The Declaration of Helsinki: A Matter of Principles

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Before the Declaration of Helsinki

- Nuremberg Code (1947) or the original misunderstanding about the nature of research governance

  Jay Katz once remarked that most investigators felt that «*It was a good code for barbarians but an unnecessary code for ordinary physician-scientists*»

  Jay Katz 1992

- The West's Dismissal of the Khabarovsk Trial as «Communist Propaganda» : Ideology, evidence and international bioethics, Jing-Bao Nie, *Journal of bioethical inquiry* **vol. 1 (2004), n° 1, pp. 32-42**

Declaration of Helsinki (1964)

- The medical profession self declared independance

  «*The World Medical Association interpreted the Nuremberg Code so it was responsive to the needs of the practice* »

  Robert J. Levine 2002

- US/pharmaceutical industry influence
  - Research with prisoners (banned in the DoH 1962 draft)
  - Research with institutionalised children (banned in the DoH 1962 draft)

The DoH: A Predictable Success?

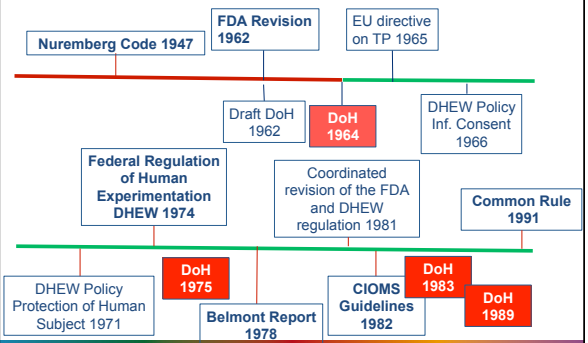
- Taking as a point of departure the ten "basic principles" set forth by the Nuremberg judges, numerous attempts have been made to propose "improved" codes of ethics to guide medical research. **The proliferation of such codes testifies to the difficulty of promulgating a set of rules that does not immediately raise more questions than it answers. At this stage of our confusion, it is unlikely that codes will resolve many of the problems, though they may serve a useful function later.** Even the much endorsed *Declaration of* Helsinki" - praised, perhaps, because it is the newest and therefore the least examined - will create problems for those who wish to implement it.

Jay Katz, The Education of the Physician-Investigator, in *DAEDALUS*, Journal of the American Academy of Arts and Sciences, Spring 1969, pp. 293-314

Effectiveness of the DoH at its Origin

- 1966: Henry K. Beecher, Ethics and Clinical Research (NEJM)
- 1967: Maurice H. Pappworth, Human Guinea Pigs: Experimentation on Man
  - 1962: Human Guinea Pigs: A Warning, special edition of *Twentieth Century*

DoH and the Development of Health Research Regulation



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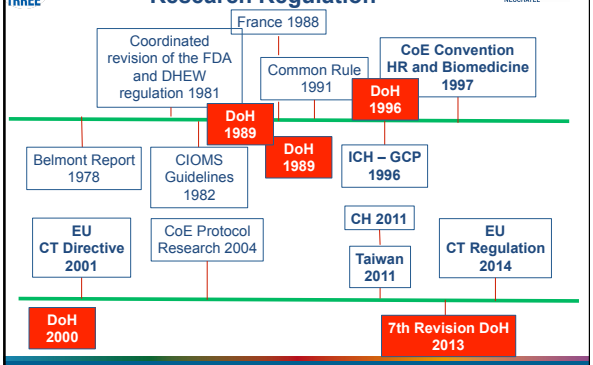


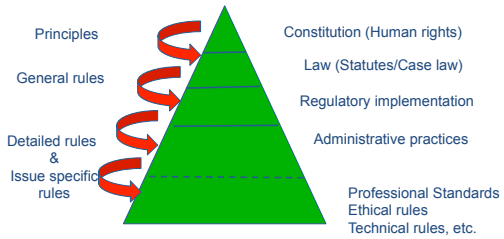
Why rules need to be formalized into ethical codes or laws?

- Rules exist because they are violated
- The violation of a legal or ethical rule preceeds its adoption. In other words, if everyone would act according to the recognized ethical and legal standards, there would be no need to specify them.
  - If doctors would always spontaneously inform their patients before asking their consent, there would be no need to specify the rule of informed consent…

Clarification of the relation between the DoH and research ethics

- The law is not limited to the legislation and case law
- Research ethics is not limited to code of ethics such as the DoH or professional standards such as the ICH – GCP
  - ➢The value of the DoH is not based primarily on the fact it was adopted by the WMA, but on the fact it has been and still is reflecting the accepted and applicable ethical principles in the field.

Parallelism between the legal order and ethical reasoning (a theoretical view)



«Ethical reasoning is, and ought to be, hierarchical and deductive»
(Robert Levine on the Belmont Report)

Normative density (rule of law)

- Every rule or norm is characterized by its normative density that includes two elements:
  - Specificity
  - Clarity
- The more specific and the more detailed is a rule, the higher is its normative density

Nature of the DoH

- The DoH is focusing on principles. It may be considered as the Constitution of research ethics.
- The normative density of the DoH is low. It requires more detailed rules to be implemented
  - The fact a principle requires more detailed instruction to be implemented does not mean the principle should be revised
  - In principle, the rules of implementation do not belong to the DoH as they are not principles…

Nature of the DoH: a Matter of Principles Seeking Harmony within Differences

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Why is there a mix of principles and specific rules in the DoH?

- The DoH is not merely an academic document. It is the product of history, lobbying from various stakeholders, of the development strategy of the WMA, etc.
- Its present structure and contain is the expression of a careful consensus within the medical profession and also the research community, the RECs and the competent authorities worldwide

Trends in research ethics and regulation during the last 50 years

- From broad principles to detailed regulation
- From a limited set of norms to a dense and complex regulatory framework
- From self-regulation to legislation
- Institutionnalization of research (REC/CA)
- Bureaucratization of research (EU regulation/ FDA)
- Globalization of the research ethics and regulation (ICH – GCP)

The Declaration of Helsinki: Challenges and Opportunities

- Globalization:
  - If there can be a consensus at the level of principles (human rights), it is unlikely that it could be achieved at the regulatory level (see EU v. US regulation)
- Regulatory inflation:
  - While researchers/industry ask for more detailed and precise regulation, they are simultaniously limiting their own freedom and responsibilities

The DoH: a Matter of Principles

- The WMA should maintain the DoH as it stands: a document of principles focusing on the protection of human participants
- If people have a clear understanding of their responsibilities in view of the ethical principles, there is less need for specific regulation

WMA should assess carefully the need for further revision of the DoH and, if need be, develop specific guidance documents for emerging issues

Happy Anniversary and Long Life To the Declaration of Helsinki and WMA

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