

## Chapter 1

### Quality strategies in the Italian health care system

*There are a range of laws and regulations in Italy that in various ways address quality of care to ensure effective, safe and patient-centered health service delivery. The devolution of power to regions has, however, resulted in a range of quality initiatives at regional level: some regions have very well developed approaches towards the systematic measurement and management of quality improvement while other regions still have rather weak quality governance models.*

*The challenge for Italy will be to achieve a more comprehensive and uniform approach towards quality monitoring and improvement throughout the country. Some steps have already been taken in this direction, but more could be done to guide all regions towards the robust quality improvement for the health system.*

*A stronger central role for the Ministry of Health and/or its agencies (such as AGENAS), the development of more robust inspection functions to monitor minimum levels of care and patient safety standards are key priorities. Efforts are also needed to develop a stronger information infrastructure which, used appropriately, can contribute to quality improvement efforts. Data should be used more effectively as part of on-going initiatives around performance monitoring of both health providers and health care facilities. A strategic focus on increasing patient involvement is also needed to steer more systematic quality improvement.*

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The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

## 1.1. Introduction

Italy's regionally-based health system, the *Servizio Sanitario Nazionale* (SSN), has been in place since 1978. Health coverage is assured for the whole population through a tax-based National Health System model, in which health services are delivered and managed by the 19 regions and two autonomous provinces. A particular struggling emerges around the need for Italy to balance national quality strategies with a decentralised model of health care governance, where ultimately responsibility for service provision and quality care lies with the regions. Recent policy debate in Italy has mainly been focused on financial consolidation and responding to the strains of the financial crisis, which has affected regions unequally. Going forward a focus on quality needs to be brought into the foreground. Nationally, there is an extensive legal framework to monitor and improve the quality of care, but the impact of these policies could be increased. In the regions there are also a wide range of quality initiatives, but these approaches have varying levels of sophistication and varying degrees of completeness. The challenge will be to bring a cohesive, robust approach to quality assurance in Italy, to ensure that the whole Italian population has access to high quality health care, whilst leaving space for regional autonomy and innovation.

This chapter takes stock of the existing quality of care policies in Italy, and assesses how effective they are at securing high quality health care. The description of policies in this chapter is structured according to a framework for categorising quality policies detailed in Table 1.1 below. After setting out initial background information, this chapter will go on to consider the legislative framework and governance for quality of care in Italy; the quality assurance of health system inputs (such as health care professionals, pharmaceuticals and medical devices, as well as hospitals); the information infrastructure to monitoring quality; and the extent of patient involvement in quality improvement, and the patient safety policies. Throughout the chapter areas of weakness are identified, and recommendations for improvement are developed. Core recommendations are summarised in the conclusion.

A short description of the Italian health care system is provided in Box 1.1. For more detailed information on the Italian health care system, the European Observatory's Health Systems in Transition report on Italy offers a useful source of information (2009; new version is due to be released in 2014).

**Table 1.1. A typology of health care policies that influence health care quality**

Policy	Examples
Health system design	Accountability of actors, allocation of responsibilities, legislation
Health system input (professionals, organisations, technologies)	Professional licensing, accreditation of health care organisations, quality assurance of drugs and medical devices
Health system monitoring and standardisation of practice	Measurement of quality of care, national standards and guidelines, national audit studies and reports on performance
Improvement (national programmes, hospital programmes and incentives)	National programmes on quality and safety, pay for performance in hospital care, examples of improvement programmes within institutions

### Box 1.1. Key characteristics of the Italian Health Care System

The Italian National Health Service (*Servizio Sanitario Nazionale*, SSN) is decentralised and organised into three levels: national, regional and local levels. The state defines the general objectives of the National Health Service and sets the “essential levels of care” (*livelli essenziali di assistenza*, LEAs) which constitute the health services that must be available to all residents in the country. The organisation of health services is the exclusive responsibility of the 19 regions and the two autonomous provinces. At more local level, local health enterprises (so-called *Aziende Sanitarie Locali*, ASLs) which are geographically-based institutions are responsible for delivering public health, primary and community care, as well as specialist care through either their own hospitals or by public hospital enterprises (*Aziende Ospedaliere*, AOs). ASLs and AOs are directly managed and financed by regions which have full autonomy to define their geographical boundaries, allocating resources to them and appointing their directors.

The Italian health care system offers universal health coverage to all citizens and access to a wide range of services is largely free of charge at point of delivery. Citizens have the free choice of GP, who acts as gatekeeper. Patients are allowed to access specialist care only after approval and referrals from their GP. After referral, patients are free to choose their provider among those accredited by the SSN. The SSN is fully tax-based with national and regional taxes financing more than 97% of public health care.

Total health expenditure in Italy is 9.2% of GDP, slightly below the OECD average of 9.3%. Public expenditures account for nearly 78% of total expenditure, compared to an average of 72% across OECD countries. Out-of-pocket payments (OOP) account for much of the remaining financing (18% of total expenditure, which is below the 20% on average among other OECD countries). The share of OOP spending in Italy has decreased by 5.1% between 2000 and 2011, compared to the 1.2% average decline seen across OECD countries. Although nearly 15% of Italian have private health insurance (mainly for ambulatory specialist care and private hospital care), it plays a small role in covering nearly 1% of total expenditure.

### **Box 1.1. Key characteristics of the Italian Health Care System (cont.)**

Relative to its population, Italy has slightly more doctors than most OECD countries, with 4.1 practicing doctors per 1 000 population. Specialists outnumber generalists in Italy, while the importance and cost-effectiveness of generalist provider is widely recognised. In 2011, generalists made-up only 23% of all physicians, compared to an average of 30% across OECD countries. With 6.3 practicing nurses per 1 000 population in Italy in 2011 (compared to the OECD average of 8.8 per 1 000 population), there are concerns about shortage of nurses who constitute a relatively small group of health workers. In 2011, the ratio of nurses to physicians was one of the lowest among OECD countries, at 1.6 nurses per doctor compared to an average of 2.8 in OECD countries.

Important recent reforms over the past decade relate to a greater devolution of power to regional government that occurred after the 2001 constitutional reform (see Chapter 4). Regions are today entirely responsible for legislative and administrative functions for planning health care activities with mostly all policies developed and implemented by region and autonomous province. The recent health planning legislation (Balduzzi Law 189/2012) provides, among other things, instruments for the organisation of community care networks and community hospitals. The overarching aim of this reform is to improve co-ordinated and integrated care through the development of multi-speciality groups involving generalists, specialists, nurses and social workers (see Chapter 2). The development of such community service is one of the foremost priorities in the Italian policy agenda given the challenges brought by the demographic and epidemiological changes.

*Source:* Lo Scalzo, A. et al. (2009), “Italy: Health System Review”, *Health Systems in Transition*, Vol. 11, No. 6.

## **1.2. Context**

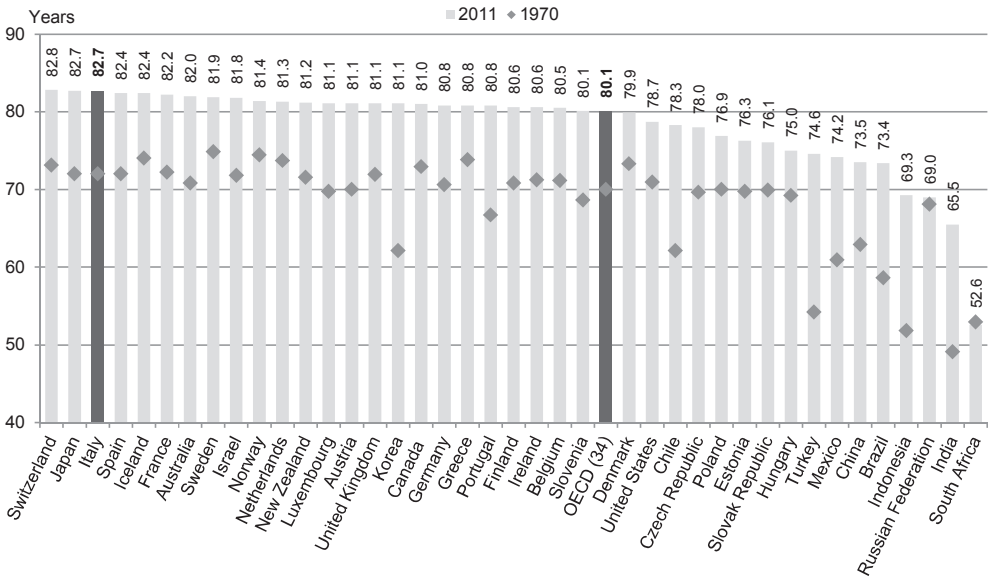
Overall, the decentralised Italian National Health Service produces excellent results, with good health indicators, high quality of care and spending levels significantly lower than those of most European countries. There are however key areas of concern with regard to community, long term care and preventive health services, which are not adequately developed to meet the challenge brought by the rapidly ageing population and the risen burden of chronic illnesses.

***The health status of the Italian population is amongst the best across OECD countries and performance indicators display favourable results***

From a high level perspective, the performance of the Italian health care system demonstrates relatively favourable scores on most health indicators. Life expectancy at birth was 72 years in 1970 and has improved to 82.7 in 2011. This puts Italy at the top of OECD countries with the highest

life expectancy alongside Switzerland (82.8) and Japan (82.7) (Figure 1.1). The increase in longevity is greatly explained by improvement in living conditions, a better lifestyle and progress in medical treatment. In a similar vein, Ischemic Heart Disease (IHD) rate in Italy are well below the OECD average, with a reported age-sex standardised rate at 88 per 100 000 population (OECD average of 122 per 100 000 population) and it has declined by 38% since 1990. Improvement in medical care and the decline in tobacco consumption have significantly contributed to reduce IHD mortality rates. Diabetes, which increases the risk of developing a cardiovascular disease such as heart attack and stroke, is less common in Italy than in other OECD countries. Nearly 5.3% of Italian aged 20-79 years suffer from diabetes in 2011, which is below the OECD average of 6.9%.

**Figure 1.1. Life expectancy at birth, 1970 and 2011 (or nearest year)**

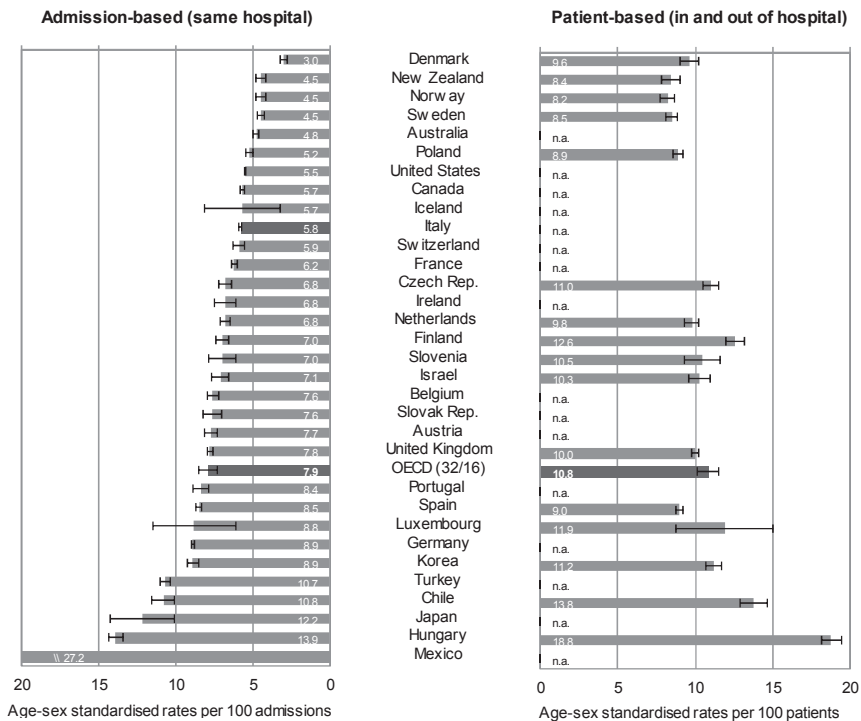


Source: OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>; World Bank for non-OECD countries, <http://data.worldbank.org/>.

