PATIENT SAFETY AND MEDICAL LIABILITY IN ITALY

By: Fidelia Cascini, Mariangela Contenti, Giada Scarpetti, Federico Gelli and Walter Ricciardi

Summary: The World Health Organization estimates that one in ten patients in high-income countries is harmed while being treated in a hospital setting. The 2017 law on patient safety and medical liability in Italy aims to improve the safety of care and provide more structured regulation for the organisational, insurance and medico-legal/juridical fields. An assessment of the implementation of the law shows that progress has been uneven: the level of implementation of legislative provisions varies by region, and decrees on insurance coverage for liability are lacking. Further engagement from regional and national institutions is required.

Keywords: *Patient Safety, Medical Liability, Hospital Care, Italy*

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Introduction

In 2019 the World Health Organization (WHO) declared September 17th as Patient Safety Day, thus raising awareness of patient safety as a global priority.[1] In the same year, Italy celebrated two years since the introduction of Law No. 24/2017 on patient safety and medical liability, also known as "*Gelli Law*". A survey conducted by the Fondazione Italia in Salute in March 2019 provided an opportunity to assess the implementation status and impact of the law two years after its introduction.[2] The survey included two questions: 1) were the reforms adopted? and 2) what were the effects of the reforms' implementation?

Evidence related to this survey was gathered through desk research, as well as interviews with six stakeholders, in particular Chief Executive Officers or General Directors of different regions and public organisations. The classification of results was based on two criteria: a) the field of application of the law, which is divided into organisational, insurance and medico-legal/juridical; and b) the level of jurisdiction, which is divided into national, regional and local.

Overcoming the fragmentation of organisational requirements remains challenging

Two years after the introduction of the law, one of the main consequences concerns responsibilities in the organisational field at the national and regional levels.

Article 3 of the law established the National Observatory on Best Practices for Patient Safety *(Osservatorio Nazionale per le buone pratiche sulla sicurezza in sanità)* at the Italian National Agency for Regional Healthcare Services *(Age.na.s)*. The Observatory collects information annually about risks, adverse events, incidents and controversy for public and private providers through the Regional Centres for the management of healthcare risk *(Centri regionali per la gestione del*

rischio sanitario) through a web-based unified procedure. The Observatory uses SIMES, the Information System for the Monitoring of Errors in Healthcare *(Sistema Informativo per il Monitoraggio degli Errori in Sanità),* which has several functions, including identifying prevention measures and monitoring of best practices. The activity of monitoring best practices is organised by Age.na.s, through a national annual tender; after its publication, Age.na.s receives all the best practices concerning the thematic priorities of the tender itself, validated by regions.

The Observatory took office in March 2018, with six working groups responsible for different tasks (**see Box 1**), who share their progress during quarterly plenary meetings.[8]

According to the law, the Observatory should be continuously updated about adverse events and health incidents occurring in the national territory, with this information reported by Regional Centres for the management of health care risk *(Centro regionale per la gestione del rischio sanitario).* These Centres were also introduced by Law No. 24/2017 with the aim of increasing the level of knowledge of care safety and improving the homogeneity of prevention measures and management of health care risk at the national level. However, this legislative provision was only integrated within the guidelines for the establishment and functioning of these centres by the Health Commission of the Conference of Regions two years later. The Regional Centres should receive information directly from public and private health care providers.

Two years after the introduction of the law, the Italian landscape remains fragmented

In response to the first question of the survey (has a centre for the management of healthcare risks and patient safety been established?), the analysis of institutional sites by region shows a fragmented landscape (**see Figure 1**): in 13 regions relevant legislation or an explicit acknowledgement of a previous law for the establishment of a Regional Centre exists (in green in Figure 1), while none was found in five regions (in red in Figure 1). The two remaining regions (in orange in Figure 1) report intermediate situations where the Centre is not formally established, but there are organisations that partially perform its function.

