Risk management in surgery

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SUMMARY: **Risk management in surgery.**

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Malpractice is the responsible for the greatest number of legal claims. At the present time, legal actions against physicians in Italy are

15,000 per year, and a stunning increase about costs to refund patients injured by therapeutic and diagnostic errors is expected. The method for the medical prevention is "Risk Management", that is the setting-up of organizational instruments, methods and actions that enable the measurement or estimation of medical risk; it allows to develop strategies to govern and reduce medical error. In the present work, the reconstruction about the history of risk management in Italy was carried out. After then the latest initiatives undertaken by Italy about the issue of risk management were examined.

Introduction

By "Risk Management" is meant the setting-up of organizational instruments, methods and actions that enable the measurement or estimation of medical risk and subsequently evolve strategies to handle it. The introduction of a logical systematic methodology which, by means of successive steps, would allow for the identification, evaluation, communication, monitoring and elimination of risks associated with medical activities, promoted by the consideration or 'risk culture' concept that if mistakes are analyzed correctly, they can become vital and valuable opportunities for learning and improvement. An error is not necessarily the consequence of a single human mistake but, quite often the result of technical, organizational and procedural interaction. It would therefore be advisable, to make an in-depth analysis and research of the causes that brought about such error in order to prevent recurrence of a one similar event or even limit damage that could have already occurred, rather than to approach the issue punitively (1). This therefore calls for a profound change in the policy of how to avoid risk. If there is a risk and it should be my task to find it and you consider it your duty to hide it, we would then be up against system dysfunction (2). Therefore to bring about change, it is necessary that each and every person involved in the system, should feel himself or herself directly responsible regarding the management of, or dealing with, such risks. All those professional working within an organizational entity/structure should therefore take personal responsibility for their own actions within the limits of their own personal competence and so monitor their performance according to principles of professional assessment that are shared. Thus medical services management is a participatory process initiating in the practice of a policy of communication and information exchange - both inside and outside the health structure or entity. Management adhesion within a system is nothing more than the inter-active relationship existing between the people who are also its vehicle, and therefore necessitates the need for areas of co-ordination among those responsible for operating units, an integrated

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view of patient-centered care and a 'walking' down the same road of patient-care together. This implies having better communication with the patient, which is then directed to greater collaboration with the medical operators in order to achieve the desired clinical objective (3, 4). Citizens too as 'entity customers', are more than ever aware of medical risk and consequently demand greater guarantees in health care services. The Assistance may no longer be only fairly good, but should be better or even excellent.

Therefore to be effective, Risk Management should concern itself with all such areas in clinical processes that are subject to error in patient care. Only an integrated management of medical risk will bring about changes in clinical practice, promote an increase in health care awareness that is ever closer to both patient and operator, and contribute indirectly to a decrease in the cost of health services, thus ultimately facilitating the allocation of resources to interventions directed to the development of safe and efficient health organizations and facilities (5).

This paper does not intend to replicate the many seminars and training courses on the management of health risk that have taken place in recent years. First and foremost, the purpose of this research is to recognize that when it comes to risk management, we ought to be aware that it is a challenge that will test our ability both to assess and manage risk - as well as reduce it. So we have to be certain that in our assessment, we ascertain from the outset what the critical issues are in any process – even those most basic such as that of a nurse administering medicine to a patient. Several theories have been put forward concerning error and the analysis of the causes and risks that lead up to it. The common factor in many of these theories is shown by a different approach which tends to reduce the lifting of human factor related action from a general blaming, universally invoked as being the main cause, and organization which transfers the analysis of latent conditions that lead to the different commission of error. In analyzing however the short history of Risk Management in Italy - one of the leading countries in the world - we have taken a look at its progress in both its national and international context, and pointed out the light and shadow patterns of regional imbalances and geographic stigmatizing, still today unfortunately all too obvious in a country like ours.

In logical conclusion, we chose to demonstrate that the latest initiatives of the Ministry of Health, have as their prime goal, the unification of the many proposals put forward by the various regions and business, into one sole and integrated mission. Thanks to technological innovation, a prior investment made at a slightly higher cost, will lead to savings over the medium term and reduce current spending as well as augment services to the benefit of citizens and businesses alike.