At the same time, performance indicators around quality of care indicate positive results. In Italy, several of the OECD’s set of health care quality indicators are well above the OECD average. Figure 1.2, which shows admission-based acute myocardial infarction (AMI) 30 day in hospital mortality, places Italy above the OECD average, with an AMI 30 day in-hospital mortality rate below Switzerland, France or the Netherlands.

Indicators on potential preventable hospital admissions also display good results, suggesting well-functioning primary care services. On for example hospital admission rates for asthma, Italy reports the lowest age-sex standardised rate at 11.4 per 100 000 population, compared to an average rate of 45.6 per 100 000 population across OECD countries. A more in depth analyses of the functioning of primary care is provided in Chapter 2.

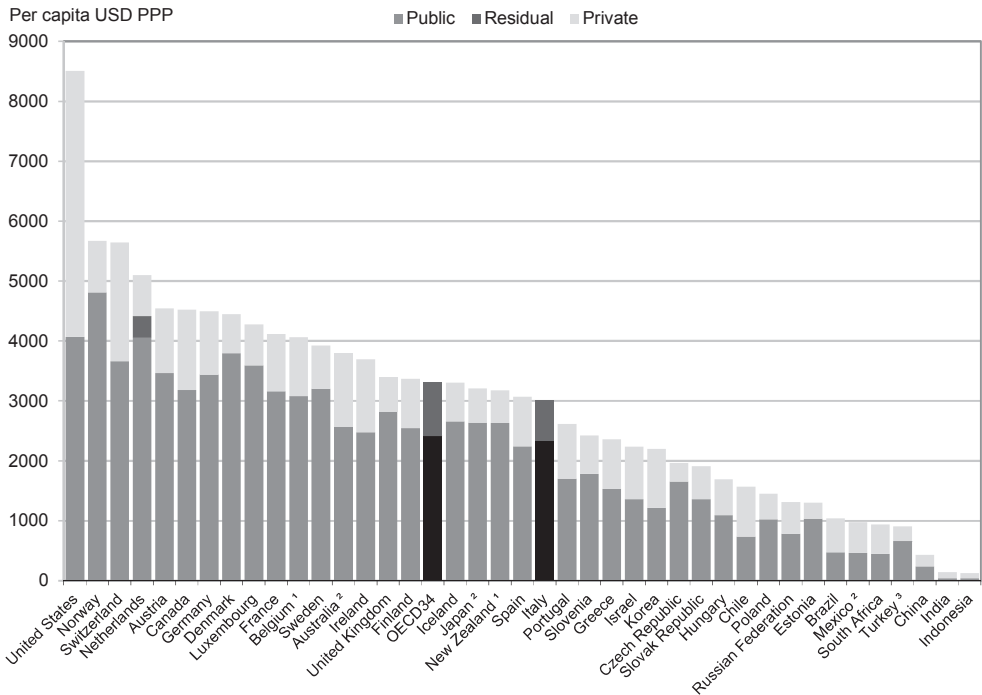
**Figure 1.2. Case-fatality in adults aged 45 and over within 30 days after admission for AMI, 2011 (or nearest year)**



Note: 95% confidence intervals represented by H.

Source: OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>.

Taken together these international comparisons demonstrate that Italy is performing quite well regarding the quality of care. Further analysis however demonstrates marked heterogeneity between the Italian regions in the quality and sustainability of the health system. The Italian health care system is fragmented, with a high degree of variability found in the pattern of care and outcomes between regions and autonomous provinces (R&AP) (see Chapter 4).

**Figure 1.3. Health expenditure per capita, 2011 (or nearest year)**

1. Current health expenditure.

2. Data refers to 2010.

3. Data refers to 2008.

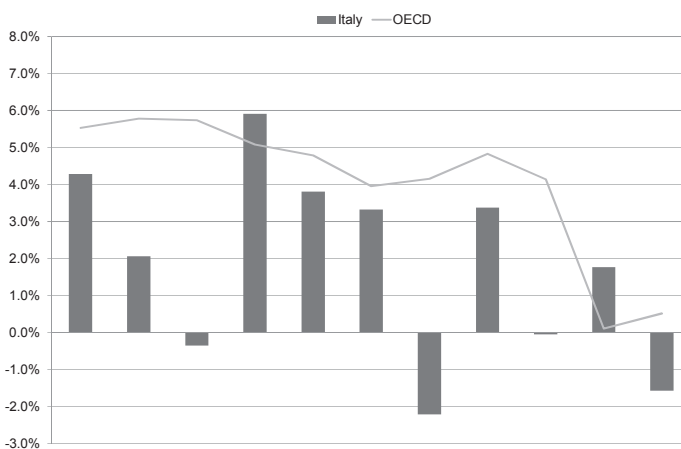
Source: OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>; WHO Global Health Expenditure Database, <http://apps.who.int/nha/database>.

### ***Italy reports one of the lowest health expenditures in OECD countries but there are key areas of concern with regard to long term care and preventive health services***

As a share of GDP, Italy spent 9.2% on health in 2011, which is close to the OECD average of 9.3%. Total health expenditure per capita was USD 3 012 in 2011 (Figure 1.3), below both the OECD average of USD 3 322, and neighbour countries such as Switzerland (USD 5 643) and France (USD 4 172) but similar to Spain (USD 3 072). Italy experienced a slight decline in the annual average growth rate in per capita health spending between 2009 and 2011. Per capita health spending fell by 0.4% in 2010 and 2011, after a yearly growth rate of 1.6% between 2000 and 2009.

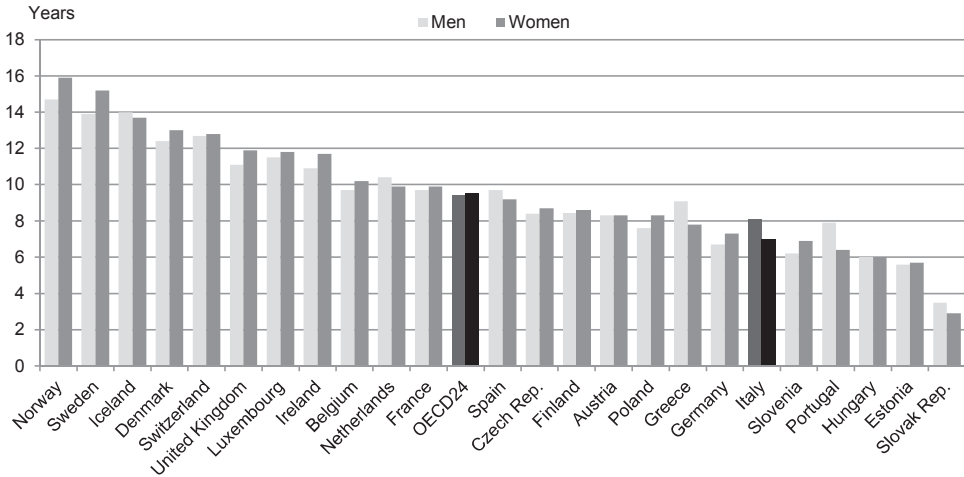
International comparison furthermore suggests that growth in health spending has not kept pace with other OECD countries. Significant differences in the growth of health spending are found between Italy and other OECD countries in 2003, 2007, 2009 and 2011 (Figure 1.4). While health care spending has declined in real terms in Italy during these different periods, significant growth rates have been reported in other OECD countries. Differences in health care spending are also found between Italy and European countries. In 2011, public health spending (after control for price levels) was 36% higher in European countries than in Italy. A more in depth analysis of volume activity suggests that health spending differentials between Italy and other European countries arise from differences in the delivery of non-acute health services (Sassi, 2013). While differences in the volume of hospital services appeared limited between countries, the analysis strongly points to the fact that community, long term care and preventive services are underdeveloped in Italy compared to other European countries. This might account for the low healthy life year at age 65 that is reported in Italy. As demonstrated by Figure 1.5, Italy had one of the lowest number of healthy life years at age 65 in 2011, with nearly seven years free of disability for women and about eight for men (compared to 9.5 years for women and men on average across OECD countries). The rapidly ageing population in Italy will be significantly associated with an increase of prevalence of chronic illnesses and long-term conditions, which altogether strongly call for strengthening the supply of community and preventive services into the primary care sector.

**Figure 1.4. Annual average growth rate of health spending in real terms, 2000-11, Italy and other OECD countries**



Source: OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>.



**Figure 1.5. Healthy life years at age 65, European countries, 2011**

Source: Eurostat Statistics Database 2013, <http://epp.eurostat.ec.europa.eu>.

### 1.3. Health system design

In Italy, there are several laws and regulations that in various ways address quality of care to ensure effective, safe and patient-centered health care services. The *Patto per la Salute* and the *Piano Sanitario Nazionale* are the key legal frameworks to assure high quality of care, supported in this task by through the essential levels of care and the National Programme for the Permanent Promotion of Quality in the National Health Service. Since its inception in 1978 and following the 2001 constitutional reform, the Italian National Health Service (SSN) has been run by the R&AP with support of national institutions. All regions have a considerable degree of power to legislate on a regional basis and freely allocate funds received from the central government. Regional and local levels are thereby exclusively responsible for the organisation and the financing of health service delivery, while the Ministry of Health fulfils the function of the overall steward of the National Health Service.

#### ***There is a strong legislative basis for monitoring and improving quality of health care in Italy***

The *Piano Sanitario Nazionale* (National Health Plan, NHP) and the *Patto per la Salute* constitute the key legal frameworks for assuring quality of care in Italy. The *Piano Sanitario Nazionale* is the main programming tool to define

public health objectives (Art. 1 of Legislative Decree No. 502/1992 and subsequent amendments). It is prepared by the government based on the proposal of the Minister of Health and of the R&AP and is adopted by decree of the President of the Republic after consideration by the Council of Ministers, with the agreement of the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces. The NHP has a term of three years. Released for the first time in 1994, the NHP is a financial and planning agreement between the government and the regions related to the expenditure and planning of the Italian SSN. The NHP is the formal planning mechanism used to address national health policies, aimed at improving the quality of health care services, and promoting the appropriate and uniform provision of health care services. The fundamental principles and values of the health system, the general goals of the SSN and the strategic directions for quality improvement are defined within the NHP. The NHP for 2011-13, which was passed to the Parliament but not yet approved as a law, contains a range of requirements to ensure quality of care. It emphasises the importance of clinical and organisational appropriateness as well as the design and testing of clinical models, organisational and managerial innovation aimed at ensuring the effective provision of health care services that adequately meet health needs. It further defines criteria for resource allocation of regional funds across individual ASLs and determines criteria for adapting national goals with the epidemiological features and health needs of regional populations.

The *Patto per la Salute* is a three year financial and programming agreement between the government and the regions, aims at improving the quality of services and at promoting the appropriateness of care. The *Patto per la Salute 2014-2016* has recently been adopted with the objective of ensuring that each citizen has access to health and care services of high quality. The *Patto per la Salute* focuses in particular on reducing waste and inefficiency, while enhancing preventive activities and improving care continuity to provide more effective and patient-centered care (Presidenza del Consiglio dei Ministri, 2014). A core focus will be shifting care away from hospitals and into primary and community care. To achieve high quality of care, the *Patto per la Salute* contains the following requirements:

- The *Patto per la Salute* plans to increase the funding of the SSN. The funding has been fixed to EUR 112.06 billion for 2015 and to EUR 115.44 billion for 2016, while it is estimated at EUR 109.92 billion for 2014.
- The *Patto per la Salute* places great attention to the expansion of community care networks such as *Unità Territoriali di Assistenza Primaria* (UTAP) and *Unità Complesse di Cure Primarie* (UCCP) (see Chapter 2). Community care network might be the only forms of primary care delivery and it will replace the many different types of

associative forms that have been developed in R&AP. Community care networks are open 24 hours a day and are able to operate in a co-ordinated way with a direct connection with hospitals. Such model of primary care creates more comprehensive pathway of care, involves better care co-ordination and entails more effective prevention. While community care networks have already existed for several years following the Balduzzi Law n.189/2012, the *Patto per la Salute 2014-2016* gives an added impetus to their systematic establishment. To this end, the *Patto per la Salute* provides guidance to support R&AP in the process of setting-up community care networks, to enhance the use of chronic care model and to better use information and communication technology (ICT) to monitor the appropriateness, quality and efficiency of community care networks.

