Introduction:

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Throughout human history, the search for medical remedies has advanced through trial and error. No doubt even early healers questioned or rationalized whether or not to give a treatment whose efficacy could never be fully guaranteed in order to test its effect.

In the Western world, ethical reflection often refers to the medical practice of Hippocrates, the famous Greek physician born in the fifth century B.C. The Hippocratic Oath defines the principles of proper conduct and ensures physicians are honest and respectful of any suffering individual who seeks their help. This code, the first to be recognized in the West, applies to the healing arts and the physician's practice and how his or her knowledge is used. However, it does not concern the experimentation that physicians use to acquire new knowledge.

Today, although routine care and experimentation are closely linked, they are seen as emerging from different approaches. Care is the implementation of knowledge recognized by members of the profession, even if it does not always produce the desired result, while research confronts the unknown while exploring how a healthy or sick body functions. Routine care and research must respect ethical principles, which may not completely overlap, despite a common foundation—respect for the human individual.

Conducting research, at least theoretically, has always conformed with underlying social values. In Ancient Greece, the physicians Herophilus and Erasistratus (300 B.C) performed human dissection on convicts to study human anatomy.[1] Clinical knowledge progressed in hospitals where the poor

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1. von STADEN, H. (1989). *Herophilus: The art of medicine in early Alexandria,* Cambridge, Cambridge University Press.

were treated for free.[2] In eighteenth-century Europe, smallpox inoculation was tested on convicts condemned to death in exchange for a lighter sentence,[3] and experimentation on prisoners continued well into the twentieth century.[4] Throughout human history, experiments on potentially dangerous or painful treatments were often performed at the expense of those considered marginal, dependent, or inferior (e.g., prisoners, the disabled, the poor).[5]

National codes of conduct for physicians did not prevent large-scale experimentation in Manchuria in the 1930s or in the Nazi concentration camps of World War II.[6,7] The Doctors' Trial held in Nuremberg in 1945–1946[8,9] led to the development of the Nuremberg Code in 1947. This code spells out 10 principles to ensure that any medical research on a human being is ethical.

Research ethics were further codified under the leadership of the World Medical Association (WMA), resulting in the first Declaration of Helsinki (1964), entitled *Ethical Principles for Medical Research Involving Human Subjects.* Yet during this same period, several studies were denounced in the United States, including injections of cancerous cells in the elderly and inoculation of viruses in mentally disabled people in institutions. The biggest scandal involved an experiment that lasted from 1932 to 1970 in which researchers observed the effects of syphilis on 400 untreated African Americans in Tuskegee despite the availability and proven efficacy of penicillin.[10] These revelations led to the creation in 1974 of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which in 1979 authored the Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Today, the WMA Declaration of Helsinki—which has been repeatedly updated, most recently in 2013—and the Belmont Report are the main international frameworks for ethics in medical research to prevent the abuse of study participants.

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2. Foucault, M. (1963). *Naissance de la clinique : une archéologie du regard médical.* Paris: Presses universitaires de France.
3. Moulin, A.M., & Chuvin, P. (1991). *L'islam au péril des femmes*. Paris: La Découverte.
4. Bonah, C. (2007). *Histoire de l'expérimentation humaine en France. Discours et pratiques 1900-1940*. Paris: Les Belles Lettres
5. Chamayou, G. (2008). *Les corps vils. Expérimenter sur les êtres humains aux XVIII^e^ et XIX^e^ siècles*. Paris: Les Empêcheurs de penser en rond/La Découverte.
6. Isambert, F.A. (1983). Aux sources de la bioéthique. *Le Débat 25*: 83–99.
7. Isambert, F.A. (1987). L'expérimentation sur l'homme comme pratique et comme représentation. *Actes de La Recherche en Sciences Sociales*, *68*, 1: 5–30.
8. Wieviorka, A. (2006). *Le procès de Nuremberg.* Paris: Éditions Liana Levi.
9. Halioua, B. (2007). *Le procès des médecins de Nuremberg. L'irruption de l'éthique médicale moderne*. Paris: Vuibert.
10. Jones, J.H. (1993). *Bad blood: The Tuskegee syphilis experiment*, New York, Free Press.

Ethics documents address new medical techniques as they appear (e.g., medically assisted reproduction, transplant), and they examine methodologies (e.g., placebo use). Ethical positions are fine-tuned as new ethical gaps are found in interventions that modify the human body and its essential functions. Ethics also considers how values change over time and how societies across the globe view them from potentially contrasting perspectives. For example, an animal's status and suffering during a scientific experiment may be viewed by Buddhist and Hindu cultures in a different light than by Christian ones.

