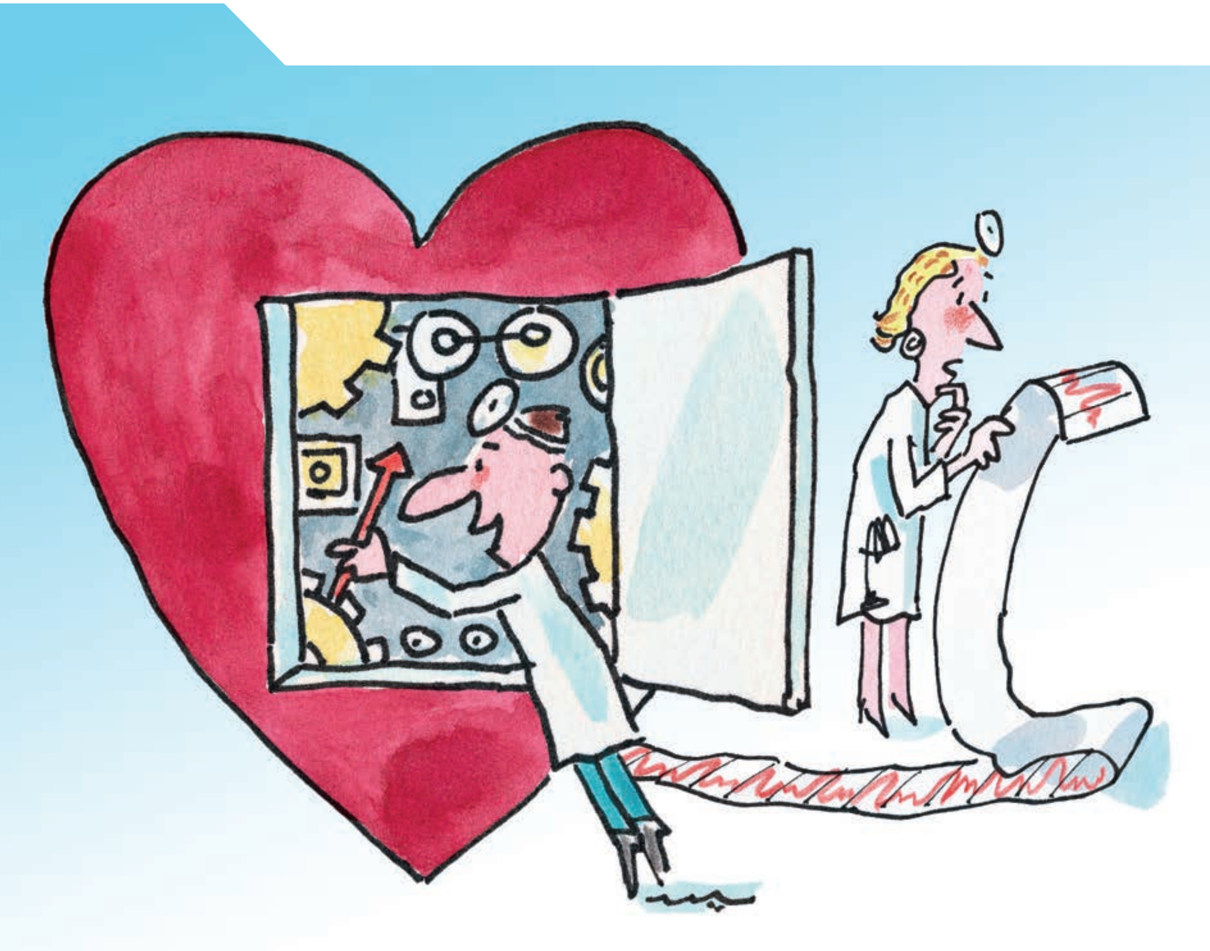
OECD Reviews of Health Care Quality

ITALY

RAISING STANDARDS



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OECD Reviews of Health Care Quality: Italy 2014

RAISING STANDARDS

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Foreword

This report is the seventh of a series of publications reviewing the quality of health care across selected OECD countries. As health costs continue to climb, policy makers increasingly face the challenge of ensuring that substantial spending on health is delivering value for money. At the same time, concerns about patients occasionally receiving poor quality health care have led to demands for greater transparency and accountability. Despite this, there is still considerable uncertainty over which policies work best in delivering health care that is safe, effective and provides a good patient experience, and which quality-improvement strategies can help deliver the best care at the least cost. *OECD Reviews of Health Care Quality* seek to highlight and support the development of better policies to improve quality in health care, to help ensure that the substantial resources devoted to health are being used effectively in supporting people to live healthier lives.

Italy has made significant progress in improving the quality of health care in recent decades. Admission rates for asthma, chronic pulmonary disease and diabetes (markers of the quality of primary care), and case-fatality after stroke or heart attack (markers of the quality of hospital care) are well below OECD averages. Quality monitoring and improvement have taken a back-seat, however, as the economic crisis has hit – even as health needs rapidly evolve. Dementia prevalence, healthy life years and daily activities limitations at age 65, for example, are all worse in Italy than OECD averages and Italian children are amongst the most overweight in the OECD. To address these challenges, Italy must urgently prioritise quality of its health care services alongside economic sustainability. Regional differences must be lessened, in part by giving central authorities a greater role in supporting regional monitoring of local performance. Proactive, co-ordinated care for people with complex needs must be delivered by a strengthened primary care sector. Fundamental to each of these steps will be ensuring that the knowledge and skills of the health care workforce are best matched to needs.

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Acronyms and abbreviations

AGENAS	*Agenzia Nazionale per i Servizi Sanitari Regionali* (National Agency for Regional Health Services)
AIFA	*Agenzia Italiana del Farmaco* (Italian Medicines Agency)
AMI	Acute myocardial infarction
AO	*Azienda Ospedaliera* (Hospital trust)
ASL	*Azienda Sanitaria Locale* (Local Health Authority)
CENSIS	*Centro Studi Investimenti Sociali* (Social Study and Research Institute)
CME	Continuing medical education
COPD	Chronic obstructive pulmonary disease
CPD	Continuing professional development
EudraVigilance	European network for pharmacovigilance
FFS	Fee for service
GP	General practitioner
HAI	Healthcare-associated infections
IHD	Ischemic heart disease
IRCCS	*Istituto di Ricovero e Cura a Carattere Scientifico* (Scientific Institute for Research and Care)
ISS	*Istituto Superiore di Sanità* (Italian National Institute of Health)
LEA	*Livelli essenziali di assistenza* (Essential levels of care)
NHP	National Health Plan
NSIS	*Nuovo Sistema Informativo Sanitario* (New Health Information System)

PCP	Primary care physician
PDTA	*Percorso Diagnostico Terapeutico Assistenziale* (Path Diagnostic Therapeutic Care)
PNE	*Programma Nazionale Esiti* (National Outcomes Programme)
PNLG	*Piano Nazionale Linee Guida* (National Programme on Clinical Guidelines)
PROQUAL	*Programma nazionale per la promozione permanente della qualità nel servizio sanitario* (National Programme for the Permanent Promotion of Quality in the National Health Service)
PTCA	Percutaneous transluminal coronary angioplasty
RNF	*Rete Nazionale di Farmacovigilanza* (National Network of Pharmacovigilance)
R&AP	Regions and autonomous provinces (*Regioni e Province Autonome*)
SDO	*Scheda di Dimissione Ospedaliera* (Hospital Discharge Abstract)
SIMG	*Società Italiana di Medicina Generale* (Italian Society of General Medicine and Primary Care)
SiVeAS	*Sistema nazionale di Verifica e controllo sull'Assistenza Sanitaria* (National System for the Monitoring and Control of Public Health Care)
SNLG	*Sistema Nazionale per le Linee Guida* (National Guidelines System)
SSN	*Servizio Sanitario Nazionale* (Italian National Health Service)
TRAC	*Tavolo di lavoro per lo sviluppo e l'applicazione del sistema di Accreditamento nazionale* (Technical Group for Accreditation)
TS	*Tessera Sanitaria* (National Health Card)
UID	Unique Identification Number

Executive summary

This report reviews the quality of health care in Italy. It begins by providing an overview of policies and practices aimed at supporting quality of care (Chapter 1). The report then focuses on three areas that are of particular importance for Italy's health system at present: the role of primary care (Chapter 2), improving the training of the health care workforce (Chapter 3) and improving systems for monitoring and improving the quality of care in a regionalised health system (Chapter 4). In examining these areas, this report examines the quality of care currently provided, seeks to highlight best practices, and provides a series of targeted assessments and recommendations for further improvements to quality of care.

The Italian *Servizio Sanitario Nazionale* (or National Health Service, SSN) was established in 1978 to grant universal access to a uniform level of care throughout Italy, free at the point of use, financed by general taxation. The Ministry of Health fulfils the function of the overall steward of the health system and defines the *livelli essenziali di assistenza* (or essential level of care, LEA) to be delivered across the country. Beyond this, Italy's 21 regions and autonomous provinces (R&AP) are responsible for the actual planning and delivery of services. Articulation between central government's steering role and regional government's delivery role is expressed in the *Patto per la salute* (Pact for health), a three-year plan that is agreed jointly between central and regional governments.

In recent years, however, many regional health budgets ran into substantial deficit, leading to central authorities to imposing *Piani di Rientro* (Recovery Plans) on ten of them, of which eight are on-going. These plans signalled the introduction of a dominant new player in national health care policy – the Ministry of Finance. Although the Ministry of Health maintained its role in ensuring that essential levels of care were provided at regional level, the Ministry of Finance became actively involved in designing and approving health care delivery. To a large extent, then, the focus of this abrupt resumption of central control was financial and quality of care risked becoming secondary.

Italy is facing, therefore, two major challenges. The first is to ensure that ongoing efforts to contain health system spending do not subsume health care quality as a fundamental governance principle. The second must be to support those R&AP with weaker infrastructure and capacity to deliver care of equal quality to the best performing areas. A more consolidated and ambitious approach to quality monitoring and improvement at a system level is needed. Over the past decade, a range of quality-related activities have been developed, with varying depth and scope, and with little co-ordination across these approaches by central agencies. Different accreditation models have been developed, for example, and performance management tools used by R&AP are diverse, making comparison against national standards difficult and limiting the accountability of providers toward users. These divergent approaches must now be consolidated. At the same time, other key quality strategies are poorly developed or absent. Requirements for recertification and for professional development are not established and payment systems do not systematically reward improvements in clinical care and patient outcomes. These deficiencies must be addressed to ensure that Italian health care quality architecture is comparable to the best seen in OECD health systems.

Primary health care in Italy performs well – rates of avoidable hospitalisation are amongst the lowest in the OECD. Italy faces, however, a growing ageing population and a rising burden of chronic conditions, which are likely to result in higher health care costs and place further pressures on the primary care sector. Whilst the management of chronic conditions requires a co-ordinated patient-centered response from a wide range of health professionals, the Italian health care system has traditionally been characterised by a high level of fragmentation and a lack of care co-ordination. Italy has made considerable efforts to experiment with new models of community care services (such as community care networks and community hospitals) that aim at achieving greater co-ordination and integration of care. Although the expansion of community care services is an appropriate policy response to meet the growing demand for health care, they are still unevenly distributed across Italian regions. Greater guidance and support from national authorities is needed to ensure a more consistent approach. At the same time, there are other shortcomings in Italy’s primary care sector that require attention to guarantee high quality primary care. Efforts are needed to increase transparency, develop performance measurement and strengthen accountability in the sector. The development of a set of standards around the processes and outcomes of primary care, the setting-up of smarter payment system, and increase the involvement of primary care physicians in preventive activities are options that Italy should consider pursuing if it is to meet the challenge of an increasing burden of long-term conditions.

The ***medical workforce*** delivers, in general, care of a high quality. Looking to secure this high performance for the decades to come, and push back against any regional disparities in quality and outcomes, Italy has also been taking important steps towards ensuring nationally cohesive workforce training programmes. However, going forward, good medical education and nationally standardised continuing medical education may not be enough to secure a high quality, high performing medical workforce. There is scope to look to the scientific literature, and the experiences of other OECD countries, to try to maximise the impact of medical education, from the undergraduate level and beyond. This chapter suggests ways that Italy could promote workforce quality when selecting future medical professionals prior to undergraduate education, and ways to improve the quality of undergraduate medical teaching. There are also opportunities to maximise the positive impact of Italy's existing continuing medical education programme, as well as a need for Italy to eventually develop more modern models of workforce quality insurance, including a move to continuing professional development, and using data to encourage health professionals to reflect on their practice.

Italy's ***regions and autonomous provinces*** (R&AP) differ substantially. GDP per capita varies more than two-fold and unemployment rates more than four-fold. Italian health care services, being fully regionalised, reflect this heterogeneity. Whilst it cannot be said that any one region delivers consistently "poor" health care, it is clear that some regions struggle to provide the same quality as others. Large numbers of patients move between regions in search of health care, with northern R&AP being net importers. Italy has established a number of mechanisms to try and ensure an evenness of approach to quality measurement and improvement. These include activities to ensure dialogue between national and regional authorities as well as professionally led initiatives to measure quality consistently. While it would be unrealistic and undesirable to seek complete homogeneity in how regional health systems are configured, more can be done to achieve a more even approach to quality measurement and improvement across R&AP.

Key priorities are to develop a more consistent approach to using information to manage performance and strengthen local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important. Actions that strengthen the regional approach to health care governance and delivery in Italy are also needed. Developing the responsibilities and capacities of the national authorities whose role is to support the R&AP should continue. Reframing governance as a whole, such that quality improvement is emphasised as much as financial control, is also necessary.

Assessment and recommendations

Italy's indicators of health system outcomes, quality and efficiency are uniformly impressive. Life expectancy, at 82.3 years, is the fifth highest in the OECD. Admission rates for asthma, chronic pulmonary disease and diabetes (markers of the quality of primary care) are amongst the very best in the OECD, and case-fatality after stroke or heart attack (markers of the quality of hospital care) are also well below OECD averages. Good health care is achieved at low cost – at USD 3 027 per capita, Italy spends much less than neighbouring countries such as Austria (USD 4 593), France (USD 4 121) or Germany (USD 4 650). These remarkable figures, however, mask profound regional differences. Five times as many children in Sicilia are admitted to hospital with an asthma attack than in Toscana, for example. Despite this, quality improvement and service redesign have taken a back-seat as the economic crisis has hit. Financial consolidation has become an over-riding priority, even as health needs rapidly evolve. Dementia prevalence, healthy life years and daily activities limitations at age 65, for example, are all worse in Italy than OECD averages and Italian children are amongst the most overweight in the OECD. To address these challenges, Italy must urgently prioritise quality of its health care services alongside economic sustainability. Regional differences must be lessened, in part by giving central authorities a greater role in supporting regional monitoring of local performance. Proactive, co-ordinated care for people with complex needs must be delivered by a strengthened primary care sector. Fundamental to each of these steps will be ensuring that the knowledge and skills of the health care workforce are best matched to needs.

The Italian *Servizio Sanitario Nazionale* (or National Health Service, SSN) was established in 1978 to grant universal access to a uniform level of care throughout Italy, free at the point of use, financed by general taxation. The Ministry of Health fulfils the function of the overall steward of the health system and defines the *livelli essenziali di assistenza* (or essential level of care, LEA) to be delivered across the country. Beyond this, Italy's 21 regions and autonomous provinces (R&AP) are responsible for the actual planning and delivery of services. The R&AP have considerable legislative, executive and evaluation functions to enable them to fulfil this role. An important partner is the network of Local Health Authorities (*Azienda Sanitaria Locale* – ASL) and hospital trusts (*Azienda Ospedaliera* – AO) within each R&AP, to whom executive functions are largely delegated. The ASL provide primary care, secondary care, public health, occupational health and health care related to social care at local level, with the R&AP providing technical support and performance management. Articulation between central government's steering role and regional government's delivery role is expressed in the *Patto per la salute* (Pact for health), a three-year plan that is agreed jointly between central and regional governments.

The most significant reforms of recent years concern the governance of the health system. Constitutional reforms in 2001 granted substantial legislative powers to the R&AP with regards to the organisation and delivery of health care. The Constitutional reforms led to the creation of 21 distinct health systems, but it is widely acknowledged that the necessary information infrastructure and technical capacity to adequately discharge these new responsibilities was lacking. Many regional health budgets quickly ran into deficit, requiring central authorities to impose *Piani di Rientro* (Recovery Plans) on eight of them. These plans signalled the introduction of a dominant new player in national health care policy – the Ministry of Finance. Although the Ministry of Health maintained its role in ensuring that essential levels of care were provided at regional level, the Ministry of Finance became actively involved in designing and approving health care delivery. To a large extent, then, the focus of this abrupt resumption of central control was financial and quality of care risked becoming secondary.

Italy is facing, therefore, two major challenges. The first is to ensure that ongoing efforts to contain health system spending do not subsume health care quality as a fundamental governance principle. The second must be to support those R&AP with weaker infrastructure and reduced capacity to deliver care of equal quality to the best performing areas. A more consolidated and ambitious approach to quality monitoring and improvement at a system level is needed. Over the past decade, a range of quality-related activities have been developed, with varying depth and scope, and with little co-ordination across these approaches by central agencies. Different accreditation models have been developed, for example, and performance management tools used by R&AP are diverse, making comparison against national standards difficult and limiting the accountability of providers toward users. These divergent approaches must now be consolidated. At the same time, other key quality strategies are poorly developed or absent. Requirements for recertification and for professional development are not established and payment systems do not systematically reward improvements in clinical care and patient outcomes.

These deficiencies must be addressed to ensure that Italian health care quality architecture is comparable to the best seen in OECD health systems.

A number of other challenges remain to improve the quality of care in Italy:

- The information infrastructure in Italy is insufficiently exploited due to weak data linkage capacity and limited use of electronic health records. In particular, the current depth and breadth of indicators around primary and community care is insufficient to build a comprehensive picture of the effectiveness, safety and patient-centeredness of care in this sector.
- Despite a rapidly emerging burden of chronic disease, Italy is making rather slow progress toward a health system model where chronic disease management and prevention are at the forefront. Italy spends less than one-tenth of what the Netherlands and Germany spend on preventive care, for example.
- The medical profession continues to rely on one-time certification and relatively undemanding systems of continuing medical education compared to other OECD countries. Insufficient policy attention has been given to mechanisms that promote workforce quality, such as re-certification or peer-to-peer reviews as part of continuing professional development.
- There is a lack of quality-related information oriented toward patients. In general, dissemination of information on the performance of health care providers remains underexploited as a potential driver of continuous quality improvement.

Italy's priority must be to move from a system that prioritises budgetary control, to one that gives an equal priority to quality. Informational and financial incentives must be aligned to the outcomes and quality of care, which will require enriching the information infrastructure. Limited data linkage and reluctance to publish some data (such as patient safety metrics) limit the capacity of R&AP and hospitals to learn and improve. In parallel, a more consistent approach to quality monitoring and improvement across the country is needed. A greater role for central agencies such as the *Agenzia Nazionale per i Servizi Sanitari Regionali* (AGENAS, National Agency for Regional Health Services) may be needed to lead this work, not to performance manage R&AP but to support them to performance manage the hospitals, clinics and professionals in their territory more effectively. At service level, it is clear that primary care needs to step-up to fill a bigger role, particularly with regards to the management of chronic disease. The lack of standards and effective use of guidelines in primary care should be addressed, and a wider range of quality indicators used to incentivise better care. Optimising the skills and knowledge of Italy's health care workforce will be central to all of the foregoing priorities. Introducing more ambitious forms of continuing professional development and assurance of workforce quality, such as peer-to-peer appraisal, will place Italy in a good position to ensure that good health care at low cost continues to be delivered.

The rest of this chapter makes a more detailed assessment and set of recommendations for the Italian health care system. It starts with an overview of the strengths and opportunities for improvements in Italy's health care quality architecture. It then considers three topics in detail: primary and community care, workforce competencies and continuing medical education, and measuring and improving the quality of care in a regionalised health care system.

Strengthening Italy's quality governance model

Although a number of national quality monitoring and improvement frameworks exist in Italy, they are not consistently applied across the R&AP. Further efforts are needed to embed a coherent approach to quality governance across the Italian health system, and to push back against any regional disparities in performance management. This will likely entail a stronger central role. At the same time, deficiencies and gaps in national approaches need to be addressed. In particular weaknesses around the information infrastructure, public reporting tied to patient empowerment, and patient safety should be addressed.

National initiatives to improve health care quality are not consistently applied at regional level

Although recent policy debates have focused predominantly on reducing the health sector financial deficit, a number of initiatives at national level have sought to ensure that effective, safe and patient-centered health care remains a priority. Together, the *Patto per la Salute*, the *livelli essenziali di assistenza,* the *Sistema nazionale di Verifica e controllo sull'Assistenza Sanitaria* (SiVeAS) and, more recently, the *Programma nazionale per la promozione permanente della qualità nel servizio sanitario nazionale* (PROQUAL) constitute the legal framework through which high quality of care in Italy should be maintained. In addition, the *Agenzia Italiana del Farmaco* (AIFA) authorises and monitors the safe use of pharmaceuticals and medical devices throughout the country.

Despite the existence of these national agencies and frameworks, specific quality monitoring and improvement activities are not implemented in a consistent way. While accreditation for health care facilities is mandatory, for example, there are 21 different accreditation models with varying minimum standards across the country. Some R&AP have established well-developed accreditation programmes based on recognised international standards, while other regions have more rudimentary systems. This issue calls for a stronger steering and oversight role from the national authorities, to ensure a standard, equitable approach, but also to promote learning and disseminate regional experiences in developing and tailoring accreditation pathways. Steps in this direction are, encouragingly, underway: the recent agreement on new rules for accreditation has led to the identification, by a commission composed of representatives of the Ministry of Health, AGENAS and regions, of quality standards to be uniformly implemented within regional accreditation systems and achieve a more uniform approach.