Risk management in Italy

Governmental procedures made in Italy, to cope with clinical risk, have had neither homogeneous distribution nor application and are in fact constituted of working groups at regional level, with the presence of more advanced leaders in certain regions. These working groups aim to set processes going for risk analysis and clinical research which will include organizational instruments and support within the area, that are to promote campaigns directed to health education, awareness and promotional activity which involves also persons at professional level who are not directly engaged with health care (6). The situation is not particularly sound at present as there are regions on the one hand which have been engaged in health risk management for years and shown excellent results, while on the other hand, there are regions that have only recently set up a Health Risk Management Unit (UGR) and that often only on paper.

Italian Ministry of Health

First steps

As things stand at the moment, the Ministry of Health and the Agency for Regional Health Services (ASSR) are the national referents for clinical risk management. These have undertaken a unification policy for different initiatives at regional and/or local level, especially with regard to a strategic goal for the creation of a coordinated system of error-monitoring, divided into three different levels - national, regional and that of enterprise - that will use a standardized method of data collection and analysis, supported by an IT network. In 2002, a first tentative approach was undertaken by each structure of the NHS to solve the problem of clinical risk when the first working group was made available to collect investigative initiatives concerning patient safety. Then on the 5th March 2003, the Technical Commission for the Department of Clinical Risk was instituted by MD (Ministerial Decree). Since then the Commission has furnished documents and recommendations aimed at the keeping of safety measures for both operators and patients alike.

The Commission made its debut with the publication in 2004 of the paper; *"Risk Management in Healthcare. The problem of mistakes"* in which, beginning with a in-depth analysis of the issue of clinical risk, furnished a collection of reflections and recommendations, useful to all who work in health care services (24, 25).

Subsequent to the publication of this paper, certain initiatives have been undertaken with the purpose of achieving the aims defined therein. Working groups were

set up to point out solutions to three particular aspects of priority:

- A system for the monitoring of adverse events;
- Development of recommendations;
- Methods for *training* health workers.

With a view in mind to the aspect of training, the Health Ministry produced in July 2006, a glossary of *"Patient Safety and Clinical Risk Management"* so as to furnish a common vocabulary at international level. This was followed in May 2007 by a *"Manual for the Training of Health Workers "*, produced together with the collaboration of the Federation of National Order of Physicians and Surgeons and Dentists (FNOMCeO) and the National Federation of Nurses' Colleges, (IPASVI). This manual proposed a 'learning at a distance' course directed to all health care workers.

In the National Health Plan of 2006-2008, it was expressly stated in chapter 4.4 (Promotion of Clinical Governance and Quality in the National Health Service) that "*the monitoring of activities must be conducted according to a graduated criteria based on the severity of the event, providing that the three levels, national, regional and corporate, can promote respective actions, according to a coherent and practicable design. A monitoring of the sentinel events that result in a loss of public confidence against the Health Service has to be activated "* (25).

The check-list for safety in the operating room

Based on the recommendations of "Guidelines for Surgery", WHO has prepared a guide-line list of 19 points to implement safety controls in the operating room and give support to the operating team. This list is aimed at systematically promoting adhesion to recommended safety standards in order to prevent mortality and post-operative complications.

This means of control sustains changes in the system and individual behaviour, reinforces safety standards and communication and contrasts possible failure factors.

This check-list underwent recent tests in a prospective study and a performance sample of *before – after* was taken in eight hospitals in different countries. It was found by this study that implementation of the check-list was associated with a concomitant reduction in mortality rate and post-operative complications.

It was noted in particular that the rate of complications before implementation of the check-list was 11%, but that this was reduced by 7% (p <0.001) after its introduction.

Similarly intra-hospital mortality rate was reduced from 1, 5% to 0.8% (p <0.003), the rate of surgical site infection from 6.2% to 3.4% (p <0.001), while a not-scheduled return to the operating room decreased from 2.4% to 1.8% (p = 0.047).

Despite the limits of the different studies, the results observed clearly suggest that the use of the check-list would improve patient safety and reduce the number of deaths and post-operative complications.

Even the national agency for patient safety in the United Kingdom (NPSA) has recently complied by officially recommending the WHO check-list to their own local situation, and through a national alert, its use to all patients undergoing surgery in England and Wales.