- The *Patto per la Salute* intends to reorganise the hospital network. Community or county hospitals (such as *Ospedale di Comunità* or *Ospedale di Distretto*), as well as intermediate care facilities (such as *Strutture di ricovero intermedie*), are being developed as new forms of residential and rehabilitative facilities. The objective is to reduce length of hospital stays, prevent hospital admissions and readmissions, improve transitions from hospitals to community settings and retain people's independence as long as possible. The importance of keeping people closer to their home is a key instrument to reduce cost and increase quality of care.
- The *Patto per la Salute* plans to revise the legislation around cost-sharing and exemptions to safeguard universalism and remove barrier to access to health care services.
- The *Patto per la Salute* addresses the verification of the essential levels of care (*livelli essenziali di assistenza*, LEA). It is agreed that LEAs will be updated by the end of 2014 according to principles of fairness, innovation and appropriateness. The *Patto per la Salute* confirmed the duties and functions of the National LEA Commission for monitoring the implementation of the LEAs throughout the country (see below).
- The *Patto per la Salute* focuses on the increasing use of information and communication technology (ICT) in the health sector. Specific interventions aimed at disseminating electronic health information have been agreed such as the *Patto per la Sanità Digitale* (the eHealth strategy) and the *Piano di Evoluzione dei Flussi NSIS* (the evolution plan for the NSIS). These strategies intend to develop a comprehensive electronic system for monitoring the LEAs and related costs, as well as to encourage traceability and transparency.

The essential levels of care (established by governmental decree November 29, 2001) is the uniform core benefits package that must be guaranteed free of charge or with cost-sharing throughout the country. Following the State/Regions Agreement of 23 March 2005, the state and the regions have to mutually commit themselves to ensure compliance with the principle of uniform delivery of the LEAs in line with the planned resources provided by the National Health Service.

Defined annually during the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces (described below), the LEA system is the backbone of the Italian health benefit catalogue ensuring that the population has equal access to high quality care. The definition of the LEAs is based on the criteria of human dignity, effectiveness, appropriateness and efficiency. Health care services uniformly covered by the Italian health care system are delivered at three levels of care: i) public health services, ii) community health services and primary care, and iii) hospital care.

Monitoring the implementation of the LEAs throughout the country is the responsibility of a specific technical body, the National LEA Commission. Founded in 2004, the National Commission is responsible for the definition and updating of the LEAs on the basis of scientific, technical and economic evidence (Torbica and Fattore, 2005). It is made-up by seven representatives from the regions, seven representatives from central bodies such as the Ministry of Health, the Ministry of Economics, and the Department for Regional Affairs of the Presidency for the Council of Ministers. The LEA Commission is committed to annual verification, through appropriate indicators, of the compliance of regions with the LEA requirements. The regions with special statute are not included in the LEA verification, except for Sicilia. The *Griglia LEA* is the quantitative tool used for LEA verification and is therefore given particular attention by Italian Authorities. A report presenting regional achievement delivering the LEAs is issued annually (Ministry of Health, 2011a). Positive results trigger the release of full financial resources required for the provision of health services, while negative results trigger a support programme by the Ministry of Health and guidance to the region to improve the provision of health care services. In September 2014, the following regions were undergoing Recovery Plans: Abruzzo, Calabria, Campania, Lazio, Molise, Piemonte, Puglia, Sicilia. Tight deadlines have been imposed upon all regions to ensure the maintenance of the LEAs (Torbica et al., 2005).

The LEA system is subject to continuous revision, and appropriate indicators against which to assess fulfilment of the LEAs are regularly updated. For example, at present indicators are selected to fit with the following objectives:

- reorganisation of primary care and the hospital network
- review of policies for the accreditation of health facilities and implementation of the programme to evaluate results
- Implementation of a programme for the safety of patients including for example the introduction of a system to report adverse events, strategies for training, the adoption of recommendations and safety solutions.

Alongside the LEAs, the National Programme for the Promotion of Quality in the Permanent National Health Service (the so-called *PROQUAL programme*) was established as part of the *Patto per la Salute 2010-2012*. The programme intends to embed clinical governance more deeply within the Italian national health system in order to strive for continuous quality improvement in health care delivery. The programme is implemented through different work programmes, each co-ordinated by one region or AGENAS leading a group of four or five regions towards the finalisation of the following: i) instruments aimed at testing the applicability and/or improving the functionality of specific health services; ii) recommendations for regional policies and/or practices of local health authorities and hospital trusts. The PROQUAL programme plays a central role in quality strategies by targeting five key areas: patient involvement, appropriateness, efficacy, safety and integrated clinical governance.

The following specific objectives have been set up as part of the PROQUAL programme:

- promoting the involvement of citizens and patients at the national, regional and professional levels, as well as implementing consistent and structured forms of assessment
- promoting the effective provision of health care services included in the LEA system
- improving the appropriateness of the health care services included in the LEA system
- promoting patient safety and clinical risk management through improved processes, developing and managing an integrated system of services according to a model of clinical governance
- promoting patient safety, according to the set of recommendations agreed between the state and the regions in 20 March 2008 regarding clinical risk management and patient safety

- implementing training programmes in the field of clinical governance, clinical audit and methods of analysis of adverse events
- implementing at the central, regional and professional level, initiatives of information and communication for all actors involved in the system, even for the purpose of transferring experiences in meaningful and effective ways.

The PROQUAL programme is a key instrument to promote quality initiatives, but it is still in its early phase of implementation and it is therefore difficult to assess its impact on quality improvement.

The National System for the Monitoring and Control of Public Health care (*Sistema nazionale di Verifica e controllo sull'Assistenza Sanitaria*, SiVeAS<sup>1</sup>) established pursuant Law 266/2005 is another important quality instrument in the Italian Health system. The SiVeAS programme provides support for the development of tools for the evaluation and implementation of good practices in terms of efficiency, efficacy and quality of care.

Finally, it is worth mentioning that quality and safety priorities have also been laid down in the following legislative decrees and *Patto per la Salute* that have been developed over the past 20 years:

- The national legislation of 1995 required that information on service performance, as well as information around quality indicators and waiting times should be issued in a health service chart set up by all public health care providers. Public health care providers are further required to develop a strategy for quality assurance.
- The *Piano Sanitario Nazionale* for 1998-2000 and the Legislative Decree No. 229 of 1999 contain a number of quality requirements. A procedure for institutional accreditation of public and private providers was established through assessing the quality of both the facility and health care professionals. The NHP has also resulted in a national programme on health care quality to direct improvement through continuous assessment and monitoring. In particular, the National Programme on Clinical Guidelines (*Piano Nazionale Linee Guida*, PNLG) has been established to steer the behaviour of health care professionals towards appropriate and effective provision of health care services. Further, human resources appeared to be a cornerstone for enhancing both health care quality and patient satisfaction, and the concept of continuing medical education was introduced in 1999. Several steps have since been taken to give health professionals additional qualifications to improve their skills through courses, meetings, seminars, study tours and research activities. To this end, the National Commission for Continuous

Education in Medicine and the National Programme on Continuing Education in Medicine were set-up in 2000 to determine training objectives of national interest, and to assess and validate training activities for health care professionals.

- Quality of care is further embedded in legislation on accreditation and on quality standards. The Legislative Decree No. 502/1992 for example introduced institutional accreditation, which must be granted by regions to authorised health care organisations (see Section 1.4).

Overall, there are national instruments that are already used to promote quality, and quality assurance and improvement does already hold a central place in national legislation and governance tools.

### ***The Ministry of Health fulfils the function of the overall steward of the National Health Service***

The Ministry of Health is the principal health authority in Italy, and is responsible for the definition of the health system general objectives and fundamental principles. The Ministry of Health is also responsible for allocating resources between different health care settings (hospitals, primary and community care). Its health care financing role involves setting the overall budgets, collecting taxes and allocating funds to regions to ensure uniform availability of resources across regions. Funds are allocated according to a complex formula taking into account population size, average age, mortality rates and other regional characteristics. Beyond health care financing, the Ministry of Health regulates health care activities through the promotion of healthy behaviour, the development of prevention programmes and the management of human resources (Lo Scalzo et al., 2009).

To formulate the general objectives and define health targets, the Ministry of Health relies on different institutions and permanent government agencies including the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces, the National Health Council, the National Institute for Health, the Italian Medicines Agency and the National Agency for Regional Health Services.

### ***The Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces***

The Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces was set up in 1988 to foster collaborative arrangement between the different levels of government. It is an essential structure where regional and central authorities can meet to



discuss, negotiate and make agreements around a range of public services including health care services. The Standing Conference is chaired by the Prime Minister and is composed of several Ministers (Ministry of Health or Ministry of Finance for instance), the presidents of the associations representing municipalities, provinces and mountain communities, as well as 14 mayors and six regional presidents.

The conference promotes cooperation and encourages the involvement of R&AP in the development and implementation of legislation. The conference is expected to co-ordinate actions between the regions and the state, and to foster debate regarding matters related to legislative arrangements and general government measures. The conference objective is also to monitor the economic and quality level of public performance in light of the objectives set out in the plans and projects approved by the conference. It is a place of negotiation and agreement between the heads of regions, senior civil servants and the central government. It is therefore the main forum for co-ordination between the state and the regions.

#### *The National Health Council (Consiglio Superiore di Sanità)*

The National Health Council is a central body of the Italian National Health Services. It is a technical and consultative body in charge of ensuring adequate access to health care, decreasing health inequalities and developing educational and prevention programme to promote public health. It collaborates with regions to drive improvement in health care quality. It is chaired by a president and is composed of nearly 50 members having expertise in health care (scientists, physicians and other experts). Under the authority of the Ministry of Health, the National Health Council:

- analyses public health and carries out study covering epidemiology and public health
- offers scientific investigations on events of major interest in the field of hygiene and health
- proposes the formulation of schemes, rules and measures for the protection of public health
- proposes the preparation of standards for the construction of health facilities such as hospitals or nursing homes
- expresses opinions on the regulations and international conventions relating to public health.



### *The Italian National Institute of Health (Istituto Superiore di Sanità)*

Founded in 1934, the Italian National Institute of Health is the main scientific institution involved in public health. It produces about 1 600 research papers including a technical report, a monthly newsletter, national epidemiological bulletin and a peer-reviewed journal in order to provide technical and scientific assistance to the Ministry of Health. The Institute is involved in research, clinical trials, control and training. It supports scientific research and national programme by allocating funds, increasing the scope of Italian participation in international activities. The Institute is the competent authority for the authorisation of phase I clinical trials and is also involved in phases II and III of clinical trials. Clinical trials are frequently conducted in collaboration with the *Istituto di Ricovero e Cura a Carattere Scientifico* (IRCCS) and hospitals.

The ISS further conducts inspection and quality control of medical and diagnostics devices, pharmaceuticals and food product and packaging. It is also engaged in scientific monitoring regarding trends in disease, mortality, or health determinants. Technical support for health related environmental survey and for investigations of epidemics and other public health problems at national, regional and local levels is also provided by the ISS. To address the need of the National Health Service, the ISS develops, implements and evaluates training activities covering areas such as health service management, epidemiology and biostatistics as well as health promotion. It is involved in the organisation of national and international conferences and research projects.