Nevertheless, challenges remain. Many OECD health systems have developed an inspectorate function which can provide independent verification that accreditation standards are being met, identify centres of excellence and support weaker centres to improve their standards. This function, at present, does not exist in Italy and the authorities should consider developing it. At the same time, Italy might consider extending the focus of accreditation to other sectors beyond hospitals, including for example primary and community care. An increasing number of OECD health systems are pursuing this path, and the experience of countries such as Australia or the United Kingdom could inform Italy in this field.

Italy's approach to the use of clinical guidelines is another example of where good policy intentions are not backed up by adequate mechanisms to ensure implementation. Guidelines are developed by both central and regional authorities, including professional and scientific societies. Implementation, however, is the responsibility of the R&AP. Despite the creation in 2004 of the *Sistema Nazionale per le Linee Guida* (National Guidelines System) to make clinical practice guidelines easily accessible, there are no systematic incentives to stimulate guideline uptake, and no consistent framework to monitor their implementation at service-level. One model to emulate may be from Sweden, where central government provides grants to regional governments to encourage guideline implementation. New guidelines on dementia, for example, were accompanied by grants to be disbursed to local government. Regions were then free to use the additional funds as they saw fit. This approach maintains regional autonomy and responsibility for effective implementation, whilst drawing in national resources and support.

Italy should better exploit its information infrastructure

Italy has a large number of rich national and regional databases that contain information on the quality and outcomes of health care. The *Griglia LEA* is used by the Ministry of Health to monitor local access to the *livelli essenziali di assistenza.* The *Griglia LEA* is applied uniformly across the country and contains quality-related outcomes such as the rates of hip fracture surgery within 48 hours and case-fatality rates following acute myocardial infarction. Although this is a strong basis for a nationally consistent approach to performance monitoring, the utility and impact of the *Griglia LEA* is limited by the fact that it only contains 31 indicators. The *Programma Nazionale Esiti* (PNE – National Outcomes Programme) is a more ambitious framework. Designed by clinicians and co-ordinated by AGENAS, the *Programma Nazionale Esiti* covers nearly 129 indicators, including both process and clinical outcome measures, disaggregated to municipal and hospital level. Beyond these national frameworks, a range of health databases exist at regional and local level. In addition, there are numerous patient registers, most of which are operated by professional and scientific societies. In general, these patient registers are highly fragmented, with uneven coverage and linkage across the country. Patient registers are not considered a formal component of the national information infrastructure.

In an effort to make best use of this data, the *Nuovo Sistema Informativo Sanitario (*NSIS – New Health Information System) was established in 2001. A key aim of the NSIS has been to standardise the type and format of health data collected across Italy's regional health systems. Creation of the NSIS was an important step, but the full potential of data within the health system remains unexploited because of persisting difficulties in linking data on individual patients from different databases. Without linkage, building a multidimensional picture of the quality and outcomes of care across a patient pathway is impossible. Yet despite the existence of a unique patient identifier, the NSIS still has a very incomplete picture of patients' care outside the hospital setting.

Most of the difficulties in linking data arise at regional level. At present, only R&AP and ASL are allowed to link databases, but some of them do not have the technical capacity to undertake such data linkage. Further, procedures to obtain approval for linkage are not standardised and criteria used to evaluate proposals not transparent. Both facts reduce the scope for monitoring quality improvement and for conducting health research.

Standardisation of the approval process needed to link and analyse health data, and diffusion of best practices in the processing of personal health information are needed. In addition, support for weaker R&AP in developing technical capacities around data linkage will be necessary if Italy is to better exploit the health data that currently exist. At the same time, Italy needs a richer information infrastructure to paint a fuller picture of quality and outcomes, particularly in primary care. At present, most performance measurement tools focus on acute care. Hence, there is a clear need to put greater emphasis on primary and community care indicators. Other OECD countries are beginning to collect quality indicators such as pressure ulcers, falls, management of chronic disease and effective care co-ordination which provide a measure of quality in these sectors. Italy should seek to do the same.

Greater focus on public reporting would encourage patient empowerment and drive higher quality of care

Substantial effort is made in Italy to convert health data into usable information, disseminated to professionals and to the public in various formats. The *Griglia LEA* and *the Hospital Discharge Report* for example, use a traffic-light scoring system and interactive maps to make its data accessible to the public. In contrast, dissemination of PNE data is relatively technical and poorly oriented to the public. Instead, findings are disseminated through a series of events and regional workshops, targeted to health service managers and clinicians. The PNE web portal is, however, highly customizable and allows sophisticated comparisons of quality of care indicators for local benchmarking. Other national reports on health system performance include the *Osservasalute*, published by the National Observatory on Health in the Italian Regions, and the *Rapporto Sanità* published by the University of Rome II. As with the PNE, however, both of these products are of a technical nature and firmly oriented to professional groups.

The opportunities available to patients to make use of quality data and to be involved in quality assurance of health care remain, therefore, rather limited in Italy. As work to build the information infrastructure underpinning Italian health care continues, it will be essential to make sure that sufficient attention is given to how patients and civic society more broadly can make an effective contribution to quality assurance, quality monitoring and quality improvement. Plans for this would be best made at local/regional level to maximise the potential for patients and the public to influence service redesign, and should include primary and community care services as a priority. In addition, there is a particular need to conduct patient satisfaction surveys more extensively and systematically across Italian health care services to better develop monitoring of the patient-centered dimension of health care quality. Although patient experiences are reported in some datasets, their impact on changing service delivery and quality improvement is not clear.

Going further on ensuring patient safety

A key action to improve patient safety was the setting up of the National Observatory on Good Practices in 2008. The overarching aim of the Observatory, which is co-ordinated by AGENAS, is to encourage continuous improvement of quality and safety of care by sharing learning from adverse events in hospitals and clinics, and to promote transfer of good practices. A bottom-up approach is implemented, through regional and inter-regional workshops in which all 21 R&AP participate. Learning from these workshops is consolidated, and emerges as improvement actions applicable across the country and made publicly available on the Observatory portal. The implementation of these actions, together with the Recommendations for preventing sentinel events issued by the Ministry of Health, is supported by AGENAS. Using a questionnaire, AGENAS monitors compliance with the recommendations and seeks to understand the barriers that R&AP have encountered in implementation. In addition, the Ministry of Health collects data about sentinel events, which is considered as one of the best practices at European level to monitor such events.

The Observatory is an excellent demonstration of the Plan-Do-Study-Act cycle in action. Although the Observatory is internationally regarded as a successful model to emulate, there are still opportunities to further develop the patient safety work done at national and local level. A national health inspectorate as already mentioned, for example, could enforce implementation of Observatory recommendations and apply sanctions where services are failing to meet required safety standards. National targets for reducing adverse events and patient safety incidents could be set. Other OECD countries provide examples of what is being achieved elsewhere. Several countries have 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. Importantly, these campaigns do not teach new science or new techniques. Instead, they are multi-layered initiatives which focus on the implementation science of changing behaviour.

Strengthening primary and community care in Italy

The Italian health care system has traditionally delivered high quality primary care, as demonstrated by quality indicators such as avoidable hospital admission. Admission rates for asthma, chronic obstructive pulmonary disease (COPD) and diabetes are amongst the lowest in the OECD. Patient satisfaction levels are also high. Current demographic and epidemiological shifts will, however, place new pressures on primary and community care services, particularly with respect to the management of chronic diseases. Italy has taken an important step towards ensuring greater co-ordination and integration of care with the Balduzzi Law (No. 189/2012) which encourages the establishment of community care networks. Going forward however, Italy should look to a renewed approach where i) national authorities better support R&AP in the setting-up of community care services and ii) where quality strategies are broadened towards the primary and community care sector.

The primary care system has served its role well up to now, but an ageing population and a growing burden of chronic conditions call for a renewed approach

The Italian primary care system serves as most patients' first point of entry into the health care system. The provision of primary care services is organised by health districts, which are sub-units of *Azienda Sanitaria Locale* (ASL). General practitioners (GPs) and paediatricians are grouped together and can be considered primary care physicians (PCPs), who act as "gatekeepers" for the Italian Health System. PCPs work under a government contract as independent professionals, and are paid through a mixed system including both capitation and fee-for-services negotiated within a collective agreement signed every three years. In 2012, there were around 0.76 GPs per 100 000 inhabitants and 0.91 paediatricians per 100 000 children aged between 0 and 14 years old.

While the primary care system has served its role up to now, Italy now faces a demographic and epidemiological shift with a growing ageing population and a rising burden of chronic conditions. The share of the population aged over 65 years in 2011 was the third highest among the OECD countries and it is expected to grow 1.7 times by 2050. This inevitably implies an increased prevalence of chronic illnesses and long-term conditions. This, combined with very worrying risk factor profiles amongst Italian adolescents (who are amongst the most overweight, least active and most frequent smokers in the OECD) point to an urgent need for primary and community care to play a bigger role in the health system, delivering effective primary and secondary prevention as well as avoiding unnecessary hospitalisation. Comparative data, however, strongly indicates that community, long term care and preventive services are underdeveloped in Italy compared to the other OECD countries. Italy spends less than one-tenth of what the Netherlands and Germany spend on preventive care, for example, and has the lowest share of long-term care workers (as a share of the population aged 65 years or over) in the OECD. Italy should without delay place chronic care management and prevention at the forefront of the health care system.

Care co-ordination and integration between health and social care need better support and leadership at national level

Given the challenges brought by the demographic and epidemiological changes, the past few years have seen efforts to reorganise the primary care sector and experiment with new models of service delivery. The National Health Planning and the Balduzzi Law (No. 189/2012) introduced new organisational forms in primary care. Practitioners were encouraged to establish community care networks to foster continuity and integration of care, as well as to further develop chronic disease management programmes. Community care networks (including *Casa della Salute*) and Community hospitals (*Ospedale di Comunità*) are characterised by a high level of integration between levels of care and rely on multidisciplinary care teams and personalised care plans. Primary care services and specialised health services have linked together to create integrated networks of community care. These networks are promising innovations, but a lack of guidance and absence of a national leadership have resulted in their low and uneven diffusion across the country (although the *Patto per la Salute 2014-2016* is likely to address these issues). Of even greater concern perhaps, is the fact that health spending across some ASLs still appears to be predominantly directed toward traditional types of primary care services, i.e. single-practice GP, with little spending allocated to services for frail patients or those with chronic conditions.

The Italian Ministry of Health should consider playing a greater steering role so that a more consistent regional development of community care networks and community hospitals occurs. National authorities should better support R&AP in the setting-up of such facilities. Additional resources, guidelines on setting-up and running community care services, training programmes, better use of ICT and expansion of the chronic care model are all specific themes that would benefit from greater guidance from national authorities. Steps in this direction are, encouragingly, underway: the *Patto per la Salute 2014-2016* provides guidance to support R&AP in the process of setting-up community care networks and community hospitals. Looking to secure co-ordinated and integrated care, the *Patto per la Salute 2014-2016* also places great emphasise on the need to expand the use of chronic care model and ICT. Exchanging good experiences through learning from the top-performing regions or facilities is another avenue to encourage more extensive and ambitious development of primary and community care networks.

The information system needs further development to better capture activity and outcomes around primary and community care

Another important challenge for Italy is to increase the collection of data around processes and outcomes of care in the primary and community sector. At a national level, there are some broad measures of primary care such as vaccination coverage, screening rates or hospital admissions for chronic conditions that are collected in the *Griglia LEA* or the PNE programme. These do not provide a comprehensive picture of the effectiveness and safety of primary care. At local or regional level, there are a plethora of initiatives, using different performance methods and collecting different indicators. Although the database developed by the Italian Society of General Medicine is an excellent system to measure performance among GPs, it only covers 15% of the GPs in Italy which substantially limits its potential impact in monitoring quality of care.

The current deficit of information on the patterns of care and outcomes in primary and community care, alongside a lack of standardised health datasets, means that it is not possible for stakeholders to consistently assess and benchmark the quality of primary care being delivered. While Italian authorities seek to modernise the primary care sector, there is a need to ensure that ongoing reforms do not adversely affect outcomes of care. Collecting indicators around the management of chronic conditions, the co-ordination between levels of care, and the patient's experience with the new community care services will be critical for the success of the Balduzzi Law. The collection of such indicators would enable health providers and policy makers to appropriately explore any shortcomings and identify areas that may require improvement. Israel and Denmark offer a model of where comprehensive and actionable indicators to support quality improvement in primary care have been developed.

Italy could use existing datasets such as the *Griglia LEA*, PNE or the New Health Information System to introduce primary care quality indicators to build a multidimensional picture of the quality and outcomes of care across a patient pathway. The exchange of uniform electronic patient records, that are portable across different levels of care, is another potential way to track patient pathways so that a fuller and more detailed picture of the effectiveness, safety and patient-centeredness can be built.

There are several other opportunities for extending quality strategies towards primary and community care

As renewed efforts are underway to increase care co-ordination and integration, Italy should ensure that primary and community care are brought into the various quality initiatives being set up at national and regional level. Thus far, this has not always been the case. The focus of the new harmonised accreditation programme, for example, is on hospitals. Expanding coverage to primary care and community care networks will be critical to guaranteeing high quality, high performing primary care sector. Other federalised OECD health systems such as those in Australia or Canada have developed a set of national standards and a robust accreditation model that applies uniformly across the country to the primary care sector. At the same time, there are few mechanisms to ensure guideline implementation by primary care professionals. Evidence shows a low degree of adherence to disease specific guidelines for major chronic conditions such as COPD or asthma. If Italy wants to encourage more efficient management of chronic disease at primary care level, central or regional governments must first set-up economic incentives or sanctions to encourage guideline implementation. Given that population ageing will be associated with an increased complexity of health needs and multiple chronic health conditions, it would also be highly appropriate to produce guidelines that address care for elderly patients, patients with multiple morbidities, and patients with particular care co-ordination needs.

There is also a pressing need to enhance primary care's contribution to primary and secondary prevention. At present, R&AP's implementation of preventive health care initiatives has been inconsistent. Principles and tools for primary and secondary prevention are not sufficiently embedded into the primary care sector, despite increased expectations are placed on the latter to engage in more preventive work and deliver a wider and more co-ordinated response to community health care needs. More emphasis on the pivotal role that nurses and GPs could play is needed to improve preventive activities across regions. Developing educational programmes in prevention or detection through for example continuing medical education programmes should be a key instrument to encourage primary care professionals to more fully implement the ambitions of the National Prevention Plans. Investing more in the community nursing workforce to manage the prevention and the treatment of the disease is another way to guarantee a co-ordinated and patient-centered management of chronic conditions.

Perhaps more crucially, the setting up of smarter payment systems into the Collective National Agreement to better reward quality initiatives and to be linked to preventive work should be a priority. The fee-for-service (FFS) component has the potential to drive more effective primary care (around primary and secondary prevention for example) but mostly pertains to the use of computer system or the recruitment of support or other medical staff. Future FFS negotiations should make more explicit links to national priorities around preventive interventions, care co-ordination or more broadly to standards of care. The FFS sum could also be adapted to reward compliance with specific clinical guidelines around preventive activities and the management of chronic conditions. There are key examples for learning from other OECD countries, such as the United Kingdom, where the introduction of financial incentives had favourable effects on primary care physician's compliance, leading to improvements across a range of indicators around secondary prevention and the management of chronic conditions.

Securing a high quality workforce: Medical education and training in Italy

The relatively good results that Italy's health system is delivering suggest that the medical workforce is, in general, delivering care of a high quality. Indicators such as low avoidable hospital admissions for asthma, COPD and diabetes, rates lower than the OECD average for mortality following hospital admission for stroke and acute myocardial infarction (AMI), and relatively low rates of surgical complications, reflect well on the quality of both the primary care and specialist workforce. Looking to secure this high performance for the decades to come, and push back against any regional disparities in quality and outcomes, Italy has been taking important steps towards ensuring nationally cohesive workforce training programmes. The recent step to standardise accreditation for continuing medical education (CME) providers is, in particular, an encouraging move. However, going forward, good medical education and nationally standardised CME may not be enough to secure a high quality, high performing medical workforce. Italy should look to more modern and self-regulatory models of workforce quality insurance, pushing practitioners to play a more active role in evaluating their own care – for example, through more active use of data and outcome indicators – and could learn from other OECD countries in developing more pertinent quality assurance mechanisms for the medical workforce.

Keeping quality high from the start: Entry into medical school and undergraduate education

Medical education in Italy is regulated by the Italian Ministry of Education, Universities and Research, meaning that teaching uniformity is secured across the national territory. Medical education is also consistent with the EU directive on medical education allowing free movement of medical professionals within Europe (Directive 2005/36/EC). Physicians trained in Italy follow an undergraduate programme which lasts at least six years, during or after which students must work within a hospital ward for at least six months. After graduation medical school graduates must pass a national examination so as to be placed on a national physician register and be allowed to practise. The license issued is valid for the whole of Italy, not only for the province in which the licence is granted, and this licence is of unlimited duration. Following licencing, physicians can choose among various professional paths depending on the kind of postgraduate specialisation programme they attended. Specialisation consists of a four to six year course at a chosen specialist school, and is required for physicians to work in the hospital sector. Legislative Decree No. 256/1991, which implemented the EU directive on GP training, made participation in this three-year course compulsory to practise family medicine.

A degree in nursing is obtained after a three-year course of study and the acquisition of 180 credits and immediately enables the degree holder to practice as a nurse, following registration with the Professional Board of Nurses and Midwives, in the public sector as well as in the private sector.

Italy could take further steps to promote excellence in the workforce even from the beginning of training, and could consider the value of aptitude tests in selecting applicants after they finish school. A large number of OECD countries – Australia, New Zealand, Canada, the United Kingdom, the Netherlands – use tests which consider candidates' capacity to succeed in medical school across a range of domains, for example logic and reasoning, communication, application of knowledge, and not just scientific or medical knowledge. Given that Italy already has a national examination for entry into medical school, the addition of a component of these aptitude tests to this test is an avenue to consider.

Keeping the quality of education provided high is another consideration. Educational standards in Italy are maintained by the Italian Ministry of Education, University and Research nation-wide, and the national examination for qualification keeps curricula fairly standard. Nonetheless, there is always scope to improve educational quality, and international literature and research offers some important insights. A "student-centered" or "learner-centered" approach to medical education has been supported by some studies, and promoting communication skills, and effective interaction with patients is seen as increasingly important. A consideration of the broad skill set that medical students will eventually need – team work, patient communication, self-reflection – should guide the content of undergraduate education and assessment methods, as well as the traditional scientific and medical teachings.

Maintaining and improving professional standards through Continuing medical education

Continuous learning and keeping up to date with medical knowledge is an accepted requirement for health professionals. Often this is done through continuing medical education (CME). CME is mandatory for all physicians practising in Italy, who must obtain 50 CME credits per year. Credits are assigned by an accredited CME provider and awarded for according to hours of training activities, the type and characteristics of the programme. As it stands, accreditation of national providers is carried out by the National Commission for Continuous Education (*Commissione Nazionale Formazione Continua*), while regional accreditation is awarded at the regional level by regions or autonomous provinces (about 10% of CME programmes are run by regional providers). Some positive steps have been taken towards introducing a layer of quality assurance for CME, with all administrative functions for CME having been passed to AGENAS (from the National Commission for Continuous Education) as part of an attempt to harmonise different standards for CME provision in different regions, in particular through improving information collection. AGENAS has already signed specific agreements with ten regions for continuing medical education, involving the implementation of the programme for the accreditation of regional providers, which requires the use of the software needed for administrative tasks. For nationally accredited CME providers, which make up the majority of providers, a series of biennial administrative checks – staffing, building infrastructure, checks by a scientific committee – are carried out by the National Commission for Continuous Education, which can be followed up with unplanned inspections. AGENAS can also push providers to provide CME that meets some of the key challenges of the health care systems – for example maternal health, or sexual health – but take-up of CME relies upon professional choice.

There are some ways that Italy could look to maximising the impact of the existing CME system, even without making significant changes to structure of CME delivery, or surrounding requirements and legislation. To have a real impact on care quality, CME should match with identified shortcomings in the health system, as well as helping to address areas of weakness of individual health professionals, and should be delivered in such in way as to maximise positive impact. Italy could consider ways to incentivise the uptake of certain CME activities which are judged to meet the health system's needs, for example by increasing the number of CME credits attributed to these activities.

Furthermore, at present there is no link between individual health professionals' performance evaluation, either systematic self-evaluation or evaluation by peers, and CME accreditation. The selection of CME activities is left open to the individual professional, who can choose between all accredited courses and providers. There is more potential to improve the quality of the professional's care if their CME activity maps onto areas of weakness or gaps in skills and knowledge. Systematic reviews of practice can disclose weaknesses or educational needs, which can then be used to target CME uptake more effectively. Again, there should be an effort to give particular support and incentives to programmes that encourage physicians to reflect on their own practice, and to improve it. In general, tools that facilitate physician self-evaluation and reflection upon practice should be further encouraged. One way that CME activities could be mapped more closely to anticipated skill needs is through the specification of expected CME completion in local contracting, which is already in place in some areas. For example, the contract of a nurse who will be working with low income communities and children could be required to take a CME programme on health promotion or prevention of obesity or childhood obesity, issues that are growing concerns in Italy and known to be associated with poorer income groups.