The check-list

According to WHO guidelines, the Ministry of Health and Welfare has adapted the WHO check-list of 19 items to the national situation and furthermore adding an additional one that concerns the monitoring plan for venous thrombosis-embolism prophylaxis.

The check-list covers 3 phases (Sign In, Time Out, Sign Out) and the 20-items or points indicate the controls to be carried out during surgery. The appropriate box-spaces are to be marked (_) only after the relative control has effectively been carried out.

1st phase: Sign In

'Sign In' takes place before induction of the anesthesia. The presence of all components of the team are required and includes the following controls:

- **Confirmation of the patient, procedure, surgical site and approval**

The coordinator is to verify verbally with the patient that identity, site and procedure are correct and that assent has been given for the surgery.

If, due to medical condition or age, the patient is unable to answer questions as to his correct identification, it is therefore necessary to involve family members or other persons who are able to answer this correctly.

- **Marked site**

The coordinator is to mark the corresponding box-space only after checking that the site for surgery has been marked, unless such monitoring is not applicable to that particular type of surgery (e.g. surgery to be carried out on single organs) as indicated in *"Regional Procedure for identification of the patient undergoing surgery, identification of the site for surgery and confirmation of such. "*

- **Controls for the safety of anesthesia**

The coordinator is to carry out a verbal check together with the anesthetist that the required safety controls have been made for the anesthesia induction, patient management, drugs and equipment, and that correct oximeter positioning and functioning has been confirmed.

- **Identification of risk to patient**

The coordinator is to carry out a verbal verification with the anesthetist that evaluation has been made regarding the following risks: allergic reactions, difficulty related to management of nasal passages and blood loss.

2ⁿᵈ phase: Time Out

By 'time out' is meant that short moment of 'surgical rest' which takes place after the induction of anesthesia and before surgical incision. It requires participation by all the team members and involves the following seven tests:

- **Team introduction**

The team members and their roles are to be explicitly known to each other either through their consolidated knowledge or by explicit statement thereof, especially should there be any change of team members. It is the duty of the coordinator to verify this.

- **Surgeon, anesthetist and nurse confirm patient identity, site of surgery and the procedure and the correct positioning thereof.**

The coordinator is to ask the operating team to give spoken confirmation of the name of the patient, surgical procedure, site of the surgery and the correct positioning of the patient in relation to the scheduled surgery. e.g. The coordinator shall declare aloud: "It is now the moment for 'Time out '. He shall then continue, " Do you agree that the patient's name is XY? Do you agree that XY is to undergo emergency surgery for right inguinal hernia? "

The relevant box-space is then to be filled in, only after the surgeon, anesthetist and professional nurse have confirmed the above points.

- **Criticality anticipation**

Subsequently, alternately each component of the team is to review the critical elements of their own surgical program using the question check-list as a guide. e.g. The surgeon could say: "This is routine X-term surgery." He would then ask both nurse and anesthetist if there are any elements for concern. The anesthetist might reply, "No, I have no particular concerns about this case," while the nurse might add, "Instrument sterility has been verified. There are no other elements of particular concern. "

- **Antibiotic prophylaxis**

The coordinator is to make the spoken enquiry if antibiotic prophylaxis has been given 60 minutes earlier. The person responsible for the administration of antibiotic prophylaxis is then to provide verbal confirmation thereof.

If the antibiotic has been administrated more than 60 minutes before, then the additional dose of antibiotic should be given. Until administration of the additional dose, the coordinator is to leave the appropriate box-space blank.

- **Diagnostic images visualization**

The image display is important to ensure appropriate planning and performance of surgical procedure. The coordinator is to ask the surgeon whether display of the images is required for the surgical intervention. Should this be so, confirmation that the essential images are available in the room is required and that these are ready to be displayed during the operation.

3ʳᵈ phase: Sign Out

The objective of 'Sign Out' is facilitation of the appropriate and efficient transfer of information to the team and staff responsible for patient care after surgery.

'Sign-out' is to be completed before the patient leaves the operating room and may also coincide with closure of the surgical wound, 'Sign out is to be completed before the surgeon has left the operating room. It entails the following six controls.

- **Operating room nurse is to confirm verbally with all the members of the team:**

- **Name of the procedure performed:**

Since the surgical procedure may have been changed during the intervention, the coordinator is to confirm with the surgeon and the rest of the team, the nature of the procedure performed by asking for example, "What surgical procedure was performed?" or request confirmation, "Did we carry out process X or not? If not, what other process was carried out?".

