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Risk Management for a Legally Valid Informed Consent

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Abstract

Gelli-Bianco law (Law no. 24/2017) intervenes both in order to divide healthcare liability between the healthcare professional and the facility in which he/she exercises and to incentivize the latter to adopt an organizational model suitable for managing the risk associated with the provision of any healthcare service, including the information for consent. In fact, the healthcare facility must guarantee clear, complete and adequate information on the specific case, which, therefore, cannot consist of standard forms to be signed by the patient, under penalty of a flawed consent to treatment and consequent healthcare liability in the event of an adverse event.

The regulation mandates that safety must be guaranteed through proper prevention tools and health care risk management, in conjunction with the most effective use of structural, technological and organizational resources available. It further spells out the obligation of health care professionals to contribute to risk prevention while administering health care procedures.

For this reason, the consent information constitutes a source of risk for the responsibility of the healthcare provider and the Facility and it must necessarily be managed.

Risk Management is the management tool that can allow the healthcare facility to improve the quality and safety of the services provided, optimizing the risk of adverse events through proper monitoring of the same.

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The institution of the information for consent (also known as informed consent) takes on a certain centrality both in the healthcare-patient relationship and in the division of legal responsibility between the healthcare professional and the Structure where he/she works in case of an adverse event.

It seems appropriate, therefore, to become aware of the institution in question, to search for its origins, to identify the guidelines useful for formulating and correctly acquiring a consent to the medical act that can be defined as informed and, finally, to identify the most suitable tool to manage the risk of the occurrence of an unjust damage connected with the provision of a flawed consent.

Informed consent has its origins in the twentieth century, when there was a transformation of the doctor-patient relationship: from the duty of care to the right to treatment.

At the time, medicine was considered a social science for the protection of public health and for the prevention of pathogenic risks given by the precarious living conditions of populations. Moreover, the clinic was seen as the highest expression of the act of care, redefining - on the one hand - the role of the doctor in the civil community and - on the other - determining the search for a clear methodology in the doctor-patient relationship. (1)

Referring to a future work in which the ethical origins of informed consent will be sought, it is sufficient here to mention that medical experiments date back to when the art of treatment was pure *empiricism*, based on observable data on the effectiveness or otherwise of a treatment, to increase the anatomical-physiological knowledge. (2)

In the nineteenth century, the progress of knowledge in the pathological field and the development of new investigative tools required an innovative methodology for research on the patient aimed at exploring new frontiers. Medical science thus begins to be able to discover the causes of certain diseases and to find related treatments.

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A fundamental step for the affirmation of the patient's right to care is undoubtedly the decision of 1914 by which the US Supreme Court affirmed the principle according to which "*every adult and sane human being has the right to decide what will be done on his body, and a surgeon who performs an operation without the consent of his patient commits an attack for which he is liable for damages*". (3)

The transposition of this principle in the international context dates back to the Nuremberg trial (9 December 1946) against Nazi doctors where it was established that the voluntary consent of the subject is absolutely essential.

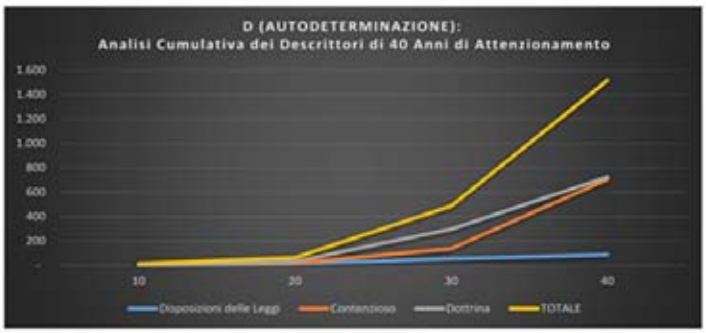
In fact, despite many interventions that sanctioned the prohibition to carry out experiments on humans without consent (Prussia in 1891, Weimar Republic 1931) in the aftermath of his accession to the government, Hitler initiated a policy of racial hygiene, which involved the entire government, state and military apparatus.

