Historical developments of research ethics*

"Ethics are principles of right conduct, guiding what ought to be done. Although they may reflect enduring moral values, ethics are not static but evolve with time and public perception. Because the issues at the interface between science and society are so important, the public must be involved."

Benevolent paternalism was without doubt a dominant force not only in the early ethics of experimentation but in all social organizations in the early recorded history of mankind. Even the Ptolemies' consent to the vivisection of criminals in the third century B.C.[1] is an example of the ethics of human experimentation at that time. A good measure of this paternalism remained up to modern times. Individual ignorance, poverty and powerlessness would allow the researcher licence limited only by the researcher's power, conscience and religious beliefs of the times. Ethics, it seems, were left to the individual judgment of the physician/investigator.

It is also clear, however, that early experiments with human subjects, undertaken with minimal regulation, have resulted in significant medical advances. These include the discovery by Edward Jenner in 1796 of the preventive vaccination for smallpox through the inoculation of a healthy eight-year-old boy. Also, by way of example, major advances were made in yellow fever prevention through the deliberate infection of volunteers with yellow fever in order to confirm disease transmission through mosquito bites (1900). There were, of course, many, many more. On the whole, biological and medical research enjoyed a great deal of freedom, as major experimental advances and improvement of health care reinforced acceptance of this limited ethical guidance.

The philosophy of *laissez faire* in medical research, like its counterpart in the market place, has now been greatly curtailed. This has taken place through the rise of liberalism and western democratic thought. As well, a number of incidents, some of which we will relate, have focussed public interest on medical research and brought about change.

The philosophy of liberalism rests on a number of principles. Foremost amongst these is the primacy of individuals, their freedom and their right to be left alone. This respect for persons led to the rise of the concept of autonomy.

The origins of this fundamental philosophy, now deeply held in the occidental world, are scattered through ancient, medieval and modern history. A chronicle of Roman Law, the *Institutes of Justinian*, records "Freedom, from which we get the description of men as free, is a man's natural capacity of *doing what he pleases* unless he is prevented by force of law . . ."[2]

The *Magna Carta* of 1215, Chapter 29, states: "No Freeman shall be taken or imprisoned . . . *or in any way destroyed* . . . excepting by the legal Judgment of his peers, or by the laws of the land."[3]

In the *American Declaration of Independence* of 1776, these principles grew stronger: ". . . endowed by their Creator with certain unalienable rights, that among these are *Life, Liberty and the pursuit of Happiness* . . ."[4] That Declaration and the British Bill of Rights became the model in France in the Revolution of 1789. The *Declaration of the Rights of Man and the Citizen* followed. It was meant to be of universal application, and states in Article 4, "Liberty consists in the freedom to do everything *which injures no one else*."[5] The classical statement of this liberal principle is that of Mill: ". . . the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. *His own good, either physical or moral, is not a sufficient warrant*. He cannot rightfully be compelled to do or forebear because it will be better for him to do so, because it will make him happier, because, *in the opinions of others, to do so would be wise or even right*."[6]

The elements of consent, so important now in law and ethics, flow in great part from this philosophy.

A number of incidents have focussed public concern on the application of these principles to medical research.

The most shocking was the revelation at Nuremberg of the research atrocities conducted under Hitler on unwilling captives during World War II. This led to the *Nuremberg Code* which emphasized respect for persons and the importance of voluntary informed consent.

The need for vigilance in these matters is evident from the fact that there existed in Germany ethical guidelines for experimen-

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tation[7] issued by the German Minister of the Interior in February 1931, well before the atrocities took place.

Abuses were not limited to Germany. Prominent in cases of North American abuse was the so-called "Tuskegee" study. In that case, the US Public Health Service Veneral Disease Division conducted a 40-year project on the effects of *untreated* syphilis in several hundred black men. Initially, no treatment was available, so there was no prejudice to them. But even after the discovery of the effectiveness of penicillin, the study was continued and no treatment was given. This conduct apparently received official approval as late as 1969.

Another celebrated abuse that triggered public sensitivity was a study of cancer through injection of cancer cells into unsuspecting senile patients in a hospital in Brooklyn, New York.

There have been abuses uncovered in Canada as well. In the case of *Halushka v. The University of Saskatchewan*,[8] a university student was not told, in the course of his involvement in testing an anaesthetic, either that the drug was new or that a tube would be advanced through his veins to his heart. He claimed grave injury. In that case, Mr. Justice Hall stated:

> There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risk involved in the treatment itself . . . The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.[9]

Though these cases seem outrageous now, ethics are very much related to the times. Jenner's experiments in 1796 undoubtedly passed unquestioned. The same research today could only be conducted on a statistically significant sample of consenting subjects in an approved clinical trial.

In the face of an evolution of ethical values and the recognition of abuse, public policy has developed ethical codes to protect subjects of research.

Established subsequent to the Nuremberg Code, the *Helsinki Declaration*, adopted by the World Medical Association in 1964 and significantly modified in 1975, serves as a base for these efforts. In recent years, studies of research ethics have been conducted in France, the United Kingdom, the United States and Canada, among others. In 1982, the World Health Organization and the Council for International Organizations of Medical Sciences elaborated "Proposed International Guidelines" which address special needs encountered in research in developing countries. In Canada, the MRC has built upon the tradition developed in these codes of ethics.

References

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7 In Journal of Medical Philosophy, 1983, volume 8, pp. 95–111.
8 (1965), 53 Dominion Law Reports (2d) 436.
9 Ibid., p. 444. See also Zimmer v Ringrose (1978), 89 Dominion Law Reports (3d) 646.

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