Strengthening quality assurance: International experience and recommendations for Italy

While the basics of good quality assurance for Italy's medical workforce appear to be in place, and functioning well, Italy may not be keeping up with other OECD countries in taking steps towards a more modern, rigorous system of quality assurance. Internationally, there is a growing realisation that the historical organisation of the medical profession, and reliance upon self-governance and individual physician integrity and responsibility, is not sufficient or appropriate for new models of health care delivery and medical practice, and additional checks and standards need to be introduced. There are some areas in which Italy could take action – drawing on examples from other OECD countries – and in doing so drive improvements in the quality of care delivered by medical professionals.

Moving beyond a strengthening of the existing CME system, Italy would do well to consider the experiences of countries which have introduced recertification or relicensing protocols for physicians. Relicensing is increasingly seen as an important workforce quality assurance measure, backed by the argument that the awarding of a licence to practice at the end of medical education is not sufficient to ensure high quality care across a quality assurance career of fifty years or more, particularly considering the rapidly changing nature of health care delivery (for example changing evidence bases for treatments, pharmaceuticals, new technologies). In a number of countries completion of CME activities has been linked to re-issuing of the licencing to practice (relicensing), as a means of enforcing CME participation. For Italy, interesting examples are found in the Netherlands and in the United Kingdom, where highly comprehensive systems of re-licencing have been introduced. These re-licencing procedures include more rigorous appraisal aspects such as comprehensive peer-review, the requirement that physicians have reflected upon and changed their practice through activities that improve professional competence – often referred to as "continuing professional development", and that physicians can demonstrate that they have reflected upon feedback from patients and colleagues. Such systems could be seen as examples for Italy to learn from and follow in coming years.

One further challenge that Italy faces, and that medical professionals practicing in Italy face, is a lack of data that tells authorities or individual physicians anything about the quality of care that they are delivering. At present no physician-level quality or outcome indicators are collected. Some small scale initiatives around quality of care indicators do appear to be in place, and are encouraging. For instance, a small number of physicians are participating in outcome indicator collection as part of an initiative launched by the scientific society for general practitioners, SIMG as part of which they get feedback on their performance and outcomes. More widespread collection of physician-level or practice-level quality and outcome indicators would be highly desirable, if challenging to introduce. There are obvious anxieties about ranking of practitioners, and exposure to criticism, blame and legal liability. There are avenues for Italy to explore in this respect, for example the partial anonymisation of practitioner-level data, or initially use of data privately amongst physicians but not publically. Whilst physicians may feel anxious about such collections, in other countries – for example a very impressive data collection and benchmarking scheme in primary care in Denmark – doctors have in fact been pleased with the availability of data that allows them to reflect upon their own practice, and compare it to that of their peers. Indeed, availability of outcomes data, and transparency of data, can help practitioners with self-reflection and improvement in their own care. More comprehensive data collection could benefit both patients and the Italian health system, as a quality improvement measure, but also physicians, if they are encouraged and supported in reflecting on their own results in a productive way.

Measuring and improving quality in Italy's regionalised health system

Italy is a very heterogeneous country, in both social and economic terms. The autonomous province of Bolzano near the Austrian border has a GDP per capita of USD 39 170, more than double that of Campania's USD 17 120. The difference in unemployment rate between these two areas is even more stark, at 4.1% and 19.3% respectively. Such heterogeneity is reflected in the health system. Since the reforms federalising health care delivery a decade ago, 21 distinct health systems have developed – with markedly divergent patterns of care and outcomes. Such variation in activity and outcomes across regions is both inefficient and inequitable, a reality which is not lost on the public given the large number of patients crossing regions in search of health care. Balancing the advantages of decentralised governance against the needs to ensure equitable quality of care is a persistent and complex challenge.

In an effort to moderate the less advantageous aspects of this heterogeneity, Italy has established a number of mechanisms to try and ensure an evenness of approach to quality measurement and improvement across its R&AP. The *Unified Conference between the State, Regions, Municipalities and Local Authorities*, for example, was established in 1997, a key institutional mechanism to co-ordinate the relationships among the central government, R&AP and local authorities. It addresses issues such as administrative simplification, probity, quality of services, impact analysis and feasibility studies. Other key mechanisms include discussion and ratification of the *Patto per la Salute* which supports regions to develop a three-year health plan, in conjunction with local priorities, and analysis and discussion of the *Griglia LEA* and PNE data.

Regional variations in the health care practice and outcomes are significant, across regions as well as within them

Despite these efforts towards harmonisation, regional differences in health care quality across Italy remain significant. The proportion of patients receiving coronary angioplasty within 48 hours of a heart attack, for example, varies from ~15% in Marche, Molise and Basilicata to almost 50% in Valle d'Aosta and Liguria. Variation *within* R&AP is even more profound: the same indicator ranges from ~5% to over 60% when disaggregated to ASL-level. 30-day mortality after a heart attack, disaggregated to ASL level ranges from ~5% to 18% with a national mean of 10%. The north-south differential is also reflected in indicators linked to the quality of primary care. Hospital admissions for COPD are lowest in Piemonte (1.51 per 1 000 population, age-sex adjusted) and Trento (1.55) and highest in Puglia (3.84), Campania (3.13) and Basilicata (3.07). The same is seen for childhood asthma, where admissions are fewest in Toscana (0.21 per 1 000 population, age-sex adjusted), Veneto (0.23) and Valle d'Aosta (0.25) and most frequent in Sicilia (0.95), Abruzzo (0.82) and Sardegna (0.74).

The fact that variation in health care processes and outcomes is greater *within* R&AP than across them underlines the need for R&AP to performance manage local hospitals, clinics and professionals in a consistently effective manner. There is great variation, however, in the way health system performance is managed across Italy. Regions such as Lombardia, Marche, Sicilia, Trento, Umbria, Valle d'Aosta, Basilicata and Toscana use local quality of care information in a systematic fashion, including using performance metrics in their contracting with service providers and sometimes linking to external organisations (such as universities) for expert technical support. Other R&AP use local performance measures in a more ad hoc fashion. Abruzzo, Calabria, Campania, Molise and Piemonte, for example, have been noted to use health data for mainly epidemiological purposes, with infrequent use of quality and outcome measures to inform local policy debate or negotiation with service providers.

Work to develop a more consistent regional approach to performance management should be prioritised

The Italian Ministry of Health, together with the Italian regions and other key national agencies such as AGENAS should work together to define a more consistent regional approach to the performance management of health systems. While it is understandable that national authorities have avoided imposing one or other model, there is scope to work toward a more consistent national approach. National authorities should not be seeking to performance manage R&AP per se, but to support R&AP to performance manage the local hospitals, clinics and professionals in their territory in an effective manner.

A more consistent and ambitious approach would encourage all R&AP to see performance management as a collective exercise that influences policy and leads to continuous quality improvement, rather than as a technical problem that involves few stakeholders and leads to few policy-relevant outputs. Performance management should be multidimensional, focus on outcomes and equity (rather than activities and outputs), be widely disseminated and supported by a dedicated performance management unit within each R&AP. Consistency along these lines would still allow ample scope for a regionally tailored approach, guided by local priorities. Key themes to address would be the extent to which performance metrics are used in contracting with hospitals, other providers and their management boards, and the extent to which performance metrics are made available for public scrutiny and open comparison.

Denmark offers a model of considerable interest. There, the *Danske Regioner,* or association of Danish regions, has agreed a common approach to performance management. Although national legislation increasingly sets out requirements on topics such as waiting times, safety of pharmaceuticals and adverse event reporting, more detailed regulation is carried out through the agreement between the national level, the regions, and the municipalities. Quality targets are an increasing feature of these agreements. The agreement on the regional budget for 2013, for example, stipulates a 10% decrease in hospital standardised mortality rate and a 20% decrease in adverse events for the next three years. Although these agreements are not legally binding, they are considered to be an important mechanism to govern the Danish health care system, whilst leaving sufficient room for regional and local adaptations according to needs.

Finances should also be used to incentivise quality improvement

Better use of financial resources and incentives should be developed alongside better use of information to improve the quality of care in Italy's poorer performing R&AP. Poorer areas do from time-to-time receive additional block grants to support particular needs or finance new initiatives. These grants should be used to incentivise quality improvements where possible. This could be through ensuring that each grant has a ring-fenced element for impact evaluation, or includes specific resources to extend the quality-improvement infrastructure or personnel, or making part of the grant conditional upon achieving certain targets or implementing new processes.

A second aspect concerns the regional resource allocation formula. Whilst it is clearly important that regional allocations are matched to need as closely as possible, and reward efficiency, they should also support and reward quality. Less efficient R&AP are likely to see their budgets being squeezed – whilst efficiency gains are being sought, adequate safeguards should be in place to ensure that access to care and the quality of care do not suffer. An important action in this regard would be to monitor the impact of financial consolidation on the health of vulnerable individuals and communities.

Sweden demonstrated deployment of both informational and financial incentives during its recent reforms to drive better integrated, community-based care. In 2011, for example, the government allocated SEK 325 million (EUR 35 million, USD 47 million) to counties that demonstrated a statistically significant improvement in reducing unnecessary hospitalisations. Monetary rewards are given to counties that reduce the use of inappropriate drugs, reduce the inappropriate combinations of drugs and the use of psychotropic drugs among elderly people in institutional care.

Strengthening and clarifying the role of national authorities, whilst redefining mutual accountabilities between the centre and the regions and autonomous provinces, will be important

The regional structure of Italy's health service is well established and should be valued. In parallel, however, there is scope to develop the responsibilities and capacities of some national authorities, particularly those whose role is to support R&AP. Even in highly decentralised systems, it is clear that central authorities have several important roles and functions. These include producing overviews of current knowledge, current practice or current performance; setting standards, on performance or performance reporting, for example; and developing tools such as evaluation frameworks, IT platforms, deep dive teams to visit and support areas with special needs.

The Norwegian Association of Local and Regional Authorities (KS) is a national interest association for municipalities, counties and public enterprises which demonstrates many of these functions. Recent work has sought to strengthen primary health care services, for example, with an emphasis on patient participation, prevention, rehabilitation and the use of new technologies. These are all priority activities for the Italian health system as well. The Norwegian Association actively communicates with the members, disseminates information and facilitates the exchange of experience.

In Italy, there is scope to consider developing the role of AGENAS more fully, modelling it on equivalent organisations in other countries such as *Danske Regioner* in Denmark, or the KS in Norway. Examples of quality improvement work which AGENAS is well placed to undertake include:

- development of a nationally consistent approach to performance management and quality improvement cycles across regions
- thought-leadership around developing a more consolidated national health information infrastructure, for example, on how a national institute for health information might be created
- technical advice to support national planning, including possible revision of the formula used to allocate regional resources
- thought-leadership around the next phase of minimum quality standards, including extensions to the *Griglia LEA* and development of a more rigorous health inspectorate function, at national or regional level.

Shifting governance from a financial focus to give equal prominence to quality improvement needs to happen at all levels of government

Underpinning all of these recommendations must be a commitment from both national and regional authorities to equal commitment to quality improvement as to financial control. In particular, the *Piani di Rientro* (Recovery Plans) of recent years represents an abrupt rebalancing of central versus regional authority in financial terms. It is essential that governance driven by quality imperatives is given equal prominence. The scaling-back of performance management capacity in some regions as a result of the crisis underscores the importance and timeliness of this argument. Although this shift is needed at all levels of government, clear leadership from central authorities will be essential.

National authorities such as the Ministry of Health and AGENAS should develop a stronger operational role around monitoring health care quality and outcomes as described above. The same priority needs to be reflected at regional level. Whilst some regions do this already, other regions need targeted support to build robust and effective quality governance. In particular, regions should be encouraged or required to publish regular quality improvement plans with specific goals and milestones and national authorities may wish to establish performance contracts with regional authorities on this basis.

Recommendations for improving health care quality in Italy

Italy's priority must be to move from a system that prioritises budgetary control, to one that gives an equal priority to quality. Informational and financial incentives must be aligned to the outcomes and quality of care and a more consistent approach to quality monitoring and improvement across the country is needed.

1. Strengthen quality governance in health care by:

- Ensuring more consistent application of national quality initiatives at regional level, especially those around accreditation and minimum standards. Creation of a national health inspectorate would give this function a secure base.
- Considering additional, earmarked resources to encourage the use of quality guidelines at regional level. Strengthening the capacity of the National Guidelines System to disseminate guidelines and monitor their impact will support their implementation.
- Consolidating and extending the health service information infrastructure. In particular, expanding the range of indicators collected in the *Griglia LEA* and making better use of PNE indicators in contracting with providers is needed.

Recommendations for improving health care quality in Italy *(cont.)*

- Getting more value out of data that currently exists by overcoming barriers to linkage across databases. Standardisation of the approval process to link and analyse health data and diffusion of best practices in the processing of personal health information are needed.
- Enriching the possibilities for patients and the public to make use of quality data and to be involved in quality assurance of health care. In particular, there is a need to conduct patient satisfaction surveys more extensively and systematically.
- Going further on the excellent patient safety work that Italy has already started. National targets, underpinned by focused, grass-roots campaigns to change practice at ward and clinic level are now needed.

2. Improve the quality of primary care services and community care services by :

- Strengthening the information infrastructure underpinning quality and community care, for example by collecting indicators around the management of chronic conditions, co-ordination between levels of care or patient's experience with the new community networks or associative forms of PCPs.
- Expanding community care networks and community hospitals throughout the country, through the provision of financial resources, the development of guidelines for the setting up of these community services or organisational support to encourage the use of chronic care models.
- Establishing smarter payment systems that reward quality, activity or the achievement of national objectives using the fee-for-service component. Specific attention should be directed toward preventive strategies, the efficient management of chronic disease or better co-ordinated care.
- Encouraging compliance with clinical guidelines, through financial and informational incentives. Produce guidelines that address care for elderly patients, patients having multiple morbidities or care co-ordination to best response to the challenges brought by the demographic and epidemiological changes.
- Improving the role played by primary care providers in primary and secondary prevention. Developing educational programmes in disease prevention and early diagnosis through continuing medical education (CME) programmes, or investing more in the nursing workforce are possible avenues for consideration.
- Developing national standards for the primary care sector and broadening the focus of the new harmonised accreditation programme to primary and community care services including the new suite of community health networks and community hospitals.

Recommendations for improving health care quality in Italy *(cont.)*

3. Improve medical education to strengthen the quality of Italy's health care workforce by:

- Considering whether procedures around entry into medical school, qualifying examinations, and the move to specialist schools promote the qualities – communication, team work, self-reflection on practice and competency – required of Italian health professionals working in the system today.
- Encouraging medical schools to promote high quality teaching and learning methods, moving away from traditional didactic approaches and exploring active and participatory learning approaches.
- Maximising the positive impact of CME by incentivising CME activities that match well with health professionals' desired skill-set, and with weaknesses in their existing practice. Considering introducing more modern forms of continual assurance of workforce quality, including relicensing which includes more rigorous appraisal aspects such as comprehensive peer-review and pushes medical professionals to reflect on their strengths and shortcomings.
- Exploring ways of introducing physician-level or practice-level quality and outcome indicators, which can help physicians reflect on and improve their own care, if they are encouraged and supported in reflecting on their own results in a productive way.

4. Strengthen the measurement and improvement of health care quality in Italy's regionalised health system:

Improve health care quality and health care outcomes in poorer performing R&AP by:

- Developing a more consistent approach across R&AP to using information to manage performance and strengthen local accountability. Key themes to address would be the extent to which performance metrics are used in contracting with hospitals, other providers and their management boards, and the extent to which performance metrics are made available for public scrutiny and open comparison.
- Working toward a less fragmented information infrastructure underpinning the Italian health system, perhaps by creating a single national institute for health system information to collect, analyse and disseminate health system metrics.
- Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement. This could be through ensuring that each grant has a ring-fenced element for impact evaluation, or includes specific resources to extend the quality-improvement infrastructure or personnel, or making some, or all, of the grant conditional upon achieving certain targets or implementing new processes.
- Drawing on innovative models of resource allocation in other countries to ensure that allocation matches need as far as possible and, where appropriate, reward quality.
- Monitoring the impact of financial consolidation and introduction of co-payments on the health of vulnerable individuals and communities.

Recommendations for improving health care quality in Italy *(cont.)*

5. Strengthen the regional approach to health care governance and delivery in Italy by:

- Developing the responsibilities and capacities of the national authorities whose role is to support the R&AP. In particular, there is scope to consider developing the role of AGENAS more fully, modelling it on equivalent organisations in other countries such as *Danske Regioner* in Denmark or the *Kommunesektorens organisasjon* in Norway.
- At the same time, be constantly alert to any tensions or inefficiencies that may arise as a result of multilevel government. In particular, gaps in accountability, information, capacity or funding should be identified and addressed.
- Reframing governance as a whole such that quality improvement is emphasised as much as financial control across all levels of government. The Ministry of Health should consider deepening and extending the range of indicators it monitors through the *Griglia LEA*. At regional level, quality improvement plans should be agreed with specific goals and milestones.

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.

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.

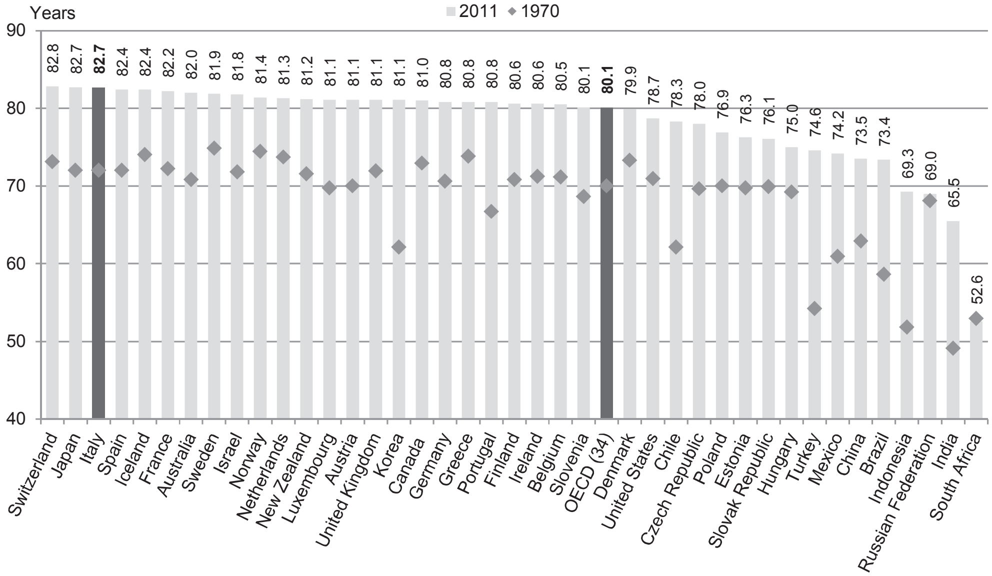
1.2. Context

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)

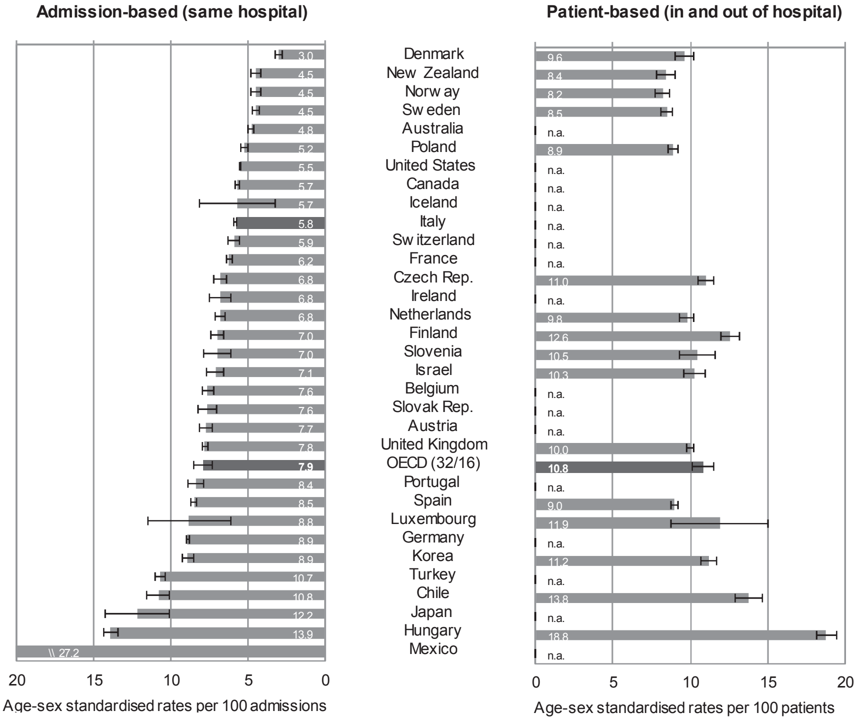


Source: OECD Health Statistics 2013, http://dx.doi.org/10.1787/health-data-en; World Bank for non-OECD countries, http://data.worldbank.org/.

