F12 A New Informed Consent in View of the 2017 Italian Law 219—Marketing and Communication

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Learning Overview: After attending this presentation, attendees will understand that informed consent is a prerequisite for exercising the medical arts and is based not only on the law, but also on professional ethics.

Impact on the Forensic Science Community: This presentation will have an impact on the forensic science community by showing that a new type of informed consent is possible as well as desirable.

The Italian Constitution primarily recognizes and protects the inviolable rights of the person, including individual freedom and health, guaranteeing the citizen the respect of his free choice in terms of health treatments that he may, or may not, be required to undergo. Regarding informed consent, the 1992 National Bioethics Committee document "Information and Consent to the Medical Act'" outlined its characteristics. The prevailing powers of jurisprudence define it as "a fundamental principle in terms of protection and health ... a real entitlement of the person in question." On a national and European level, adequate information about health treatment is recognized and guaranteed in which every subject must provide a valid and preventive consent. Considering this, it is imperative to recall the legislative text No. 219 of December 2017, which, in Article 1, expresses itself in terms of informed consent and underlines how much the patient-doctor relationship is based on an individual's self-determination.

A prospective study was carried out in collaboration with the Video Laparoscopic Surgery Department of the Policlinico of Bari and the University of Liverpool. The goal was to verify both the effectiveness and efficiency of both medical and legal purposes, being a consensus constructed according to the rules of marketing and communication.

The study includes the sampling of 54 patients undergoing laparoscopic cholecystectomy from April to June 2018. After formalization of their willingness to participate in the study, patients were randomized into the control arm and given the classic form for informed consent to the surgical intervention and experimental arm for the study of the innovative module. At discharge, a customer satisfaction questionnaire was administered, consisting of different items, all sharing an evaluative purpose, with the goal of highlighting whether the information included during the pre-operative phase was better conveyed by the classic or experimental questionnaire.

Fifty-four patients who had undergone laparoscopic cholecystectomy (29 females, 25 males) were recruited. Their average age was 53 years. The sample presents a level of education that is equally distributed (high school diploma 45%, college degree 55%). There was no statistically significant difference between the two groups by index of understanding (p=0.5568), clarity of definition of the pathological process (p=0.6702), or patient satisfaction (p=0.7062). Subsequently, the analysis shifted to the interpretation of the Likert scale, both by evaluating the response trend within the general population and by evaluating the response within the two arms of the study, independently. It became evident that in total, without discerning between control and experimental arms, the study population considered the issue of giving consent to be a useful, clear, crucial tool for their condition as a patient.

The results (even considering the small size of the analyzed sample) demonstrate the equivalence of the two modules for both content and clarity. It is undeniable that the new, more concise, dynamic module, developed by a marketing expert, led to a more marked appreciation from those to whom it had been submitted. Therefore, modernizing the module's tool could be a starting point from which to reduce the distance between the practitioner and the patient.

Consent, Marketing, Communication