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Risk management and Healthcare responsibility. How to guarantee legal protection in Medicine

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Abstract

Having regard to the increasing attention to the issue of safety and health of patients and workers by low, the hypothesis that this topic will be the growing trend in the next years does not seem to be manifestly unfounded.

For this reason, it is wise for healthcare professionals to already be aware that any violation of the interests underlying the legislation in question entails a ruling on civil and/or criminal liability. It is therefore necessary to identify the most suitable means to prevent undue harm occurring, partly to exempt healthcare professionals and hospitals from compensation costs, thereby providing them with recourse to insurance coverage.

Healthcare facility organisations must adopt Risk Management techniques as a tool to simultaneously guarantee the effectiveness of health services (in this case), the efficiency of the management economy, and finally compliance with all legally required precautions. This will relegate the occurrence of an adverse event to remote and unpredictable hypotheses, thus guaranteeing useful recourse to insurance coverage to compensate any harm that does occur. ***Clin Ter 2021; 172 (1):e63-66. doi: 10.7417/CT.2021.2285***

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Every healthcare worker is well aware that there is a vast system for regulating all health activities.

However, the large number of laws on the matter has been perceived by healthcare professionals as excessive bureaucratisation of the system, a set of actions and behaviours that must be complied with to avoid incurring any fines following inspections and checks.[1]

However, it is worth asking whether this perception is correct and if the consequent attitude is then congruent with their real interests.[2,3]

In fact, by analysing the regulations, it is possible to understand not only the logic and importance of such a large number of laws but also – and above all – that the legislator intended them to give healthcare facilities (and those who work there) the means to avoid, as far as possible, any undue harm occurring that would entail a ruling of liability and the consequent compensation costs.[4,5]

In this perspective, it is therefore necessary to take a look at the past.

As can be seen, the legislator's attention went far beyond regulating health authorisations and patient safety, turning to other matters such as privacy, clinical risk, informed consent and medical devices.[6-8] The "unranked" position of worker safety[9] will certainly be explored in a future paper.

If we look at two tables above, we note how in the last six years considered, the annual average by area has increased 170% on average, compared with the first 21 years considered.

Closely connected to these matters there are, inevitably, interests (or rather rights) borne in various capacities by both doctors and patients. For example, the legislation on privacy and informed consent aims to protect patients' rights of self-determination, health and dignity. Similarly, the guidelines on medical devices and workplace safety protect the health rights of both doctors and patients.

In the matter of occupational safety we point out the Legislative Decree No. 149 of 14/09/2015 that in order to "rationalise and simplify supervisory activity in the workplace and social legislation, and to avoid inspections overlapping (omitted)", the "single agency for labour inspections was established, called the "National Labour Inspectorate" (omitted), which integrates the inspection services of the Ministry of Labour and Social Policies, the INPS [National Social Security Institute] and the INAIL [National Institute for Insurance against Labour Accidents])", which already has, to its credit, highly respectable diversified campaigns and forms of supervision.

Of particular importance, we consider the new legal principle introduced by Regulation 2017/745/EU which, for the first time, puts worker and patient safety on the same level.

The violation of these rights is then protected in both civil and criminal matters whenever this is caused by undue harm owing to the intentional and negligent conduct of a doctor or healthcare facility (see, for example, the provisions of Article 590-sexies of the Italian Criminal Code and those found in Legislative Decree 231/01).