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)

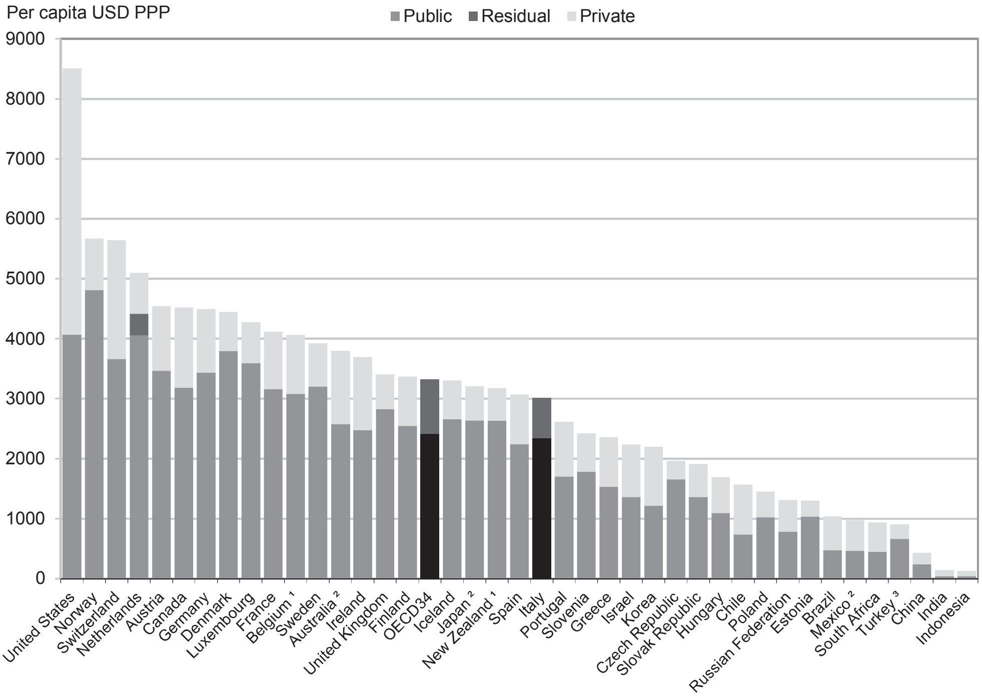


Note: 95% confidence intervals represented by H.

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.

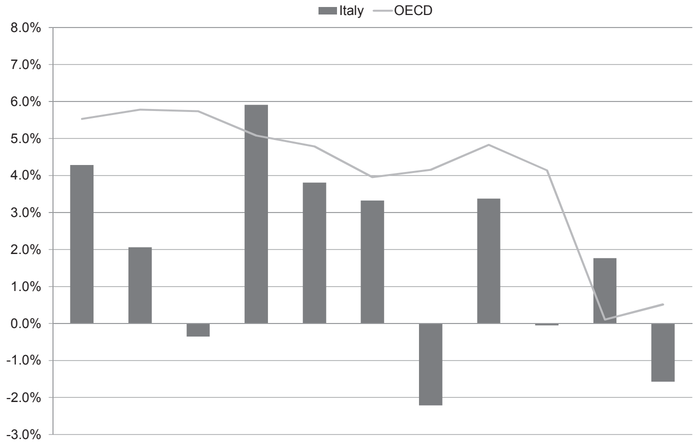
Source: *OECD Health Statistics 2013*, http://dx.doi.org/10.1787/health-data-en; WHO Global Health Expenditure Database, http://apps.who.int/nha/database.

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 2001, 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.

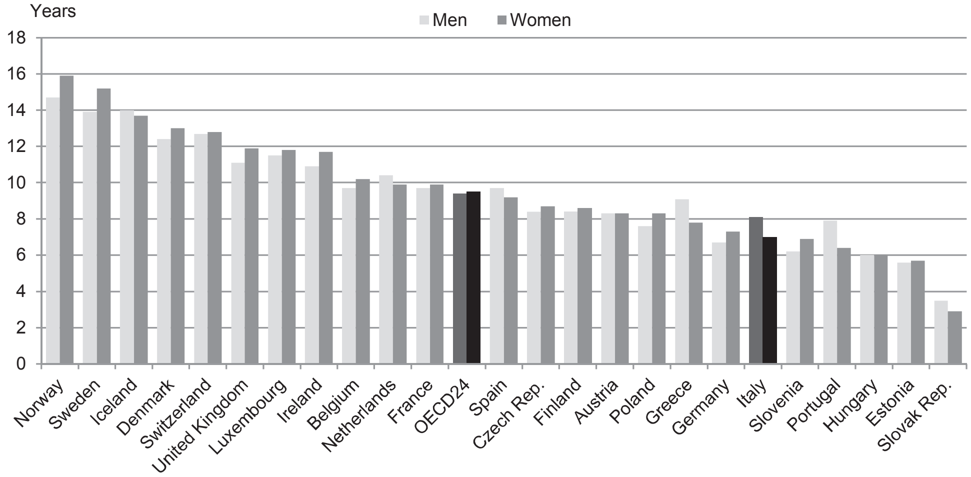
International comparison furthermore suggests that growth in health spending has not kept pace with other OECD countries. Significant differences in the growth of health spending are found between Italy and other OECD countries in 2003, 2007, 2009 and 2011 (Figure 1.4). While health care spending has 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[1]) 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 20th 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 goup 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 Midwifes, 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[2]). 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).

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). 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 Eurobservational 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/). 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).

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 miso 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).

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 (Fruili, 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 rare, 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.
2. www.agenziafarmaco.gov.it/it/content/osservatorio-sull%E2%80%99impiego-dei-medicinali-osmed.

Bibliography

Agenzia Sanitaria Regionale Emilia Romagna (2010), "La governance delle politiche per la salute e il benessere sociale in Emilia-Romagna. Opportunità per lo sviluppo e il miglioramento", Dossier 192/2010, Bologna.

Alfonsi, V. et al. (2012), "Immunisation Registers in Italy: A Patchwork of Computerisation", *Eurosurveillance*, Vol. 17, No. 17, available at: www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20156.

Carinci, F. et al. (2012), "Performance Measurement in Response to the Tallinn Charter: Experiences from the Decentralized Italian Framework", *Health Policy*, Vol. 108, No. 1, pp. 60-66.

Caracci, G., B. Labella and Q. Tozzi (2010), "Buone pratiche per il miglioramento della qualità e della sicurezza delle cure", *CARE*, No. 4, pp. 25-29.

Caracci, G. et al. (2013), "Indagine sui modelli regionali di gestione di sinistri e polizze", in *Quaderno di Monitor 2013,* Rome, Italy, available at www.agenas.it/images/agenas/monitor/quaderno/pdf/14__indagine_sui_modelli_regionali.pdf

CEIS – Centre for Economic and International Studies (2012), *8th CEIS Healthcare Report: Welfare Options and Policy Integration,* Università degli Studi di Tor Vergata, available at: http://rs-ceis.4healthinnovation.org/sanita/public/file/volumi/8th_ceis_health_report.pdf.

Conferenza Stato Regioni (2013), "Deliberazione del progetto interregionale "Portale della trasparenza dei servizi per la salute", available at www.statoregioni.it/Documenti/DOC_039309_20%20%20csr%20punto%2017%20odg.pdf.

De Belvis, G. et al. (2011), "The Osservasalute Health Report 2010: The Contribution of a Wide and Independent Italian Research Network to Decision Making in Healthcare", *Italian Journal of Public Health*, Year 9, Vol. 8, No. 4, available at: http://ijphjournal.it/article/download/5687/5423.

Di Stanislao, F. and F. Carinci (2012), "Verso un sistema nazionale di valutazione della qualità dell'assistenza sanitaria", *Monitor*, Vol. 30, pp. 8-21, AGENAS, Rome.

Di Stanislao, F. et al. (2012), “L’accréditation en Italie et ses différences entre les régions”, Décentralisation système de santé : l’exemple italien, *Revue Sociologie Santé,* Vol. 32.

European Commission (2014). “Patient Safety and Healthcare-Associated Infections”, Report from the commission to the Council on the implementation of Council Recommendation 2009/C151/01 on patient safety, including the prevention and control of healthcare associated infections, COM(2014) 371, June 2014

France, G., F. Taroni and A. Donatini (2005), “The Italian Health-Care System”, *Health Economics*, Vol. 14, Suppl. 1), pp. 187-202.

Fusco, D. et al. (2012), “Il Programma Nazionale di valutazione Esiti (PNE). Breve guida alla consultazione”, *Monitor*, Vol. 30, pp. 22-42, AGENAS, Rome.

Labella, B. et al. (2012), “L’Osservatorio Buone Pratiche di AGENAS”, *Monitor*, Vol. 31, AGENAS, Rome.

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

Ministry of Health (2010), “Piano Sanitario Nazionale 2011-2013”, Draft, Rome, available at www.salute.gov.it/imgs/C_17_pubblicazioni_1454_allegato.pdf.

Ministry of Health (2011a), “Report on the Health Status of the Country”, Minestro della Salute, Rome.

Ministry of Health (2011b), “Sistema di valutazione e monitoraggio della qualità dell'assistenza e delle performance dei sistemi sanitari”, *Relazione sullo stato sanitario del Paese 2009-2010*, Ministero della Salute, Roma, available at www.rssp.salute.gov.it/rssp/paginaParagrafoRssp.jsp?sezione=risposte&capitolo=valutazione&id=2677.

Ministry of Health (2012a), *Adempimento “mantenimento dell’erogazione dei LEA” attraverso gli indicatori della Griglia Lea*, Minestro della Salute, Rome, available at www.salute.gov.it/imgs/C_17_pubblicazioni_2154_allegato.pdf.

Ministry of Health (2012b), *Rapporto Annuale sui Ricoveri Ospedalieri 2011*, Ministero della Salute, Rome, available at www.salute.gov.it/imgs/C_17_pubblicazioni_1930_allegato.pdf.

Ministry of Health (2014), *Rapporto Annuale sui Ricoveri Ospedalieri 2013*, Ministero della Salute, Roma, Italia, available at www.salute.gov.it/imgs/C_17_pubblicazioni_2190_allegato.pdf.

Nuti, S., C. Seghieri and M. Vainieri (2013), "Assessing the Effectiveness of a Performance Evaluation System in the Public Health Care Sector: Some Novel Evidence from the Tuscany Region Experience", *Journal of Management and Governance*, Vol. 17, pp. 59-69.

OECD (2013a), *Health at a Glance 2013: OECD Indicators*, OECD Publishing, Paris, http://dx.doi.org/10.1787/health_glance-2013-en.

OECD (2013b), *Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges*, OECD Health Policy Studies, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264193505-en.

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

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

Piano regionale per la Salute e il Benessere Sociale 2011-2013 (2011), "Regione Valle d'Aosta", available at www.regione.vda.it/gestione/gestione_contenuti/allegato.asp?pk_allegato=10416

Presidenza del Consiglio dei Ministri (2014), "La Conferenza Permanente Per I Rapporti Tra Lo Stato, Le Regioni E Le Province Autonome Di Trento E Bolzano. Patto per la Salute per Gli anni 2014-2016", Rep No.°82/CSR del 10 luglio 2014.

Pinnarelli, L. et al. (2012), "What Drives Hospital Performance? The Impact of Comparative Outcome Evaluation of Patients Admitted for Hip Fracture in Two Italian Regions", *BMJ Quality & Safety*, Vol. 21, No. 2, pp. 127-134.

Quaderni AGENAS (2008), "I sistemi di valutazione dei servizi sanitari", *Quaderno di Monitor n. 1*, ASSR, Rome, available at www.agenas.it/images/agenas/monitor/quaderno/pdf/3_I_SISTEMI_DI_VALUTAZIONE.pdf.

Sassi, F. (2013), "Indagine conoscitiva sulla sostenibilita del servizio sanitario nazionale", Audizione al Senato, December 2013.

Torbica, A. and G. Fattore (2005), "The 'Essential Levels of Care' in Italy: When Being Explicit Serves the Devolution of Powers", *European Journal of Health Economics*, Vol. 6, Suppl., pp. 46-52.

Tozzi, Q., G. Caracci, R. De Blasi and B. Labella (2012), "Il sistema di monitoraggio on line dell'implementazione delle raccomandazioni per la prevenzione degli eventi sentinella", *Monitor*, Vol. 31, AGENAS, Rome.

Database references

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

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

World Bank, http://data.worldbank.org/.

World Health Organization (WHO) Global Health Expenditure Database, http://apps.who.int/nha/database.

Chapter 2

Primary and community care in Italy

The Italian health care system delivers high quality of primary care services as demonstrated by rates of avoidable hospitalisation that are amongst the lowest in the OECD. Italy faces, however, a growing ageing population and a rising burden of chronic conditions, which are likely to result in higher health care costs and place further pressures on the primary care sector.

Whilst the management of chronic conditions requires a co-ordinated patient-centered response from a wide range of health professionals, the Italian health care system has traditionally been characterised by a high level of fragmentation and a lack of care co-ordination. Italy has made considerable efforts to experiment with new models of community care services that aim at achieving greater co-ordination and integration of care. Although the expansion of community care services is an appropriate policy response to meet the growing demand for health care, they are still unevenly distributed across Italian regions and autonomous provinces. Greater guidance and support from national authorities is needed to ensure a more consistent approach.

At the same time, there are other shortcomings in Italy's primary care sector that require attention to guarantee high-quality primary care. Efforts are needed to increase transparency, develop performance measurement and strengthen accountability in the sector. The development of a set of standards around the processes and outcomes of primary care, the setting-up of smarter payment systems and an increase in the involvement of primary care physicians in preventive activities are options that Italy should consider pursuing if it is to meet the challenge of an increasing burden of long-term conditions.

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.

2.1. Introduction

Italy, similarly to many other OECD countries, faces a demographic shift with a growing ageing population. The share of the population aged over 65 years in 2011 was the third highest among the OECD countries and it is expected to rise almost two-fold by 2050. The ageing population inevitably implies an increased prevalence of chronic illnesses and long-term conditions. Italy reports, for example, one of the highest dementia prevalence rates among the population aged 60 and over. Indicators of healthy life years and daily activities limitation at age 65 are also worst in Italy than OECD averages (OECD, 2013a). These, combined with a growing prevalence of obesity among children, is likely to increase health care costs and place pressures on the primary care sector to deliver complex care outside the hospital in order to improve the efficiency of care.

Whilst the management of chronic conditions requires a co-ordinated patient-centered and community-based response from a wide range of health professionals, the Italian health care system has traditionally been characterised by a high level of fragmentation and lack of care co-ordination. Over the past decade, Italy has begun reorganising its primary care sector by experimenting with new models of service delivery that aim to create more comprehensive, safe and effective pathways of care. Primary care services and specialised health services have linked together to create integrated networks of community care. A lack of guidance and the absence of a national leadership however, have resulted in low and uneven diffusion of such initiatives across the country.

At the same time, the Italian authorities should consider enhancing quality initiatives in the primary care sector that are still lacking to nurture a quality improvement culture. Tools to increase transparency, performance measurement and accountability of primary care providers are all needed, as well as setting-up smarter payment system and to increase the involvement of primary care physicians in secondary prevention and care co-ordination.

This chapter examines the provision of primary care in Italy. It starts with an overview of the Italian primary care system and then points to its performance in examining some indicators of primary care quality across OECD countries. Section 2.4 discusses the challenges the Italian primary care service needs to tackle and how it can be further developed to guarantee high quality of primary care services. The chapter concludes with some key suggestions to secure high quality of primary care services and guarantee the effective management of chronic diseases.

2.2. The provision of primary care in Italy

The Italian primary care system represents the first point of contact between citizens, families and communities and local health services. Primary care physicians (PCPs) are asked to provide first-contact care to a range of population health needs that are increasingly characterised by multiple chronic diseases, disabilities and risk behaviours. Following the rapid economic, social and cultural changes occurred over recent decades, primary care has taken on an increasingly important role within the Italian health care system. It is seen as a central specialty that offers holistic, integrated care centered on the patient and the process of care, rather than on the disease. In order to harmonise the approach to primary care across the country, and maximise its potential to manage demand for specialist health care, recent reforms have sought to encourage group practice and develop local networks across primary and secondary care.

Health districts are responsible for primary care, and primary care physicians are paid according to a mix of capitation and fee-for-services

Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organisations (Local Health Authorities – ASLs). As further described in Chapter 1, ASLs provide care directly through their own facilities or through services supplied by independent hospital trusts, research hospitals and accredited private providers (acute and rehabilitation hospitals, diagnostic laboratories, nursing homes, outpatient specialists). For patients, primary care is provided free of charge by general practitioners (GPs) and paediatricians, self-employed and independent physicians working under a government contract.

Health districts are geographical subunits of ASLs responsible for co-ordinating and providing primary care, non-hospital based specialist medicine and residential or semi-residential care to their assigned populations. As defined, health districts represent the ideal setting for the integration between health services and between health and social services (Accordi Collettivi Nazionali, 2009). The district network has become the organisational solution for the management of chronic diseases and disabilities. According to the recent investigation conducted by AGENAS, there were 711 districts in 2009, although the number of districts in each ASL depends on its size and on other geographical and demographic characteristics. GPs and paediatricians play a central role in this organisational framework. Through integrated care, GPs and paediatricians determine new models of primary care that will allow responding to the citizens' needs 24 hours a day, 7 days a week.

Primary care physicians are involved in delivering various primary care services including preventive care activities, diagnosis and treatment, community health care services (such as nursing, rehabilitation and day care), follow-up of chronic conditions and may also provide home care assistance (Ministry of Health, 2011; Lo Scalzo et al., 2009). As part of the primary care sector, there are also emergency GPs (*Guardia Medica*) operating during out-of-hour, who can make in home examination. Patients can self-refer to emergency GPs in case of an urgent health need. This service is free of charge for users.

PCPs work under a government contract as independent professionals. A collective agreement is signed every three years by consultation between the central government and the GP's trade unions to specify the duties, responsibilities and payment levels of PCPs. The number of patients primary care physicians can have on their list is also determined by the collective agreement. The collective agreement might be integrated by regional agreements accordingly to local policy for improving specifically primary health care targets. Currently, full-time GPs and paediatricians can register up to 1 500 and 800 patients on their list respectively. These numbers are reduced to 500 and 400 patients for part-time GPs and paediatricians. In 2009, each GP had on average 1 134 patients and each paediatrician 857 patients on their list (Moscarola, 2013). Evidence shows that the average number of patients between 2001 and 2009 has increased by 3.4% and 9.4% for GPs and paediatricians respectively, reflecting higher medical needs and a growing demand for primary care services (Moscarola, 2013).

Primary care physicians are paid through a mixed system comprising both capitation and fee-for-services sums (Lo Scalzo et al., 2009). Both components are negotiated during the collective agreement and are applied uniformly across the country. In 2009, the per capita sums for GPs was fixed to EUR 40.05 (Moscarola, 2013), this amount being then adjusted according to the age of patients, the number of patients on PCPs' patient list and on years elapsed since graduation. The fixed payment is further dependent to the condition of working in group practices and from the hiring of nurses and the use of additional administrative and IT staff. PCPs might receive additional allowances from the Local Health Authorities if the latters are engaged in the delivery of planned care for patients with chronic conditions receiving care at home. The capitation payment is further adjusted if PCPs are working exclusively in the NHS and for those working in group practices. Specific medical interventions or treatments aimed at cost-containment or more efficient use of health resources such as minor surgery, preventive activities, therapies and post-surgery follow-up are covered in fee-for-services sums (Bruni et al., 2009).

Primary care physicians act as gatekeepers to secondary care

GPs and paediatricians should act as "gatekeepers" and co-ordinators for the Italian SSN. They are expected to assess patients' needs and to deliver primary care services including the prescription of pharmaceuticals, ordering medical procedures and referring patients to specialist or hospitals if medically necessary (Lo Scalzo et al., 2009). PCPs are the first line provider of care and only patients who had a referral from a PCP can receive specialist, outpatient or inpatient hospital care. Self-referrals are only allowed for specialist psychiatric services, services for dental care and gynaecological services. This gatekeeping and co-ordination system means that PCPs manage the interface with the most expensive levels of health-care and they connect and create the needed interaction with them.

Citizens residing in each health district must by law enrol with a named GP or a paediatrician. There is no constraint for residents, they can choose any physician they prefer supposing that PCPs have not closed their list in reaching the maximum number of patients allowed. Once a resident chooses a PCP, he is allowed to change at any time if the former is not satisfied. Registered patients have free access to their PCPs, as well as access to other specialist services in ambulatory care or in hospital departments after approval by their GPs through the central booking point (*Centro Unico di prenotazione* – CUP) or directly in the public/authorised place where the patient intends to receive specialist service. Specialist service generally implies co-payment on diagnostic, therapeutic procedure and specialist care but for the exemptions for pathology and income.

In 2012, there were around 0.76 GPs per 100 000 inhabitants and 0.91 paediatricians per 100 000 children aged between 0 and 14 years old (OECD, 2013a). At the same time, the number of GPs or paediatricians per 100 000 residents did not vary significantly across Italian R&AP, although figures for PCPs are higher in the South of Italy and the Islands. In the South for example, there is 0.80 GPs per 100 000 inhabitants while in the north of the countries there are 0.72 GPs per 100 000 inhabitants. The density of GPs is even higher in the central regions with 0.83 GPs per 100 000 inhabitants (ISTAT, 2012).

According to the 2010 CENSIS survey conducted on the general population, patient satisfaction with Italian GPs is high (CENSIS, 2010). Users place great confidence on the GPs, who are considered as the cornerstone of the Italian health care system to ensure continuity of care.

General practitioners follow a formalised training programme

To become a GP requires to first completing a degree of five years in Medicine and Surgery in a public or private medical university. A three-month practical training must be undergone during the programme including a one month training in a medical department at hospital, a surgical department at hospital and in a general practitioner's office. This means that all Italian medical students are exposed to general practice as part of their training. As further explained in Chapters 1 and 3, a public examination must be completed to be registered as physician and to be allowed to practice. A final degree of three years is required to achieve the speciality of general practice.

In Italy, there is an imbalance in the physician workforce between generalists and specialists. GPs only made up 23% of all physicians which is below the OECD average of 30%. Discussion with key stakeholders in Italy and recent studies (Moscarola, 2013; Carelli, 2010; Greene, 2012) point to major challenges related to the GP workforce. There are concerns about the number of GPs approaching retirement, which will make difficult for Italian authorities to maintain overall levels of primary care provision.

