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Ensuring Operating Room Safety: The Italian Approach

Policies for the management and control of risks associated with healthcare constitute one of the priorities of the modern health systems. Like most European countries, the Ministry of Health in Italy has recognised the importance of assessing quality and safety on all levels of the system, taking into account patient expectations and enhancing the role and responsibility of health professionals.

Through the establishment of a ministerial working group dedicated to patient safety, there have been many clinical governance initiatives, the most significant being the Information System for Monitoring of Sentinel Events (SIMES). SIMES allows the collection of information on the spread of sentinel events in healthcare facilities needed for the analysis of contributing factors and determinants, and develops specific recommendations for the safety of patients. The major care priorities are identified and the systematic use of best practices for patient safety is promoted.

Operating Room Safety

Particular attention has been placed on safety in the operating room in the light of guidance and awareness initiatives launched by the WHO in the World Alliance for Patient Safety and the Safe Surgery Saves Lives programme in particular. Surgical activity, the volume of surgical activity and the inherent complexity of all procedures related to it, even the simplest, is one of the areas with the highest probability of error. The many critical points of each surgical procedure have the potential to cause serious harm to the patient and that is why safety in the operating room is a challenge and a priority for health systems and the management. Using risk assessment we can implement the best solutions for organisational and logistical security so that they constitute an effective barrier system for errors.

In Italy, operating room safety is often the centre of attention due to the occurrence of particularly severe adverse events. In Sicily, for example, the emergence of a number of incidents in the operating room, in different contexts and over a relatively short period of time, led to the establishment of a regional commission of experts for a large scale verification of safety procedures. The survey was completed in a few months and resulted in the closure of several facilities operating without safety requirements. This confirmed the role of the organisation and maintenance in causing adverse events and has led to increased risk control and dissemination of a safety culture. The next step is a special plan for modernisation and increase the safety of the medical devices.

The Italian Ministry of Health considered it essential to launch a major campaign to raise awareness among health professionals on the issue of safe surgery. This was done through the creation of a manual for safety in the operating theatre derived from the WHO Guidelines for Surgery and centred on 16 goals for the safety of the perioperative process including 10 derived from the cited WHO document.

Within the scope of the manual for safety in the operating room, a ministerial working group has also developed an Italian adaptation of the WHO OR checklist including controls on the most important aspects of the surgical safety, such as the confirmation of the identity of the patient and type of surgery, the verification of systems for monitoring and maintenance of vital parameters and confirmation, within the team, of the knowledge of the procedure that they are going to perform. Compared to the 19 items of the original version, the Italian checklist presents an additional item to control the prophylaxis of venous thromboembolism, which is considered essential for the prevention of adverse events in the postoperative period.

The checklist should not only allow for the verification of the process and a reminder mnemonic for the proper performance of a particular task, but also facilitate communication within the team, especially with regard to critical information about the patient and intervention, with better identification of roles within the team and a more optimal exchange of critical information regarding the clinical condition of the patient and the type of work that he is going to perform. The Ministry has also recommended that the health facilities in the National Health Service also take into account the recommendations of the WHO. The checklist will be adapted locally based on the characteristics of each healthcare organisation or particular procedures used. Altered versions could include the addition of further control or elimination of items of routine use and therefore unnecessary.

Promoting the Checklist

In order to raise awareness among health professionals and promote the use of the checklist, the Ministry of Health has developed some explanatory videos to explain the correct procedures for carrying out checks during the course of surgery.

A working group composed of influential figures in the Italian health system took the WHO video as a starting point along with other similar experiences in different countries and adapted the scenes and content to the Italian situation. Particular attention was paid to the choice of surgical procedures on which to apply the checklist, to ensure they are consistent with the local situation.

In order to create a tool that can positively influence the behaviour of the operating team it was also decided to include testimonials from prestigious figures in the national health system, including presidents and members of scientific societies and organisations for the protection of patients: Francesco Basile, Dean of the Faculty of Medicine, University of Catania; Louis Conte, Italian Hospital Surgeons Association (ACOI); Giorgio Della Rocca, the Italian Society of Anaesthesia and Intensive Care (SIAARTI); Giuseppe Greek, chairman of the Standing Conference of regions Cittadinanzattiva Tribunal for Patients' Rights; Giuseppe Mancini, President of Operating Room Nurses (AICO); Barbara Mangiacavalli, Secretary of the Central Committee of the Federation of Colleges IPASVI; Walter Mazzucco, national president of the Italian Secretariat of Postgraduate Doctors; Gianluigi Melotti President of the Italian Society of Surgery (SIC). Famous faces from the world of culture, Maestro Nicola Piovani and actress Mariella Lo Giudice created the soundtrack and narrated the video. In order to facilitate the sharing of the video within the international scientific community, scenes filmed in the Italian language were captioned in English.

The ministerial working group also considered strategies to highlight the key role of managers as facilitators of the use of the checklist. At the beginning and end of the video a short presentation was inserted to draw attention to the purpose and the importance of corporate policies of clinical risk management in preventing error. Stefano Cencetti, Director General of the Hospital Policlinico of Modena and Gianfranco Finzi, Medical Director of Presidio dell'Azienda University Hospital S. Orsola Hospital in Bologna and president of the National Association of Doctors of Hospital Management (ANMDO) described the purpose of the initiative. These statements put in proper perspective the role that health managers play in the governance of healthcare organisations and emphasise the importance of the organisational aspects at all stages of surgery in which important decisions are made or activities that require high attention especially in terms of communication between the team members and the exact identification of the tasks assigned to the operators.

The video, made in 2009, was presented to health professionals as part of a dissemination campaign launched at the annual Risk Management Forum of Arezzo; one of the main Italian events in training and updating clinical risk. The key strategy was the involvement of scientific societies including ANMDO to stress the important role of doctors as facilitators of the adoption of the checklist.

There is a risk that the use of a largescale national checklist, although highlighting sensitivity to the issues of clinical risk, is likely to remain a bureaucratic formality with no added value for safety. Particular attention has therefore been paid to the verification of the use of the checklist on a regional level. This was implemented by the Ministry of Health through a questionnaire to gather information on the adoption of the manual and checklist and local training initiatives. The first results of the national survey, although still incomplete, already show a high level of adherence by all health facilities across Italy thus confirming the important role that health policies play in the construction of an error proof system. It is significant that the ministerial handbook for safety in the operating room and related checklist has favoured the creation of a national network for safe surgery. Evidence of this success can be seen through the large number of reports on the theme presented during the last Risk Management Forum of Arezzo.

For a comprehensive approach to safety, which covers all aspects of structural, technological and organisational management, the contribution of the professionals involved is of paramount importance. Strategic synergy is needed to ensure seemingly minor aspects, which may be fundamental to the prevention of the error, are not ignored. A logical system of safety and quality assurance is decisive for the prevention of error.

In this context, of particular importance is the role of the medical director and medical management. Acting as the pivot and facilitator of the process and as a reference for the establishment of a proactive vision for safety, management can ensure error analysis is used as a tool to learn how the same error can be avoided in the future.

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