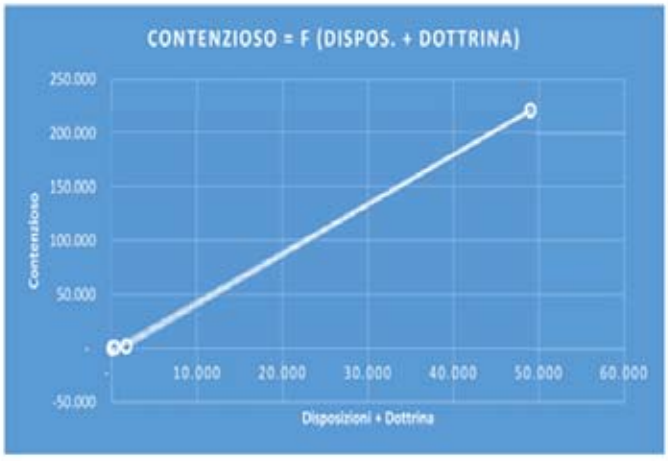
Among the various interventions that took place (such as the promulgation of the Nuremberg Laws and the Reich Citizenship Law), the promulgation of the Law on the Prevention of New Generations Affected by Hereditary Diseases (July 1933) which imposed the forced sterilisation of people with disabilities, criminals, alcoholics, drug addicts and psychiatric patients. The racial hygiene project resulted in 1939 in Aktion T4 for the so-called "euthanasia program" (which lasted unofficially until the end of the world war), an operation which consisted in the killing of people affected by those conditions that were not compatible with "a life worth living ". (4)

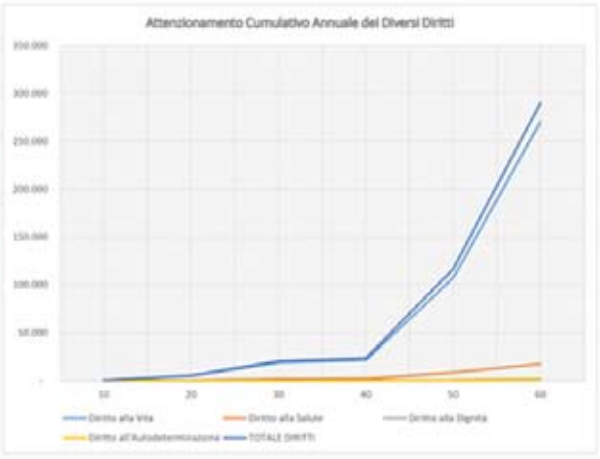
The progressive affirmation of these principles has led to the emergence of new rights and this has in turn increased the number of claims for damages for their injury and, therefore, of disputes. (5)

The following tables highlight the phenomenon in question, having 1978 as the reference year when the National Health Service was established with Law no. 833.

To date, in Italy the information for consent is governed by Law no. 219/2017 (in the Official Gazette from January 16, 2018) in which Art. 1 para. 1 indicates the rights protected by the institution in question such as: right to life, health, dignity and self-determination.







At the constitutional level these rights are guaranteed and recognised by the combined provisions of Articles 2, 3, 13, 32 of the Constitution.

In light of the principles expressed in the aforementioned law and in the code of medical ethics, it seems possible to indicate the guidelines that the health care worker must follow to ensure that consent is validly expressed and collected.(6)

From a subjective point of view, the information for consent can only be made by a healthcare professional towards the patient who is able to understand and consent.

The law in question provides for mandatory exceptions in which, due to the urgency of medical treatment or the state of natural or legal incapacity of the person being treated, the doctor must act in the absence of consent or obtain it from third parties (e.g. parents, guardian, deputy/conservator).

