancet* of December 7, 1946, in which he stated, “at times I felt a good deal of sympathy for some of those who were responsible for carrying out the experiments. . . . If one were given the chance of using prisoners for experiments which one believed to be of great importance and value to mankind, what would one do, particularly if government propaganda had convinced one that the victims were dangerous criminals who were anyhow condemned to death and likely die in some particularly abominable manner?”⁷ He was severely criticized by several people, but this example shows that it is time to seriously think about a clear definition of the limits of what is permitted when experimenting on humans.⁸

Another argument in favor of the establishment of such limits is the fact that dangerous experiments on human beings have been conducted for a long time. Many classic heroes of modern medicine performed such experiments. They performed them on “colored” natives in the colonies, in hidden orphanages, in closed psychiatric hospitals, in institutions for the incurably ill, and in prisons.⁹ This issue is rarely discussed, but it was brought to the fore by advocates of the Nazi scientists and this is regrettable. In one Polish city that harbors two universities, the municipality’s administrators are reluctant to transfer the direction of local hospitals to a medical

school, “because you’ll make experiments on us.” A strategy of silence about what is going on is not very helpful. Rather, laws and deontology rules should openly and clearly define what doctors are allowed to do for the benefit of patients and science, and how they should do it. Only then will it be possible to eliminate the distressing ambivalence of many situations. These steps are necessary to avert doctors’ abuses that cannot be legally persecuted as well as the possibility, for patients, of blackmailing their doctors; and above all, to prevent a schism between science and society which may produce mistrust of doctors and lead to the rise of charlatanism, which will harm both science and people’s health.¹⁰

The Nuremberg trial made visible important gaps in the legislation of all countries and the absence of clear rules concerning experiments on humans. The court became aware of these gaps. I propose therefore to recognize as illegal all experiments on human beings that may harm or put at risk the experimental subjects when:

- a) such experiments are conducted without informing the subjects about the experiment’s aim and the level of risk,
- b) if such experiments are conducted without the explicit consent of the subjects. When the experiment’s goal is to directly cure an unconscious or mentally ill person, consent can be provided by the family. In all other cases, it is not possible to conduct experiment on such persons,
- c) when experiments are useless from a scientific point of view, and
- d) when experiments are performed in an incompetent way and without applying all the possible precautions to reduce their danger,

Totally harmless and risk-free experiments, such as diagnostic skin tests, may therefore be conducted even without the explicit permission of the experimental subject.¹¹ By contrast, all other experiments cannot be made without clearly explaining to the involved persons what the magnitude of risk is. The main point is that in each case the physician has to tell the individual undergoing a given experiment, using terms accessible to a non-professional, why the question being studied is important for medicine. Only through such an approach will the physician-experimentalist become closer to society, instead of distancing himself or herself from it. At the same time, the experimental subject, instead of being relegated to the disreputable role of “human guinea pig,” will become, to some extent at least, a conscious collaborator of the researcher.¹² The latter point, I believe, is so crucial that I view as repulsive and criminal all the experiments on mentally ill patients

that do not aim directly at curing them. A psychiatric patient is a sick human being and the behavior of a physician who exploits his physical or intellectual advantage over such a patient is especially repugnant.

All the individuals participating in an experiment have to provide their explicit consent, without any pressure or threats. Prisoners often do not have the possibility to freely refuse participation in experiments. For this reason, medical experiments on prisoners are always morally suspect.¹³ Nevertheless, prisoners lawfully condemned to death may be given an opportunity of rehabilitation through submitting themselves to dangerous experiments, and thus providing a valuable service to society. They should be pardoned if they survive. I believe that experiments on condemned prisoners without their explicit consent and without a promise of pardon are not appropriate, because juridical norms vary and there is always the possibility of a juridical error.¹⁴ A physician should be, above all, respectful and grateful toward an individual who, through taking risks, allows him or her to acquire an important truth, while the individual who accepts to be an experimental subject should be proud of this act. Only under these conditions, experiments on humans will not lead to the moral degradation of doctors and will not produce a public aversion to science.¹⁵

Physicians, researchers, and doctors specialized in legal medicine should, I believe, participate in a debate on the questions evoked in this article. It would also be desirable to hear the opinion of jurists. Perhaps such a debate will lead to legislation, or a new code of deontology, that will provide a solution to this problem. Such a solution is crucial in the present stage of development of medical science. I would like to add that an ideological and formal regulation of experiments on humans is important not only within each country but should be discussed on the international level as well.