With regards to the second survey question, the level of publicly available information on management of health care risk on Regional Centres' websites was analysed. The aim was to evaluate what information was available for citizens, and if they could understand the functioning level of Regional Centres, identify the reference standards and reach the competent coordination authority. Following some pre-defined criteria of accessibility, clearness and completeness, we classified the results from 0 to 5, where 0= no accessibility (null); 1= only office contact details are present (mediocre); 2= presence of unintentional and obsolete information (insufficient); 3= information only partially organised (decent); 4= accurate and well-organised information (good).

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The resulting scenario, (**see Figure 2**) shows greater variation by region than that observed in the first survey question.

At the local level, i.e. health districts, compliance to the regulation is also rather limited. Law No. 24/2017 states that citizens should have access to information on health care providers and insurance policies or similar measures (article 10), compensation paid for health care incidents (article 4) and risks and adverse events in the form of an annual report (article 2). Furthermore, these instructions have been included in guidelines, written in October 2017 by the Conference of Regions and the Autonomous Provinces. Nevertheless, the system of classification and management of information according to the law across the various health districts appears highly fragmented. For example, only certain regions require public providers to publish an Annual Plan of Risk Management, containing part of the above-mentioned information. Two years after the law came into force, the latest published reports about health care risk are still: 1) the monitoring of health care incidents reports, performed by Age.na.s in 2015; and 2) the monitoring of sentinel events, produced by the Ministry of Health in 2012.

Another aspect of great relevance in the national organisational field considered by Law No. 24/2017 is the establishment of a National System for Guidelines *(Sistema Nazionale per le Linee Guida* – SNLG*)* at the National Institute of Health (ISS). The SNLG is the central authority in charge of studying, writing and making guidelines available and it is the only point of access for professionals and health care providers, managers, policymakers and

Box 1: National Observatory on Best Practices for Patient Safety working group tasks

1) creating an updated glossary, identifying and classifying information sources and indicators;

2) elaborating guidelines for the prevention and management of health care risk and for the monitoring of best practices;

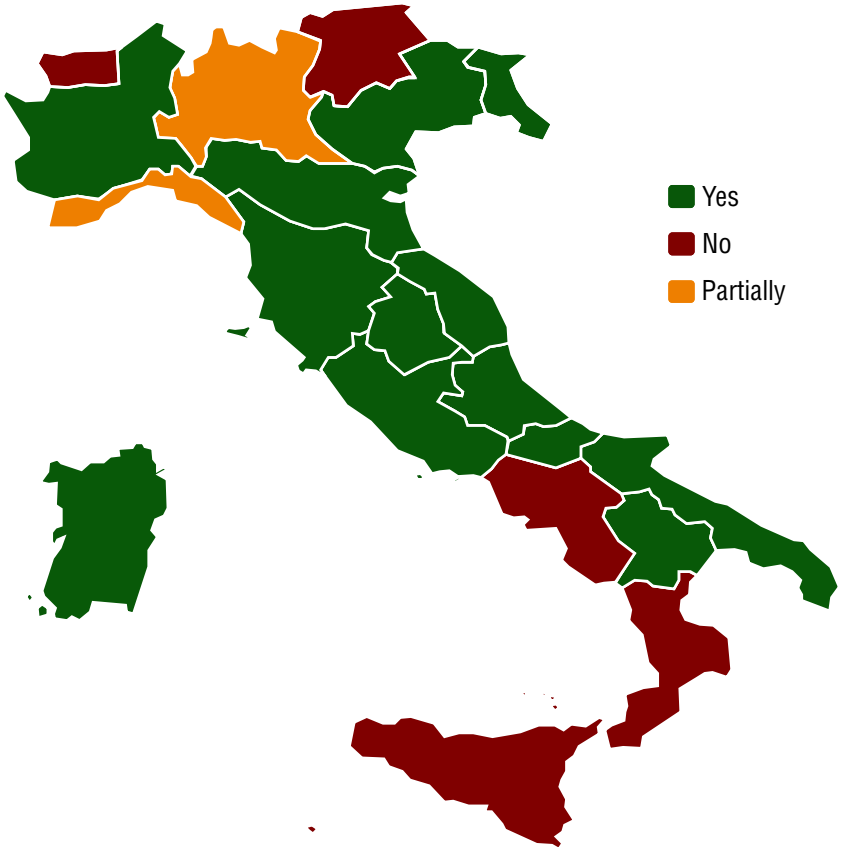
3) identifying training needs and indicators for monitoring and guidelines for education of health care staff;

4) defining strategies and programmes for international and European exchanges;

5) creating models for the management of controversy with reference to medico-legal aspects;

6) organising communication modes for best practices.