- **Count taken of gauze, scalpels, surgical needles and other surgical instruments used.**

The scrub-room or operating theatre nurse is to make and confirm the count by speaking out loud.

The surgical team is to be notified promptly should there be discrepancies in the final count in order they may take the appropriate action.

- **Labelling of the surgical specimen (including name and description of patient).**

The operating room or theatre nurse is to confirm correct labelling of the surgical specimen by reading aloud both the name and description of the patient concerned.

- **Problems or failures in the use of devices:**

The coordinator is to ensure that no problems have arisen in the operation of all surgical devices. If so, such problem are to be promptly identified and reported so as to avoid further use or re-use of the said device before the problem has been resolved.

- **Revision of critical elements for post-operative care:**

The coordinator is to confirm that the surgeon, anesthetist and nurses have reviewed all important issues and critical elements necessary to the correct handling of the post-operative patient while also focusing on any intra-operative or anesthetic problems that may adversely affect the course of post-operative recovery.

- **Postoperative thrombosis-embolism prophylaxis**

The coordinator is to ask the surgeon whether the plan for post-operative thrombosis-embolism prophylaxis has been prepared as per health organization procedure, early mobilization, compression devices, drugs.

The completed check-list may be placed in the patient's medical records and / or filed for an assessment of the quality of surgical intervention carried out.

Adaptation of the check-list for your organization

Even on the basis of positive results presented in international medical papers, it has been recommended to the NHS to ensure implementation of the check-list in all operating rooms for health reasons, adapting to list to the particular characteristics of each health structure. Indeed, the check-list is not exhaustive but it is expandable with amendments and supplements based on specific local needs were foreseen.

The removal of check-list items or points is recommended where these be motivated by circumstances that hinder implementation of the check-list - such as for example incompatibility within the work context (e.g. the team does not fully appreciate or understand its usefulness).

If special local needs or specific procedures make additional controls appropriate, additional items or points may be included while taking care at the same time that management and viability of the controls has not been made too complex (29).

Conclusion

"We envision a Health Care system in which those who provide health care can derive satisfaction from their work while those who receive health care, feel secure and have full confidence in the assistance they receive".

This thought of Donald M. Berwick, President of the Institute for Health Care Improvement, may seem only an utopian vision of the problem of health care taken in the light of so many incidents of medical malpractice. Through the analysis carried out here, there does emerge however a greater awareness of the need to establish a Risk Management function within the health sector, derived from a consciousness of the need to reduce errors. Thus we ought to act through a change of our approach to hospital management and move away from a paternalistic attitude regarding the physician - patient relationship, towards and onto a plane of the equality of rights and duties, acting also on a service-oriented organization that has its vision directed towards patient needs rather than only those of the physician.

As already shown above, Risk Management requires an integrated view of the risk-error problem, however difficult it may be to achieve over the medium term.

In fact in reality, each health structure which sought to apply the concepts of Risk Management in its own management, had only some of the instruments for risk analysis available, and then those only for a specific sector. This mere fact proves that the application of Risk Management is indeed really rather complicated. The-

refore the entire process is in itself quite complex, requiring a coordinated, multi-disciplinary approach that will ensure that the measures taken are complementary and above all, that the objectives of the proposed actions are shared and understood by all the players within the practical realities of the existing hospital structures.

The priority of system efficiency reminds us of certain features in our National Health Service - a system characterized by the best and worst of practices, a system within which there are strong contrasts in terms of system efficiency.

We shall not discuss the points of excellence - the presence of a professionalism much higher than that lower to be found in the country. However what is notable is the profound difference between the North and the Centre as seen in terms of overall quality and organizational models when compared to the widespread systemic inefficiency still so common in models calibrated on the hospital generalist often typical of the Centre-South.

This prime consideration shows as clinical risk is rooted primarily in the absence of essential instruments, achievable only through modern organizational forms. We refer primarily to the personal electronic dossier, the absence of which at the time of patient admission, is the determining cause of some of the 'blind' interventions with which the doctor is, too often forced to operate today.

On the contrary, the immediate availability of information relating to the overall medical history of the patient, undoubtedly reduces the size of clinical risk.