### *The National Agency for Regional Health Services (Agenzia Nazionale per i Servizi Sanitari Regionali)*

Founded in 1993, the National Agency for Regional Health Services (AGENAS) is a scientific and technical body of the Italian National Health Services in charge of supporting national and regional health planning. It promotes quality in health care by comparing costs and efficiency of health care services, detecting malfunctions in managing health resources (human resources, materials and provision), spreading health innovation and experimentation of new of models of care. Its involvement is based on guidelines approved by the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces.

Lead officials are jointly agreed by the Prime Minister and the R&AP, and must be approved by the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces. The agency is accountable to the regions and the ministry. AGENAS plays an important role in assuring convergence between the quality approaches in the regions,

especially in the field of indicator development and reporting, accreditation, patient safety and continuing medical education. In the Italian governance structure, the role of AGENAS is mainly a supportive one and focuses on development and co-ordination.

AGENAS' main areas of activity are:

- quality, efficiency and equity of health care services (evaluation and monitoring)
- analysis of health expenditure
- support to regions in health planning and evaluation and managing health innovation (Health Technology Assessment)
- support to regions with financial troubles complying with plans for solvency and requalification
- managing continuing medical education providing administrative support to the National Commission for Continuous Medical Education and to other activities, as requested by the Italian regions or by other public institutions.

#### *The Italian Medicines Agency (Agenzia Italiana del Farmaco)*

The Italian Medicines Agency (AIFA) is the national authority in charge of drug regulation in Italy. Under the direction of the Ministry of Health and the Ministry of Economy, the AIFA co-ordinates all activities related to pharmaceuticals and it operates autonomously and transparently.

The AIFA aims at promoting good health status through the development and evaluation of medicines and it encourages investment in research and development in Italy. Pharmaceutical policies are set by the agency and are supposed to be applied uniformly across the country. Through negotiation with pharmaceutical companies, it determines the price of medicines reimbursed by the NHS. The value and cost of medicine are also managed by the agency in order to ensure rapid access of innovative and efficient drugs. The agency is in charge of clinical trials and carries out inspections of good clinical practice. It is responsible for the registration process of medicine and for drug safety after their commercialisation. With this respect, AIFA deals with quality defects, withdrawals and suspension of medicines and also provides information and training for health care professionals.

### ***The regional and local governments have exclusive responsibility for the funding and the organisation of health care services***

Although the Ministry of Health is responsible for the general administration of the NHS and the definition of health standards, the 19 regions and two autonomous provinces are exclusively responsible for funding, organisation and administration of health care services (Lo Scalzo et al., 2009). With the devolution of political power and the shift towards financial federalism, health care planning, the organisation of health care supply and the development of quality strategies are to a large extent the responsibility of the regions through regional health departments.

On the legislative side, regions have full autonomy for the organisation of health care delivery, the financing of health care organisations and they provide technical and management guidelines for service provision and planning. Beyond its legislative role, the regional level has also executive functions carried out through the regional Department of Health. Based on the *Patto per la Salute*, the *Piano Sanitario Nazionale* and on regional health needs, regional governments develop their own regional health plans which are also three-year plans. Through the definition of the regional health plan, regions establish objectives, financial and organisational criteria for managing health care organisations around for instance the location of hospitals, strategy to improve quality of care or to achieve greater integration between health and social care. The delivery of the LEAs, the monitoring of quality of care, the definition of criteria for authorising and accrediting public or private providers and ensuring co-ordination between health and social care are functions carried out at regional level. However, the latest trends on cost containment, particularly following the spending reviews conducted during the last two years, led to the closure of some of the earliest experiences of this kind (namely Friuli Venezia Giulia, Piemonte, Lazio and Veneto). Currently, regional health agencies operate in the following regions: Abruzzo, Campania, Emilia Romagna, Liguria, Marche, Puglia, Sardegna and Toscana.

At more local level, Local Health Authorities (so-called *Aziende Sanitarie Locali*, ASLs) which are geographically-based institutions are responsible for delivering public health, primary and community care, as well as specialist care through either their own hospitals or by public hospital trusts (*Aziende Ospedaliere*, AOs). ASLs and AOs are directly managed and financed by regions which have full autonomy to define their geographical boundaries, allocating resources to them and appointing their directors. Regional health departments must co-ordinate health care activities and monitor the efficiency, effectiveness and appropriateness of the services provided by ASLs and AOs. In some regions, a regional agency

for health has been established to provide technical support directly to the ASLs and to AOs around for instance the implementation of quality strategy, and also to support regional health departments.

Due to the devolved government, it is noteworthy that quality strategies have not been uniformly implemented across regions, depending upon their capacity to find suitable mechanism to realise them. This might suggest that the devolution of greater competence to the regions was not underpinned by sufficiently effective mechanisms for central oversight and steering to ensure greater transparency and standards of quality across Italian regions. As a result, there are large variations of quality and efficiency of care across regions, and particularly between the north and the south (France et al., 2005; Ministry of Health, 2011b). One of Italy's priorities is to ensure a more evenness of approach toward quality measurement and improvement throughout the country.

#### **1.4. Assuring the quality of inputs to the Italian health care system**

While there is a good basis for monitoring the quality of the use of pharmaceuticals and of medical devices in Italy, more robust quality assurance mechanism should be developed around individual professional performance. As further described in Chapter 3, re-certification and systematic assessment of individual health care professionals' performance is not a reality yet in Italy to ensure high quality of care and good system outcomes in the health system. At the same time, Italy has progressively strengthened its accreditation process for health care facilities through several legislative decrees. At present, accreditation is mandatory for hospitals to be eligible for funding from the SSN, but a number of accreditation models have been developed across regions with varying levels of sophistication. There is therefore a need to achieve a more coherent approach towards national standards of care and harmonised accreditation systems. Positive steps have already been taken to achieve a more co-ordinated approach, through the Technical Group for Accreditation (TRAC), which will be a key instrument to guarantee high quality of care and equity in health service delivery throughout the whole country.

##### ***The safety of pharmaceuticals and medical devices***

As described in Section 1.3, the Italian Medicines Agency (AIFA) is the competent authority in charge of the pharmacovigilance, production, research, pricing, reimbursement and drug approval in Italy. It ensures a safe and appropriate use of pharmaceuticals and medicinal products to citizens. Before a pharmaceutical product can be sold in Italy, it must be authorised and registered by the AIFA through the national and community procedures

provided by the European set of laws. The national procedure consists of the assessment and registration process of a medicinal product, enabling its marketing authorisation in Italy. Because the Italian legislation fully implements the EU directives, the criteria used for the national procedure is the same than those established by the EU procedures. The community procedures rely on i) a mutual recognition procedure, or ii) a decentralised procedure. The mutual recognition procedure refers to the extension of a marketing authorisation that is granted by a member state to one or more other countries of the European Union. The decentralised procedure enables to obtain a single marketing authorisation that is simultaneously valid in other countries of the European Union for pharmaceuticals which are not yet authorised in Europe.

The assessment and registration departments at the AIFA are responsible for all stages of the process of market authorisation that must be consistently implemented with the national and international procedures. The assessment procedure intends to achieve standards of quality, and to ensure safety and efficacy of pharmaceutical or medicinal products through chemical, pharmaceutical, biological and clinical assessments. With respect to the registration process, the AIFA verifies the completeness and consistency of the administrative dossier with national and European legislation and then reports its decision to the Ministry of Health.

The safety of pharmaceuticals is further ensured through a post-marketing surveillance system. The system continuously monitors safety information and adverse reaction for all authorised drugs. To this end, the AIFA has developed a National Network of Pharmacovigilance (*Rete Nazionale di Farmacovigilanza*, RNF). The RNF is an extensive network covering the national territory and including more than 200 Local Health Authorities, 100 hospitals, 43 research institutes and more than 800 000 pharmaceuticals companies. It collects all suspected adverse drugs reaction spontaneously reported by health care professionals and consumers. The database allows for the collection, management and analysis of spontaneous reports of suspected adverse reaction. The network works in collaboration with the European network for pharmacovigilance (EudraVigilance), which collects in a single database all European data.

The AIFA monitors medical devices through inspection at manufacturing sites of finished medicinal products and medicinal gases. To ensure adequate manufacturing process of medical device and guarantee high quality of pharmaceutical dosage form, all sites on the Italian territory are regularly inspected. In particular, inspections at manufacturing sites producing raw materials that make up the pharmacologically active medicines are conducted by the agency to comply with quality standards. An information system has been developed to monitor medical devices bought

or used by all public health providers. Health technology assessments in the field of medical devices are carried out by AGENAS, which publishes reports for the Directorate General of Medical Devices.

### ***Towards a national and broadened accreditation approach***

In Italy, institutional accreditation is mandatory in order to be eligible for funding from the Italian National Health Care System. It is granted by the regional government and aims to identify, based on pre-defined quality standards, the providers of health care services on behalf of the SSN.

The national health care legislation of 1992 (Legislative Decree No. 502/1992 as modified by Legislative Decree No. 517/1993) introduced the concept of accreditation into the Italian National Health Service. The decree required the definition of minimum standards for public and private health care organisations to carry out health care activities. The general provision of the decree stated that accreditation might be established by all regional governments according to their regional health plans. Regions must thereby define their own models and standards based on national guidelines. The decree also called for frequent controls of health care organisations and assessment of health care activities to ensure that requirements continue to be fulfilled. Authorisation is an essential pre-requisite to apply for accreditation.

In 1997, the presidential decree required the setting-up of minimum structural, technological and organisational standard to be met by public and private health organisations. These requirements are made mandatory to be eligible for authorisation. The presidential decree assigned to regions the task of setting-up additional quality standards for the accreditation of health care organisations. Public and private facilities that have already fulfilled the minimum standard must meet these further requirements to be accredited. The 1999 legislation (Legislative Decree No. 229/1999) has systematised the issues of institutional accreditation to ensure quality of care and promote fair competition between providers.

The following four-step process was established:

- *Authorisation to establish health care structures*: Measure that allows building new health care facilities or adaptation and transformation of the existing facilities by public or private entities. This is granted after verification of compatibility by the region based on real needs with respect to regional planning.
- *Authorisation for delivering health care services*: Measure that enables public and private subjects to provide health care services. This authorisation is issued after ascertaining the minimum set of

structural, technological and organisational requirement have been met.

- *Accreditation*: The tool through which the region gives facilities the status of potential provider (it is a necessary but not sufficient condition) of health care services on behalf of the National Health Service. It implies ascertaining additional standards (compared with the minimum standards required for authorisation) and assessing compliance with needs and functionality with respect to regional planning.
- *Contractual agreement*: The tool through which regions and Local Health Authorities define, together with public and private accredited bodies, the type and amount of services that can be delivered to patients, as well as remuneration to be charged to the health service within the boundaries of the expenditure levels fixed in compliance with the choices in regional planning.

The 1999 health care legislation made regional governments responsible for establishing and managing the accreditation process. As a result, structural, organisational and technological standards are defined at regional level to respect regional autonomy. The Decree however required that regional accreditation processes follow some general principles to guarantee that all health care facilities operate according to common quality criteria and to ensure homogeneous level of quality across the country.

The modification of Chapter V of the Italian Constitution (as by Constitutional Law 3/2001) has then allowed the regions to develop their own accreditation models. Because accreditation is since then a regional responsibility, 21 different accreditation models have been developed in Italy. Due to organisational and cultural differences among regions, some of them have not a well-developed accreditation process while in other regions, the accreditation system is established according to well-known international programmes.

The need to agree upon common standards to conduct accreditation has progressively arisen in order to guarantee equity in health service delivery across the country. The harmonisation of the accreditation process has started with the setting-up of the “technical specification for reviewing legislation on accreditation”, which established a shared framework for the accreditation of health care facilities. The technical specification – drafted by the TRAC – continues and clarifies the results of an extensive discussion and sharing promoted by AGENAS since 2010, in collaboration with the R&AP and Ministry of Health, for setting up quality standards to be shared within the regional accreditation systems. The selection was made among



standards already existing in the authorisation/accreditation manuals or in the regional legislation of the most part of R&AP.