In 2017, numerous documents provide a framework for the various ethical aspects of research: the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, the UNESCO Universal Declaration on Bioethics and Human Rights, the Oviedo Convention and its Additional Protocol, the Guideline for Good Clinical Practice of the International Council for Harmonisation (ICH), the WMA Declaration of Taipei, and so on. In addition to these documents that are international in scope, most individual countries have established structures to evaluate research ethics and have drawn up regulatory texts that encode the principles of international documents into local laws.

• Ethical principles of medical research

The three fundamental principles of medical research ethics are respect for the individual, beneficence of the research for study participants, and justice.

– Respect for the individual refers to the concept of individual autonomy. Individuals have the right to decide for themselves whether or not to participate in a study. Therefore, they must be informed of the research objectives and procedures in order to determine freely to participate and to have the right to terminate their participation at any time.

– The risk-benefit ratio of the research means that the individual's interest must take precedence over that of society. The expected benefit for participants must be greater than the risks. These risks should be assessed and minimized and may result in stopping the study. By maintaining participants' anonymity and confidentiality, researchers protect individuals socially from revelations being made about them without their consent.

– Justice implies the obligation to treat everyone equally. In the ethics of research on human subjects, distributive justice means the benefits of participation in research should be distributed equally (CIOMS 2003).

Ethical reflection also focuses on:

– Methods for providing study information that are adapted to research participants (individual and/or collective),

– Methods for obtaining consent, which may be by someone independent of the research process; written or oral; based on age, degree of literacy, mental and physical state; etc.,

– The study's direct and indirect benefits (quality of care compared to a reference standard, reimbursement of expenses, compensation for the time spent on the study, etc.), use of biological samples or any medical and social information collected (biobanks, databases, anonymization methods, etc.),

– The modalities of medical management once the study ends for people presenting a chronic disease related to the study object, and

– Compensation for people who have suffered injury during the study, information on their results, provision of medicines arising from the study for the study participants, etc.

Numerous texts address these various aspects.

• Applying the ethics principles of health research

Is there a single model of ethics in health research? The various international declarations and recommendations do not carry the force of the law or have any criminal penalties. They represent "soft law"—something health research actors have agreed to comply with, for fear of moral condemnation from their peers. Today, all international organizations that fund research and most institutions, editors of scientific reviews, and new social actors such as patient associations require that ethical principles are respected.

Since 2000, nearly every country in the world has created an Ethics Committee for Health Research that applies international recommendations to evaluate research projects. The projects must prove they respect ethics in the objective, methods, and resources envisaged for the research. Those that fail to respect ethical principles are denied.

• The example of ethics in health research in Laos

In Laos before 2001, health research proposals received technical approval from the Ministry of Health Council of Medical Sciences, which was not an ethics committee. An Ethics Committee for Health Research was established in 2001 in the former Faculty of Medical Sciences at the National University of Laos (currently the University of Health Sciences, or UHS). This committee was set up following requests for ethical approval by a clinical research group at the Vientiane central hospital. Later in July 2002, the Ministry of Health of Lao PDR established another ethical committee at the national level, which is called the National Ethics Committee for Health Research, or NECHR.

Although a growing number of research projects are submitted to these two ethics committees, there remains a significant need for training in

research ethics for the committee members and researchers since some members still have not received any. In fact, bioethics is still not taught in medical training programs in Laos.

- **Case studies**

The relevance of research ethics principles is best understood in the context of their application in actual practice. The six chapters that follow describe how ethical principles guided the approaches to and practices of research in a variety of situations. Two chapters focus on Laos: one describes the ethical dilemmas health professionals face in their treatment practices, and the other raises ethical issues in cervical cancer screening research. Two other chapters look at examples in Thailand: one is a general reflection based on research in preventing mother-to-child transmission of hepatitis B while the other is based on a survey among adolescents. A fifth chapter addresses the topic of consent to participate in medical research in Cambodia, and the last is an ethical examination of the use of biological samples.

ETHICS AND REGULATORY REFERENCE DOCUMENTS

* The Nuremberg Code, 1947
  https://history.nih.gov/research/downloads/nuremberg.pdf
* The Belmont Report, 1979
  http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf
* Declaration of Helsinki, World Medical Association (WMA), 1964
  https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
* International Ethical Guidelines for Health-related Research Involving Humans, (CIOMS), 2016,
  https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/
* Universal Declaration on Bioethics and Human Rights, UNESCO, 2005
  http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
* The Oviedo Convention, 1997
  https://www.coe.int/en/web/bioethics/oviedo-convention
* Guidelines for Good Clinical Practice, International Council for Harmonization (IHC), 1996
  http://www.ich.org/home.html
* WMA Declaration of Taipei, 2002
  https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

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Health, Environment, Societies

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