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Commentary

MEDICO - LEGAL SUGGESTIONS FOR YOUNG DOCTORS: THE APPLICATION OF CLINICAL RISK MANAGEMENT TO REDUCE THE RISK OF LITIGATION AND CREATE AN ENVIRONMENT OF TRUST

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ABSTRACT

The figure of the junior doctor is defined in different ways depending on age, educational path, and contract terms related to the conditions of the work contract. The issues related to this particular professional figure should be considered one of the greatest tests to which Health Systems have to respond. In this paper, these aspects are discussed together with practical advice that could be tailored to individual working situations in order to adequately address these issues. Cornerstones and common practices of clinical risk management which may be successfully applied in these contexts are also discussed. The application of Risk Management tools can both provide proactive solutions to reduce the risk of litigation, and create an environment based on trust and one in which junior doctors feel encouraged to signal adverse events and to learn from them. This could result in overall growth in the system, also from a cultural perspective, and better healthcare both for staff and patients.

1. Introduction

The figure of the junior doctor is defined in a different ways depending on age, educational path, and contract terms related to the work contract.
Despite the support activities in national and international networks of young doctors provided by the World Medical Association (WMA),[1] the problems related to supporting this professional figure should be considered one of the greatest tests to which Health Systems have to respond. It is widely recognized that it is necessary to adopt a proper strategic plan that acknowledges the starting point for junior doctors and the point at which they need to arrive to function independently. This is certainly a path full of pitfalls and risks, due to the social, economic and legislative contexts in which junior doctors of the new millennium have been trained and in which they exercise their profession.

Indeed these issues need to be seen in the new cultural context, given the fact that paternalistic attitude in the doctor-patient relationship was abandoned long ago and that legal systems have rightly evolved over the years to include a strong regulatory framework that protects patients. This framework has an impact on junior doctors' daily work in terms of blame, defensive medicine, over-prescription and under-reporting of adverse events, being perceived as a constant threat and not – as it should be – as an opportunity for the implementation of the training standards and quality levels.[2]
In order to achieve the latter positive interpretation of the framework, it is necessary to reactivate and proactively separate processes in order to identify active and latent sources of risk and to apply risk management tools in medical practice.

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Moreover, the influence of the developed regulatory framework on the practice of medicine has pushed junior doctors to associate the well-known diagnostic and treatment skills with the often neglected knowledge and comprehension of the legal and organizational systems that regulate medical care.[3]

In fact, some surveys show that young doctors often have an incomplete understanding of the basic principles of the legal aspects of their profession, as frequently this information is learned only by colleagues who have experienced legal issues first hand.[4] Other surveys show that young doctors even ignore the basic principles of risk management and obligations towards the patient.

This situation is worsened also by the lack of planning and long-term outlook of the training systems that often adopt payment by compensation through inconvenient or, in the worst of the case, even illegal contracts that result in dissatisfaction, powerlessness, and uncertainty also in the possible request of coverage by insurance companies.[5]

In this paper these aspects are discussed together with practical advice that could be tailored to individual working situations in order to deal with this issues adequately. Cornerstones and common practices of clinical risk management which may be successfully applied in these contexts are also discussed.

2. General aspects and young doctor's claims: practical advice

A first clear suggestion is the one to limit the exposure of junior doctors to the risks related to deficiencies in the systems of healthcare and medical training. This means taking issue with unclear contracts, especially in areas such as the Emergency Department or in surgical disciplines which are the ones with the highest risk index.[6] In order to mitigate this risk, contractual forms have to be carefully evaluated assessing their strengths and weaknesses in light of national regulations also to ensure the compliance with the provision of law. This clearly reflects also on insurance policy conditions that have to be stipulated.[7]

The subject of training quality is also closely linked to the quality and safety of healthcare, since inadequate or hasty professional training courses or direct post-graduate hiring with on-the-job training contracts expose junior doctors to a high level of risk without the basic skills necessary to deal with the complexity of care systems.[8] National Health Systems need to seriously consider the information coming from young doctor associations who clearly state the need for a comprehensive strategic vision based on planning access to schools of medicine, specialization and public health and their educational path. This plan should be based on the real needs of patients and citizens without taking refuge in urgent reparative interventions that are clearly detrimental and risky for the new generations of doctors and for the population itself. All this also with a view to taking account of the responsibilities that young doctors will have in the future such as for example, the evolution of telemedicine that poses a series of legal and medico-legal problems. [9]

A second crucial point is in relation to curricular training. In Italy, there is an ongoing debate on the need to clarify, in medical residents, the legal aspects related to clinical activities. [10] However, in most countries these themes have not been added to the curriculum within the teaching subjects, so that techniques of clinical risk prevention and litigation management are unknown to most.[11]