Analysis and comparison of the different regional methods and experiences were thus carried out. As a result, eight standards (further divided into 28 criteria) have been defined as part of the technical specifications (formally approved by the State/Regions Agreement of December 20<sup>th</sup> 2012):

- *Management system implementation for health care organisation:* Management of a health care organisation that governs the dimensions most strongly connected to the specific activities of care and assistance – in the pursuance of continuous improvement – is a guarantee of good quality of social and health care.
- *Services:* It is good practice for the organisation to describe the type and characteristics of services delivered and to identify the working methods to be adopted, as routine parts of clinical governance on which to base performance evaluations and communications with patients and citizens.
- *Structural aspects:* The organisation assures the suitability of health care facilities and the punctual application of rules concerning their maintenance; it is good practice to highlight staff contributions to the management of these structures.
- *Staff skills:* The organisation should assure that the staff has acquired and will maintain the necessary knowledge and skills to achieve certain levels of quality and safety of specific activities they carry out.
- *Communication:* Good communication and relationships between professionals and with patients ensure that expectations of professional behaviour will be met and that safety in the delivery of care and patient involvement in treatment choice will increase.
- *Clinical appropriateness and safety:* Effectiveness, appropriateness and safety are essential elements of the quality of care and must be monitored.
- *Improvement process and innovation:* The governance of continuous improvement, adoption of technological and organisational innovations, together with facilitation of clinical research, demonstrate the organisation's ability to adapt to new contexts by assuming ethically-based, professionally adequate, socially acceptable and sustainable behaviours.



- *Patient centeredness*: Making treatment patient-centered and diagnostic and therapeutic pathways oriented as much as possible to the person as a whole – including physical, social and psychological aspects – should be a commitment common to all facilities.

Each standard was converted into one or more criteria including description of objective, background and useful evidence to demonstrate compliance with the criteria. These standards and criteria must be included within the relevant legislation of each R&AP, and subsequently evaluated by using uniform methods throughout the country. The R&AP are committed to adopt the agreement within six months from its formal approval, while the procedures and deadlines of adaptation to the contents will be defined by an ad hoc working group (Di Stanislao et al., 2012).

The working group (also known as “Tavolo di lavoro per lo sviluppo e l’applicazione del sistema di Accreditamento nazionale” or TRAC), established at the Ministry of Health with the decree of 6 February 2013, is composed of representatives of the Ministry of Health, AGENAS, regions and autonomous provinces. In its first year of activity, the working group has worked to define procedures and deadlines for implementation of the contents of the technical specifications and to develop requirements for the functioning of the accrediting bodies that will be performing evaluations. In compliance with its mandate, the working group drew up an implementation roadmap for each criterion and defined uniform requirements for the functioning of the regional accrediting bodies, with the aim of ensuring transparency in the management of the assessment activities. The final documents are currently brought to the attention of the Minister of Health for her final approval.

The national attempt towards standardisation of the accreditation process is an encouraging move to achieve a co-ordinated approach at system-level, ensuring transparency and accountability around the performance of health care facilities throughout the country. The challenge for Italian authorities will be to keep in place the nationwide accreditation programme and to ensure its uniform implementation across the country. AGENAS has a role to play in such a process, by taking for example a stronger inspection role to ensure that agreed minimum standards are applied in all regions. At the same time, the focus of accreditation seems mainly on hospitals and it would seem desirable to expand the programme to other sectors beyond hospitals including for example primary and community care.

### ***Training of health care professional and continuing medical education in Italy***

Like many other OECD countries, Italy has recognised the importance of having an adequately trained workforce to deliver high quality of care. As demonstrated in Chapter 3, physicians have to follow an undergraduate programme which lasts at least six years and have to undergo a three-month practical training. A national examination must then be completed in order for physicians to be placed on a national register and be allowed to practice as physician. Specialisation consists of a four to six year course at a chosen specialist school, and it is required by law to be authorised to work in a hospital. To become a general practitioner, physicians have to participate in a three-year course programme. The degree in nursing is obtained after a three-year course of studies and the acquisition of 180 credits. After registration in the Professional Board of Nurses and Midwives, it is possible to practice as registered nurses in the public and private sectors.

Although the policies for licensing health care professionals are well developed in Italy, there is no policy for re-certification. Health care professionals receive their medical licence for life, with no requirement for renewal or expiration date. Continuing medical education (CME) is, however, recognised as an important element to ensure physician fitness to practice. Italy has launched in 2000 the National Programme on Continuing Education in Medicine (NPCEM) to ensure that physician knowledge are constantly updated and to guarantee that medical doctors possess the adequate skills to meet the growing demand for health care. The NPCEM requires health care professionals to obtain 50 CME credits per year. Credits are assigned by an accredited CME provider and are awarded according to hours of training activities, the type and characteristics of the programme. The National Commission for Continuous Education (*Commissione Nazionale Formazione Continua*) is the competent institution to accredit national providers, while regions or autonomous provinces are responsible for the accreditation of regional providers. The National Commission for Continuous Education guarantees that CME provider is active and qualified to organise the training for medical activities.

In 2008, AGENAS took over the administration and organisation of the CME programme and it collaborates with the NPCEM (or regions) to achieve a system capable of verifying and promoting high quality of continuing medical education. AGENAS also supports regions that have signed agreements for the accreditation of regional providers. The agency has already signed specific agreements with ten regions for continuing medical education, involving the implementation of the programme for the accreditation of regional providers.

The quality of training and the Italian programme of continuing medical education are further described in Chapter 3. As this chapter emphasises, re-certification and systematic assessment of individual performance are not yet a reality in Italy, although interesting initiatives to encourage continuing professional development have been set-up. Going forward, good medical education and nationally standardised CME may not be enough to secure a high quality, high performing medical workforce.

## 1.5. Health system monitoring

In recent years, the evaluation of quality and outcomes has been increasingly considered by the national institutions and the R&AP as a fundamental tool to improve the effectiveness of policy making (Quaderni AGENAS, 2008; Carinci et al., 2012; Agenzia Sanitaria Regionale Emilia Romagna, 2010; Piano regionale per la Salute e il Benessere Sociale 2011-13, 2011). In some cases, these functions have been performed directly by regional health departments, in others, regional agencies for health and health care have been specifically funded to provide technical and scientific advice to the regional health departments and to the ASL. Furthermore, some public health observatories have also been set up in different regions, provinces and ASLs to deliver a range of quality indicators for planning and monitoring purposes.

Italy has, as a result, a large number of databases on quality of care at both national and regional levels, and remarkable efforts have been made to strengthen the information infrastructure by setting-up the New Italian Health Information Structure. However, the existing datasets are not being fully exploited, due mostly to difficulties with data linkage. In addition, a number of clinical registries are also in place in Italy but they are not sufficiently developed to address comprehensive monitoring and improvement in quality of care. Finally, the information infrastructure underpinning primary and community care is still rather weak compared to the hospital sector.

### *Italy has a large number of databases on quality of care*

At the national level, different databases are routinely collecting indicators of care quality and are regularly used to monitor quality and improve performance across the country. Quality standards and indicators are included into the *Griglia LEA* which constitutes one of the official national systems of indicators for monitoring regional performance. Indicators and assessment criteria are published annually in the National Health Status Report and on-line (Ministry of Health, 2012a).

This report includes 31 indicators around prevention in life and work environments (immunisation, screening, costs, veterinary and food control), community care (avoidable hospital, residential care for disability and elderly patients, hospice, ambulatory care, home care, mental health, pharmaceutical prescriptions) and hospital care (hospitalisation rates, caesarean rates, hip fracture intervention within 72 hours, appropriateness indicators, emergency interventions). The *Griglia LEA* allows monitoring and comparing the provision of standard in each Italian region and autonomous province. The range of indicators allows results to be stratified by region, increasing the scope for evaluating performance with regards to the accomplishment of national standards.

Beyond the *Griglia LEA*, the *National Outcomes Programme (Programma Nazionale Esiti – PNE)* is a national initiative that monitors 129 health care indicators (input, process and outcomes) across hospitals and municipalities in Italy. The PNE is co-ordinated by AGENAS and it provides the most extensive presentation of quality of care related to acute care with very specific definitions for high priority intervention areas (Fusco et al., 2012). At present, most indicators refer to hospital care but the coverage of the programme is going to be extended by including primary care indicators. The definitions and number of indicators included in the PNE is constantly evolving. The current version includes results at the national level, available for each hospital and ASL, grouped by region, for the following indicators: 30 days mortality (in and out of hospital) for stroke, AMI, hip fracture, CABG, colon/lung/gastric cancer; readmissions for stroke, COPD, CABG; hip fracture interventions within 48 hours, complications for cholecystectomy; caesarean sections, second knee arthroscopy intervention within six months. Data for each hospital in the country are also available in terms of volumes of activity and area-based results are available for hospitalisation rates for asthma, diabetes, hypertension, heart failure, angina or diabetes complications.

The National Database of Hospital Discharges (*Scheda di Dimissione Ospedaliera*, SDO database) provides comprehensive and accurate data around acute care for the whole country and all Italian hospitals. It is maintained by the Ministry of Health as an official data collection from hospital discharge abstracts submitted by law by all Italian regions. The national data collection has been active since 1994. The data collection has been improved in completeness and quality during the subsequent years. Moreover, since 2001 the database has been improved with further relevant information about every patient. The database is archived every year by date of discharge. It provides indicators of case history, volumes of care and lengths of stay for every patient discharged from all public and private hospitals. Both clinical and organisational information of hospitalisation are

gathered in the database. Hospital discharges can be computed by type of hospital, type of stay (acute inpatient or outpatient care), type of DRG and type of transfer. Other appropriateness indicators are collected including readmissions rates, the percentage of short stays by medical DRGs or the percentage of discharges with a length of stay beyond threshold for subjects aged over 65. Results are published in the SDO annual report and are made available stratified mainly by region and by the main characteristics of the discharge (DRG, type of hospital).

The SDO database includes casemix classification based on ICD-9-CM 2002 and DRG v.19 (2006-2008), ICD-9-CM 2007 and DRG v.24 (2009-today). It includes one Principal Diagnosis and one Main Procedure (including Date of Intervention) and up to five Secondary Diagnoses and five Secondary Procedures. In 2013, the SDO database included a total of N=6 634 977 inpatient discharges and N=1 459 hospitals. Diagnoses codes for accidents (“E codes”) have been introduced in 2010 and began to stabilize after one year. The platform has been regularly used by the Ministry of Health, recently in collaboration with AGENAS, to deliver quality indicators to the OECD (Ministry of Health 2012b, 2014).

At national level, the availability of primary care and community indicators is still limited and only covered by the OECD Health Care Quality Indicators, for instance around avoidable hospitalisations for asthma, diabetes or COPD. Other primary care indicators covering the general population include pharmaceutical prescriptions collected by the Italian Medicine Agency and published in the OSMED report (“The Use of Medicines in Italy”). The OSMED report is a major annual publication on pharmaceutical prescriptions, representing the most reliable source for pharmaceutical quality monitoring and planning.

The calculation of population-based indicators is usually supported by a regularly updated national population data warehouse at the National Institute of Statistics (ISTAT), freely accessible to the public via the official website (<http://demo.istat.it/>). Data from the general population with different disaggregation levels and the results of a number of annual surveys for health care analysis are gathered and presented online. The activity of ISTAT also includes carrying out various surveys of interest to health and health care, particularly the “Multipurpose” survey on the “Health Conditions and Utilisation of Health Services”, which includes a representative sample of Italian families. The survey includes information on acute and chronic diseases, as well as disability and lifestyle conditions (obesity, physical activity, smoking), participation to social activities, health services utilisation (visits, diagnostic test, rehabilitation, patient experiences), pharmaceutical consumption, complementary medicine, maternity and breastfeeding.

