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Informed consent in human experimentation before the Nuremberg code

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This Nuremberg issue of the BMJ comprises seven papers in this special section, editorials by Jennifer Leaning and Donald Acheson, two personal views, four news items and three book reviews. In addition, we are publishing on pp 1448-9 the Nuremberg code from 1947 and the Declaration of Helsinki that was derived from it. All the Nuremberg material is available on the BMJ's homepage: <http://www.bmj.com>

The issue of ethics with respect to medical experimentation in Germany during the 1930s and 1940s was crucial at the Nuremberg trials and related trials of doctors and public health officials. Those involved in horrible crimes attempted to excuse themselves by arguing that there were no explicit rules governing medical research on human beings in Germany during the period and that research practices in Germany were not different from those in allied countries. In this context the Nuremberg code of 1947 is generally regarded as the first document to set out ethical regulations in human experimentation based on informed consent. New research, however, indicates that ethical issues of informed consent in guidelines for human experimentation were recognised as early as the nineteenth century. These guidelines shed light on the still contentious issue of when the concepts of autonomy, informed consent, and therapeutic and non-therapeutic research first emerged. This issue assumes renewed importance in the context of current attempts to assess liability and responsibility for the abuse of people in various experiments conducted since the second world war in the United States, Canada, Russia, and other nations.

First Prussian directive on informed consent

The introduction of scientific and experimental methodology into clinical medicine in the nineteenth century brought with it an increased demand for experimentation on human subjects, particularly in bacteriology, immunology, and physiology. This research was done mainly on patients in hospital, often without their consent, under an "ethos of science and medical progress." As a result of injury to some patients subjected to non-therapeutic research, however, controversy and public debate ensued about the ethics of human experimentation.¹⁻⁴

In 1891 the Prussian minister of the interior issued a directive to all prisons that tuberculin for the treatment of tuberculosis "must in no case be used against the patient's will."⁵ But the first detailed regulations about non-therapeutic research in Western medicine came from the Prussian minister for religious, educational, and medical affairs in 1900. They were issued after critical public discussion and political debate on the Neisser case in the Prussian parliament and set forth the legal basis of disclosure and unmistakable consent.^{1,2} Of particular interest is the debate within the medical profession and the political circumstances.

The Neisser case

In 1898 Albert Neisser, discoverer of the gonococcus and professor of dermatology and venereology at the University of Breslau, published clinical trials on serum therapy in patients with syphilis. In order to find a



Albert Neisser, 1855-1916

method of syphilis prevention he injected cell free serum from patients with syphilis into patients who were admitted for other medical conditions. Most of these patients were prostitutes, who were neither informed about the experiment nor asked for their consent. When some of them contracted syphilis Neisser concluded that the "vaccination" did not work. However, he argued that the women did not contract syphilis as a result of his serum injections but contracted the disease because they worked as prostitutes. Liberal newspapers published these and other cases, triggering public debate.

Most academic physicians at the time supported Neisser. An exception was Albert Moll,⁶ a psychiatrist in private practice in Berlin, who collected in his *Physicians' Ethics* 600 cases of unethical non-therapeutic research on humans and emphasised the need for informed consent. Moll also developed a legally based, positivistic contract theory of the patient-doctor relationship, which is widely ignored in current bioethics publications.⁷

In 1898 the public prosecutor investigated the case, and Neisser was fined by the Royal Disciplinary Court. The court ruled that, though Neisser as a well known medical authority may have been convinced that the trials were harmless, he should have sought the patients' consent. Not questionable science but lack of patients' consent was the main principle for the legal judgment.

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