A revision of the curriculum would therefore be necessary together with a more general negotiation of greater efforts, including the implementation of adequate tools, which are required both at national and regional level in order to provide medical workforce planning in line with a continuously changing health context.[12]

Since it is clear that if the management of clinical risk in health facilities is essential for the analysis and the prevention of adverse events occurring to the patients, it is also clear that a correct application of these tools has positive effects on the quality of the working life of health staff. This will eventually create and promote a safety culture aimed at guaranteeing safer, more efficient and sustainable health systems that see error as a source of learning and the application of evidence-based medicine as a tool to achieve this goal.[13]

Since patient safety is one of the determining factors in the quality of care and one of the priority objectives of the national health systems, it is therefore necessary for junior doctors to follow individual refresher courses on practical tools of clinical governance.[14] Moreover, individual updates must necessarily be accompanied by a general action aimed at increasing the awareness of the medical community on the importance of these issues, trying to include clinical risk management as an obligatory teaching subject in pre- and postgraduate.

3. The application of Risk Management

International literature reports a rate of adverse events on 1000 days of hospitalization of between 8 and 12% in advanced health systems and several studies have indicated that of these adverse events the preventable ones would be 43.5%, in some Western countries death of the patient occurs in 9.5% of cases.[15, 16]

There are numerous potential areas of intervention to reduce adverse health events and to implement patient safety standards. These areas have been outlined over the years by the World Alliance for Patient Safety (WHO) and by the International Patient Safety Goals of the Joint Commission International (JCI) [17,18]:

1. Correct patient identification;
2. Improve the effectiveness of communication;
3. Improve the safety of high-risk drugs;
4. Guarantee surgery correctness (patient identification, correct procedure, right body part);
5. Reduce the risk of healthcare-associated infections;
6. Reduce the risk of injury following a fall.

3.1 Correct patient identification

Patient identification errors can occur at all stages of the care pathway and may involve non-critical patients, but also patients who are sedated, disoriented, not completely alert, or patients who have changed rooms, beds or wards. These and other situations expose patients to the risk of incorrect identification.[19] The patient's identifiers are the name, surname and date of birth and they must always be recorded in the medical, nursing and administrative health records. It is inadvisable to identify the patient by only one of the identifiers (i.e surname) or even worse by the room number or the bed number.[20]

Patient identification methods must include an active identification request to pronounce the surname, name and date of birth and, in the case of an uncooperative patient, by checking personal data reported in the identification documents.

In the case of an unknown and temporarily unidentifiable patient, it is advisable to proceed with the identification with an alphanumeric code to be reported on all the health documentation up to the confirmation of identity.

Moreover, personal data must be reported on the identification instrument (e.g. bracelet) with indelible block letters. The professional who writes the data, affixes to the patient the identification tool, asking them to pronounce their name, surname and date of birth and checking that the data reported by the patient are consistent with what is transcribed on the bracelet.

The patient must be identified before the execution of the following activities: administration of drugs; administration of blood and blood components; collection of biological samples; carrying out of any diagnostic and therapeutic procedures.

Every junior doctor must know these methods of correct identification and remember that a fundamental safety rule is to carry out a double identification (surname and name; date of birth; identification tool; unique identification number).

3.2 Improve the effectiveness of communication

Improving the effectiveness of communication is a second fundamental objective to reduce the risk of an adverse event, considering that every day the individual communication processes are innumerable and each of them hides pitfalls, especially when they take place verbally or by telephone. Good communication skills can make up for organizational and structural deficiencies, and can also improve the relationship of trust between the citizen and the health system.[21]

Scientific literature indicates that communication errors are the most frequent cause of adverse events as ineffective communication can lead to misunderstandings, disagreements and misinterpretations, especially in relation to the multidisciplinary complexity, and the multiplicity of the human, technological, and organizational/managerial elements that interact in the health systems.[22] Indeed communication among patients and professionals, and among professionals in any healthcare setting should be considered as a substantial factor, so that the ability of healthcare professionals to listen effectively to the patient and to converse equally effectively with both patients and colleagues is a key element that must be constantly promoted during the delivery of care. Effective communication in healthcare must not be entrusted only to personal attitudes, but it is necessary for each health worker to acquire and develop specific communication skills through training and training courses.