Figure 1: Map of the presence of Regional Centres for the management of health care risk as of 31 March 2019, two years after the introduction of Law No. 24/2017



Source: Authors' own

interested users. Through the National Center for Clinical Excellence, Quality and Safety of Care *(Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure),* the ISS acts as guarantor of the guidelines' development process by Medical Associations and Technical-Scientific Associations. The ISS identified the path for integrating the guidelines in the SNLG and defined the instructions to write the guidelines, which have to be evaluated by the SNGL before their publication. Meanwhile, the Ministry of Health has selected 335 accredited medical associations and technical-scientific associations for the development of guidelines.

The limited progress on obligatory insurance requires attention

The law also concerns insurance, with article 10 mandating insurance coverage (or, alternatively, a similar form of guarantee) for public and private health care providers and for health professionals. The law refers to the definition of minimum insurance requirements, as well as to the protocol of data flow, and surveillance and control, that have to be regulated through specific executive decrees. Although two years have passed, the fate of these decrees is still uncertain, leaving the field of medical-malpractice still lacking rules and with concerning statistics.

The issue of health care incidents is an area of concern and shows alarming data for Italy. 'Incidents' is defined as any compensation request for damages and/or any launch of legal action for civil liabilities, reported by the insurance company or managed by firms. A recent report from Marsh[4] identified 20,947 reported health care incidents in 42 public health care providers, in the period 2004–16. The median cost per incident was over €88,000, which represents a cost of over €900 million to the Italian health system across the period analysed.

In our analysis we considered incidents in the period from 2004 to 2016, updated (through changes or status confirmation) throughout the year 2017. The majority of incidents (45.1%) were linked to surgeries, followed by the field of maternal and child health (13.8%) and internal medicine (12.1%). The emergency department, compared to previous editions, is affected to a lesser extent (10.6%). This represents a change from the previous Marsh report,[5] where orthopaedics and traumatology came in first followed by general surgery, emergency department, and obstetrics and gynaecology.

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Marsh has also developed a system of specific indicators of risk rates and insurance values, which estimated the total insurance risk rates for insurance companies to range from: 1.1 per 100 administrative employees, 6.5 per 100 doctors, 2.8 per 100 nurses, 1.3 per 1000 hospitalisations.[4] Accordingly, the insurance values for the same sample have been estimated to be: €943 per administrative employee; €5,659 per doctor; €2,434 per nurse; and €113 per hospitalisation. Both the risk rates and the insurance values consider the skill mix and specialisations of the public health care providers analysed in this report. Therefore, they cannot be extended to providers with a different distribution of medical, administrative or nursing staff, nor to highly specialised health care organisations.

Steps have been taken to provide a better structure for the juridical and medico-legal field

Law No. 24/2017 also deals substantially with the matter of health care professional liabilities and the related themes of fault

Figure 2: Map of the level of availability and clarity of information on regional health care institutions websites concerning the management of health care risk and patient safety

Source: Authors' own

(article 6), classification of the kinds of liability for the health care providers or professionals (article 7) and possible recovery actions like compensations (article 9).