Whilst the demand for GP services is expected to increase given the ageing population and the rising burden of chronic conditions; it is likely that there will be more GPs leaving the profession than new inflows of GPs. According to current projections, there will be a potential lack of primary care physicians by 2020 of between 5 402 and 10 338 GPs and this gap is expected to even increase by 2025 (Moscarola, 2013). At the same time, it seems that GP training is becoming less attractive than other medical specialities (Greene, 2012). One possible explanation is that following GP education programme, newly qualified doctors might work during more than ten years as a locum, or as a substitute doctor before achieving a fixed post (Greene, 2012).

2.3. Recent initiatives to strengthen primary and community care

Over the past decade, Italy has begun reorganising its primary care sector by experimenting with new models of service delivery that aim to create more comprehensive, safe and effective pathways of care. The Balduzzi Law (No. 189/2012) has sought to encourage group practice and to develop community care services to improve co-ordinated and integrated care at community level.

Recent reform has sought to encourage group practice

Italian R&AP regulate the organisation of health districts to ensure that primary care setting implies care co-ordination and to achieve greater integration between health and social care. To this end, the Italian government has recently introduced different associative forms of primary care practitioners. The Law 189/2012 has been an important step to foster continuity and integration of care, as well as to further develop chronic disease management programmes in Italian R&AP.

National Collective Agreements regulate relationships with GPs and pediatricians, identifying the modality of work. At present, associative forms are a key instrument to reach targets of health protection, quality improvement and appropriateness of care. Collective agreements (Accordi Collettivi Nazionali, 2009) specify an "additional compensation" for the "voluntary adhesion" to a range of associative forms and the adoption of technological equipment such as a network connection. Associative forms outlined by the National Collective Agreement include: the "*Medicina in associazione*", the "*Medicina in rete*", and the "*Medicina di gruppo*".

- *Medicina in associazione* is an organisational structure gathering between three and ten PCPs who are working from their own office. Although associates do not operate in the same office, they share clinical experience, participate on common project, and work jointly to develop guidelines. An additional EUR 2.58 is allocated to PCPs for each patient registered on their list.

- *Medicina in rete* has the same structure of *Medicina in associazione*, but PCPs further need to share a *common* patient electronic health record. An additional EUR 4.7 is allocated to GPs for each patient registered on their list.

- *Medicina di gruppo* is the most extensive organisational structure for PCPs. It consists of between three and eight PCPs sharing the same office and a common patient electronic health record. Associate can deliver care to patient entitled in their associate's list. PCPs working in this type of group practice *receive* an additional EUR 7.0 for each patient registered on their list. At the same time, economic incentives are given to these PCPs to encourage them employing support or medical staffs such as secretary, physician's assistant or nurse. In this case, they can receive additional sums ranging from EUR 3.50 to 4.00 per patient registered in their list. Finally, the use of advanced IT services or computer systems implemented by the region entitles PCPs to receive an additional payment of EUR 77.47 per month.

Although supply side incentives encourage PCPs to work in group practice, there is no pay-for-performance component in the current payment structure that is negotiated centrally. Quality discussion did not appear to be a significant part of trade-unions negotiations over the GP contracts at national level. R&AP have a large degree of autonomy in defining additional payment for PCPs. Each region may introduce economic incentives to complement the national current payment structure. These economic incentives can relate to performance, appropriateness of care or the adoption of patient referral.

Recent years have also seen the development of community care networks and of community hospitals

As in many other OECD countries, a key priority in Italy is to achieve better co-ordination of services across the continuum of care to improve quality and curb health care costs. This is critical given the ageing population and the growing burden of chronic diseases which require a patient-centered response from a wide range of health professionals (Naylor et al., 2013; Hofmarcher et al., 2007). In Italy, there have been concerns about the lack of co-ordination, continuity of care, and about fragmentation of health care services (Lattanzio et al., 2010). As a result, the past few years have seen efforts to reorganise its primary care sector and experiment new models of community care services in order to create more comprehensive pathway of care and meet the needs of patients having complex chronic conditions.

The recent health planning legislation (Balduzzi Law No. 189/2012 and the *Patto per la Salute 2014-2016*) provides instruments for the organisation of community care services according to operational forms that include single profession organisation, also known as *Aggregazioni Funzionali Territoriali* (AFT) and *Unità Complesse di Cure Primarie* (UCCP). While the former is defined as a group of PCPs which are functionally integrated in a homogeneous territory to share health objectives, UCCP is identified as the community health care facility set-up within the AFT and made of PCPs, nurses, specialists, administrators and other social workers. The Balduzzi Law No. 189/2012 settled the contents of PCPs' Collective Agreement for the establishment of AFTs and UCCPs.

The overarching aim of the reform is to identify organisational models based on professional integration that involves direct participation of patients and families. The reform modifies the role of hospitals – now more specialised and technologically equipped for acute care – while strengthening the role of primary and community care as an interface between the population and the health care system. Taking impulse from national regulations, R&AP have implemented targeted plans for restructuring the primary care sector through the setting-up of organisational models capable of providing integrated care.

Specifically, the legislation involves the establishment of community care networks open 24 hours a day, that are able to operate in a co-ordinated way with a direct connection with hospitals. The development of community care services is expected to reduce unnecessary hospital admission and to prevent inappropriate visit to emergency services, to promote healthy behaviour and improve patient's quality of life, in particular for those affected by chronic conditions.

The reference model for such a new concept of health care provision is the Chronic Care Model (CCM). CCM is considered as the key instrument to efficiently manage chronic diseases, while improving the value of primary prevention. Proactive medicine known as *Sanità di Iniziativa* is what is developing in Italy, an organisational approach focusing on health needs prior to the occurrence of the disease, using targeted planning to organise a concerted response to the provision of care, to manage and slow the progression of the disease in a proactive medical approach. Within this framework, PCPs are required to meet the needs of local communities, to promote health and prevent disease.

Multi-professional community care networks which are implemented across the country include:

- *Casa della Salute* (CdS) constitutes an organisational and structural solution aimed at fostering unified and integrated *social* and health care services. CdS might act as a reference point for citizens through a concerted response to health needs.
- *Unità Territoriali di Assistenza Primaria* (UTAP) represents community care structures at high multidisciplinary and inter-professional integration.
- *Unità Complesse di Cure Primarie* (UCCP) is a community care network aims at efficiently manage chronic conditions through multidisciplinary care teams, personalised care plans or *chronic* care models.

These regional models of community care networks imply effective communication between professionals, decreasing hospital use and health expenditure (Shaw and Meads, 2012). Compared to traditional model of primary care, community care networks are better involved in care co-ordination, they entail more effective prevention and suppose a lower use of technical resources (Calvaruso and Frisance, 2012; Carbone et al., 2012; Compagni et al., 2010). Another critical feature of community care networks is that they are developed alongside the other parts of the health care system, with a high level of integration between different levels of care (see Box 2.1 for Toscana and Emilia Romagna).

Box 2.1. Example of community care networks

The Nuclei of Primary Care and Casa della Salute in Emilia Romagna

Emilia Romagna had a long tradition of redefining its primary care services since the process started as part of the 1999-2001 Regional Health Plan. In 2011, there were 38 Health Districts and 2 146 Nuclei of Primary Care (NCP) consisting of an organisational model of primary care operating in geographical areas with homogeneous characteristics. NCPs are the core of *Casa della Salute* (CdS), the frontline access to regional health care services and they are responsible for the public health planning and the management of the community care facilities. From 2011, there were 124 CdS forecasts, of which 50 CdS functioning and providing care at the community level, delivering minor emergency care, managing chronic diseases and offering diagnostic services (Calvaruso and Frisance, 2012; Donati, 2013; Servicio Sanitario Regionale Emilia-Romagna, 2011; Maio et al., 2012; Carbone et al., 2012).

The CdS is an integrated network of health care services in the same geographical location which bring into relation PCPs, specialist, nurses, hospitals and other social workers. It is based on vertical integration from primary care to secondary care and constitutes a point of reference for citizens to be steered through the health care system. CdS provides a single point of access to citizens, ensures continuity of care 24 hours a day, co-ordinates health services and develops prevention programmes. GPs participation is made mandatory since the 2011 Regional Agreement. The 2011 Agreement also states that a care co-ordinator must be established in each NCP to play a critical role in the clinical governance of care pathways.

Most importantly, *Percorso Diagnostico Terapeutico Assistenziali* (PDTA) has been developed in the Emilia Romagna region. PDTA are Path Diagnostic Therapeutic Care for the management of the most common chronic diseases such as diabetes, COPD, congestive and chronic renal failure. PDTA consists of new models of care that imply sharing guidelines for the management of chronic conditions, the development of educational programme and the establishment of programmes for active monitoring of chronic conditions such as follow-up telephone, outpatient counselling, teleconsultation and service of integrated home care. The care co-ordinator is a GP, and a nurse can be defined as a care-manager to guarantee continuity of care. Care co-ordinator has to share with local professionals and hospitals all relevant clinical information through the SOLE health network (*Sanità On Line*). In 2011, nearly 98% of PCPs are connected to other health and social professionals through the SOLE network, which enable to share patient electronic health records across different health care settings (Servizio Sanitario Regionale Emilia-Romagna, 2011).

As demonstrated by Shaw and Meads (2012), the setting up of CdS in the region of Emilia Romagna have resulted in a decrease in specialised health care cost and thereby provides tangible results to shift health resource away from hospital care.

Box 2.1. Example of community care networks *(cont.)*

Casa della Salute in Toscana

The region of Toscana experimented CdS following the 2002-2004 Regional Health Plan and the 2002-2004 Integrated Health Plan (Calvaruso and Frisance, 2012). The region had turned away resources from the hospital network to invest in the establishment of CdS. It is important to note that Toscana received EUR 43 million from the central government to develop these 16 community care networks (Calvaruso and Frisance, 2012; AGENAS, 2013; Carbone et al., 2012).

CdS in Toscana constitutes the single point of access to visit health care services. Care co-ordination and integration are achieved through the application of care protocols for different chronic diseases, and due to the use of clinical guidelines that are established at the regional level. The collaborative work between GPs, nurses and others health or social workers is facilitated by the use of electronic medical records to share information about patients' chronic diseases, to plan health interventions and organise therapeutic patient programme. A great emphasis is given to home care, primary and secondary prevention programmes and to patient participation.

To guarantee care co-ordination and to ensure the continuity of care across clinical settings, Chronic Care Models (CCM) have been implemented since 2008 to increase proactive health care intervention for patient with complex chronic health problems. A clinical team is defined within the CCM with 5 to 15 GPs, one nurse, and one health worker. Although GPs participation to CCM is voluntary in Toscana, they have a central role in acting as a care co-ordinator and as a supervisor. GPs are responsible for co-ordinating health interventions and have a determinant role in clinical governance by providing guidance to the clinical team towards desired objectives, by carrying out evaluation and audits and by ensuring that all GPs undertake mandatory training programme. Nurses play an important role in being responsible for counselling, self-management support and performing clinical measurement or diagnostic tests.

The development of CPCCs in Toscana has been a great success. In Empoli for example, its establishment has resulted in a reduction of hospitals referrals and inpatient admissions. The shift from secondary care to primary care accounted for cost savings of 6% and 22% in 2008 and 2009 respectively (Shaw and Meads, 2012).

Furthermore, "Ospedale di Comunità" and "Ospedale di Distretto" are community or country hospitals developed to provide intermediate care for patients discharged earlier from hospital or at risk of being admitted and frequently readmitted to hospital because of chronic conditions. These community hospitals imply nursing management and the involvement of self-employed physicians and GPs. Given the current efforts to shift care from the hospital sector and towards primary care settings, these intermediate care facilities provide a range of services for bridging acute, primary and social care (see Box 2.2 for Campania, Lombardy, Pugliaand Veneto).

Overall, the objectives are to reduce the length of hospital stays, prevent hospital admissions and readmissions, improve transitions from hospital to community and primary care settings, and to retain patient's independence as long as possible (Plochg, 2005).

The setting-up of community care networks and community hospitals constitutes an adequate response to anticipate the rising burden of long term conditions and of chronic morbidities. Given that a core focus of the *Patto per la Salute 2014-2016* is shifting care away from hospitals and into primary and community care, the Italian Government should consider playing a more prescriptive role to strengthen and expand these community care services throughout the country (see Section 2.5).

Box 2.2. Description of community hospitals and intermediate care facilities

Community or county hospitals ("*Ospedale di Comunità"* or "*Ospedale di Distretto"*), as well as intermediate care facilities (such as "*Strutture di ricovero intermedie"*) have been developed in several R&AP including for example – Campania, Lombardia, Puglia and Veneto. These structures provide integrated care for patients with intermediate needs for institutionalised care. Patients discharged earlier from hospitals or at risk of being admitted and frequently readmitted to hospital are potential users of these alternatives sites of care. The intention of establishing community hospitals or intermediate care facilities is to improve patient's experience of care and to promote a more efficient use of acute care by shortening or avoiding inappropriate hospital stays. Such community hospitals preserve the independence of patient and keep them closer to their homes. Nurses play a role of case-manager and multi-disciplinary interventions are implemented.

In Campania, "*Ospedale di Comunità*" and "*Ospedale di Distretto*" have been established as part of the Regional Health Plan for 2011-13. These community hospitals provide intermediate care between home care services and acute hospital services. "*Ospedale di Comunità*" and "*Ospedale di Distretto*" are specifically set-up for elderly patients with complex chronic conditions or patients discharged from hospital in need for rehabilitative care and clinical surveillance. Lengths of stays are expected to be rather short, between 15 and 30 days.

In Lombardia, community facilities set-up to provide intermediate care range from "*La rete dei servizi socio sanitari e territoriali*", "*La integrazione tra ospedale e territorio*", or "*Le structure di degenza sub-acute/post-acuta*". These interventions have been shown to improve care continuity between different levels of care and to provide more efficient management of chronic disease.

Similar facilities such as "*l'Ospedale di Comunità*", "*la Strutture Sanitarie Territoriali*", "*la Strutura Complessa Cure Primarie e Intermedie*" or "*la Strutture sanitarie territoriali*" are also present in the region of Puglia. These facilities or community care networks have been set-up close to or on same premises as hospitals. The objective is to create more comprehensive, safe and effective pathways of care for frail patients having long-term conditions. It fosters continuity and integration of care between health and social care.

In Veneto, "*Strutture di ricovero intermedie*" and "*l'Ospedale di comunità*" are specifically developed to provide rehabilitative care for patients for whom it is hoped hospitalisation could be avoided but who are too sick to remain in their homes.

Source: Information provided by the Italian authorities.

The Italian Society for General Medicine aims to promote quality in primary care

The scientific society for primary care (*Società Italiana di Medicina Generale* – SIMG) was founded in 1982 as a research unit. The Scientific society has set up an extensive number of initiatives to underpin continuous quality improvement in the primary care sector. However, participation in this professional organisation is voluntary, and covers only 15% of Italian GPs.

The overarching aim of the scientific society is to promote the role of GPs within the Italian NHS. To this end, the society organises conferences, develops vocational and undergraduate training. The Society is also involved in national researches on drug safety and drug utilisation including for example improvement in antibiotics prescription. A research centre, called Health Search Network, has been specially set up to organise training, share clinical and organisational standards. The Centre has also developed a database where GPs might collect patients' information. This constitutes a key outcome measurement system to monitor and provide feedback for health providers. At the same time, SIMG publishes a regular journal (*Medicina Generale*) and further disseminates clinical guidelines and patient pathway by looking at international literature across several area of practice including for example long-term conditions, multi-chronic pathology and new or specific drugs. It works in collaboration with national research centres, central government and with international universities.

Although SIMG conducts impressive initiatives to steer improvement in quality of care in general practice, it appears difficult to move towards a quality-based approach at system-level since 85% of GPs are not currently involved in the professional organisation. A wider participation to the professional organisation should be considered by PCPs and Italian authorities might also look upon existing initiatives for nurturing a quality improvement culture in the primary and community care setting.

2.4. Outcomes associated with primary care in Italy

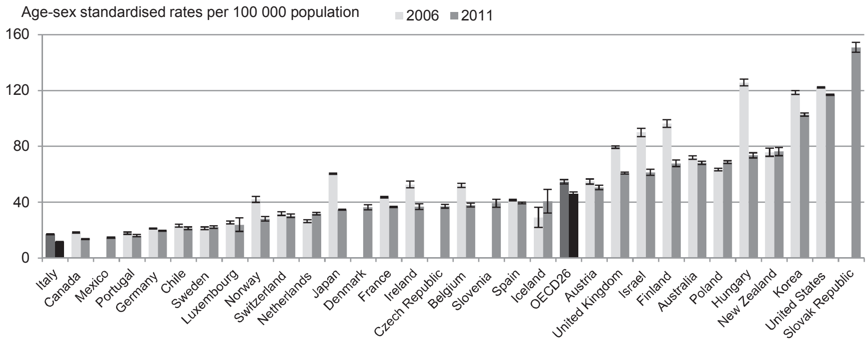
Some indirect measures, such as avoidable hospitalisation for chronic conditions, suggest good quality primary care in Italy. There are however large variations across R&AP and data from prescribing and screening in the primary care sector are a cause of concern. This suggests that primary and community care networks may not be ready to cope with the increasing demand for health care that will arise from the ageing population and the growing burden of chronic conditions.

Avoidable hospitalisations for chronic conditions indicate good quality primary care, but there are large variations across Italian regions

In line with the good overall health status of the Italian population outlined in Chapter 1, Italy performs well on some Health Care Quality Indicators submitted for the OECD project. Hospitalisations for chronic conditions, also known as avoidable hospitalisations, are used as an indirect indicator of the overall effectiveness of primary health care. There is growing evidence that proactive management of some chronic conditions may prevent or reduce the need for acute hospital admissions (Purdy et al., 2009). Effective treatment for asthma, chronic obstructive pulmonary disease (COPD) and diabetes should be increasingly managed in primary care settings to avoid acute deterioration and also to prevent their admission to hospital. A high performing primary care sector not only is cost-saving but also preferable to the patient in avoiding hospital admission.

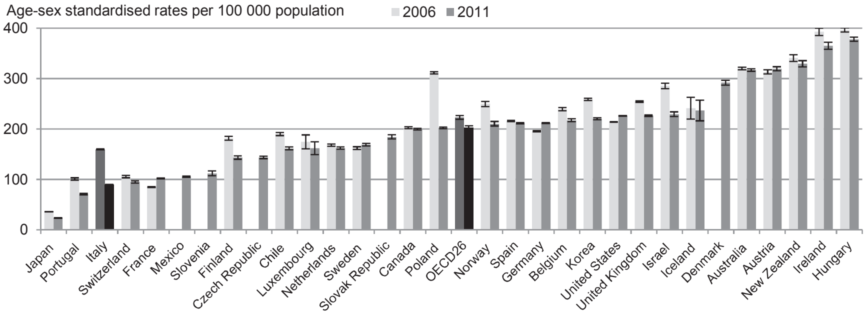
As shown by Figure 2.1, Italy reports one of the third lowest rates for COPD hospital admission rates, behind the Japan and Portugal standardised rates. In 2011, the Italian COPD hospital admission rates at 90 per 100 000 population are well below the OECD average of 203 (OECD, 2013a). In a similar vein, Italy reports the lowest rates for both asthma and diabetes hospital admission among the OECD countries (see Figures 2.2 and 2.3). Most importantly, for each of the three conditions Italy reports a reduction in avoidable admission over recent year, representing either improvement in the quality of the Italian primary care sector or a variation in the prevalence of chronic conditions over time.

Figure 2.1. COPD hospital admission in adults, 2006 and 2011 (or nearest year)



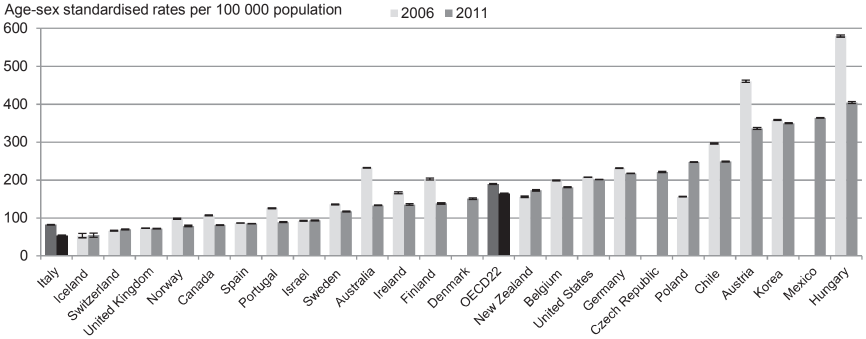
Source: *OECD Health Statistics 2013*, http://dx.doi.org/10.1787/health-data-en.

Figure 2.2. Asthma hospital admission in adults, 2006 and 2011 (or nearest year)



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

Figure 2.3. Diabetes hospital admission in adults, 2006 and 2011 (or nearest year)



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

Whilst the primary care sector in Italy performs well on average, there are significant differences across R&AP. Empirical evidence suggests, after adjustment for demographic factors, a North-South gradient where Southern regions show higher hospitalisation rates for chronic conditions[1] (see Figure 2.4) (Rosano et al., 2013; Rosano et al. 2011). The higher risk of avoidable hospitalisation for chronic diseases in Southern regions compared to Northern regions might be explained by several factors including health-care resources (such as the availability of health professionals and hospital beds), individuals' socio-economic conditions and the epidemiology of the diseases. Regarding the latter, one should note that southern regions are found to have the highest prevalence of some chronic conditions such as diabetes and hypertension (Istituto Superiore di Sanità, 2012).

Figure 2.4. Average hospitalisation rates for chronic conditions among adult population along the years, 2001-08 (rates per 100 000 persons)

Source: Rosano, A. et al. (2013), "Preventable Hospitalization and the Role of Primary Care: A Comparison Between Italy and Germany", *Journal of Public Health*, Vol. 21, pp 445-454.