On Prof. Dr. Ludwik Fleck's Article on Medical Experiments on Human Beings

A Reply by Tadeusz Kielanowski¹⁶

I'm persuaded that it is impossible to ignore the questions raised by Professor Fleck. The issue is much broader than taking a stand on criminal experiments conducted by German doctors during the war: these experiments have already been amply condemned. The Germans did not perceive their victims as human beings; when they conducted experiments on Jews, Poles, and Russians, they viewed them, in the framework of their pseudo-philosophy, as inferior creatures.

The question of experiments on human beings reappears from time to time under the form of not very serious polemical debates in the press on so-called vivisection. I followed two such press campaigns, one in Poland and one in France. The majority of the expressed opinions came from people who were perhaps endowed with noble feelings but were totally unprepared to discuss this issue, were excessively sentimental, and in all probability would not hesitate to use, for example, anti-tetanus serum if they needed it. Statements by scientists, factual and calm, appear pale when contrasted with the heated declarations of “antivivisectionists.” Such polemics disappear rapidly, replaced by other sensational topics.

The question of causing pain to animals is, however, far from being a banal one. And the more so is the issue of causing pain to human beings, and putting them at risk of disease and even death, in order to conduct an experiment the usefulness of which is attested by one person only, however, knowledgeable. How can one be sure that a scientist holds truly high moral standards and is not, for example, a psychopath? How can one ascertain that the consent of the human-object (a doctor, a prisoner, a soldier) was not coerced, even in a not very subtle way?

When I was conducting experiments on the Schwartzman phenomenon in rabbits, I always had the impression, which persists today too, that similar mechanisms could play a role in spontaneous pathological phenomena in humans. I therefore found a volunteer, a medical student interested in this question, who agreed that I experiment on him. I hesitated for a long time, thought about the danger of the so-called “generalized Schwartzman phenomenon,” took into account the somewhat diminished responsibility of the candidate, who was an alcoholic, and finally gave up the idea of an experiment. I do not know even today whether I made the right decision.¹⁷

Fleck raises important issues in his article. He rightly claims that every surgical method applied for the first time, and every drug used for the first time, is an experiment on a human being. What should one therefore think about ambitious but poorly prepared physicians (I am thinking of several concrete cases I am personally acquainted with) who apply new methods they have invented, and which can have important consequences for the patient’s health. According to the existing laws and regulations, it is impossible to condemn these doctors. Even if the patient dies, it is very difficult to prove that their activity was a transgression or a crime.

Do the arguments and reasoning advanced by Fleck, which show the growing need for increasingly extensive experimentation on human beings, indicate at the same time the need for a serious debate about such experimentation? I believe that this is indeed the case. This issue should become

part of the agenda of all our medical societies; clinicians, medical scientists, and above all our—alas so rare—philosophers of medicine should be invited to discuss it. I also believe it is important to organize a meeting dedicated exclusively to experiments on humans; the initiative can come from the Health Ministry or the Polish Academy of Sciences. Such a meeting should awaken the collective conscience of scientists burdened by a heavy load—and not only of crimes committed by German physicians.

Author's Note

Fleck's article was first published in *Tygodnik Lekarski (The Medical Weekly)*, 1948, 3(35): 1052-1054. It is reasonable to assume that Fleck decided to write or was asked to write about experiments on human beings in 1948, because at that time he had just come back from Nuremberg where, in February 1948, he testified about the Nazi murderous "experiments" in the Buchenwald concentration camp (reproduced in Werner, Zittel, and Schmaltz 2007). In a February 22, 1948, letter to professor Ludwik Hirszfeld, a leading Polish serologist and immunologist, Fleck explained that he was shocked and disgusted by the attitude of German physicians who during the war scrambled to benefit from the Nazi experiments, then brazenly lied about their past. See "Ludwik Fleck's testimony in the Nuremberg trial of doctors," in Sylwia Werner, Claus Zittel, and Florian Schmaltz (eds). *Ludwik Fleck: Style mysłowe i fakty: artykuły i swiadectwa*. (Ludwik Fleck; thought styles and facts, articles and testimonies). Warsaw: PAN, pp. 358-365.