This is crucial considering that, as a matter of the fact, incorrect grammar internal communication can invalidate an entire diagnostic and therapeutic process, leading to the management failure of the care path and more easily exposing doctors to a possible dispute. Also the so called external communication, that is media communication, should be just as correct and structured, sending messages in which miraculous expectations are not solicited and in which scientific claims are not distorted.[23]

Even the concept of a correct communication of the error must be well-known to young doctors, both in the general perspective, and for the well-known ethical and deontological reasons.[24] This allows the patient to get timely treatment with the aim of mitigating damages and starting compensation procedures in case the damage has occurred anyway. The correct communication of the error can promote and strengthen the trust in the doctor-patient relationship, decreasing at the same time the likelihood of litigation and favouring learning from error and the implementation of clinical practice. Thus, when an adverse event occurs, the approach towards patients must be open and transparent, information on the event must be provided and it is necessary to explain the accident to the patient to prevent and reduce the number of legal medical disputes arising from medical errors; an immediate analysis of the incident should be started; immediate physical and psychological support should be provided.

3.3 Improve the safety of high-risk drugs

Improving the safety of drugs, especially those at high risk, represents a further area of intervention considering the role of young doctors not only in correct administration, but also in pharmacovigilance. Pharmacovigilance is the monitoring of the use of drugs to detect negative outcomes or adverse events that exploded when the WHO organized an International Drug Monitoring Program in response to the thalidomide tragedy that occurred in 1961. [25]The reporting of adverse reactions is made to the regulatory authorities who can take numerous actions: firstly by providing feedback to doctors who prescribe, secondly by spreading warnings, thirdly by limiting the prescription to certain groups of patients or allowing it only to specialized doctors.

An adverse event in a patient treated with a medicinal product does not necessarily have a causal relationship with the therapy. Some examples are suspected interactions with other drugs, drug abuse, therapy errors, events resulting from an overdose, failure to achieve the expected therapeutic effect, worsening of the disease after using a product, birth defects and other events following the use of the product during pregnancy. A serious adverse event may result in death, an immediate life threatening, hospitalization or prolongation of hospital stay, a significant or persistent disability, a birth defect or congenital anomaly, or in general any important medical event such as to jeopardize the patient.[26]

Updating young doctors on the Periodic Safety Update Reports (PSUR), which are pharmacovigilance documents aimed at providing an assessment of the risk-benefit balance of a medicinal product, and to the Development Safety Update Reports (DSUR), which are documents aimed at representing a common standard for periodic reporting on medicinal products in development, and above all post-authorization efficacy and safety studies.[27]can guarantee a high standard in terms of quality and quantity of prescriptions and efficacy safety studies.

In addition, the learning of basic notions in terms of clinical drug risk cannot be neglected considering that the estimated percentage of therapy errors is between 12 and 20% of total errors.[28]

Preventable events that can cause or lead to inappropriate use of the drug or to endanger the patient, which can be defined as "therapy error", could be consequent to errors in prescription, transcription/interpretation, preparation, distribution and administration. Indeed, these are events not directly related to the nature of the drug, such as those due to poor handwriting, ambiguous abbreviations, poor information on doses, ways and timing of administration. To prevent adverse events not directly related to the nature of the drug and therefore due to human or system errors, it is advisable:

- to know, disseminate, request and use the mechanisms for sending prescriptions through a computerized system;
- to adopt barcodes in drug use processes;
- to develop systems for monitoring and archiving adverse reactions;
- to adopt, where possible, unit doses and centralized mixing of intravenous drugs;
- to collaborate directly with prescribers, nurses and pharmacists, verifying the prescriptions from the latter before the initial dose;
- to detect, in general, any error related to the administration with subsequent process of solutions to prevent them.

A junior doctor, especially in a situation of new employment or unknown environment, must first check and verify the existence of these safety standards, with frequent periodic checks and promptly report the absence of such.

3.4 Guarantee surgery correctness

Interventions in the wrong patient or in the wrong part of the body or with wrong procedures represent particularly serious events, which can be determined by various factors and which often expose the doctor to criminal trials and to particularly onerous compensation in relation to the caused damage, also for the relevant media exposure. This led to the development of universal protocols for the correct identification and the development of numerous corporate signaling systems. Especially from the legal medical point of view, it is important to establish the different pre-operative phases. [29](Tab.1).

The first one is the period of preparation for the intervention (days/hours before the operation) that consists of the informed consent phase and the identification phase of the surgical site.

Informed consent is a key element of the lawfulness of the medical act and the legal medical implications that it determines. Informed consent is regulated differently in different countries according to the legislative and regulatory systems of reference, but some points remain firm also considering the ethical aspect that related to the fact that the patient has the right/duty to know and understand all the information available for his own health and illness. [30] The informed consent is, therefore, a particularly important moment in the care process, so every patient must be provided with correct and complete information on the proposed treatment, including the benefits and risks associated with it, as well as alternative treatment procedures and methods. Correct forms for informed consent must contain at least the following information: patient data; name and description of the procedure; location of the intervention; possible laterality of the procedure; reasons for which the procedure is carried out.