Other quality indicators show a mixed picture while further challenges place pressure on primary and community care in Italy

Beyond avoidable hospitalisation for chronic conditions, information on prescribing in primary care sector is a further indicator enabling to get a more comprehensive picture of quality in the primary care sector. The data collected by OECD regarding the volumes of antibiotics prescribed in primary care show that Italy reports one of the highest volumes, around 1.5 times the OECD average. This high volume of prescribed antibiotics might be related to the general lack of guidelines and incentives that primary care providers are exposed to (Akkerman et al., 2005; Koller et al., 2013).

In a similar vein, screening rates which are a core primary care activity in order to prevent and early diagnosed disease also need improvement in

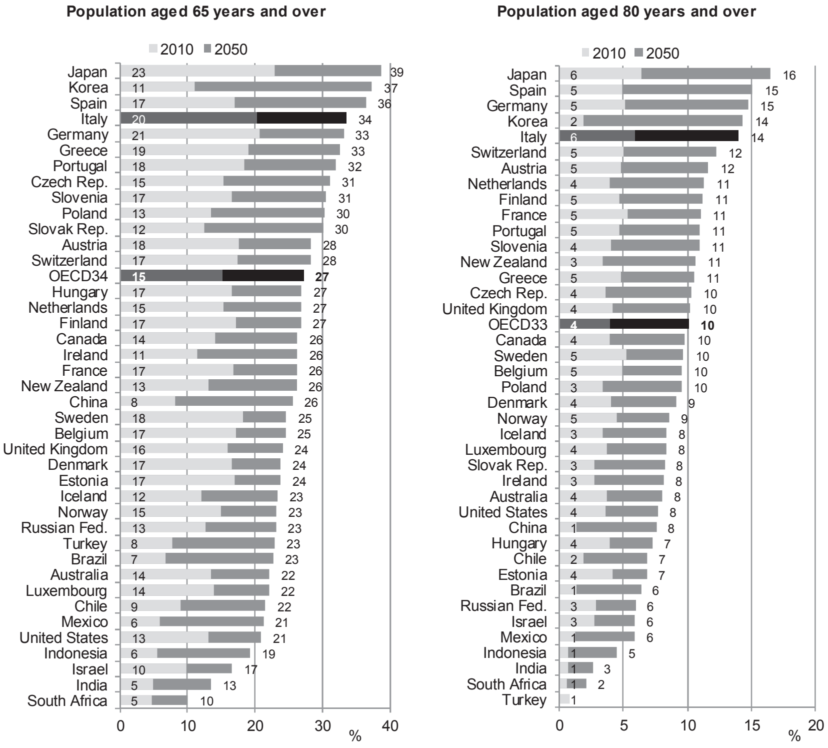
Italy. For example, on mammography and cervical cancer screenings, Italy is below the OECD average (OECD, 2013a). As outlined previously, there are also large variations of screening rates across Italian R&AP. The Valle d'Aosta (87%) and the province of Emilia Romagna (89%) present the highest rates of cervical screening, while the lowest rates are reported in Calabria (56%) and Campania (60%) (Istituto Superiore di Sanità, 2012). A similar North-South gradient is observed regarding mammography and colorectal screening rates (Istituto Superiore di Sanità, 2012).

A cause of additional concern, the share of the population aged over 65 years in 2011 was the fourth highest among the OECD countries. As demonstrated in Figure 2.5, the share of the population aged over 65 reached 20% in 2011 and it is expected to rise by 1.7 times by 2050 (Figure 2.5, left panel). The rise of the population share aged 80 years will be even faster since it is expected to grow from 6% to 14% over the next four decades (Figure 2.5, right panel). The rapidly ageing population in Italy goes hand in hand with an increased prevalence of chronic illnesses and long-term conditions. This is demonstrated by indicators of dementia prevalence, healthy life years and daily activities limitation at age 65 that are all worse than OECD averages (OECD, 2013a). At the same time, obesity rates among Italian aged 15 and over are the second highest among OECD country, which means higher risk of cardiovascular diseases or diabetes during adult age putting further pressure on the primary care sector (Lobstein, 2010; Currie et al., 2012).

Taken together, these international comparisons call for developing initiatives to strengthen primary care services. The contribution of the primary care sector needs to be enhanced to meet the challenge of an increasing burden of long-term. As the following section examines, this might involve actions in the following directions:

- Increase initiatives aimed at guaranteeing high quality of primary care services. These initiatives range from the process of strengthening the information system, developing quality standards and setting-up smarter payment system, to mechanisms aimed at enhancing preventives activities into the primary care sector.
- Consolidate the development of community care networks or community hospitals to encourage co-ordination and integration of care, specifically for patients having chronic and long-term conditions.

Figure 2.5. Share of the population aged over 65 and 80 years, 2010 and 2050



Population aged 65 years and over

Population aged 80 years and over

Source: *OECD Historical Population Data and Projections Database, 2013*, http://dx.doi.org/10.1787/888932919194.

2.5. Areas for quality improvement in Italy's primary care sector

Although the Italian primary care sector performs well on some health care quality indicators, there are shortcomings in Italy's primary care sector which require attention to guarantee high quality of primary care services. As the development of community care networks and community hospitals moves forward, it makes sense for Italy to evolve towards a more broaden and consistent quality approach. In particular, Italy needs to focus on the collection of a more comprehensive set of primary care indicators, the development of quality standards or the enhancement of preventive activities. At the same time, the setting-up of smarter payment systems to better reward quality initiatives and to be linked to desired activities is likely to be a useful driver of quality improvement. The central government should further consider providing more guidance and support to Italian R&AP to uniformly strengthen and expand model of community care services throughout the country.

The information system underpinning primary care needs further development

Several initiatives have been implemented to monitor the quality of care in the Italian primary care sector. This is demonstrated by a relatively important number of information systems around clinical practice. As presented in Chapter 1, a defined set of 31 indicators (the *Griglia Lea*) is collected at national level to monitor the provision of the essentials levels of care (*livelli essenziali di assistenza*). The *Griglia Lea* comprises indicators around primary prevention (such as vaccination coverage and screening rates), indirect quality measure of primary care (through avoidable hospitalisations) and also gathers some indicators around community care (such as coverage and number of places in residential facility for example). Beyond the *Griglia Lea*, the National Outcomes Measurement Programme (*Programma Nazionale Esiti*) which was set up by AGENAS to promote quality improvement in the delivery of health care services, includes 17 clinical quality indicators but most of them relate to hospitals utilisation. Much less information on the activities and outcomes achieved within primary and community care is available in Italy, although experimental projects are ongoing with some R&AP and AGENAS (the Valore Project, Matrice Project and the PIC and Luna Project monitoring the elderly disability process of care). This means that it is not possible for stakeholders and users to build a full and detailed picture of the effectiveness, safety and patient centeredness of primary care.

At local and regional level, there are a range of interesting initiatives to measure and monitor the quality of primary and community care. The Italian Society of General Medicine and Primary Care (SIMG) (see Section 2.3) has for example developed a database in general practice to collect information around clinical practice for a volunteers network of GPs. This information system aims at supporting GPs to improve the quality of their practice, enabling to analyse epidemiological trends, prescription of primary care physicians and to identify patient with high health risk. Beyond clinical practice, SIMG database comprises data recorded by each GP covering areas such as patient’s previous history, patient’s demographic characteristics, prescriptions and prevention information. Although the SIMG database is an excellent system to track pathways of care and measure performance among GPs, it only covers 15% of the GPs in Italy which moderates substantially it impacts in monitoring quality of care.

To support quality development, the existing information systems should be strengthened by considering the following challenges:

- To date, the routinely published national indicators do not provide a comprehensive picture of the effectiveness and safety of the primary care sector. While Italian authorities seek to modernise the primary care sector through the development of community care networks and community hospitals, there is a need to ensure that the ongoing reforms do not adversely affect outcome of care. Italy should thereby consider giving greater attention to the outcome of care and performance measurement. The limited set of collected indicators should be extended around preventive activity and elderly care for example. Collecting indicators around the management of chronic conditions (such as COPD, diabetes or heart failures), the co-ordination between levels of care or the patient's experience with new community care services will be critical for the success of the Balduzzi Law and the *Patto per la Salute 2014-2016*. This will ensure that PCPs and community networks or hospitals are meeting community health care needs. To this end, Italian authorities should have the ambition to develop data collection as it is performed in Israel or Denmark (see Box 2.3). In these countries, the information system is sophisticated with a large number of quality indicators around both process and outcome of primary and community care. In Israel for example, the Quality Indicators in Community Healthcare (QICH) programme covers six areas of primary care activity such as asthma, cancer screening, immunisation for older adult, child and adolescent health, cardiovascular health and diabetes. Italy could be better using some existing dataset, such as the Griglia Lea, the PNE programme, as well as the New Health Information System to introduce primary and community care quality indicators. This would increase performance measurement, transparency and accountability of primary care provider.

- As already mentioned in Chapter 1, the Italian health information system is not fully standardised and linkage of personal health data across different health care settings is highly difficult in Italy. This means that it is not possible to measure and compare performance across Italian primary care physicians and that pathway of care cannot be followed to evaluate the quality and effectiveness of health care treatment. Because ASLs and R&AP process personal health data for their own area, it makes difficult to share data and information across R&AP. At the same time, evidence shows that the share of electronic patient records between PCPs and other health care providers appears particularly low. As evidenced by Tamburini et al. (2010), only 3% of Italian GPs exchange administrative data with other health care providers. In this respect, Italian authorities should have the ambition to develop compatible electronic patient records across regional health system that would be portable through different health care settings. This would support the sharing of information among physicians, laboratories, diagnostic centres and patients. Last, there is a need to explore the possibilities for linking data from clinical and administrative databases to health and social care. AGENAS is carrying out promising initiatives in this direction with the Matrice project (see Box 2.3), which aims at integrating datasets on hospitals, diagnostics, specialist visits and GPs services in order to track pathways of care of highly complex patients.

Box 2.3. The MATRICE Project

The MATRICE Project is aimed at developing tools to exploit Italian administrative databases to produce information on the prevalence of chronic diseases and on standards of care across the country. In the Italian system, R&AP are required to collect patient-centered administrative information on health care activities according to a national common data model (IAD) and to transmit this information to the Ministry of Health and to the Ministry of Finances. Data cover demographic information, disease-specific exemptions from co-payment, outpatient drug prescriptions, inpatient diagnosis and procedures and a simple description of outpatient activity. When data are sent to the central government, due to confidentiality rules the personal identifier is discarded, making data integration at the national level impossible.

The MATRICE Project developed a solid methodological approach to measure prevalence and relevant indicators of quality of care for diabetes, hypertension, ischemic heart disease, heart failure and dementia, in order to assess the process of care provided in a comparable manner throughout Italy.

The results of the Project can now be used to test the possibility of using already existing data on complex and chronic illnesses, so as to measure the equity of PHC, and to evaluate clinical and organisational appropriateness of the care provided at different levels of governance. The Matrice standardised reports can constitute a useful governance tool allowing Italian authorities and key stakeholders to monitor pathway of care and to identify areas that may require improvement.

Source: www.agenas.it/images/agenas/In%20primo%20piano/Matrice/Monitor35__Matrice.pdf.

- Once new indicators would have been established around outcomes of primary and community care, health data should be made accessible to both PCPs and patients. This would help patients to make better informed choices and facilitate peer-to-peer benchmarking, which both foster competition and steer improvement in quality of care. The Tuscan Performance System has for example led to an improvement in quality of care for 50% of indicators between 2006 and 2010. In a similar vein, the experience from other OECD countries such as Denmark or Israel could guide Italy in such a process (see Box 2.4). The collected indicators within the Danish Quality Unit of General Practice are made available to GPs, allowing them to benchmark their practice and improving quality of care for diabetics' patients.

Box 2.4. Measuring quality and performance in primary and community care: Learning from Israel and Denmark

The Quality Indicators in Community Healthcare in Israel

The Quality Indicators in Community Healthcare (QICH) programme in Israel is an innovative quality monitoring system focused on community care. The indicators in QICH cover six areas of primary care activity (asthma, Cancer screening, Immunisation for older adult, Child and adolescent health, Cardiovascular health and Diabetes). It aims to inform all stakeholders on the quality of primary and community care across the country. Most of the indicators examine clinical outcomes based on national and international guidelines, and also have a strong focus on prevention.

The programme enables a continuous feedback of comparative data around clinical performance for both practitioner and patients, which has certainly facilitate the work toward quality improvement. Although the programme is voluntary and do not rely on financial incentives, it has resulted in noticeable improvement regarding for example the quality of care for diabetics patient (OECD, 2012). One of Israel's health funds, Maccabi, reports that amongst diabetic patients between 2004 and 2009, poor HbA1c control fell by 29% and adequate cholesterol control increased by 96.2%.

Its success is thought to be due to its robust scientific basis, consensual development of the indicator set involving GP and health insurance companies early on, clear patient-oriented objectives and, crucially, systematic and continuous feedback of comparative data to both professionals and the public (OECD, 2012).

The Danish Quality Unit of General Practice in Denmark

The Danish Quality Unit of General Practice in Denmark (DAK-E) has developed a system of automatic data capture from primary care records to monitor the quality of care. Over 30 indicators are captured including diagnoses, procedures, prescribed drugs and laboratory results regarding for example management of chronic conditions.

It also provides a platform through which GPs have access to quality reports from their own practice and it allows them to benchmark their practice against others practitioners at regional or national level. Patients can also monitor their own clinical data. Analyses using the data collected have reported significant improvements in the proportion of diabetics on appropriate anti-diabetic, antihypertensive and lipid-lowering medications. (OECD, 2013b).

Smarter design of payment systems needs to be a priority

At present, Italian PCPs are paid through a mixed system comprising both capitation and fee-for-services sums which are both negotiated during the Collective Agreement. The fee-for-service component includes financial incentives to encourage PCPs working in group practice. These supply-side incentives pertain to structure indicators such as the use of computer system or the recruitment of support or other medical staff. The FFS element of PCPs payment does not contain quality-related measure. This means that quality discussion does not appear to be a significant part of trade-unions negotiations over the PCPs contracts at national level. Although R&AP are allowed to define additional payment for PCPs, there is scope in Italy to introduce financial incentives to better reward high quality of primary care or to achieve specific targets set-up in the *Patto per la Salute* or the National Prevention Plan.

Smarter payment system could be developed into the Collective National Agreement through the FFS component. A possible policy option would be to ensure that future FFS negotiations make explicit links to national priorities and standards of care. Italian authorities for example should consider linking the FFS to the national priorities around preventive interventions or care co-ordination. Compliance with specific clinical guidelines should also be considered in the FFS component to give priority to preventive activities and to the management of chronic conditions. There are key examples for learning from other OECD countries, such as the United Kingdom where the primary care sector has achieved improvements in a range of indicators around secondary prevention and the management of chronic conditions through the use of financial incentives (Doran et al., 2006). As the development of community care networks and community hospitals occurs, Italian authorities could also adapt the FFS schedule to reward a greater set of activities undertaken by nurses. As mentioned in Box 2.1, nurses play en expanding role in community care networks in being for example responsible for counselling, self-management support and performing clinical measurement. Given that nurse led-care is associated with greater patient satisfaction, higher health outcomes and more effective chronic disease management (Keleher et al., 2009), adapting the FFS component to encourage the hiring of nurse-led preventive health checks, long-term conditions monitoring or care co-ordination activities would be a useful step.

Requirements around the continuing professional development of primary care physicians could be strengthened

In Italy, CME is compulsory for all clinicians and health professionals since 1998. Primary care physicians are required to gain 50 credits per year or 150 credits every three years. These credits are assigned to PCPs depending on the number of hours of training, the types and characteristics of the programme. CME providers are accredited by the National Commission for Continuous Education (with administrative supports from AGENAS) and the 21 CME committees at regional level. Although mandatory, the current requirement toward continuing medical education appears weak in Italy. The existing system is mostly based on a self-regulatory approach, with no peer evaluation requirement or re-certification requirement. Further, there is no consequence for non-compliance with the CME national requirements, making difficult to apply the law (Murgatroyd, 2011). At present, it is unclear whether and how many PCPs have achieved the required number of credits each year. As a result, the current system for CME does not guarantee high standard of competencies for primary care physicians and does not ensure their fitness to practice.

Further attention needs to be paid to secure compliance of PCPs towards CME requirements. The setting up of economic incentives or sanctions in case of non-compliance might facilitate such a process. The experience of the United Kingdom or Australia could guide Italian authorities in their effort of building a strong quality assurance model for primary care physicians. In the United-Kingdom and Australia, CME is linked to re-certification. Primary care physicians need to demonstrate that they have regularly participated in CME activities and there is a peer evaluation regarding professional skills. To be successfully re-certificated, primary care physicians need to achieve at least 50 CME credits per year. In Norway, specialists GPs are able to charge higher fees for each consultation than regular GPs if they have followed a number of CME courses (Murgatroyd, 2011). These initiatives might constitute notable incentives for PCPs to comply with national requirement, improving health care performance and quality of health care services.

The general lack of standards and effective use of guidelines for primary care is a stumbling block for quality improvement

Whilst developing standards for primary care would provide specific recommendations for clinicians and managers to deliver care of high quality and to monitor undesirable outcomes, there is at present no agreed national standard for primary care in Italy. Given the growing burden of long term conditions, this is especially needed because of the increased expectations to shift care out of acute hospitals and into the new community care services. There are only fragmented approaches toward quality standards of primary care services across Italian R&AP. While national standards on accreditation are rather generic, many different accreditation approaches have been developed in the R&AP but they mostly relate to hospital sector and have not yet reached the primary and community care settings. The ongoing national attempt towards the standardisation of accreditation programme (the so-called TRAC) needs to be implemented in the primary care sector to assess performance of primary care providers and identify areas that may require improvement. This would be especially important to increase PCPs and managers' knowledge around what levels of quality are required for delivering primary and community care services.

The Central authority might consider developing a sophisticated set of standards focussing on both processes and outcomes of primary and community care as implemented in other decentralised countries such as Australia or Canada (O'Beirne et al., 2012). Although voluntary, primary health care accreditation in Australia covers 75% of GPs. It is organised through the Australian General Practice Accreditation Limited (AGPAL) and offers financial incentives to support activities that encourage continuing improvements in quality of care (Buetow and Wellingham, 2003). A set of 15 nationally recognised Standards must be achieved by primary care services to be accredited by AGPAL. Further, the Australian Authorities have recently developed national standards for community and home care to develop guidance about the way community and home care should be delivered.

At the same time, clinical guidelines are weakly followed by Italian PCPs while they are defined to help health care professionals in meeting defined standards and reducing unwarranted variation in care. In Italy, they are developed by AGENAS, the National Institute of Health (*Istituto Superiore di Sanità*, INIH), Local Health Units or the SIMG professional organisation. Although the Italian National Guideline System (SNLG) has been developed in 2006 to make clinical guidelines easily accessible for PCPs, their implementation is not mandatory and is the responsibility of each of the 21 Italian R&AP (see Chapter 1).

As a result of these arrangements, evidence shows a low degree of adherence to disease-specific guidelines in the primary care sector. A recent study demonstrates that adherence to the international COPD Guidelines by Italian GPs is not consistent because characterised by a low usage of spirometry and a small proportion of patients receiving respiratory therapy (Bertella, Zadra and Vitacca, 2013; Cazzola et al., 2009; 2011). Results are similar for other chronic conditions such as asthma (Cazzola et al., 2011). Taken together, these findings prove that there might be major barriers to guidelines adherence for Italian PCPs. In the region of Emilia Romagna for example, PCPs reported the least favourable attitudes toward clinical guidelines, considering them as useless for they daily practice (Formoso et al, 2001).

Further efforts are thus required to encourage information strategies for improving professional understanding and adherence to disease-specific guidelines. Setting formal educational programmes including learning sessions on disease knowledge and treatment, and practical session to prove the utility of the guidelines are specific avenues for consideration. In addition, there is no economic incentive to enhance adherence to clinical guidelines in Italy. The Quality and Outcome Framework (QOF) introduced in 2004 in the United Kingdom could be used as a role model for Italy. Financial incentives had favourable effects on primary care physician's compliance to practice guidelines and it resulted in substantial improvements in quality of care (Doran et al., 2011). At the same time, given the challenge brought by the ageing population and the rising burden of chronic health conditions, it seems advisable to produce guidelines that take into account broader clinical pathways, multiple morbidities and the management of chronic conditions.

Primary care's contribution to primary and secondary prevention needs to be enhanced

National initiatives to improve preventive care are included in the National Prevention Plan (NPP). The 2010-12 NPP, which is part of the *Patto per la Salute*, is structured into four areas of intervention: i) predictive medicine; ii) universal prevention; iii) prevention in high risk groups; and iv) prevention of complications and recurrences of chronic diseases (Ministry of Health, 2011). The agreement between national and regional government establishes that Italian region adopts and develops its own Regional Prevention Plan (RPP) for implementing interventions. The Ministry of Health, through the NPP, provides general guidance in order to support the regional prevention projects. This governance models might however have led to a mixed prevention approach across the R&AP.

The Italian R&AP have not implemented projects homogeneously and as a result, some of the desired targets set up within the *Griglia LEA* have not been achieved uniformly. In 2012, regional projects focussing on primary and secondary prevention (such as predictive medicine, prevention of complications and recurrences of chronic diseases) account respectively for only 4.4% and 4.9% of the total number of projects (Boccia et al., 2013). These figures clearly suggest that there is room for improvement in both primary and secondary preventions.