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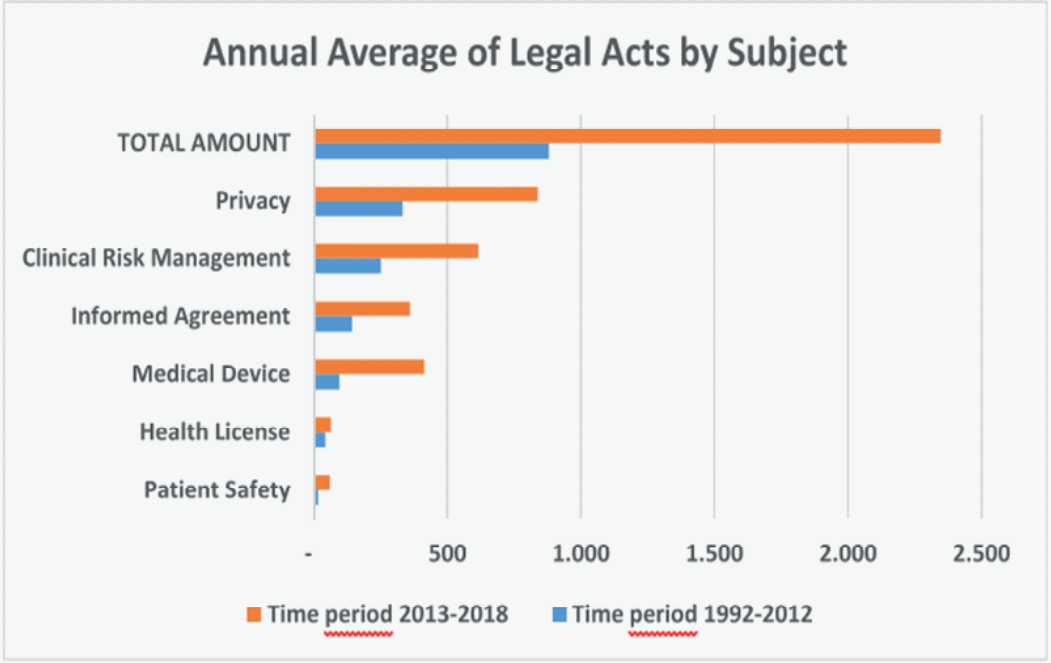

The concept of "undue harm" arises from the provision of Article 2043 of the Italian Civil Code and indicates any violation of an interest that is protected by law. The violation is caused by an "unlawful act" which can give rise to a liability ruling (and therefore sanctions) in both the criminal and civil sphere.

For a more in-depth analysis of the liability of healthcare facilities and healthcare workers when undue harm occurs (Law No. 24/2019), see the next paper.

However, while on the one hand the relevance of wilful misconduct as a source of liability does not raise major interpretative problems, since if a doctor intentionally violates the regulatory prescriptions he can reasonably expect some kind of sanction, on the other, the same cannot be said of the concept of fault.[10]

This occurs whenever the harmful event is not directly desired by the agent but is caused by his behaviour, characterised by negligence, imprudence or inexperience, or contrary to laws, regulations, orders or guidelines.

This means, for example, that a healthcare professional whose own culpable conduct causes undue harm to a patient will bear the civil and/or criminal liability for such harm, even if it was not his intention.

In light of these observations, it is possible to provide a first answer to the initial question, of whether or not viewing the set of rules as excessive bureaucratisation of the procedure – to be respected for the sole purpose of avoiding sanctions – is a suitable response from healthcare professionals.

The set of interests/rights underlying such vast regulations, in fact, suggests that it makes more sense to comply with the obligations laid down therein to constitute, far more judiciously, an adequate "prophylaxis" to criminal and/or civil consequences.

In fact, the best way to manage the risk of a harmful event occurring appears to be prior identification of the behaviours required by law, which aim to protect the rights arising from healthcare treatment.

Consequently, it will be easier for healthcare professionals and healthcare facilities (in any dispute) to prove that they have complied with all legal obligations, and therefore demonstrate that any undue harm that occurred, despite everything, was the direct consequence of an objectively and subjectively unforeseeable event.

Only in this way, in fact, will it be possible to ensure the safety of patient care, avoid culpable liability for wrongdoing (civil and/or criminal), and also ensure financial protection for healthcare professionals and facilities.

It is worth clarifying that the following analysis has the main purpose of indicating how to avoid a ruling of culpable civil and/or criminal liability since – as mentioned – wilful misconduct requires the harmful action to be intentional, it being irrelevant in this sense whether all legally required precautions were implemented in advance.

At this point, it is essential to highlight the function of an organisation[11] (large or small) that is composed of a building (or part of it), systems and medical technologies, and human resources.

The term "organisation" refers to social bodies, economic enterprises, public administrations, etc., based on the division of labour and skills and featuring a complex internal structure, normally inspired by criteria of such division.

These three aspects are the so-called production factors (which will be discussed shortly) that must work together, in a coordinated way, to manage – as much as possible – the risk of an adverse event occurring.