After having provided all the necessary information to the patient, to guarantee the correct site identification it is necessary to mark the surgical site in situations characterized by laterality of the intervention and in the case of involvement of structures or multiple levels. The surgical site must be marked with a permanent marker, so that the mark remains visible even after the application of skin preparation solutions using symbols that do not lend themselves to confounding and possibly standardized within the healthcare facility and taking into account confounding factors (e.g. tattoos). Before tracing this sign it is necessary to carefully check and verify the site based on documentation and radiological images. The symbol must be made directly by the operator or his delegate who must be present at the time of the procedure.

The second phase is the one immediately before the entrance to the operating room. In this phase it is important, as mentioned above, to identify the patient in the manner previously described and to verify the adequacy of answers, documentations, identification systems and informed consent.

The third phase is the one that takes place into the operating room and immediately before the operation. In this phase all the previous steps must be verified, involving the entire operating team through active communication. All team members must agree, and any discrepancies must be clarified before starting the surgical procedure. Finally, a double check must be made.

The operator performing the intervention must carry out the first check; the second check by another member of the team, and everything must be documented through the use of a check list.

3.5 Reduce the risk of healthcare-associated infections

Referring to the reduction of the risk of healthcare-associated infections, please consider what has been said in the other sections of the paper. Considering the burden of healthcare-associated infections on the amount of litigations, it is important to adopt a comprehensive approach that considers the general Risk Management tools and the reference Guidelines for the prevention of infectious complications that can cause detriment to the patient.[31]

Sepsis is a leading cause of morbidity and mortality worldwide. It is defined as the presence of a Systemic Inflammatory Response Syndrome, and it represents a significant burden for the healthcare system. This is particularly true when it is diagnosed in the setting of nosocomial infections, which are usually a matter of concern with regard to medical liability being correlated with increasing economic costs and public loss of trust in healthcare. [31] The issue of nosocomial infections is constantly evolving also because from a medico–legal viewpoint, this particular situation represents a new frontier of professional liability, which includes manufacturers of electromedical equipment. [32]

3.6 Reduce the risk of injury following a fall

Falls are among the most frequent adverse events in health facilities and can lead to immediate and even serious consequences, leading in some cases to patient death, especially in frail patients and in patients at greater risk of falling such as elderly, children and disabled. The risk of falling is always present and is different in the various care settings. In addition to physical damage, falls that occur in the context of hospitalization lead to an increase in hospitalization, diagnostic and therapeutic activities with an increase in health costs and disputes. [33]

The first action necessary for the prevention of falls is to identify the possible intrinsic risk factors, which are related to the patient's health condition, and extrinsic factors which are related to the organizational aspects of the hospitalization, to the environmental and ergonomic characteristics of the structure and to the medical devices employed. Once these risk factors have been identified, it is necessary to assess the risk of falling of the individual patients by choosing methods provided by the most appropriate guidelines for the structure where the patient is.

The assessment of the risk of falling patients must be made upon admission of the patient, especially if elderly (age 65 or older), following significant changes in health status, following a previous episode of fall; with checks at regular time intervals in the event of prolonged hospital stays, before transfer or discharge or in the case of drugs' exposing the patient to greater risk.[34]

Once the risk has been calculated, it must be clearly indicated on the health documentation by the person who proceeded with the evaluation. In the event of a fall, it is important that the Company is equipped with necessary tools for the collection of fall reports, regardless of whether or not it has caused damage to the patient.

As a means of protecting forensic medicine and increasing the care quality, a practical legal suggestion for young doctors is to attend and request from the company management important training courses both to learn about tools for preventing falls and for actions to be taken after the fall.

4. Conclusions

All human beings make mistakes, and all doctors, considering the complexity of systems in which they operate, make mistakes, especially junior ones who inevitably lack experience.

What is important is to be aware of the tools to respond and react to mistakes correctly and unfortunately most junior doctors are not aware of how medicine and the law interact.

The principles of Forensic Medicine are the basis of every move a doctor makes. In a climate that has been created in which, rightly, doctors must increasingly justify their actions towards patients and colleagues, knowledge of the laws that underlie, in every single state, the exercise of the medical profession, will allow doctors to justify both medical actions undertaken and to obtain a more peaceful relationship with patients and their families.

The application of Clinical Risk Management tools, whose starting point is represented by the identification of non-conforming results, can both provide proactive solutions reducing the risk of litigation, and create an environment based on trust in which junior doctors feel encouraged to signal adverse events and to learn from them.

This can provide an overall growth in the system, also from a cultural perspective, and better healthcare both for the staff and for patients. [35] Recent legal developments regarding the reorganization of and accreditation processes for specialization schools in the healthcare sector has led to a profound didactic transformation that has brought inevitable repercussions for the activities and training of post-graduate doctors.[5] This reorganization should also be reviewed in light of the future challenges launched by Clinical Risk Management.

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