At the same time, there is a North-South gradient in screening rates where Southern region shows lower rates of mammography, colorectal or cervical cancer screening rates (Istituto Superiore di Sanità, 2012). Given that screening programme enables to prevent and early diagnosed cancer to improve patient outcomes and further reduce health care costs, there is a need to enhance primary care physician's contribution to primary prevention. To date, intervention to promote healthy habits including health education or promotion of physical activity may not be effective as proved by the growing share of obesity among children aged 15 and over. In Italy, more than one in three children are overweight, representing one of the highest rates among the OECD countries (OECD, 2013). As mentioned by The Royal College of Physician (2010), the signs or symptoms of obesity are often ignored by health professionals and health care interventions are implemented once medical complications and morbidity become apparent. Because it will be sooner or later associated with higher diabetes or heart disease prevalence and incidence, actions must be taken by PCPs to halt the "obesity epidemic" among Italian children.

Beyond primary prevention, data regarding cardiovascular diseases show that only 31% of patients with hypercholesterolemia have received drug treatment, which suggests inappropriate provision of secondary prevention (Istituto Superiore di Sanità, 2012). Other studies (Filipi et al., 2003; Sturkenboom et al., 2008) find that among hypertensive patients with multiple cardiovascular risk factors, a very low proportion (less than 18%) was being treated with concomitant antihypertensive and lipid-lowering therapies. Systolic blood pressure also appeared particularly low and not in line with recognised guidelines. The reported under provision of drug treatment for some major chronic diseases calls for actions to strengthen secondary prevention into the Italian primary care sector.

A capacity building process should be implemented at national level to better plan prevention activities and to guarantee uniform projects across Italian region. To enhance the place of primary and secondary preventions into the primary care sector, the Italian authorities should put more emphasis on the pivotal role that nurses and GPs could play. To this end, educational programmes in prevention or detection must be instituted – through for example CME programmes – in order to identify existing prevention strategies, demonstrate their effectiveness and to help professionals with care plan. Authorities should also consider investing more in the community nursing workforce to manage the prevention and the treatment of disease in order to guarantee safe and patient-centered care, while reducing the use of the acute sector.

Care co-ordination and integration between health and social care need better support and a leadership at national level

Although policy attention in recent years has been focused in encouraging community care networks and community hospitals, the implementation of these health care services is unevenly distributed across Italian R&AP. Among the 20 Casa della Salute reported in 2011 by the Ministry of Health, for example, 16 were found in Toscana, one in Molise, one in Marche and two in Umbria (Ministry of Health, 2011). At the same time, a detailed analysis of volume activity suggests that health spending differences between Italy and other European countries arise from differences in the delivery of non-acute services (Sassi, 2013). While differences in the volume of hospital services appeared limited, the analysis strongly points to the fact that community, long term care and preventive services are key areas of concern in Italy. Those services are not adequately developed compared with other European countries.

At the same time, there is evidence suggesting large heterogeneity in financial resources devoted to primary and community care services in Italy (Longo et al., 2012). Across the 13 ASLs considered in the study, health spending appears to be more directed toward traditional types of primary care services such as single practice GP, while few resources are allocated to services for frail patients or those with chronic conditions. Given the increasing health and social relevance of community care networks and hospitals, local authorities should consider whether the share of spending allocated to these services is in line with the demographic ageing and the epidemiological shift towards chronic diseases.

Beyond this, the establishment of community care networks or community hospitals is currently not used to exchange good experiences across R&AP. There is no report of the existing models enabling to compare the setting and performance of these facilities. There is scope to learn from others and it would be worthwhile for Italian authorities to invest in a best practice diffusion model. The government might consider supporting the evaluation of different models of practice, disseminating information and learning from top-performing R&AP or facilities. As demonstrated in Box 2.5, some converging factors are needed to support the establishment of community care networks, ranging from educational programme for professionals, the use of information technology or the financial support from national authorities, to the share of clinical guidelines around the effective management of chronic conditions (Calvaruso and Frisance, 2012). The role of GPs is central in co-ordinating clinical practice, alongside the progressive involvement of nurses who act as care managers for patients having chronic health conditions.

Box 2.5. Converging factors enabling the set up of community care networks

The establishment of community care networks in the regions of Emilia Romagna and Toscana have been facilitated by converging factors. The active support from the local and national authorities to set-up such facilities is perhaps one of the most important. The Ministry of Health has provided large financial support – nearly EUR 43 million – to develop the 14 community care networks in Toscana. In Emilia-Romagna, specific guidelines have been provided by the regional government for setting-up and running the facility. These guidelines covered for example the size, the geographical distribution and the standardisation of primary care facility to create uniform environment throughout the region. At the same time, health care professionals had received specific training programme to improve knowledge and skills regarding for example proactive care, use of information technology and electronic medical records. It is fair to note that the tradition of GP working in group practice has facilitated the process of setting-up community care networks. In these regions, GPs had already a high propensity to work in partnership and were already aware of the importance of care co-ordination to provide high quality of community care. The use of ICT and the shared electronic medical records accessible to all health providers working in the facility has made possible the integration of health and social care services. It also ensures the achievements of common health projects and care plans. It can lastly be stated that community care networks have been mostly set-up using local hospital premises and users have been adequately informed about service delivery.

Source: Calvaruso and Frisance (2012).

To meet the challenges brought by long term and chronic conditions, the Italian authorities shall have the ambition to strengthen and expand community care networks and community hospitals throughout the country. This could require action in different directions involving providing support to regional government – whether through financial resources or central guidance to set up these networks, as well as fostering mutual learning and encouraging data collection. Furthermore, the experience from Emilia Romagna or Toscana strongly calls for a greater leadership from the central level to play a more prescriptive role in addressing the following:

- developing guidelines for the setting up of community care networks and establishing training programme for health professionals to cope with higher and different workload
- supporting a wider use of ICT to facilitate communication and care co-ordination between levels of care
- expanding the use of chronic care models or individual care plans
- encouraging the progressive involvement of GPs and nurses acting as care co-ordinator and care managers for patients with chronic disease.

Italy has already been taking important steps in this direction with the adoption of the *Patto per la Salute 2014-2016*. The new *Patto per la Salute* provides guidance to support R&AP in the process of setting-up community care networks and community hospitals. Another core focus of the *Patto per la Salute* is to enhance the use of chronic care model and to better use ICT to monitor the appropriateness, quality and efficiency of community care networks and community hospitals.

Finally, it would be critical to collect indicators around processes and outcomes of care in order to assess the impact of community care services on outcome of care. A move in this direction has already occurred with the so-called Valore project, specifically launched to measure the impact of primary and community care organisations on the quality of care for chronic conditions (see Box 2.6).

Box 2.6. The Valore project

The Valore project was launched in 2010 by AGENAS to assess the quality of care for some chronic diseases including diabetes, heart failure, ischaemic heart disease and COPD (Gini et al., 2013). Six Italian regions took part in the project: Lombardy, Veneto, Emilia Romagna, Toscana, Marche and Sicilia. The overarching aim of the project is to assess the impact of General medicine management of chronic disease in terms of appropriateness of process, intermediate outcome and also consumption of care. To this end, electronic records regarding hospitals discharge, drug dispensing, disease-specific exemptions from co-payment to health care and the Inhabitant Registry containing demographic information as well as GP’s identifier have been used in the six regions. Record linkage is made possible in each region using a unique coded personal identifier.

Available evidence from the Valore project (Visca et al., 2013) demonstrates the increasing need for GPs to work in cooperation with other health professionals such as nurses, specialists, and social workers. Multi-professionals teams engaged in proactive and patient-centered care and a greater involvement of nurses to provide continuity of care are key components to achieve efficient management of chronic disease.

2.6. Conclusions

The Italian health care system has traditionally delivered high quality of primary care services as demonstrated by rates of avoidable hospitalisation that are amongst the lowest in the OECD. The well performing primary care sector has resulted in good health outcomes and high patient satisfaction levels. The Italian primary care sector is committed to achieve better co-ordination and integration of services across the continuum of care to improve health outcomes and curb health care costs. This is critical given the demographic shift and the epidemiologic transition towards more chronic conditions. To this end, Italy has made considerable efforts to reorganise its primary care sector by experimenting with community care services aim at improving co-ordinated and integrated care.

Community care networks and community hospitals are made up of doctors, nurses, specialists, administrators and other social workers who are engaged in proactive care to meet the needs of patients with complex chronic conditions. Evidence shows that community care models efficiently manage chronic conditions through multidisciplinary care teams, chronic care models or personalised care plans and effective communication between professionals. The role of GPs is critical in co-ordinating clinical practice, alongside the progressive involvement of nurses who act as care managers for patients with chronic health problems. The establishment of community care services constitutes an effective response to anticipate the rising burden of long term conditions and of chronic morbidities. Yet, community care services are unevenly distributed across Italian R&AP and not adequately developed in Italy compared with other European countries.

There is a need for greater involvement from national authorities to play a more prescriptive role to strengthen and expand community care networks throughout the country. Evidence suggests a need for more financial support and central guidance to regional governments, through for example the development of guidelines for the setting-up of facilities, of training programme for health professionals, the spread of ICT and the expansion of chronic care models. These organisational supports are necessary to help primary care physicians acting as care co-ordinators, to meet the challenge of higher workload and to achieve greater co-ordination between health professionals. The government should also consider exchanging experiences across R&AP to learn from the top-performing R&AP or facilities.

At the same time, Italy is characterised by a number of intrinsic shortcomings that need to be addressed to guarantee high quality of primary and community care services. There is a need of a more co-ordinated national approach toward quality in the primary care sector, and the Italian authorities should consider strengthening quality initiatives that appear still rather limited. Strengthening the information system to improve transparency, performance measurement and enhance accountability of primary care providers, and the development of a set of standards on process and outcomes of primary care are specific avenues for consideration. Available evidence also points to the urgent need for enhancing the contribution of primary care to primary and secondary prevention to improve both patient experience and outcome of care. Developing formal educational programmes in prevention or early detection through continuing professional development and introducing financial incentives through the fee-for-service component would certainly facilitate such a process. The setting-up of payment system to better reward quality initiatives and to be linked to outcome of primary care ought to be a priority to steer quality improvement.

Note

1. Chronic conditions include diabetes, amputation of lower limbs in patients with diabetes, hypertension, angina pectoris, heart failure, asthma, and COPD.

Bibliography

Accordi Collettivi Nazionali (2009), "Accordo collective Nazionale dei Medici di Medicina Generale del 23 marzo 2005", Integrato con l'CAN 27 maggio 2009, A cura della sezione OSS, AGENAS.

Akkerman, A.E. et al. (2005), "Prescribing Antibiotics for Respiratory Tract Infections by GP's: Management and Prescriber Characteristics", *British Journal of General Practice*, Vol. 55, pp. 114-118.

Bertella, E., A. Zadra and M. Vitacca (2013). "COPD Management in Primary Care: Is an Educational Plan for GPs Useful?", *Multidisciplinary Respiratory Medicine*, Vol. 8, No. 24.

Boccia, A. et al. (2013), "The Governance of Prevention in Italy", *Epidemiology Biostatistics and Public Health*, Vol. 10, No. 1.

Buetow, S.A. and J. Wellingham (2003), "Accreditation of General Practices: Challenges and Lessons", *Quality and Safety in Health Care*, Vol. 12, pp. 129-135.

Bruni, M.L., L. Nobilio and C. Ugolini (2009), "Economic Incentives in General Practice: The Impact of Pay-for-Participation and Pay-for-Compliance Programs on Diabetes Care", *Health Policy*, Vol. 90, pp. 140-148.

Calvaruso, C. and R. Frisance (2012), “The House of Health: The Need for a New Welfare”, in F. Foglietta and F. Toniolo (eds.), *New Models of Governance and Health System Integration*, Salute e Società XI – No. 1, pp. 182-203.

Carbone, C. et al. (2012), “Scenari per lo sviluppo dei servizi territoriali:confronto tra modelli regionali di presa in carico della cronicità”, in Elena Cantù (ed.), *Rapporto OASI 2012*.

Carelli, F. (2010), “New Competencies Ignored: General Practice Is in Danger in Italy”, *British Journal of General Practice*, Vol. 60, No. 578, pp. 692-693.

CENSIS (2010), “Aspettative e soddisfazionedeicittadinirispettoalla salute e allasanità” [Expectations and satisfaction of citizens with regard to health], Fondazione CENSIS, Rome.

Currie, C. et al. (eds.) (2012), *Social Determinants of Health and Well-being among Young People. Health Behaviour in School-aged Children,* (HBSC) Study: International Report from the 2009/2010 Survey, Copenhagen, WHO Regional Office for Europe, 2012 (Health Policy for Children and Adolescents, No. 6).

Compagni, A, F. Tediosi and V.D. Tozzi (2010), “L’integrazione tra ospedale e territorio nelle Aziende Sanitarie”, in Elena Cantù (ed.), *Rapporto OASI 2010*.

Donati, A. (2013), “Casi studio, Esperienze regionali per la riduzione degli accessi al Pronto soccorso”, *Quaderni di Monitor 2013*, Rome, available at www.simeup.com/doc/monitor_32_sup2.pdf.

Doran, T. et al. (2006), “Pay for Performance Programs in Family Practices in the United Kingdom”, *New England Journal of Medicine*, Vol. 355, pp. 375-384.

Formoso, G., A. Liberati and N. Magrini (2001), “Practice Guidelines: Useful and ‘Participative’ Method? Survey of Italian Physicians by Professional Setting”, *Archives of Internal Medicine*, Vol. 161, pp. 2037-2042.

Gini, R. et al (2013), “Chronic Disease Prevalence from Italian Administrative Databases in the VALORE Project: A Validation Through Comparison of Population Estimates with General Practice Databases and National Survey”, *BMC Public Health*, Vol. 13, No. 15.

Greene, N. (2012), “Italian Lessons: Exploring General Practice in Italy”, *British Journal of General Practice*, Vol. 62, No. 597, p. 204, http://dx.doi.org/10.3399/bjgp12X636155.

Hofmarcher, M.M., H. Oxley and E. Rusticelli (2007), "Improved Health System Performance Through Better Care Coordination', *OECD Health Working Papers*, No. 30, OECD Publishing Paris, http://dx.doi.org/10.1787/246446201766.

Istituto Superiore di Sanità (2012), *Rapporto nazionale PASSI 2012* [National Report PASSI 2012], www.epicentro.iss.it/passi/rapporto2012/R2012Indice.asp, accessed 15 November 2013.

ISTAT – Italian National Institute of Statistics (2012), *Italy in Figures*, Italian National Institute of Statistics, available at www.istat.it.

Koller, D. et al (2013), "Variation in Antibiotic Prescriptions: Is Area Deprivation an Explanation? Analysis of 1.2 Million Children in Germany", *Infection*, Vol. 41, No. 1, pp. 121-127.

Lattanzio, F. et al. (2010), "Health Care for Older People in Italy: The ULISSE Project (un link informatico sui servizi sanitari esistenti per l'anziano – A computarized network on health care services for older people)", *Journal of Nutrition Health and Ageing*, Vol. 14, No. 3, pp. 238-242.

Lobstein, T. (2010), "The Size and Risks of the International Epidemic of Child Obesity", *Obesity and the Economics of Prevention: Fit Not Fat*, OECD Publishing, Paris, pp. 107-114, http://dx.doi.org/10.1787/9789264084865-en.

Lo Scalzo, A. et al. (2009), "Italy: Health System Review", *Health Systems in Transition,* European Observatory on Health Systems and Policies, Vol. 11, No. 6.

Longo, F., D. Salvatore and S. Tasselli (2012), "The Growth and Composition of Primary and Community-based Care Services. Metrics and Evidence from the Italian National Health Service", *BMC Health Services Research*, Vol. 12, No. 393.

Maio, V. et al. (2012), "Physician Profiling in Primary Care in Emilia-Romagna Region, Italy: A Tool for Quality Improvement", *Health Policy Newsletter*, Vol. 25, No. 1.

Ministry of Health (2011), "Report on the Health Status of the Country", Minestro della Salute, Rome.

Moscarola, F.C. (2013), *Impact of Ageing on Curative Health-care Workforce – Country Report Italy*, Supplement to NEUJOBS Working Paper D12.1.

Murgatroyd, B. (2011), *Continuing Professional Development – The International Perspective,* General Medical Council, available at www.gmcuk.org, accessed 7 February 2014.

Naylor, C. et al. (2013), *Transforming Our Health Care System. Ten Priorities for Commissioners*, The Kings' Fund.

Nolte E., C. Knai and M. Mckee (2008), *Managing Chronic Conditions, Experience in eight countries*, European Observatory on Health Systems and Policies, Observatory Studies Series, No. 15.

O'Beirne, M. et al. (2012). *A Synthesis of Quality Improvement and Accreditation Mechanisms in Primary Healthcare.* Canadian Foundation for Healthcare Improvement.

OECD (2012), *OECD Reviews of Health Care Quality: Israel 2012: Raising Standards*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264029941-en.

OECD (2013a), *Health at a Glance 2013: OECD Indicators*, OECD Publishing, Paris, http://dx.doi.org/10.1787/health_glance-2013-en.

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

Plochg, T. et al. (2005), "Intermediate Care: For Better or Worse? Process Evaluation of an Intermediate Care Model Between a University Hospital and a Residential Home", *BMC Health Services Research*, Vol. 5, No.38.

Purdy, S. et al. (2009), "Ambulatory Care Sensitive Conditions: Terminology and Disease Coding Need To Be More Specific to Aid Policy Makers and Clinicians", *Public Health*, Vol. 123, pp. 169-173.

Rosano, A. et al. (2011), "Hospitalization for Ambulatory Care Sensitive Conditions and the Role of Primary Care in Italian Regions", *Italian Journal of Public Health*, Year 9, Vol. 8, No. 1, pp. 77-88.

Rosano, A. et al. (2013), "Preventable Hospitalization and the Role of Primary Care: A Comparison Between Italy and Germany", *Journal of Public Health*, Vol. 21, pp. 445-454.

Royal College of Physicians (2010), *The Training of Health Professionals for the prevention and treatment of overweight and obesity*, The Royal College of Physicians, available at: http://www.rcplondon.ac.uk, accessed on 28 of November.

Sassi, F. (2013, “Indagine Conoscitiva sulla sostenibilità des servizio sanitario nazionale” [Investigation of the sustainability of the national health service], Audizione Senato.

Servicio Sanitario Regionale Emilia-Romagna (2011), *The Emilia-Romagna Regional Health Service – Facilities, Expenditure, Activities as of 31.12.2011. Programs, Agreements and Organizational Models*, Emilia-Romagna Regional Health Service.

Shaw, S.E. and G. Meads (2012), “Extending Primary Care: Potential Learning from Italy”, *Primary Health Care Research & Development*, Vol. 13, No. 4, pp. 289-293.

Sturkenboom, M. et al. (2008), “Prevalence and Treatment of Hypertensive Patients with Multiple Concomitant Cardiovascular Risk Factors in the Netherlands and Italy”, *Journal of Hypertension*, Vol. 22, pp. 704-713.

Tampurini, E. et al. (2010), “Country Brief: Italy”, *eHealth Strategies*, European Commission, DG Information Society and Media, ICT for Health Unit, available at http://ehealth-strategies.eu/database/documents/Italy_CountryBrief_eHStrategies.pdf.

Visca, M. et al. (2013), “Group Versus Single Handed Primary Care: A Performance Evaluation of the Care Delivered to Chronic Patients by Italian GPs”, *Health Policy,* Vol. 113, pp. 188-198.

Database references

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

OECD Historical Population Data and Projections Database 2013, http://dx.doi.org/10.1787/888932919194.

Chapter 3

Medical education and training in Italy

This chapter considers how effective Italy's medical education system, and in particular the continuing medical education system, are for securing a high quality workforce of health professionals. The relatively good results that Italy's health system is delivering suggest that the medical workforce is, in general, providing care of a high quality. Looking to secure this high performance for the decades to come, and push back against any regional disparities in quality and outcomes, Italy has also been taking important steps towards ensuring nationally cohesive workforce training programmes. However, going forward, good medical education and nationally standardised continuing medical education may not be enough to secure a high quality, high performing medical workforce. There is scope to look to the scientific literature, and the experiences of other OECD countries, to try to maximise the impact of medical education, from the undergraduate level and beyond.

This chapter suggests that Italy could promote workforce quality when selecting future medical professionals prior to undergraduate education, and ways to improve the quality of undergraduate medical teaching. There are also opportunities to maximise the positive impact of Italy's existing continuing medical education programme, and this chapter suggests that there is a need for Italy to eventually develop more modern models of workforce quality insurance, including a move to continuing professional development, and using data to encourage health professionals to reflect on their practice.

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.

3.1. Introduction

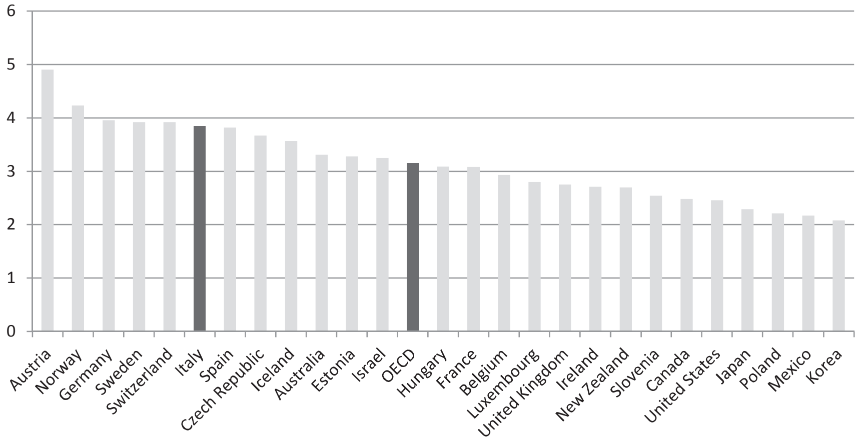
To assure high quality care and good outcomes in the health system, Italy needs a highly skilled and competent medical workforce. To help secure this, quality of medical education needs to be kept high. The generally good quality outcomes observable for Italy likely speak to the proficiency of Italian health professionals. Steps have been taken in recent years – standardising accreditation for providers of continuing medical education nation-wide, a change to the admissions process to specialist schools – which have the potential to support this high quality further. Nonetheless, going forward there are areas in which Italy could take further steps to help build a high quality medical workforce through education and training. This chapter considers the current workforce picture in Italy, and draws on examples and findings from international scientific literature and other OECD countries to make recommendations on ways in which Italy might consider strengthening the quality of medical education and training.