To do this, it seems necessary to follow guidelines that can be summarised as follows:

- recognition and knowledge (the latter by the Organisation) of the laws applicable to the case, i.e. those regulatory laws of the organisation of the health facility performing the medical act, in all its components, pro-

vided that it necessarily falls under the "medical acts" the facility is authorised to perform;
- planning the executive actions needed to complete the fulfilments required by those laws and their "strictly interconnected" legislation, taking into account "the jurisprudence and good technical standards" which enable the legal requirements to be correctly interpreted;
- correct implementation of those actions, in the various levels of the Production Organisation;
- legally significant and "certain" tracing of their correct execution, in order to produce "procedurally validable" elements of the exempt conduct, most likely "not contrary to...", "not omissive of...", but "compliant with..." "applicable laws".

Postponing further study of the guidelines now outlined, there is a wider question to be answered: how it is possible that, during the production cycle – in our case "a medical act" – someone may suffer unjust damage despite timely fulfilment of everything strictly required by all applicable laws?

To answer this question, we must primarily consider how the medical act can be configured as a process whose "output" – i.e. in this case the answer to a diagnostic question or a therapeutic service requested – must have a host building, system technologies that enable it to perform preordained activities, the medical equipment and devices necessary for these, human resources with the proven ability to perform them.

It is therefore necessary to speak of organisation to contextualise medical activity which, needless to say, like any other human activity, is never completely free from risk.

The organisation, in fact, while remaining the best way to coordinate all the production factors[12] according to the rules in place to achieve the required *output*, must deal with their significant trait of entailing a hazard, i.e. an intrinsic property or quality with the potential to cause harm[13].

Precisely because of this, it seems almost impossible for the legislator to regulate every scenario that may occur, that is to predict and regulate any hypothetical occurrence of an adverse event, for the simple reason "*our knowledge of scientific laws is very limited, in that most real situations are (omitted) so complicated that not only is it impossible to understand everything, but it is equally impossible to say, with certainty, what will happen.* "[14]

That said, while on the one hand it is therefore possible for undue harm to occur for which the legislator has not yet made any provisions, on the other, it seems right to assume that in such cases no type of liability can be attributed to healthcare facilities or healthcare professionals, with the exception of wilful misconduct.

This is certainly consistent with the concept of fault mentioned above: there can be no disregard for regulatory provisions if these do not yet exist.

This conclusion's reflection on our guidelines is already sufficient in itself to account for the need for a Health Facility Organisation management system that integrates, inter alia, the different requirements imposed by law to safeguard the protection of health and safety in all its regulatory extensions, including from the intergenerational perspective of the environment.

Risk Management aims to be the naturally interdisciplinary means that each health organisation needs to route its medical and/or business management and manage the risk of adverse events occurring.

But what is Risk Management?

Again, this tool has its roots in the field of economics but – most of all – is necessary to prevent operational risks. In fact, "*Risk Management is interpreted as a process aimed at identifying, monitoring and therefore managing events that potentially affect the performance of company activities, to provide assurances on the achievement of company objectives at different levels of management up to investor relations. Typical activities include setting objectives, identifying risks, control activities, information and communication, and monitoring […]. RM is composed of phases strictly connected to the way company activities are managed in the proactive perspective of strategic control, to maximise opportunities, aiming to identify the right solution for each risk, and thus helping to turn risks into competitive advantages and maximise opportunities*."[15]

Here too, for a more in-depth analysis on Risk Management techniques, see the next paper.

Risk Management therefore differs from other traditional systems focused on managing financial and market risks. In fact, being a broader risk management tool, it becomes managerial responsibility.

Consequently, whoever is in charge of an operating unit must take on the function of risk manager and therefore: carry out strategic activities (defining objectives) and operational ones (allocating resources and performing activities), and furthermore identify and monitor management risks.

In light of the foregoing, it seems clear that Risk Management makes it possible to handle risk, including in light of the main legal provisions, enabling any organisation to prove its non-involvement in any civil and/or criminal culpable charges concerning any harmful event, with the facility to avail itself of insurance coverage.

As mentioned before, this will never compensate for the damage caused by the wilful misconduct or fault of the facility or healthcare professionals.

The purpose of this paper (and subsequent ones) is to strongly affirm the central role Risk Management plays in all areas of medical activity such as health authorisations, patient and worker safety, privacy, clinical risk, informed consent and medical devices, but also and above all in the synergy of all organisational aspects of healthcare facilities.

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