In any case, pursuant to Art. 1 para. 4 Law no. 219/17 consent must be acquired in the ways and with the tools most suited to the patient's conditions, documented in writing (or through video recordings or through devices that allow the patient to communicate), inserted in the medical record and in the electronic healthcare file.

From a content point of view, however, the information must concern both the organisational and clinical framework: it must indicate the recommended therapy (also in light of health protocols), the means available, the risks that the therapy entails, alternative treatments, etc.

Therefore, the connection between the information for consent and the organisation that the health facility must provide is clear: the latter must be an integral part of the former, under penalty of the defect of the consent which would therefore be invalid. We shall return to this point later. (7)

As it is easy to guess, the duty of the healthcare professional to inform the patient in the manner seen constitutes a great source of risk of responsibility for the latter, especially if compared with the incessant development of technologies and with the complexity of certain decisions relating to the treatment to be addressed.

Risk that, as such, must be managed and this is possible provided that the Healthcare Structure adopts an organisational model that, on the one hand, allows it to be foreseen and prevented and to quickly work out the appropriate solutions in the event of any damage that has occurred in any case (so-called proactive and reactive analysis); on the other hand, it allows for correctly dividing the responsibility between the healthcare professional and the Structure in which he/she works.

In this sense, the legislature intervened with the Gelli-Bianco Law (Law no. 24/17) of which Art. 1 ("*the safety of care is a constitutive part of the right to health (Article 32 of the Constitution)*") seems to give full emphasis to the fact that the structures of the NHS must have a suitable organisation not only to guarantee care but safety of the same and, therefore, to manage the risk associated with the provision of health services.

To this end, Art. 3 Law no. 24/2017 provides for the establishment (in each Region and without new or greater burdens for public finance) of the Centre for the management of health risk and patient safety, which is entrusted with the task of collecting regional data on risks and adverse events and on litigation. These data are then transmitted annually to the National Observatory of best practice on safety in health which identifies suitable measures for the prevention and management of health risk, monitors best practices for the safety of care, for the training and updating of personnel exercising healthcare professions.

As regards, then, healthcare responsibility, the law in question seems to want to answer the following question: *how is the responsibility (civil and/or criminal) divided when the patient under treatment suffers damage? And what means does the structure have to limit as much as possible the risk of having to bear the healthcare responsibility and the consequent compensation burden?*

In this regard, the provisions of Art. 7 Law no. 24/17 pursuant to which the institution is responsible for the damages suffered by the patient both under the contractual terms (pursuant to Art. 1218 of the civil code) and for the work of third parties which it uses for the fulfilment of the health service, even where harm is attributable to them by way of wilful misconduct or negligence (Article 1228 of the Italian Civil Code).

In the latter case, the body is the holder of the right of recourse against the healthcare provider (Article 9 para. 1 Law no. 24/17).

Only in the latter case is the liability of the extra-contractual healthcare professional configurable pursuant to Art. 2043 of the Italian Civil Code (Article 7 and 3 of Law no. 24/17).

The procedural consequences of this approach are considerable since, in the latter case, it will be the patient's responsibility to demonstrate the causal link between the damage suffered and the behaviour of the healthcare professional and the existence of the latter's intent or negligence.

In any case, however, the obligation for the healthcare professional to comply – in the execution of all healthcare services - remains unaffected by the recommendations provided for by the guidelines, drawn up every two years under the aegis of the Ministry of Health. (Art. 3 para. 1 and Art. 5 para. 1 Law no. 24/17) (8)

This is also evident from the provision of Art. 590 *sexies* of the criminal code (introduced by Art. 6 of the law in question) which excludes the punishment of the healthcare professional if the death / personal injury event is a consequence of his or her conduct *even if characterised by inexperience*, provided that the latter gives proof of having complied with the recommendations provided by the guidelines or, failing these, with good clinical-care practices and provided that these recommendations are suitable for the specificity of the case. (9)

At this point, it is possible to grasp the importance of an organisational model which has been discussed previously.