At the regional level, there is a plethora of indicators, among which the Tuscan Performance Evaluation System, also adopted by a network of regions is worth mentioning. The performance evaluation programme (see Box 1.2) includes a range of quality indicators recognised by international organisations including the OECD, WHO and the EU Commission through the European Community Health Indicators (ECHI). Beyond the Tuscan Performance Evaluation Programme, many ASLs produce reports and scorecards for general practitioners to control and optimize health expenditure, particularly around pharmaceutical prescriptions.

### **Box 1.2. The Tuscan Performance Evaluation Programme**

The Tuscan Performance Evaluation Programme is an innovative measurement framework used as an internal evaluation tool for health care organisation. It was developed in 2005 to measure the quality of health care services in order to improve population health and to achieve higher quality of life. At present, the system is implemented in eight other Italian regions. It gathers more than 130 indicators, classified in six dimensions: population health status, capacity to pursue regional strategies, clinical performance, patient satisfaction, staff satisfaction and efficiency or financial performance. The performance results are monitored every three months with feedbacks provided to health care professionals and managers. They are also linked to the CEOs' reward system and made publicly available. Available evidence suggested that more than 50% of the indicators significantly improved in Toscana between 2006 and 2010 (Nuti et al., 2013), leading to better quality of care and increasing both population health and quality of life.

Although the Tuscan performance management system is perhaps the system most familiar to non-Italian health system researchers, it should be stressed that in Italy it is viewed as one of a number of equally valid approaches being developed by different regions.

### ***Remarkable efforts have been made through the development of the New Italian Health Information Infrastructure but several challenges remain to improve data linkage***

Italy has made significant progress over the past decades in strengthening the information infrastructure, primarily through unifying and standardising the health data collected by regions. The New Italian Health Information Infrastructure (*Nuovo Sistema Informativo Sanitario, NSIS*) was established in 2001 by national legislation (mandated by law for all regional governments, the so-called *Flussi Sanitari* – Health Flows). The NSIS has mainly been built to provide information for governance and to evaluate the qualitative and quantitative standards of the LEAs for local, regional and national governments.

The NSIS represents the backbone of all health information and is based on the establishment of official databases mandated by law for all regional governments (the *Flussi Sanitari* “Health Flows”). The NSIS enables the co-ordination of local, regional and national information system. The foundations of the NSIS have been laid down by a nationwide clinical coding programme, the so-called “bricks” or “Mattoni” programme to ensure a common language and classify or codify concepts in a uniform manner. The programme is based around 15 thematic sub-projects, with teamwork guided by a region responsible for managing each subproject (e.g. Toscana and Sicilia for clinical coding of patient records; Lombardia and Molise for outpatient performance measures; Lombardia and Puglia for primary care and home care performance measures). Given the complexity of the objectives, an incremental approach has been adopted so that different, progressive levels of achievement have been defined.

At present, the NSIS includes the following national databases made available by all regions in a standardised electronic format:

- hospital discharges (annual Ministerial Decree 26/7/1993, monthly Ministerial Decree 8/7/2010)
- maternal delivery (CEDAP, Ministerial Decree 16/07/2001)
- ambulatory care (Art. 50 Law 24/11/2003, Law 24/11/2003)
- pharmaceutical prescriptions – pharmacies (Art. 50 Law 24/11/2003, Law 24/11/2003)
- pharmaceutical prescriptions – direct (Ministerial Decree 31/7/2007 and subsequent modifications)
- emergency services (“sistema 118”, Ministerial Decree 17/12/2008)
- emergency care (“Pronto soccorso”, Ministerial Decree 17/12/2008)
- residential care (Ministerial Decree 17/12/2008)
- home care (Ministerial Decree 17/12/2008)
- sentinel events/malpractice claims (Ministerial Decree 11/12/2009)
- addiction (Ministerial Decree 11/06/2010)
- mental health (Ministerial Decree 15/6/2010)
- Hospice (Ministerial Decree 6/6/2012).

Databases established before 2008, in particular hospital discharges, ambulatory data and prescriptions are consistently reliable throughout the



country and have been regularly used for monitoring and planning purposes (e.g. Ministry of Health, 2012, and OSMED pharmaceutical reports from AIFA<sup>2</sup>). Databases most recently established – from 2008 – are still in progress. The Directorate General of Health Information in the Ministry of Health is responsible for all databases. For specific purposes of analysis and reporting, the Ministry of Health provides access to specific extracts to the following technical support: AGENAS for performance evaluation and health technology assessment, AIFA for regulation and use of medicines, and the National Institute of Health for epidemiologic research.

The common information infrastructure built by the NSIS represents a solid basis on which quality of care information may be provided at all levels. The permanent organisation and incremental nature of the NSIS ensures that additional priority areas are included in the infrastructure of health databases and can even incorporate further components, e.g. those related to primary care and clinical registries.

A core element of the Italian NSIS is the existence of a reliable unique identification number (UID) covering all served population. The UID corresponds to the tax file number assigned to each Italian citizen. Visits, diagnostic tests or pharmaceutical prescriptions are recorded in the relevant database through a National Health Card (*Tessera Sanitaria*, TS) assigned to each individual. Among the National System of Information Databases, the primary database used for the calculation of quality indicators is the National Database of Hospital Discharges (see above). Each subject included in the hospital database holds a UID (pseudonymised from the original TS database) and carefully classified according to the place of residency (council, province, and region) for reimbursement purposes. The error rate for the residency is quantified in the order of 40 per 100 000 cases (Rapporto Annuale sui Ricoveri Ospedalieri 2011, 2012).

A database directly related to the UID, equally maintained by the Ministry of Finance, is the “Tax Master Database” (*Anagrafe Tributaria*) which allows tracking the vital status of an individual for specific projects approved for data linkage (for example, mortality after discharge in the PNE). Mortality data are also mandated by law through the registration of death certificates, whose templates are provided by ISTAT and duly compiled by registered clinicians. Following the rules set by the Italian Police (*Regolamento di Polizia Mortuaria*), the certificate must be sent by the local council to the ISTAT and the citizen’s ASL.

It can be however stated that the quality of these certificates has been frequently questioned. To improve data quality, several regions have organised “mortality registers” that are used to check data quality and allow extensive usage of death certificates for health and social analysis. There are



considerable challenges to maintain such registers, given the sensitive nature of the data and the efforts required to maintain high quality standards. According to the National Institute of Health, only five regions collect reliable individual mortality data: Veneto, Emilia Romagna, Toscana, Liguria and Umbria ([www.epicentro.iss.it/problemi/mortalita/datiLocali.asp](http://www.epicentro.iss.it/problemi/mortalita/datiLocali.asp)).

Despite the establishment of the New Italian Health Information Infrastructure, several main challenges remain. At present, the Ministry of Health can identify and track a patient across time only for hospital discharges, although a plan is underway to connect all databases (Legislative Decree No. 96, 6 July 2012). Further, few regions are able to link datasets in order to track all health services for a specific patient across the entire lifetime, while mortality data cannot be routinely captured, limiting the scope for monitoring and improving quality of care. A high degree of integration between datasets and a greater interoperability between the different sectors of the public administration is needed to get a comprehensive picture of quality of care.

### ***The number of disease registers is important in Italy***

Disease registers in Italy are extremely important for a range of evidence-based, standardised clinical outcome measurements that can be obtained through direct collaboration with physicians. Disease registers are not, however, regarded as a formal component of the national information infrastructure and are not included in administrative data. Disease registers are mostly based on the activities of scientific associations and their coverage is highly fragmented across the country given the voluntary basis of the participation.

While national privacy legislation is still not clear on the organisation of national disease registers in Italy, several regional registers are covered by regional legislation and thus are allowed to operate through special arrangements. This has resulted in limited comparability of sub-national disease registries and a lack of common terms of reference for national benchmarking.

A relevant case is the network of cancer registers co-ordinated by the *Associazione Italiana Registri Tumori* (AIRTUM, [www.registri-tumori.it/cms/en](http://www.registri-tumori.it/cms/en)). In Italy, there are 34 cancer registries covering altogether a quarter of the Italian population. The information collected includes the type of tumour diagnosed, the name, address, age and sex of the patient, the clinical circumstances in which the cancer was found, the current treatment and treatment history, and the development of the disease. Although relevant, cancer registers today are far from covering the national population: they gather data about the tumours of all residents of a single

city, an entire region or province, or an ASL. They can be population-based, or specialised registries, i.e. gathering information on a single type of tumour (for example, tumours of the colon, the rectum and breasts), or for specific age groups (children aged 0 to 14, and adolescents aged 15 to 19).

Immunisation registers have been also described as a “patchwork of computerisation” (Alfonsi et al., 2012). In 2012, a total of 15 regions showed to be fully computerised, of which only four were able to obtain data in real time from ASL. Immunisations are covered for the whole country, as they are part of the *Griglia LEA*. Computerised data collection is at an advanced state of implementation through national co-ordination. In Italy, all R&AP send to the ministry data on immunisation coverage in children to allow national immunisation monitoring.

The case of clinical registers held by scientific associations is also particularly relevant, as many initiatives deliver regular performance and benchmarking reports whose results are extensively published in the scientific literature and frequently reported by the media. In most cases, scientific associations rely on the active collaboration of professionals association to collect clinical data. Under specific terms regulated by the privacy authority, clinical information included in professional registers is linked to administrative data and other sources of information, in collaboration with ASLs and the regions. Relevant cases worth to be highlighted includes general practitioners (SIMG Health Search), hospital cardiologists (ANMCO), and diabetes clinics (AMD, SID) (see Box 1.3).

### ***How Italy can fruitfully expand its current health information infrastructure? Improving primary and community care data***

As previously set out, Italy has a large number of databases on quality of care, and a very strong foundation of administrative data and clinical registers, supported by a unique patient identifier. The current development towards implementing the New Italian Health Information Infrastructure (NSIS) would allow monitoring and oversight of all levels of care within the Italian health care system. To this end, Italy must expand the information infrastructure by collecting more quality indicators around processes and outcomes at the primary and community care level.

Some of possible indicators that could be collected to improve available information on primary and community care at both national and regional level are around management of chronic diseases or care co-ordination between hospitals and primary care providers. Italy should consider incorporating more primary and community care indicators, as well as clinical registries in its NSIS, to establish a more comprehensive picture of quality care and patient pathways. This would give scope for closer analysis

for policy making, and would enable health care providers to better assess performance in delivering primary care. Furthermore, it should be stressed that the e-Government Plan 2012 which aims, among other things, to develop electronic health record (EHR) is an important initiative to keep in place. The exchange of electronic patient data is not well established in Italy. To improve the quality and safety of care, as well as to facilitate optimal care pathways and promote efficiency in the use of health system resources, better use of electronic health records seems like a key step.

### Box 1.3. Example of professional associations collecting clinical information

In the field of **general medicine**, the *Società Italiana di Medicina Generale* (described in Chapter 2) releases regular reports to the public since 1998. The report processes data collected through the commercial software “Millewin” for clinicians interested in research and voluntarily adhering to the installation of a “Health Search” module. The network includes approximately 900 general practitioners and covers around 1.1 million individuals, a representative sample of Italian population, although imbalanced in terms of geographical coverage (higher presence of Centre-North regions). The range of diseases covered by the data collection and the many aspects related to the services provided (in particular, pharmaceutical prescriptions) is extremely relevant for public health, allowing the network to appear regularly in the scientific literature and undertake international collaborations.

In the area of **cardiology**, the Italian Association of Hospital Cardiologists (ANMCO) co-ordinates large multicentre trials as well as a number of clinical registries among a network of 385 hospitals equipped with intensive care units. A number of registries, in particular that on heart failure, represent a leading source of quality of acute care in cardiology at the European level, as witnessed by the leading role in the Euroobservational Project of the European Society of Cardiology. The reports delivered by the association are mainly intended for research purposes, with less regular quality reporting. The information collected is of extremely high quality. Along the years, the activity has shown to be directly associated to significant outcomes improvement for those affected by cardiovascular events.

