

INTERNATIONAL PERSPECTIVES

Patient safety in Italy

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BACKGROUND

Patient safety, seen as the degree to which the risk of an intervention and risk in the care environment are reduced, is becoming a crucial health care issue in Italy. At present a national information system on medical error, adverse effects and near misses is lacking, but over the last few years almost all the stakeholders (health professionals, patients organizations, ministry of health, regional health care systems, hospitals, insurance companies, industry, etc.) have shown increasing awareness of patient safety and are seriously considering appropriate interventions.

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However, these stakeholders appear to be operating in isolation, with the result that their efforts are fragmented and poorly integrated with other governance issues. Patient safety is sometimes subsumed by broader issues such as quality improvement and insurance strategies.

In everyday practice, individual clinicians understand and aim to apply the classic aphorism *‘primum non nocere’* (first, do no harm), but a major problem seems to be the lack of systematic documentation of actions conducive to patient safety. Furthermore, there are still only a few Trusts which consider safety as a global result of an integrated management system.

Public opinion generally looks at each adverse event as an issue for which an individual must be named, blamed and shamed. There is an increasing rate of complaints and litigation against medical staff. Consequently, insurance premiums have risen and sev-

eral hospitals and other health care organizations are facing major problems with their insurance contracts.

Finally, Italian law does not provide any protection for those who report their errors and adverse effects (except for drugs). This is particularly relevant because it inhibits incident reporting, thereby curtailing information that could be useful in proactive planning of actions to prevent error.

NATIONAL INITIATIVES

In 2003, the Minister of Health appointed a ‘Technical Committee on Clinical Risk’ with the aim of focusing on patient safety issues and setting appropriate recommendations. A first report was published in 2004 on ‘Risk Management in the Health Care System: The Errors’.¹

This report calls for coordinated initiatives to be developed with professionals and institutions at national, regional and local levels. A list of priorities has been drawn up in order to facilitate actions and interventions: medication practice, blood storage and use, laboratory medicine, clinical pathways in radiology, surgery and anaesthesia, and communication among professionals and with patients.

In 1997 the issue of patient safety had been indirectly addressed in a Decree from the Minister of Health dealing with the minimum set of standards and requirements (on structure, organization, processes and technology) that hospitals and other health care institutions must meet to be authorised to deliver health care services (i.e. infection control systems, X-ray protection, health care buildings maintenance, health technology management, clinical pathways, continuing education).

The National Health Plan 2003–2005 established a National Programme on Drug Control based on a systematic and compulsory reporting system of adverse drug reactions. This Programme provides physicians with information on drug use to improve appropriateness of prescriptions and safety of their use.

The *Agenzia per i servizi sanitari regionali*, a national body which provides national and regional govern-

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ments with technical information and analysis, has developed several clinical guidelines and pathways to improve effectiveness and appropriateness in the health care system: this activity could also lead to improvement in patient safety.

In addition, a project has been designed to use existing hospital administrative databases in monitoring selected quality and safety indicators.

The largest national association for patients' rights (CittadinanzAttiva, which means 'active citizenship') promoted two very interesting initiatives. The first, 'Safe Hospital', is now in its sixth annual campaign and involves dozens of hospitals across the country. Working groups, including citizens, health professionals and hospital managers, check each participant hospital with reference to biological risk, building maintenance, health technology management, clinical laboratories, etc. Each campaign includes a nation-wide communication strategy to increase awareness of the issue. The second initiative, 'Learn From Error', has involved a number of hospitals in monitoring major medical errors and analyzing citizens' claims. Following this initiative, a 'Charter for safety in health care' has been written as a joint document between citizens and professional organizations, with the aim of reducing error.²

REGIONAL AND LOCAL INITIATIVES

In recent years, health care reforms turned the National Health Service, established in 1978, into a set of 21 regional/provincial health services which developed a complex governance system based on a Standing Committee between State and Regions. The regional/provincial health services provide a basic health care package (*livelli essenziali di assistenza*) supported by a national funding system, but they are entitled to expand their services and to find autonomous managerial solutions.

Risk management and patient safety issues have been included in the regional/provincial accreditation requirements dealing with structure, technology and organization. Several regions launched specific programmes on patient safety, such as hospital infection prevention, professional liability, selected policies and procedures (i.e. following JCI standards) and patient claims, etc.

A more proactive approach has been adopted by the Emilia Romagna Region, where risk management has been included in a clinical governance context with the aim of improving safety rather than just reducing risk. Several tools have been implemented such as incident reporting system, clinical records analysis and process analysis (i.e. root cause analysis, failure mode effects and criticality analysis).³

Several hospitals developed their own specific programmes in addition to the institutional ones. However, in only few cases are these programmes aimed at providing an integrated governance

approach.^{4,5} Nevertheless they try to supplement the regional/provincial initiatives with specific topics:

- Hospital infection prevention (sterilization procedures, antibiotic use, sentinel events analysis, epidemic cluster analysis);
- Medication system (pharmaceutical codex, storage, prescription, administration, drug surveillance);
- New organizational models to reduce risk (clinical networks, risk management units);
- Clinical guidelines (production, dissemination, implementation and monitoring);
- Systematic clinical audits;
- Incident reporting systems;
- Informed consent;
- Information systems (to enhance monitoring);
- New insurance contracts and litigation management.

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CONCLUSIONS

The frequency and quality of public debate on patient safety are continuously rising. Colleges of physicians, nurses and other health professionals have set up continuing education programmes on this topic; scientific associations are very active in the field; and collaborative initiatives with international publishers have been initiated.⁶ Insurance companies are also stimulating the development of risk management systems. Leading patients' associations are supporting national and regional health care services in their modernization efforts.

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