In fact, such a division of responsibility is to the advantage of both the healthcare professional and the patient, who is invited to take action against those who can more easily restore the damage suffered, namely the Healthcare Facility.

Once again, Risk Management lends itself to being an essential tool to support a correct risk management policy in healthcare. (10)

In fact, through this toolthe Structure can improve the

quality and safety of the services provided by eliminating (or at least decreasing) the risk of adverse events occurring, relegating this hypothesis to serious, extraordinary, subjectively unpredictable and objectively unlikely behaviour of the healthcare professional. (11)

To this end, it will be necessary to constantly monitor the correct training of human resources (hospital staff) and ensure the regular maintenance of technologies and systems in use. (12)

It therefore seems appropriate to outline the methodologies of Risk Management which can be traced back to four phases, based on the proactive and reactive analysis mentioned above: the identification of risks, the setting of preventive measures, the activation of systems control and finally the proposals for a progressive improvement. (13)

In particular, the reactive analyses provide for an *a posteriori* study of the accidents to identify the causes of the error, and are:

- *Incident Reporting* which consists of the half-yearly and annual report that summarises the reported events to calibrate preventive actions on the real needs of the structure;
- *Use of administrative and computer data* which have the advantage of immediate accessibility, negligible cost, completeness. On the other hand, the disadvantages include the homogenisation process of the collected data;

  The method was "replaced" with a series of health care appropriateness indicators, on an experimental basis, by the Lombardy Region with Regional Government Decree 4980 of 7 March 2013.
- *Analysis of clues and revision of documentation*, i.e. the revision of medical records and documentation;
- *Root cause analysis* means the analysis of the reasons for each action and any possible deviation, focusing the intervention on the cause and not on the problem.

Proactive analyses, on the other hand, break down the process into micro-activities which are in turn divided into single actions to study them so that the process is completed successfully.

This method starts from a theoretical analysis of the possible risks deriving from the structural characteristics of the building, from the risks related to diagnostic machinery and from the activities carried out by healthcare personnel.

Examples of proactive analysis are *Failure Mode & Critical Effect Analysis* (FMECA) and *Failure Mode & Effect Analysis* (FMEA). (14)

Implementing risk management can, therefore, help provide complete and truthful consent information and this in turn allows for consent to be obtained that can be said to be informed and, therefore, valid (15).

Finally, it should be added that the considerations made up to now are superseded both by Legislative Decree 231/01 on the subject of *"regulation of the administrative liability of legal persons, companies and associations, including those without legal personality*; and from the very recent jurisprudence on healthcare responsibility. (16)

In fact, Art. 6 of the aforementioned decree provides that the entity can overcome the presumption of guilt of the crimes committed by its employees only if it demonstrates that it has adopted organisational models (Model 231) suitable for preventing a specific type of crimes *before* the commission of the same and, moreover, if it proves that it has appointed an internal control body to monitor the effectiveness and observance of the model itself, necessary to receive accreditation with the SSN. (17)

The most recent jurisprudence of legitimacy, then, having to pronounce again on the issue of healthcare responsibility, recalled the concept of *"business risk"* thus confirming the need for the Healthcare Structure to adopt an organisation capable of managing the risk. (18)

That said, what was previously argued appears clearer, namely that the information for consent must concern both the clinical and the organisational aspects: complete information on the first aspect but not on the second does not reduce (indeed increases) the risk of running into a ruling of responsibility for damage not only to health but also to the patient's right to self-determination. (19)

It seems, therefore, possible to state that to guarantee correct and effective information, it is necessary to flee from standard forms that risk rendering a general and superficial information for consent, not adhering to the individual concrete case.

From the point of view of risk management, in which communication and organisation is necessary, the figure of the healthcare professional plays a fundamental role, who is the real link between the structure and the patient since it is their job to provide the information for consent.

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