

This section looks back on a ground-breaking contribution to public health, reproduces an extract of the original text and adds a commentary on its significance from a modern perspective. To complement the theme of this month's issue, John R Williams looks at the Declaration of Helsinki and how it has evolved over time. The original declaration is reproduced here in full with permission of the World Medical Association.

### The Declaration of Helsinki and public health

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Determining the optimal relationship between public health and individual health is a major ethical challenge for health systems and providers. In theory, there should be no conflict between the two – the public consists of individuals and public health can be considered as the sum of the health of all those individuals. However, the situation is not quite that simple. Conflicts do exist – over issues including funding, treatment, duties, rights and preferences.

The focus of this paper is the conflict between individual and public health in the ethics of research on humans. I will use the World Medical Association (WMA)'s Declaration of Helsinki (DoH) to demonstrate that, while concern for the individual has predominated over the needs of public health since World War Two, in recent years there has been some movement towards redressing this imbalance.

The DoH was first adopted at the 1964 WMA General Assembly in Helsinki. Its purpose was to provide guidance to physicians engaged in clinical research and its main focus was the responsibilities of researchers for the protection of research subjects. The advancement of medical science and the promotion of public health, although recognized as important objectives of medical research, were clearly subordinate to the well-being of individual research subjects.

The reasons for this emphasis on protection of research subjects are not difficult to discern. The DoH, like its well-known predecessor, the Nuremberg Code, was intended to prevent mistreatment of research subjects such

as had been practised by Nazi physicians. In the absence of external constraints like legal frameworks and research ethics committees, it placed the responsibility to protect research subjects on medical researchers, who at that time were mostly physicians. It drew heavily on traditional medical ethics, as summarized in documents such as the WMA Declaration of Geneva which requires of the physician that: "The health of my patient will be my first consideration."<sup>1</sup>

In relation to the Nuremberg Code, however, the 1964 DoH represented a subtle shift in the balance between the responsibilities of the researcher to individual research participants and "to further scientific knowledge and to help suffering humanity", i.e. for public health. This shift is most evident in the requirement to obtain the informed consent of participants. This requirement was absolute in the Nuremberg Code but was softened in the DoH to allow research on children, especially for vaccines, and on incompetent or 'captive' populations, such as prisoners and military personnel.<sup>2</sup> Still, the 1964 DoH was composed mainly of restrictions on medical research designed to safeguard the interests of individual participants.

The first revision of the DoH was adopted in 1975. In the wake of revelations that serious abuses of research ethics were relatively commonplace, the WMA made explicit what had only been implicit in the 1964 version that "In research on man, the interest of science and society should never take precedence over considerations related

to the well-being of the subject" (paragraph III. 4, 1975 version). As important as the needs of public health may be, they must not override the rights of individuals who take part in medical research. Since it appeared that some researchers could not be trusted to protect research participants, new requirements were added to the DoH, including advance review of projects by an independent committee and adherence to the principles of the DoH as a condition for publication of the results of the research.

Minor amendments to the DoH were adopted in 1983, 1989 and 1996.<sup>3</sup> These did not alter the predominance of the individual research subject's interests over those of society. In contrast, the version that was adopted at the 2000 WMA General Assembly represented a major revision and expansion of the document. Although the emphasis on the primacy of the individual was retained, the following amendments indicate an increased awareness of the needs of public health:

- The 2000 version did away with the distinction between 'therapeutic' and 'non-therapeutic' research that had been a hallmark of the DoH since 1964. This distinction was based on the premise that much medical research is therapeutic, i.e. is intended to benefit the research subject: "The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient"

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doi:10.2471/BLT.08.050955

(Submitted: 5 February 2008 – Revised version received: 11 June 2008 – Accepted: 11 June 2008)

(paragraph II. 6, 1996 version). In contrast, the purpose of research in the 2000 version is the advancement of knowledge for the benefit of future patients; double-blinded clinical trials clearly demonstrate this purpose and its limitations for the health needs of research subjects.

- The 2000 version introduced an entirely new concept – the responsibility of researchers and sponsors to provide benefits to populations: “Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research” (paragraph 19). Although the nature and extent of these benefits is not specified, the amendment clearly adds a significant public-health component to research ethics.