In **diabetes care**, the *Associazione Medici Diabetologi* (AMD) collects and regularly publishes reports on quality and outcomes in diabetes since 2006 ([www.infodiabetes.it/pages/annali\\_amd/](http://www.infodiabetes.it/pages/annali_amd/)). In 2012, the “Annals” included data for 320 centres, covering over 550 000 subjects with diabetes. The limitation of the model lies in the representativeness of data provided by specialists only. A multiregional observatory is organised by the *Società Italiana di Diabetologia* (SID) in collaboration with the large technology provider CINECA. The ARNO database includes automated data linkage between diabetes clinics and administrative data (master index, hospital discharges) for eight Italian regions (Abruzzo, Campania, Lazio, Liguria, Puglia, Toscana, Trentino-Alto Adige and Veneto), covering over 9 million inhabitants and a total of over 500 000 subjects with diabetes ([www.siditalia.it/pubblicazioni/784-16042012-rapporto-arno-2011/download.html](http://www.siditalia.it/pubblicazioni/784-16042012-rapporto-arno-2011/download.html)).

### ***How Italy can capitalise on its current health information infrastructure? Increasing data accessibility***

There are rich sources of health system information available in Italy which are not being fully exploited. Going forward, Italy should consider removing some of the barriers to the practical usage of available information, especially to the sharing and exploitation of data across and between regions. Primarily, the challenge will be to establish routine or standardised procedures for accessing data, as well as guidance from the central level to ease data linkage from regional to national level.

Currently, regions have legislation that authorises them to develop disease registries from health care data without consent and to use the data for research purposes. Further, from 2011 the Privacy Guarantor (the data protection authority) gave a general authorisation to enable regions to process identifiable and sensitive health data for research purposes, but some regions do not have the technical capacity to fully exploit available data. Beyond this, it is noteworthy that it is difficult to engage in research with regional data because of a lack of adequate mechanisms to share data across R&AP. Procedures to obtain approval for linkage data across regions are not standardised and criteria used to evaluate proposals are not transparent (OECD, 2013b).

To increase data accessibility, and to fully capitalise on existing rich data sources, there would be great benefit to having clear guidelines issued by (central) public authorities on the process by which approval must be sought for health research projects. Best practice examples for the processing of personal health information including data linkage should also be shared between regions. One avenue for consideration would be to set-up an office at national level or to mandate AGENAS to fulfil this role. This is currently the case with the National Outcomes Project linking hospital and death records, where AGENAS plays a critical co-ordination role. Underpinning these developments would be greater standardisation of the approval process for linking and analysing health data across regions. A standardised approach would facilitate better data, and better data linkage nationwide, allowing the SSN to read information in a standardised manner although respectful of the decentralised nature of the system. Some innovative approaches to capitalise upon and linking data nation-wide have already been started, such as the Matrice project (co-ordinated by AGENAS in collaboration with the Ministry of Health, the R&AP and ASLs) whose overarching aim is to link administrative data, in order to follow the quality of care provided to chronic and complex patients. The project shows that the promise of richer data exploitation is there, and now needs to be further expanded.

## 1.6. Health system clinical guidelines

Initiatives around standard setting and guideline distribution in the Italian health care system are undertaken at both national and regional levels. Although a national attempt has been undertaken to co-ordinate and harmonise regional activities around clinical standards and guidelines, there are still significant regional variations in clinical guidelines activities. There is a need for a stronger oversight role from the central level.

At national level, clinical guidelines have been well developed since the *Piano Sanitario Nazionale* for 1998-2000, which established the National Programme on Clinical Guidelines (the *Piano Nazionale Linee Guida*, PNLG). The overarching aim of the national programme is to ensure that health practice at all levels of the Italian sector (macro, meso and micro levels) follows the principles of evidence-based medicine to guarantee appropriate and effective provision of health services. Medical treatment should be provided at the same high standard nationwide, thereby reducing the variation in health practice and in the quality of treatment. As part of the programme, the National Programme for the Elaboration, Dissemination and Evaluation of Clinical Guidelines, was established to design and disseminate clinical guidelines around the treatment of back pain, pregnancy, hypertension, cervical cancer, breast cancer and angina pectoris.

In 2004, a National Working Group within the Ministry of Health, AGENAS and the ISS composed of experts from scientific societies was established to promote the National Programme on Clinical Guidelines. Later, the agreement signed in 2006 between the Health Ministry's General Directorate of Health Programming and the ISS resulted in the setting-up of the National Guidelines System (*Sistema Nazionale per le Linee Guida*, SNLG). The SNLG, co-ordinated by the ISS, aims at creating diagnostic and therapeutic paths, as well as developing evidence-based documents including clinical practice guidelines. The SNLG monitors regional and local health governance variability in the implementation of recommendations and also intends to assess the potential causes of such variability to improve quality of care and monitor undesirable outcomes.

The principal objectives of the SNLG programme are:

- to improve appropriateness of care and to promote a conscious, responsible, efficient and appropriate use of available resources
- to improve health care quality
- to improve education and training of health care professionals.

As part of its scientific activity, the SNLG develops guidelines, quick reviews, orientation and consensus documents. Existing guidelines developed from other institutions or expert groups are also adapted and updated. The SNLG intends to make clinical practice guidelines easily accessible and also to evaluate their impact around both results and organisation of the practice. To this end, a guideline database has been established in 2006 to give health professionals a rapid access to all guidelines produced in Italy. The database collects Italian clinical guidelines produced by the SNLG, scientific societies, hospitals, local health units and groups of experts. Each guideline in the dataset has been evaluated in terms of methodological aspects, content of recommendations and their implications.

While the SNLG is an important national programme, in the context of the devolved Italian health care system, the implementation of clinical guidelines is the responsibility of each of the 21 Italian regions. Implementation is not made mandatory for health professionals and there is no incentive to stimulate or enforce compliance. The guidelines programme developed in Sweden could therefore be used as a role model for Italy (see Box 1.4). Italy needs to establish a stronger oversight role of the central level to ensure greater standards of quality across regions through enforcing compliance with clinical guidelines. The setting-up of financial incentives or sanctions, as well as establishing a greater inspection role of governmental agencies (such as AGENAS) to monitor the compliance with guidelines are possible avenues for consideration.

#### **Box 1.4. The guideline programme in Sweden**

The Swedish Government provides grants intended, among other things, to stimulate implementation of guidelines and encourage broader quality development in the particular clinical area addressed. New guidelines on dementia and schizophrenia, for example, were accompanied by such grants, disbursed to local government who were then free to use the additional funds as they best saw fit.

The National Board of Health and Welfare conducts regular evaluations of compliance with the national guidelines, repeated after around three to four years and focused on those aspects of care deemed to have major need for improvement. The results of these evaluations are presented in the form of recommendations to regions, hospitals and municipalities, and the goal is that the recommendations form the basis for local initiatives to improve the quality of care.

*Source:* OECD (2013), *OECD Reviews of Health Care Quality: Sweden 2013: Raising Standards*, OECD Publishing, Paris, <http://dx.doi.org/10.1787/9789264204799-en>.

## 1.7. Improving patient choice and patient voice

Overall, the legislative basis to assure and strengthen the position of the patient in the Italian health care system is already in place, but on the ground mechanisms to measure user satisfaction and patient experience are limited to a few surveys. At the same time, public reporting around performance measurement is increasingly being developed in Italy, but the potential for patients to make use of quality data and to be involved in quality assurance appears to be still rather scarce, notably in the areas of primary and community care.

### *Make the voice of patients a practical reality as well as a legal guarantee*

The health care legislation of 1992 (Legislative Decree No. 592/92) established the principle of continuous adaptation of the facilities and services to meet the growing needs of citizens. To this end, regions are assigned the task of providing methods for patient involvement (through patient organisations) in activities related to health planning, monitoring and evaluation of services at regional, organisation or district level. The importance of an assessment of the quality of health service by users was confirmed by the Presidential Decree of the Councils of Ministers of May 1995 (Service Charter), by the 2003 and 2006 National Health Plans, and by the national regulations on accreditation (Decree of the Council of Ministers of January 1994 (principles on health services delivery).

Patient experience is measured using a number of surveys, and indicators in broader health surveys. ISTAT has developed the “Health Conditions and Utilisation of Health Services” survey, which includes some indicators around patient satisfaction. At the same time, an online survey of user satisfaction has been established within the SSN (Ministry of Health, 2011a). This initiative has been launched by the Department of Public Administration to gauge customer satisfaction with the quality of public services. In the health sector, the online survey is a key quality of care tool that can be used to analyse patients’ perceptions of health providers, health facilities and service quality in order to identify strengths and weakness of the health care services. The online survey investigates patients’ experiences with both online and over-the-counter health service delivery. In 2011, more than 20 000 citizens logged their own assessment on the health service they received. Among them, 12.2% of users reported dissatisfaction with reference to the counter service (mostly due to waiting times, lack of professionalism and the need to return for a follow-up service). With regard to services provided on-line, 4.4% of users reported dissatisfaction, because of the difficulties with access, a lack of clarity of instructions, and a failure to update information.



Whilst these instruments are good starting points to measure health system user satisfaction, initiatives could go further in conducting more systematic patient survey to take into consideration users' experiences, the results of which should be used to develop health services for the benefit of patients. Initiatives to measure patient satisfaction could go further by setting up an annual nationwide survey to investigate the experiences of inpatients and outpatients in Italian hospitals, as well as in other levels of care including primary, community and long term care.

### ***Increasing public reporting on performance***

There is already a relatively wide range of public health system performance reporting in Italy, which should be commended, even while areas for improvement remain. Publically reported quality of care indicators, officially released at national level (particularly those published by the Ministry of Health) are always widely communicated, usually through the organisation of formal events held at the ministry on the date of release. The main findings and trends emerging from the reports are summarised by the media to the public. At the same time, all information on health databases and indicators are published on the official website of the Ministry of Health ([www.salute.gov.it](http://www.salute.gov.it)).

The results of the National Outcomes Programme (PNE) are communicated back to providers in each region through a series of targeted events and regional workshops organised throughout the country. On these occasions, an assessment of the results is shared with all relevant stakeholders, in an attempt to contribute to a continuous cycle of quality improvement. Preliminary results show that the programme run in Italian regions effectively improves some health outcomes (Pinnarelli et al., 2011). The PNE also publishes annual results from a wide range of quality and outcomes indicators by hospital/ASL/province, made directly available to policy makers and health professionals on a dedicated website (accessible through users credentials). The PNE portal allows sophisticated comparisons of quality of care indicators and is highly customizable, making the selection of specific parameters possible for benchmarking. The system is, however, only accessible to registered users through reserved credentials. The results of the PNE have been variously reported by the media, in terms of comparison of hospital performance within and between the regions. Providing feedback through the media using league tables constitutes a key instrument having potential impact on quality of care.

In Italy, there are also other different sources of information on quality of care that are publicly available. The Italian Ministry of Health releases the "*Rapporto Nazionale SDO*" (Hospital Discharges Report) each year, a detailed descriptive analysis of the distribution of discharges by major



diseases and by R&AP (*Rapporto Annuale sui Ricoveri Ospedalieri* 2011, 2012). Other relevant national reports published each year by academic departments include the *Osservasalute* by Università Cattolica del Sacro Cuore (De Belvis et al, 2011), and the *Rapporto Sanità CEIS* by Università Tor Vergata (CEIS, 2012).