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Notes

1. This short text was published in a general medical journal intended for medical practitioners. Fleck does not provide sources for his arguments; the only exception is the reference to Claude Bernard's quotation. Eva Hedfors has argued that Fleck's views were influenced by the debate on Nazi experiments on humans

conducted in 1946–48 in the UK and US medical journals. This is a plausible hypothesis. On the other hand, Fleck worked in a poor provincial Polish university and might have had only partial access to the relevant medical journals (Hedfors 2007).

2. “Experience is but a provoked observation” (Bernard [1865] 1920, 33). This note was added by Fleck.
3. In 1947, the rules for securing consent of participants in medical experiments were fluid and poorly defined. Among the articles to which Fleck (probably) alludes, some describe studies made with a small number of volunteers who might have been laboratory workers or medical students and who might have given their consent for the experiment. Morris Polard and Coleman D. Caplovitz inoculated two volunteers with the common cold virus (Polard and Coleman 1947). John R. Moreton studied plasma lipids in eight subjects who fasted for four hours and then ate fifty grams of butter (Moreton 1947). Preston E. Harrison’s and Janet Banvard’s study of corpovirus was grounded in observations made on patients who were suffering from an intestinal infection. This study mentioned, however, an unpublished study in immunized human volunteers (Harrison and Banvard 1947). Only Mary Dodd and Florence MacLeod’s study used a larger number of volunteers (forty-one young women), “maintained on controlled intake of ascorbic acid” (i.e., vitamin C) in an unspecified setting, which might have been an institutional one (Dodd and MacLeod 1947). Still, Fleck was undoubtedly right. From the 1960s on, researchers amply documented the extent of experiments conducted on humans without adequate consent. In the mid-1960s, two studies by well-known physicians, Henry Beecher’s article, “Ethics and Clinical Research” (Beecher 1966), and Maurice Henry Pappaworth’s book, *Human Guinea Pigs* (Pappaworth 1967), attracted attention to the widespread diffusion of unethical experiments on humans, including in prestigious medical institutions.
4. In this case, Fleck may have underestimated the unethical aspects of these experiments conducted in a state psychiatric hospital. The experimental subjects, chosen “because of the chronic nature of their mental illness, the excellence of their physical condition and the presence of a reasonable amount of emotional stability,” were deprived for years of riboflavin or thiamin. Researchers frequently drew their blood, and they were submitted to multiple physiological tests. Several of the experimental subjects developed distressing and sometimes severe symptoms, such as angular stomatitis, mouth lesions, dermatitis, and scrotal skin lesions. Others developed diminished visual acuity. Scientists responsible for this experiment stated that while lesions produced by riboflavin deprivation could not be healed by usual drugs, they “improved

- spectacularly” when the subjects were given riboflavin (Horwitt, Hills, Harvey, et al. 1949; Horwitt 1955).
5. In the text in English (Dack 1943), Dack was a professor of bacteriology and the director of the Food Research Institute at the University of Chicago. In earlier publications on the induction of food poisoning through the ingestion of staphylococci, Dack stated that he employed volunteers but did not explain who these volunteers were and how they were recruited (Kelly and Dack 1936; Dack 1937).
 6. This may be an allusion to surgical, electrical (electroconvulsive therapy), and drug-induced (e.g., insulin shock) manipulation of the brain to cure psychiatric illness.
 7. In the text in English (Mellanby 1946), Major Kenneth Mellanby (1908–1993), OBE (Order of the British Empire; he received this title for his studies on the scabies mite) was the founder of the University of Ibadan, Nigeria (the first Nigerian university), and a researcher at the London School of Hygiene and Tropical Medicine. In 1945, Mellanby published a short (ninety-six pages) account of his experiments with scabies, *Human Guinea Pigs* (Mellanby 1945); the book was reissued in 1973. In 1947, he published an account of the Nuremberg trial (Mellanby 1947) in which he stated again that some of the Nazi research might have objective value, giving as an example studies on typhus vaccines conducted in Buchenwald by prisoners and supervised by Erwin Ding. Mellanby adds that in 1943 Ding published the results of these studies in a German medical journal. According to the testimony of the prisoners who participated in these studies, among them Fleck, the production of the vaccine was sabotaged, and the so-called “scientific results” published by Ding were totally worthless (Weidling 2001). It is not to be excluded that Fleck read Mellanby’s (1947) paper and knew that his argument that Nazi science occasionally produced scientifically valid results was grounded in an example he had seen, at first hand, to prove exactly the opposite. Mellanby’s (1946) letter to *The Lancet* was a reaction to an editorial in one of their previous issues entitled “The moral problem” (Editorial 1946) that asked whether potentially valid results from German criminal experiments on humans should be published or not. The *Lancet* editorial quotes a 1937 detective novel by the physician and writer Josephine Bell, *Murder in a Hospital*, in which a hospital’s director decides to burn the results of an unethical experiment that led to a patient’s death, declaring, “may I remind you that our duty to our neighbor, our fellow man, comes before even our interest in science.” The editorial then asks, “now that the same problem may arise in real life, ought we to burn the papers?”
 8. T. B. Layton strongly criticized Mellanby’s statement that some of the Nazi criminals were “serious research workers” and argued that the bestiality of the