So the first problem is systemic, a reason to speed up conversion of that part of our national health service still characterized by the widespread presence of hospitals failing as they should to take care of a person. This is something which should be carried out in the first place by adequate health and social welfare services within the territory concerned.

In order to reduce this "chronic gap" between the North and South, the Health Ministry has, as per the Special Project Health signed April 17, 2007, asked the eight regions of the South to propose projects for the purchasing of equipment and the modernization of health structures. This has been done by means of the Memorandum of Understanding, entitled "Strategic Framework for the health, development and security in the South, addresses and operational objectives of structural convergence of regional health services in the South". The goal is to restart a process of upgrading the too mistreated health service in the South. The target areas are: the intensification of investment and technological innovation of service models, acceleration of the process of computerization of regional health services and diagnostic and therapeutic technologies; activation of regional reference centres of knowledge management; development of projects for co-operation and partnership

between centres of reference and centres of excellence in the South-North Centre and elsewhere.

With regard to the legal aspects of medical care and insurance, we believe the time has come that the matter be dealt with and regulated by a new law which has as its main objectives: to ensure rapid and streamlined paths for the reimbursement of damages to citizens; to create greater peace of mind for health operators with the provision of a compulsory insurance coverage for damages by the Local Health Service and Hospitals; prevent the spread of the so-called 'defensive medicine' that leads to making more diagnostic tests than necessary; and anything that not be essential to patient care but useful simply to protect the image of the operator and professional in the event of legal litigation; encourage the reporting of errors committed by operators, provide for mandatory reporting but at the same time ensure its confidentiality. It is preferable to understand how to prevent errors rather the substantial silence which is maintained regarding them now in reports for fear of legal consequences.

Coming back to the issues of risk management, the participation of the patient and his family is also important. This theme, only delineated in efficient health systems that largely make use of information technology and which operate giving priority to the criterion of taking charge of the person's care and thus recognize the centrality of the person himself. Hence crucial to quality and openness of information, is that the patient himself give consent to the treatment.

We have perhaps some way to go still to arrive at this kind of Public Health system image. As is so throughout the entire Public Administration itself, we are at the moment facing a technological 'transitional phase'. We have for years depended almost exclusively on pen and paper methods and are now approaching a future of solely information technology.

The co-existence of these two methods tends to make life more difficult for patients and indeed still more difficult for operators within the Health Service and creates as such, complications within a new system that is slow in taking off. It is often seen in our offices that computers fulfill the function of typewriters but are still under-utilized when one thinks of the vastness of services that computer systems can provide. A similarity lies on this to our use of mobile phones, endowed with a greater technological capacity than we routinely make use of.

This process of change needs to be accelerated as we have already gone past the time when instinct led us to make innovative choices even if sporadically.

Risk Management today can benefit from a technology that assures us that the choices made are most certainly correct.

This goal is the foundation on which the national strategy for "Electronic Health" is based.

In conclusion we point out the ten golden rules to be found in the IOM (Institute of Medicine) document of 2001: "Crossing the Quality Chasm: A New Health System for the 21st Century":

1. Assistance based on an on-going relationship designed to heal;
2. Attention to the patient based on their needs and their personal individual values;
3. The patient as a source of control;
4. Shared knowledge and free flow of information;
5. Decisions based on scientific evidence;
6. Security as an element within the system itself;
7. Anticipation of needs;
8. Need for transparency of information and communication;
9. Continued reduction of wastefulness;
10. Cooperation among those working in clinics.

References

1. Ministry of Health, Risk Management in Healthcare. The problem of errors Technical Committee on Clinical Risk - Quality Department, Directorate General of Health Planning, Levels of Service and the Ethical Principles of System III Office, 2004. Available from: http://www.salute.gov.it.

2. Rasmussen J, Duncan K, Leplat J, eds. New Technology and Human Error. Chichester, England: Wiley; 1987.

3. Ministry of Health, Patient safety and clinical risk management: Manual for training of health care, Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles-III Office, 2007. Available from: http://www.salute.gov.it.

4. Nashef SA. What is a near miss? 2003 Lancet 2003;361:180-81.

5. Ministry of Health, Patient safety and clinical risk management: Manual for training of health care, Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles-III Office, 2007. Available from: http://www.salute.gov.it.