In May 2007 the WMA Council authorized a new review of the DoH.<sup>4</sup> A call for suggested amendments was distributed widely during 2007; the responses were collated and presented to the WMA Medical Ethics Committee in October 2007. Following that meeting a set of draft amendments was prepared by a working group and distributed for comment. A revised draft was considered by the Medical Ethics Committee in May 2008 and another consultation took place during the summer. The working group’s final recommendations will be considered at the 2008 WMA General Assembly.

Although it will be up to the General Assembly to decide what, if any, changes will be made to the DoH, the working group’s draft amendments suggest a continuation of the trend, noted in the 2000 version, towards a greater concern for public-health, as follows:

- Specific mention is made of epidemiological research, which by its nature aims at the improvement of public health and health systems

rather than the health of individual research subjects.

- Another suggested amendment calls for appropriate access to participation in research for populations that have previously been underrepresented, such as children and pregnant women.
- The statement on risks and burdens is expanded to include their application to the communities as well as to the individuals involved in the research.

However, the statement that “considerations related to the well-being of the human subject should take precedence over the interests of science and society” is essentially unchanged.

### Commentary

Other papers in this issue of the *Bulletin* debate whether the requirements of public health sometimes override the rights of the individual. Very few stakeholders would give an unqualified answer to this question, either affirmative or negative. However, there is a noticeable divide between clinicians, who consider that their primary duty is to their individual patients, and public-health officials, who prioritize the needs of the community over those of individuals.<sup>5</sup> Can this divide be bridged or does it simply reflect the larger unanswered, and perhaps unanswerable, question of the relation of individual and collective rights that bedevils public authorities everywhere?

One way to ensure that this question will not be resolved is to develop public-health ethics independently from traditional health-care ethics that focus on the individual. The legitimate goals of public-health interventions should not simply trump the needs and desires of individuals and the corresponding duties of health-care practitioners to serve those needs and desires. Such an approach would be both

unnecessarily conflictual and counter-productive.

An alternative approach is for public-health ethics to build on the long experience and extensive literature of traditional health-care ethics while recognizing that this traditional ethics is evolving towards a greater concern for the health needs of populations. One example of this development is the 2006 revision of the WMA’s International Code of Medical Ethics,<sup>1</sup> in which the following phrases were added: “A physician shall strive to use health-care resources in the best way to benefit patients and their community”, and “It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality.” As public-health ethics develops, it needs to show a similar openness to the legitimate rights of individuals.

Such openness should be a characteristic of public-health research ethics, something that is sorely in need of development. The 2000 version of the DoH has been severely criticized by some public-health advocates for its restrictions on medical research,<sup>6</sup> but at least some of this criticism seems to be based on a rejection of ethics (in favour of commerce) rather than an alternative public-health research ethics. There is enormous scope for the latter, in epidemiology, health systems research, disaster preparedness and relief, etc. but it needs to be consistent with, not dismissive of, traditional health-care ethics. Only then will it be able to achieve its goal of improving health care for all members of the public. ■

**Competing interests:** John R Williams is coordinating the current (2007–2008) revision of the Declaration of Helsinki for WMA.

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## DECLARATION OF HELSINKI

### Recommendations guiding doctors in clinical research

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964

#### INTRODUCTION

It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of The World Medical Association binds the doctor with the words: “The health of my patient will be my first consideration” and the International Code of Medical Ethics declares that “Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest.”

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

In the field of clinical research a fundamental distinction must be recognized between clinical research in which the aim is essentially therapeutic for a patient, and the clinical research, the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

#### I. BASIC PRINCIPLES

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

#### II. CLINICAL RESEARCH COMBINED WITH PROFESSIONAL CARE

1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.  
If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

#### III. NON-THERAPEUTIC CLINICAL RESEARCH

1. In the purely scientific application of clinical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
2. The nature, the purpose and the risk of clinical research must be explained to the subject by the doctor.
- 3a. Clinical research on a human being cannot be undertaken without his free consent after he has been informed; if he is legally incompetent, the consent of the legal guardian should be procured.
- 3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.
- 3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained.
- 4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
- 4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued.

The investigator or the investigating team should discontinue the research if in his or their judgement, it may, if continued, be harmful to the individual. ■

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