

## From informed consent to informed dissent in health care: historical evolution in the twentieth century

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In 2017 there exists a general consensus in the international medical-scientific community regarding the meaning of the expression “informed consent” in health care. Informed consent is, according to current definitions, the free acceptance, on the part of the patient, of health interventions, following complete and understandable information concerning the benefits and risks of the latter, the available medical alternatives, the method of implementation and the collateral effects (1). The expression “informed consent” is the result of a long historical trail, and in particular of the modifications, typical of the last century, of the patient-physician relationship.

In the past, from Hippocratic medicine (V-IV centuries B.C.) onwards, the doctor-patient relationship was a paternalistic one, and the patient had to conform to the point of view of the physicians. A major historical breaking point in this cognitive-behavioural paradigm took place during the eighteenth century, when the famous case of “Slater versus Baker and Stapleton” occurred. In 1767 the patient Slater, who had broken his leg, was not experiencing a satisfactory healing and he therefore looked for a second professional opinion and medical intervention. He accessed a surgeon named Baker who, together with the apothecary Stapleton, broke the injured leg of Slater again and set it in “a heavy steel thing that had teeth” to stretch it. Unfortunately, the clinical outcome was unfavourable, and even worse than the first one, and Slater sued the two health operators. In the course of the trial, three well-known surgeons testified that the applied “steel thing” should not have been implement-

ed in the case of Slater, who was awarded £ 500 by the jury. It may be underlined that this eighteenth century amount would correspond currently to around 80,000 euros. The defendants of Baker and Stapleton appealed and, as a consequence, the court confirmed the award, interestingly declaring that a clinical experiment such as that of this case could and should be considered malpractice, and this in particular in the absence of patient consent (2).

In the course of the twentieth century legal practice in the health context repeatedly intervened in this area of medical consent, both before and after the introduction, in 1957, of the expression “informed consent” in health care (3).

With reference to the period before World War I, in the 1914 judicial case of “Schoendorff versus the Society of New York Hospital”, a woman, while consenting to an abdominal investigation in anaesthesia, had not consented to a surgical intervention. However, the surgeon in charge of this clinical case removed a tumoral formation, and the patient filed a law suit against him. The judgment of the American jurist Benjamin Nathan Cardozo (1870-1938) established a historical legal turning point in the field of consent in medicine, when he wrote that “Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without the patient’s consent commits an assault for which he is liable in damages” (4).

After World War II, the 1947 Nuremberg code was a milestone, since it incorporated the ethical crite-

ria included in the famous verdict emitted by the court of Nuremberg. According to this code, the voluntary consent of humans was absolutely necessary so as to render health interventions fully acceptable on ethical grounds (5,6). The code affirmed that “The voluntary consent of the human subject is absolutely essential” and that “The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment” (5).

A further milestone was constituted by the “Recommendations guiding medical doctors in biomedical research involving human subjects” adopted by the 18th General Assembly in Helsinki (Finland) in 1964 and approved in the same year by the World Medical Association (WMA) (7). This international association, established in 1947, was targeted at setting and disseminating the best standards of health care and ethical behaviour on the part of medical doctors towards their patients. The latter, according to the 1964 WMA guidelines, had to be fully aware of the medical procedures to which they were subjected in order to give truly informed consent for their participation in biomedical research projects (8).

However, many years were to pass before this theoretical concept was translated into actual fact. A determining element was the experience of the Tuskegee syphilis study. This US research project, performed by the Public Health Service (PHS) between 1932 and 1972, aimed at analyzing the natural course of syphilis (without treatment) in Afro-American men. The PHS had the support of the Tuskegee Institute (Alabama, USA). The enrolled patients were not aware of the fact that they had an infectious transmittable disease and therefore this investigation was conducted in the absence of the consent of the participants till its conclusion in 1972, when the Washington Star revealed the design of the research program. The great stir caused by this case prompted an increase of attention towards the need for real informed consent in health care (9).

With regard to the Italian scenario, three fundamental points of reference may be identified in the area in question. The first, and a historical one, is the Italian Constitution, which in article 32 clearly states that “Nobody can be obliged to undergo a determined health treatment if not according to the provisions of the law”. The second, dating back to 1992, is the basic

document “Information and Consent for Medical Intervention” elaborated by the Italian National Bioethics Committee. In this fundamental text the authors underlined the distinction between a first concept, information, and a second one, consent, for which the information itself is a necessary and obligatory premise (10).

The third point of reference, and the most recent one, is the Italian code of medical deontology. In the last (2014) edition of this ethical-deontological text there is written the following (article 35): “The acquisition of consent or of dissent is an act of specific and exclusive competence of the physician... The physician does not begin and does not proceed in diagnostic and/or therapeutic interventions without the preliminary acquisition of informed consent or in the presence of informed dissent” (11,12).

Interestingly, the history of the evolution of the concept of “informed consent” ends with the twenty-first century concept of “informed dissent”, bearing testimony to the complex and articulated evolution of the meaning of consent in health care from the past to the present.

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