The law also introduced an Experts and Technical Consultants Register (under article 15). In cases of health care professional liability, the law establishes the institution of a panel of experts composed of specialists of the clinical branch of the specific case, enlisted in specific registers created at District Courts and uniformly regulated across the whole Italian territory. On 25 October 2017, a Deliberation of the VII Commission of the Superior Council of Magistracy *(Commissione del Consiglio Superiore della Magistratura* – CSM*)* adopted shared standards for the revision and record-keeping of all District Courts registers and of the Experts and Technical Consultants Registers. After the deliberation, various agreements have been reached among CSM, the Forensic National Council, and the Federation of the Boards of Physicians (protocol agreement of 11 April 2018) and Nurses (supplemental agreement of 19 September 2018), in addition to integrative agreements with the federations of pharmacists, psychologists, biologists, chemists, physicists and veterinarians (6 February 2019). We deduce the common intent to unify and regulate the selection and record-keeping criteria of the professional registers at courts, so that they can be balanced on a national scale.

Two years later, the implementation of the law reflects the heterogeneity of the Italian health system

The evaluation of the status of implementation of Law No. 24/2017 two years after its introduction highlights great differences among Italian regions. This once more demonstrates the different speed at which the Italian health system develops and operates throughout the country. Some regions have adopted, improved, integrated and, in some cases, even anticipated the position of the legislator, while other regions have not yet acted despite the passage of time.

Law No. 24/2017, that aims to improve the safety level of care and to manage disputes for health care professional liabilities, needs attention from institutions, both at a national and regional level. It is therefore important that policy makers and leaders start to think of Italy as a single National Health System, so that the effects of reforms can produce concrete benefits.

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NEW PUBLICATIONS

How to enhance the integration of primary care and public health? Approaches, facilitating factors and policy options

By: B Rechel

Copenhagen: World Health Organization 2020 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

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In most European countries primary care performs some public health functions, while public health can help to make the provision of primary care more effective.

This policy brief explores how primary care and public health can be brought together to improve the health of patients and populations. It describes the types of initiatives that have been undertaken; provides examples of such initiatives in Europe and beyond; and summarises the factors that can help to enhance or hinder the integration of primary care and public health. Further, it argues that there is a large overlap of activities between public health and primary care.

Organisational models of primary care that are conducive to integration with public health are identified and the key systemic, organisational and interactional factors that can facilitate integration between the two domains are described.

Contents: Key Messages; Executive Summary; Introduction; Defining key concepts; How to improve the integration of primary care and public health?; Factors facilitating the collaboration between public health and primary care; Discussion and conclusions; References; Appendix: Search strategy and results.

Screening: When is it appropriate and how can we get it right?

By: A Sagan, D McDaid, S Rajan, J Farrington, M McKee

Copenhagen: World Health Organization 2020 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

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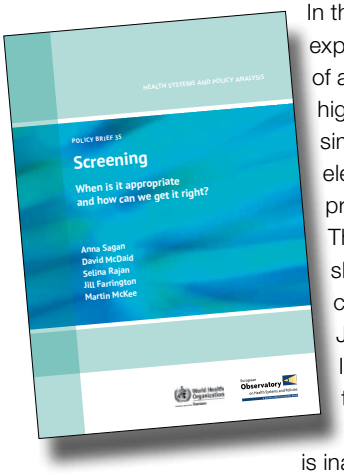
Technological and other scientific advances have made it possible to screen for ever larger numbers of molecules and see inside the human body with a level of detail that was once unimaginable. Where there is good evidence that detecting a condition early will, overall, be beneficial for those who are screened, then it may be appropriate to design and implement a formal screening programme. However, just because something can be done does not mean that it should be done as screening may bring benefits as well as harm.



In this brief, the authors start by explaining the core components of a screening programme, highlighting that, while seemingly simple, putting together all elements of a screening programme is very complex. They then ask when screening should be done, emphasising the continued relevance of Wilson & Jungner's screening principles. In addition, they examine the pressures to implement screening and, where screening is inappropriate, suggest ways to reduce it. When screening is appropriate, evidence is presented on how to achieve optimal results. This brief is an essential reading for anybody involved in the decisions on screening or its provision.

Contents: Key messages; Executive summary; Why this brief?; A systematic approach to screening; When is screening appropriate?; Supporting implementation of appropriate screening programmes; The way forward; References.