6. Ministry of Health, Risk Management in Healthcare. The problem of errors Technical Committee on Clinical Risk – Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles - III Office, 2004. Available from: http://www.salute.gov.it.

7. Ministry of Health, The Patient Safety and Clinical Risk Management - Glossary, Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles - III Office, 2006. Available from: http://www.salute.gov.it.

8. Basini V, Cinotti R, and Damen V. The root cause analysis for the analysis of risk in healthcare facilities, Aids risk management

n.6, Dossier 130 (2006), Regional Health Agency, Region Emilia-Romagna. Available from: http://asr.regione.emilia-romagna.it.

9. Basini V, Cinotti R, Denia, P. The incident reporting system in health care organizations, Aids risk management n.2, Dossier86 (2003), Regional Health Agency, Emilia-Romagna. Available from: http://asr.regione.emilia-romagna.it.

10. Tuscany Region DGR, "Regional Centre for clinical risk management and patient safety: operational approval proposed" Resolution of the Regional Council, No. 1179 of 10/11/2003. Available from: http://www.regione.toscana.it.

11. Tuscany Region DGR, "Management of clinical risk - guidelines for the management of the system of voluntary certification of good practices for patient safety and sentinel events," Resolution of the Regional Council, No. 704 of 10.08.2007. Available from: http://www.regione.toscana.it.

12. Tuscany Region DGR, "regional application of the Directives N.550/04 DGR: procedures for testing by the observers of the local health forensic prototype information system for monitoring medical-legal litigation," Resolution of the Regional Committee, No. 177 of 12/03/2007. Available from: http://www.regione.toscana.it.

13. Tuscany Region DGR, "Management of clinical risk - guidelines for the management of the system of voluntary certification of good practices for patient safety and sentinel events," Resolution of the Regional Council, No. 704 of 8/10/2007. Available from: http://www.regione.toscana.it.

14. Lombardy Region, DG Health, "Guidelines on the management of health risk." 46/SAN of Circular No. 12/27/2004. Available from: www.sanita.regione.lombardia.it.

15. Regional Research Institute of Lombardy. Risk management in health care: strategies, implementation models, comparative analysis between some Italian regions and European countries. The integration with the systems of quality assessment. Final Report (February 2008). Available from: http://www.irer.it.

16. Institute of Medicine (IOM) "Crossing the Quality Chasm: A New Health System for 21st Century" 2001. Available from: www.nap.edu.

17. JCAHO, "Sentinel Event Policy and Procedures" (2007). Available from: www.jointcommission.org.

18. Leape LL, Berwick DM. Reducing error in medicine: it's time to take this more Seriously, BMJ 1999;319:136-7. Available from: http://www.area-c54.it.

19. Reason J. Human errors: models and management. BMJ 2000;320:768-70.

20. Reason JT, Carthey J, de Leval MR. Diagnosing "vulnerable system syndrome": an essential prerequisite to effective risk management. Qual Health Care 2001;2:21-5.

21. Hughes CF, Mackay P. Sea change: public reporting and the safety and quality of the Australian health care system. Med J Aust 2006;184(10 Suppl):S44-7.

22. Wilson RM, Runciman WB, Gibber RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian health care study. Med J Aust 1995;163:458-71.

23. Roughead EE, Gilbert AL, Primrose JG, Sansom LN. Drug-related hospital admissions: a review of Australian studies published 1988-1996. Med J Aust 1998;168:405-8.

24. Acts of 2 in health risk management forum, application of technologies to patient safety, Arezzo, 28 November-1 December 2007.

25. Acts of 2 in health risk management forum , innovation research training for patient safety, Arezzo, 25 to 28 November 2008.

26. Ministry of Health, "Protocol for the Monitoring of Sentinel Events" Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles - III Office, 2009. Available from: http://www.salute.gov.it.

27. Ministry of Health, SIMES. Information System for Monitoring Errors in Health Care, Directorate General of Information Systems, 2007. Available from: http://www.salute.gov.it.

28. Ministry of Health, "Patient Safety and Clinical Risk Management - Glossary, Quality Department, Directorate General of Health Planning, Levels of Service and the System of Ethical Principles - III Office, 2006. Available from: http://www.salute.gov.it.

29. Regional Working Group of the Emilia Romagna. Recommendations for safety in the operating room. Available from: http://asr.regione.emilia-romagna.it.