conditions under which this research was done is inseparable from the results (Layton 1946). Nelson Jones (1946) argued that Dr. Mellanby's letter "is a warning to those who say 'it could not have happened here' and of the dangers of being a keen research worker with little contact with the world outside his laboratory, who believes whatever his government tells him" (Jones 1946, 882). The Declaration of Helsinki, an international agreement on the principles that should govern experiments on human beings, was adopted in 1964.

9. There is an abundant secondary literature on unethical experiments on vulnerable individuals conducted openly and officially until these practices were condemned in the 1970s, partly as a result of the Tuskegee affair (e.g., J. H. Jones 1981; Reverby 2009). For unethical experiments on humans after the Second World War, see, for example, Pappworth (1967), Hornblum (1998), Goodman, McElligot, and Marks (2003).
10. The Polish term used by Fleck, "znachor," can also mean a "lay healer," but in the context of the opposition between scientific medicine and harmful non-scientific practices, probably the term "charlatan" is more appropriate.
11. According to today's norms of bioethics, any treatment/manipulation that does not have a curative goal is forbidden without the individual's informed consent. Skin tests (for allergy, for a previous contact with an antigen) are not seen today as entirely benign.
12. The Polish generic term for a laboratory animal is not guinea pig but rabbit.
13. Until the 1970s, a large proportion of clinical trials in the United States were conducted on prisoners. The ban on such trials led to the rise of "clinical labor" in testing new drugs and the export of such testing to developing and intermediary countries (Petryna 2009, 61-66; Cooper and Waldby 2014, 146-57).
14. Fleck's view on the possible use of people condemned to the death penalty for risky medical experiments, although not exceptional at that time (e.g., Kenneth Mellanby made a similar proposal in 1946), is nevertheless somewhat surprising in light of his strong opposition to experiments conducted on prisoners. It is also surprising in light of the fact that in the immediate post-World War II period, the Polish communist government, in the midst of a de facto civil war, condemned to death and executed "enemies of the people," some for purely political reasons, others, although potentially guilty of criminal activities, following hasty and often biased "emergency" trials. Such trials are one of the subjects of Pawel Pawlikowski's Oscar winning film, *Ida* (2013)
15. On Fleck's views on the importance of patients'/users' information and consent, see also Bonah (2002, 205).
16. *Tygodnik Lekarski* (The Medical Weekly), 1948, 43: 1292-1293. Tadeusz Kielanowski (1905-1992), a physician specialized in the treatment of tuberculosis and interested in the philosophy of medicine and social medicine, was

named after the Second World War Dean of Marie Skłodowska Curie University in Lublin, where he stayed until his move to Białymstok University in 1950. At that time, Ludwik Fleck was the head of the microbiology laboratory at the Marie Curie Skłodowska University. Kielanowski befriended Fleck: he admired his professional abilities, his intellect, and his integrity, and they struggled together to develop high-quality medical teaching in the difficult material conditions of postwar Poland. (Kielanowski 1978, 1982, 1983.)

17. The Schwartzman phenomenon is a necrotic reaction to bacterial endotoxins (toxins found in some bacterial cells). In rare cases, it can be observed in humans, for example, as a result of septic abortion, and is very dangerous. With hindsight, Kielanowski's decision was in all probability the right one but not only because his candidate was not a teetotaler.

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