Some R&AP have also used different strategies to communicate results on quality of care to providers and the general public. A recent survey conducted by AGENAS in collaboration with WHO Europe for the Interim Report on the Tallinn Charter shows that the picture is extremely diverse (Carinci et al., 2012). Different regional approaches can be mapped out. Four regions (Emilia Romagna, Lombardia, Toscana and Umbria) are using performance measurement and associated evidence to negotiate targets with high management levels. In three regions (Basilicata, Veneto and Liguria), evidence is often used to compare model of care in order to highlight the most efficient one. In three other R&AP (Friuli, Marche and Trento), performance measurement is compared against targets in order to implement actions for optimising the provision of care and improving its quality. At the same time, reports on acute care are the only ones available to the public, and this is through formats which are generally difficult to browse electronically, and with scarce methodological explanations (Carinci et al., 2012). Only three regions (Emilia Romagna, Umbria, Toscana) publish performance reports on a regular basis, with a multidimensional approach clearly documented. A group of six regions (Abruzzo, Basilicata, Calabria, Campania, Molise, Sicilia) produces reports of hospital activity and health status on a non-regular basis. Two regions (Marche, Piemonte) have no systematic reporting and produce statistical documents for specific priorities, mainly as a by-product of epidemiological research.

Beyond the acute care level, it is noteworthy that data on individual long term care centres, specialists or general practitioners is not made publicly available in Italy. Clinical registries publish results only in aggregate or anonymised format to preserve the professional integrity of the provider, and as noted earlier, there are some concerns with regard to the reliability of data from clinical registries.

Some websites at the regional level allow for flexible navigation but overall, the online availability of quality indicators is still very limited. The online publication of quality information is directly related to the technical capacity available locally and the existence of strong teams in charge of health information. According to the AGENAS Tallinn Survey (Carinci et al., 2012), the degree of public information made available by Italian R&AP is generally linked to the presence of a regional health agency (RHA). Originally established to support regional health planning, RHAs for many years represented the primary source of health intelligence and

innovation in the health sector. The scenario is currently evolving with the rationalisation of resources and the different political trends coexisting across the country.

Building upon the increasing interest for performance evaluation at all governmental levels, the Italian Ministry of Health and AGENAS have strengthened their activities in this field with the creation of a national framework for performance evaluation (Di Stanislao et al., 2012). The Conference of the State and the Regions (January 2013) recognised the importance of public disclosure, which has led to the development of a “Portal for the Transparency of Health Services” (Conferenza Stato Regioni, 2013).

Overall, public reporting of performance information is underway but needs further support over the coming years to encourage citizen and patient involvement, and to make sure that information reported across all regions is equivalent and sufficient. Addressing some of the existing data access issues might be helpful in increasing transparency on performance in the Italian health care system. Public disclosure of quality performance needs thereby to be more extensively used and extended beyond acute care, notably to primary, community, and long term care, to encourage health care providers to improve quality system-wide and to make sure the users have access to consistent information to facilitate informed decision making.

## **1.8. The patient safety policy**

While the patient safety policy agenda in Italy is relatively recent and is regarded internationally as a model to emulate in other countries, more could be done in Italy to strive for still higher standards of safety and quality of care.

In Italy, the patient safety programme was initiated in 2003 by the Ministry of Health followed by the State/Regions Agreement signed in 2008. The agreement entrusted the Ministry of Health to monitor sentinel events and AGENAS to monitor malpractice claims and the good practices for patient safety (Caracci et al., 2010; Labella et al., 2012; Caracci et al., 2013). This has led to the setting-up of the National Observatory on Good Practices for Patient Safety (<http://buonepratiche.agenas.it/default.aspx>). The Italian Observatory on Good Practices for Patient Safety is designed and implemented to be:

- a strategy for continuous improvement of quality and safety of care by promoting transfer of safe practices

- a regional and national web archive of patient safety improvement interventions
- a network of health professionals who share knowledge and experiences
- a tool that facilitates transfer of experience
- a source of information for the citizen.

This patient safety strategy has been designed and implemented on the basis of principles and tools shared among AGENAS, the Ministry of Health, R&AP, Health Organisations and health professionals who are periodically asked to give their feedback. It collects and fosters the implementation of good practices in the Italian health care services.

The methodological approach of the Observatory is based on the theories of knowledge transfer (Argote, 2000), innovation in health care, diffusion of innovation, knowledge network, with particular reference to the "no blame culture" with a view to improving quality and safety. European Directives and Recommendations, such as the 2009 European Council Recommendation on patient safety, together with national guidelines, constitute fundamental references for the activities of the Observatory. A web-platform has been set-up to share and disseminate good practices between health providers, health care facilities and patients in order to exchange experiences. The Ministry of Health supported the Observatory by financing the system start-up.

The method used by the Observatory is based on five key steps:

- sharing the model and the tools developed by AGENAS with the regions and the Ministry of Health
- identification and collection of experiences of quality and safety improvement through the annual call for good practices
- classification of good practices. Once all the documentation sent to the Observatory is examined and the compliance of the experiences with the criteria defined in the call, AGENAS experts divide the practices into the following three categories: good practice; potential good practice; initiative
- dissemination of information through AGENAS website and organisation of inter-regional workshops aimed at disseminating the good practices at local level
- monitoring and promoting the transfer of the experiences. In order to encourage interregional transfer of the good practices, a bottom-

up action is implemented through regional and interregional workshops.

Available evidence shows that the 21 Italian R&AP actively participate to the patient safety programme. Altogether, 1 758 experiences were submitted between 2008 and 2013, with more than 250 health care organisations and 430 health professionals registered in the system for 2010-12. It has been shown to be a source of information for citizen since more than 12 140 people visited the Observatory web page between June 30th 2010 and May 31th 2012. Furthermore citizen information is eased by the development of a field where professionals can write and abstract aimed at communicating with non-professionals to increase trust and transparency.

It is also noteworthy that the methods and instruments of AGENAS' Observatory have contributed to setting up the tools used in the Joint Action PaSQ (European Union Network for Patient Safety and Quality of Care) in order to develop a similar patient safety programme implemented at international level within the project (European Union Network for Patient Safety and Quality of Care). AGENAS is the National Contact Point for the PaSQ project and its database has contributed by more than 100 patient safety practices selected in collaboration with the regions.

The prevention of sentinel events is furthermore a priority setting for the Italian patient safety agenda (Tozzi et al., 2012). Since 2005, the Ministry of Health has issued 16 “recommendations” for health services providers to raise awareness about sentinel events which are publicly available on the ministry website. Because there was neither information regarding implementation of the recommendations nor tools able to identify this information, the Ministry of Health assigned AGENAS a specific mandate upon which it has to develop and test a model composed of:

- a checklist for each recommendation as a support tool for implementation
- a questionnaire for monitoring level of implementation.

The questionnaire, adaptable to all the recommendations, while analysing general aspects, deepens other aspects concerning procedures and problems encountered during implementation. In particular, the questionnaire aims to understand:

- whether implementation of each recommendation is the result of a regional strategy or organisational strategy, or it is the initiatives of individual units

- whether each recommendation is fully implemented or is being implemented
- which organisations have already implemented the recommendations.

Last, it is important to mention that evidence from the EU Commission shows that satisfactory progress has been made in Italy in the development of national policies and programmes on patient safety (European Commission, 2014). The 2009 recommendation related to healthcare-associated infections (HAI) provides that member states should follow case definition agreed at EU level to develop a consistent reporting of HAI. Case definition developed at EU level includes a standardised methodology, a framework and instructions to follow for each of HAI, which is expected to improve surveillance across the European Union. The Commission's Second Report to the Council on the implementation of Council Recommendation 2009/C151/01 shows that Italian participation in the area of HAI surveillance is high in surgical site infections, intensive care units and nursing homes or other long-term care facilities (European Commission, 2014).

With an impressive number of initiatives to monitor, control and support patient safety improvement, Italy has become one of the European leaders in patient safety policies. However, more could be done to strive for even higher safety standards and quality of care. Beyond its co-ordinating role, it would seem desirable to increase AGENAS's mandate toward a robust inspection function and to ensure through on-site inspection for example, that national recommendations for patient safety are implemented. This would enforce implementation of Observatory recommendations and apply sanctions where services are failing to meet required safety standards.

Apart from the valuable Observatory on Good Practices for Patient Safety described above, no other nationwide action programmes on quality improvement have been identified. Most programmes are locally- or regionally-based, which is partly a result from the chosen governance model. National action programmes are less intensive than in other OECD countries such as Denmark (see Box 1.5). Denmark has set national targets, underpinned by focussed, grass-roots campaigns to change practice at ward and clinic level. These campaigns focus on potentially easily avoidable but commonly occurring patient safety issues, such as medication errors, pressure ulcers and catheter or venous-line infections.

### Box 1.5. The Danish Safer Hospital Programme

The past decade has seen a lot of activities related to patient safety, often initiated by the Danish Patient Safety Association. Danish patient safety initiatives started through a national study on adverse events in hospitals in 2001, and are developed and governed through an association in which all main stakeholders in the Danish health care field participate, the Danish Society for Patient Safety.

The Danish Society for Patient Safety (DSFP) was established in December 2001 and is a non-profit organisation. The aim of the Society is to ensure that patient safety aspects are a part of all decisions made in Danish health care. The society initiated various national programmes such as the Danish Safer Hospital programme which is a demonstration project designed to prevent errors, injuries, and deaths, aiming at a 15% reduction in in-patient mortality and a 30% reduction in patient harm. This would be achieved by reducing, for example, the number of cardiac arrests, eliminating hospital infections, reducing pressure ulcers, and preventing medication errors. The programme is built around five work streams (critical care, perioperative care, leadership, medicines management, general ward), each consisting of a number of care bundles, and comprehensive series of evidence-based protocols. The care bundles are designed around recognised and accepted best practices. The programme uses well proven improvement methodologies.

With these policies Denmark has positioned itself as one of the world leaders in patient safety and many of its policies can serve as an example for other countries.

Source: OECD (2013), *OECD Reviews of Health Care Quality: Denmark 2013: Raising Standards*, OECD Publishing, Paris, <http://dx.doi.org/10.1787/9789264191136-en>.

## 1.9. Conclusions

The devolution of further administrative powers to the R&AP in 2001 was achieved with some success, but there was a failure to take the need for national approaches towards quality and safety into account. This has resulted in a plethora of quality initiatives in the regions, with some very well developed approaches towards the systematic measurement and management of quality improvement, while other regions still have rather rudimentary quality models. The challenge for the coming years will be to guide all regions towards the further development of high performing health care system. Most likely, this will entail, a stronger steering and oversight role for central authorities, to ensure uniform standards of quality across regions, backed up by greater strategic attention to health care quality in national policy setting.

Elements of such a renewed approach towards quality should include:

- Strengthening the role of the Ministry of Health or its agencies (such as AGENAS) in monitoring minimum levels of care and in relation to patient safety, across regions. The strongly decentralised health care system should be complemented with robust inspection functions set up at national level.
- Further develop the national efforts toward the harmonisation of accreditation initiatives, and ensure a uniform implementation across the country to guarantee transparency of health services.
- Strengthen the information infrastructure in the Italian health care system. In particular, remove the barriers to the better exploitation of existing information, including working towards data linkage capacity. Set-up clear guidelines on the processes required for approval of data linkage, and disseminate best practice for data linkage.
- Citizens' and patients' involvement in quality assurance of health care can be strengthened through the development of a more systematic and comprehensive patient survey, and the release of more information on performance of health care providers and systems.
- In addition to approaches focused on standards and monitoring, national programmes on quality improvement could be considered, drawing from experiences of OECD countries such as Denmark. National targets in patient safety, underpinned by focussed, grass-roots campaigns to change practice at ward and clinical level are needed.

## Notes

1. Sistema nazionale di Verifica e controllo sull'Assistenza Sanitaria (SiVeAS), [www.salute.gov.it/portale/temi/p2\\_4.jsp?lingua=italiano&area=siveas](http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&area=siveas).
2. [www.agenziafarmaco.gov.it/it/content/osservatorio-sull%E2%80%99impiego-dei-medicinali-osmed](http://www.agenziafarmaco.gov.it/it/content/osservatorio-sull%E2%80%99impiego-dei-medicinali-osmed).



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