This chapter begins by describing the shape of Italy's medical workforce, both in terms of the rates and ratios of medical professionals, and the governance systems around planning and monitoring the medical workforce. The chapter then explores how Italy's undergraduate and specialist medical education system prepare medical trainees for their careers in the health system. This section points out some ways in which educational approaches in Italy could be strengthened, and the quality of education delivered could be improved. The last part of this chapter, in Sections 3.5 and 3.6, considers how quality can be kept high throughout the long career of medical professionals. Section 3.5 assesses Italy's continuing medical education (CME) system, and suggests that there is potential for this existing system to have a greater positive impact on medical competency and skills even with some relatively small changes. Section 3.6 suggests that in the years to come Italy should be taking steps towards a more modern, rigorous system of quality assurance, and suggests OECD examples from which Italy could learn.

3.2. The shape of Italy's medical workforce

In Italy practicing doctors per 1 000 population in 2011 were high compared to the OECD average, at 4.0 compared to 3.2 (OECD Health Statistics, 2013); 26% of physicians in Italy in 2010 were categorised as generalists, compared to an average 31% across the OECD (generalists per capita are just below the OECD average) (*ibid*).

Figure 3.1. Practising doctors per 1 000 population in Italy and OECD countries, 2012 (or nearest year)



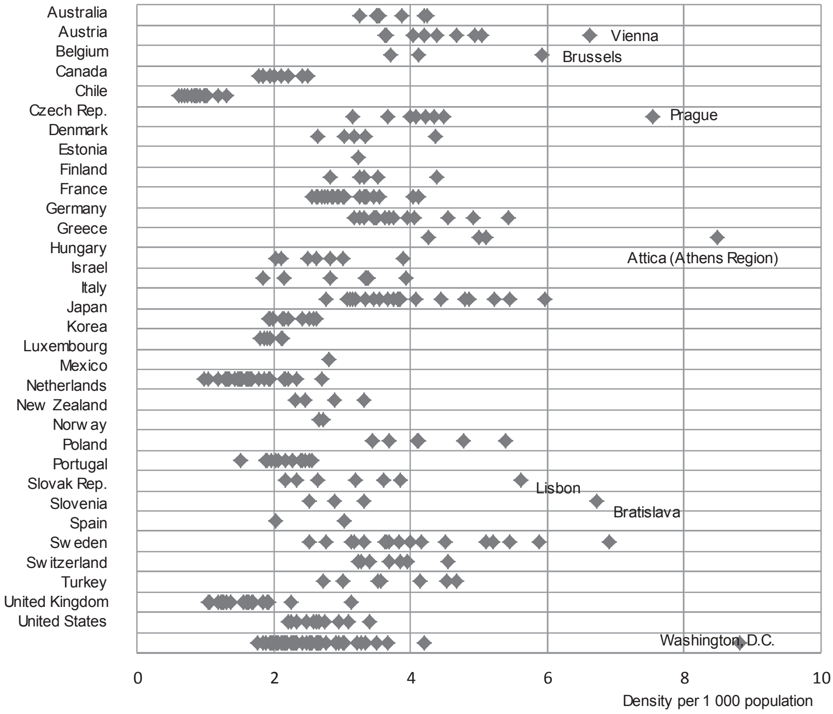
Source: *OECD Health Statistics 2014,* http://dx.doi.org/10.1787/health-data-en.

There appear to be some regional differences in workforce numbers, in the distribution of all physicians, and for some specialities for example for general practitioners and paediatricians. In most OECD countries the number of doctors per capita varies widely across regions, and Italy is no exception. Density of physicians in Italy varies from 6 per 100 000 population to below half that, at 2.8 per 100 000 (Figure 3.2).

The latest available data for 2012 reported that the mean number of GPs per 100 000 resident population in Italy was 0.76, a little higher than the OECD average of 0.7 (OECD, 2014). Although the number of GPs among regions does not differ dramatically, a slightly higher number of GPs per population can be noted in central regions. According to regional data for 2010 the autonomous province of Bolzano had the lowest number of GPs per 100 000 population (0.54).

In 2010 the average basic number of paediatricians per 100 000 residents between 0 and 14 years old was 0.91, with some variation between regions (ISTAT, 2013; Ministry of Health, 2011). The rate of paediatricians per population varied between regions, with a high of 0.11 personnel per 100 000 population aged 0-14 in Sardegna, and the lowest in the autonomous province of Bolzano (0.07). A specific study on paediatrician turnover is advising that a higher number of contracts should be given to medical schools for specialisation in paediatrics.

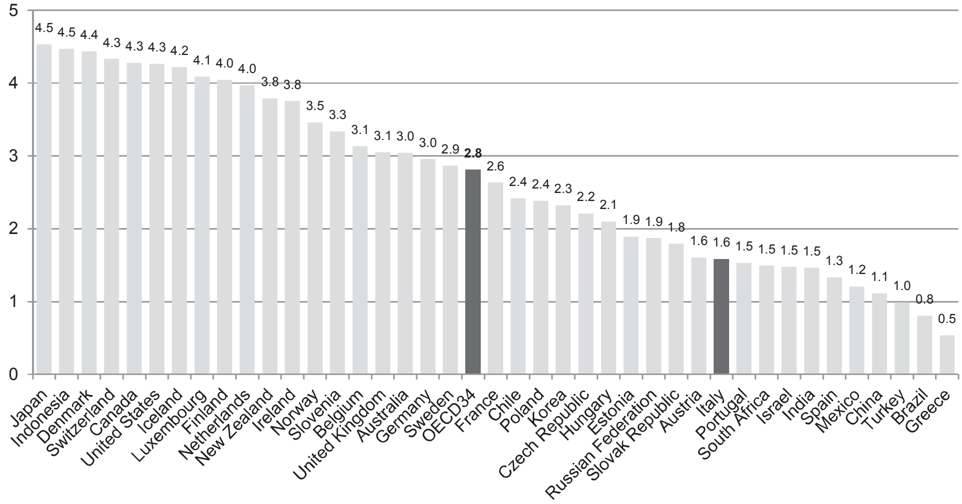
Figure 3.2. Geographic distribution of doctors, physician density per 100 000 population by Territorial Level 2 regions, 2011 (or nearest year)



Source: OECD (2013), *Health at a Glance: OECD Indicators*, Paris, OECD Publishing, Paris, http://dx.doi.org/10.1787/888932918586.

The number of practicing nurses in Italy is lower than the OECD average; the ratio of nurses to physicians in Italy is quite significantly lower than the OECD average, but rose slightly in the years preceding 2011. In terms of hospital nurses per 100 000 population, Italy has historically had one of the lowest rates among a cohort of comparable EU countries, with the rate remaining fairly stable from the mid-1990s until 2005, when a rise occurred, most probably due to policies aimed at allowing foreign-trained nurses to practise in Italy and other measures to promote the profession. Even in 2011 after this rise, the number of practicing nurses per 100 000 population in Italy was 6.3 compared to the OECD average of 8.8 (OECD Health Statistics, 2012). The rate of nurses compared to physicians in Italy is also low, at 1.6 nurses per physician, compared to the OECD average of 2.8 (see Figure 3.3).

Figure 3.3. Ratio of nurses to physicians in Italy and other OECD countries, 2011 (or nearest year)



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

Concerns about shortages of nurses did lead to a large increase in university-level nursing education programmes in Italy starting around 2000, with the number of newly graduated nurses more than tripling between 2000 and 2007 (OECD, 2013a). There are 28 000 non-Italian trained nurses in Italy, who are subject to different verification criteria. Nonetheless, nursing graduates in Italy are low compared to the OECD average, both when measured against the population (18.8 nursing graduates per 100 000 population compared to the OECD average of 42.9) or against total nurses (29.6 nursing graduates 100 000 nurses compared to the OECD average of 53.1). Contracting salaries are also an area of some concern for nurses; remuneration of hospital nurses in Italy fell by -0.5% in nominal terms between 2005 and 2011 (OECD, 2013a).

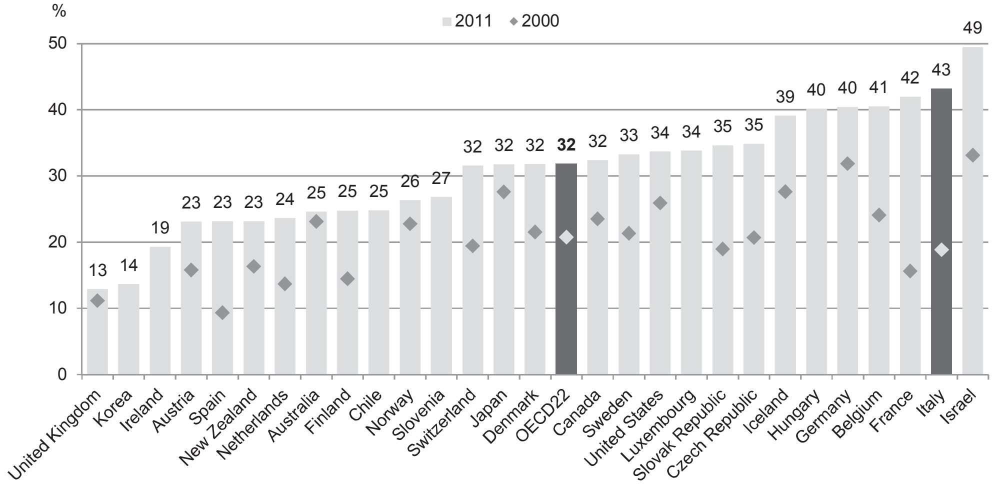
There is some discussion around the expansion of nursing specialties, and the introduction of nurse practitioners, which has been introduced with some success in other OECD countries such as Australia, New Zealand, the United Kingdom and the United States. However, the low density of nurses and relatively high density of doctors may slow any such development (Irdes, 2005).

Workforce planning

In Italy there is a bottom-up approach to NHS human resources planning (national needs overall are established based on regionally reported needs) and there is a top-down data check by the Ministry of Health. Primary responsibility for health workforce planning is therefore at the regional level, with information then fed back to the Ministry of Health, which brings together the data and forecasts from the regionals, and analyses and validates the results to make appropriate recommendations to the Ministry of Education concerning entry to medical, nursing and other health-related education programmes. The main objective of the health workforce planning in Italy is ensure a suitable number of health care professionals in order to satisfy demand and to avoid workforce imbalances in the National Health Service, and so that the Ministry of Health and the regions can agree on the number of students to enter related education and training programmes.

The Italian Ministry of Health also takes part in the EU Joint Action on Health Workforce Planning, which started in April 2013. This project is a platform for collaboration and exchange between member states to prepare the future of the health work force. The Italian Ministry of Health, in partnership with AGENAS, leads Work Package Number 5, “Exchange of good practices in quantitative planning methodologies”.

Figure 3.4. Share of doctors aged 55 years and over, 2000 and 2011 (or nearest year)



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

There has been a concern in Italy about the number of doctors, and the number of doctors approaching retirement; Italy has a very high percentage (42.2%) of doctors aged over 55 (see Figure 3.4). As such, Italy has introduced some policies that might help to prolong the working time of physicians, such as incentives for postponing retirement. Given the importance that Italy is putting upon increasing primary care coverage some increase in general practitioners may be needed in coming years. There are also shortages among some specialisations, for example paediatrics.

3.3. Building a high quality workforce

Medical education

Medical education in Italy is regulated by the Italian Ministry of Education, University and Research, meaning that teaching uniformity is secured all over national territory (Lo Scalzo et al., 2009). Medical education is also consistent with the EU directive on medical education allowing free movement of medical professionals within Europe (Directive 2005/36/EC). Physicians trained in Italy follow an undergraduate programme which lasts at least six years, during or after which students must work within a hospital ward for at least six months. The educational format is typically three years of basic medical and scientific education, followed by continued courses alongside clinical experience in a medical (usually hospital) setting, but can vary between educational institutions as Italian universities are autonomous bodies. Admission to medical school is based on a national exam, and application portfolio. The national examination is primarily a scientific exam, covering biology, physics, chemistry and maths, as well as a logic and general culture component.

After medical school, graduates must pass a national examination so as to be placed on a national physician register and be allowed to practise. The license issued is valid for the whole of Italy, and is of unlimited duration.

Following licencing, physicians can choose among various professional paths depending on the kind of postgraduate specialisation programme they attended. Specialisation consists of a four to six year course at a chosen specialist school, and is required for physicians to work in the hospital sector. The process by which newly qualified doctors apply to specialist schools has recently been changed. Previously, students applied to the specialist departments of individual hospitals, where they may have been previously doing an internship as part of their undergraduate training, or after graduating, and also sat a local examination to be eligible to access specialist schools in their geographical vicinity. Under the new system, under Ministerial Decree No. 105 of June 30, 2014 signed by the

Minister Giannini, which came into force on' August 8, 2014, allocations to specialist schools are determined by the results of a national examination. Those who pass the examination are then given the opportunity to select from available places at specialist schools according to their ranking in the test. This approach is seen as a more meritocratic and transparent way of attributing specialist training places, and may encourage hospitals to improve their performance and quality in order to become more attractive to the "best" candidates. For general practitioners, Legislative Decree No. 256/1991, which implemented the EU directive on GP training, made participation in this three-year course compulsory to practice family medicine.

A degree in nursing is obtained after a three-year course of studies and the acquisition of 180 credits, and immediately enables the degree holder to practice as a nurse, following registration with the Professional Board of Nurses and Midwifes, in the public sector as well as in the private sector (Lo Scalzo et al., 2009).

There is recognition of medical qualifications from EU member states under Directive 2005/36/EC which are automatically allowed in Italy, but practitioners – both doctors and nurses – who have received their training outside of the European Union are subject to further scrutiny. If the medical diploma does not meet the requirements of EU regulation on medical training, detailed evaluation of the training carried out by the applicant is needed, to make a comparison with the training performed in Italy to get the same qualification. This to verify whether medical training meets the required standards, and to bridge the possible gap in competency, a compensative measure can be applied, usually a practical adaptation period or an aptitude test.

Introducing further quality measures to medical education and pre-admission to medical school

With medical education already regulated nation-wide by the Italian Ministry of Education, University and Research, and a national test at the end of the university period, standardisation of the medical curriculum and teaching is already relatively secure. This type of standardisation of undergraduate medical education is relatively common, and while there may be scope to push for further quality improvements – for example a quality framework similar to that used by the United Kingdom's independent regulator for doctors the Greater Medical Council, discussed briefly below – one area that Italy could explore is further and more diverse "quality checks" pre-entry into medical education. While Italy and indeed many other OECD countries rely predominantly on end-of-school qualifications and/or a national examination – in Italy's case a predominantly scientific examination – to assess admission to medical school, a number of other countries take slightly different approaches to selecting the country's future doctors, which may have a positive effect on the overall quality of the workforce in the long term.

Additional aptitude tests for admission to undergraduate medical education

Many countries' medical schools rely predominantly on a core set of qualifications, often end-of-school qualifications or exam results. Indeed, such qualifications appear to be quite a good predictor of success at medical school (Ferguson, 2002; Lumb and Vail, 2004). However, some countries have introduced aptitude testing specific to medical degrees to try to indentify candidates who would have a particular aptitude for medical education, and to assess the potential of students even with different qualifications. Aptitude tests are standardised tests which are designed to predict *future* performance by measuring an individual's performance across a range of fields. Fields typically measured in medical aptitude tests are problem solving, data analysis, logic and reasoning, and application of prior knowledge. Some medical aptitude tests also include a knowledge component.

A number of universities in the Netherlands, the United Kingdom, and Singapore have introduced the BioMedical Admissions Test (also known as BMAT) as part of their admissions process to undergraduate medical education. The UK Clinical Aptitude Test (UKCAT) is also used in a number of universities in the United Kingdom. In the United States the Medical College Admissions Test (MCAT) has been used in various forms as part of assessment of admissions to graduate medical education since 1924, and has been revised repeatedly since then. Medical schools in Australia and New Zealand use the Undergraduate Medicine and Health Sciences Admission Test (UMAT), while the Graduate Australian Medical School Admissions Test (GAMSAT) is used for admission to graduate medicine programmes in Australia, the United Kingdom and Ireland. Some private universities in Italy are already using the International Medical Admissions Test (IMAT).

Some reviews of aptitude tests suggest that their particular strength is in widening access, and identifying students with potential to perform well, but who may have under-performed at school-level education (Lumsden et al., 2005; Cleland et al., 2012). Some aptitude tests may also predict performance at medical school better than traditional selection criteria. The UKCAT, for example, was found to be a modest predictor of performance in the later years of medical school, giving supporting evidence to UKCAT's inclusion in selection criteria at some UK medical institutions (Husbands et al., 2014). Another review, again addressing UKCAT, found that the test had predictive validity as a predictor of medical school outcome, although confirmed the validity of using all the existing measures of educational attainment in full at the time of selection (school exam results, personal statement/application letter, interview) (McManus et al., 2013).

While evidence certainly does not suggest that existing admissions criteria for medical education should be replaced entirely by an aptitude test, there is some weight to the argument that aptitude tests are a useful additional predictor of success in medical education. Aptitude tests may also help improve access to the medical profession from less represented groups, for example ethnic minorities or poorer socio-economic groups. Support for the introduction of such a test in Italy has already been set out by some scholars (Lia and Cavaggioni, 2013), who note that Italy already uses psychological and aptitude testing in the selection of personnel to the police force. The introduction of a clinical aptitude test to medical admissions in Italy would certainly be worth serious consideration.

Improving the quality of undergraduate education

Medical universities in Italy are self-governing, but the didactic system of the degrees in medicine and surgery and in nursing existing in the individual universities must comply with national system established by the Italian Ministry of Education, University and Research. In complying with the national system, teaching uniformity should be guaranteed across Italy. Medical students must also pass a national examination before being qualified as doctors, further encouraging uniformity in medical teaching, as the curriculum is shaped towards this national exam.

Keeping the quality of undergraduate medical teaching high can be assumed to contribute to workforce quality, and the competency of newly graduated doctors and nurses. However, understanding of what high quality education should be, or how to improve quality, is relatively limited both in the scientific literature and in policy making in OECD countries. Some practices do appear, from available research, to have a positive influence on undergraduate achievement, and diverge from the traditional didactic curriculum-based teaching:

- A "student-centered" or "learner-centered" approach to medical education has been supported by some studies. A student-centered approach means a shift in emphasis towards students and what they learn, and demands a fundamental change in the role of the educator from that of a didactic teacher to that of a facilitator of learning

(Spencer and Jordan, 1999). This approach encourages students to be active participants in learning, and was suggested by Spencer and Jordan (1999) based on available evidence to be the "the educational strategy most likely to produce doctors prepared for lifelong learning and able to meet the changing needs of their patients". Such an approach could include problem-based learning (Azer et al., 2013), and approaches such as peer-tutoring, self-reflection, regular feedback, application of knowledge to new problems, and "learning by doing" as an alternative to an emphasis on memorisation of factual knowledge, and written examinations.

- Promoting communication skills, and effective interaction with patients, have been made an increasing priority in the United Kingdom in recent years. In 2003 a statement of guiding principles related to communication skills in pre-registration and undergraduate education for health care professionals was jointly agreed and published by the Department of Health and the health regulatory bodies including the General Medical Council (GMC) and Universities UK. This message had been previously supported in papers by the GMC, which registers all doctors practicing in the United Kingdom, in "Tomorrow's Doctors" (GMC, 2009 and 2010), and the Department of Health's policy paper on medical schools in 2004 (Department of Health, 2004). This prioritisation of communication builds on a consensus statement developed with input from all UK medical schools giving guidance on including clinical communication, one of the central components of undergraduate medical education, in medical curricula (von Fragstein et al., 2008). Undergraduate medical education would include teaching clinical communication and role play with actors or volunteers acting as patients, and may be included in assessments at universities. From 2013 access to and choice of placement (location) during the "foundation programme" following qualification as doctor, has been determined by a tailored Situational Judgement Test (SJT) – where applicants are presented with a set of hypothetical work relevant scenarios and asked to make judgements about possible responses. "Effective communication" and "Patient focus" are two of the five professional attributes that this test is designed to assess (Patterson et al., 2012), further supporting the importance given to clinical communication in undergraduate training.

- Team-based learning is an approach that some research has supported as part of medical education for a range of medical professionals. Organisation of students into small groups, who are supervised by a teacher, can improve student outcomes (Koles et al., 2010; Freeman, 2012; Park et al., 2014), and improve verbal communication and teamwork skills (Elmore et al., 2014; Park et al., 2014). Institutional characteristics and typical teaching style were found to affect uptake of team-based learning, and its sustainability as a pedagogic method (Thompson, 2007; Freeman, 2013).

A balance needs to be struck between encouraging innovation by medical schools that could contribute to quality gains, and maintaining standards nationally. One criticism of undergraduate medical education in France, for example, is that the need to prepare students for a demanding national examination by which they are ranked – in the first year, in order to be admitted into the second year, and also at the end of the final year, in order of which students can choose their speciality – does not encourage development of innovative practices.

In the United Kingdom, where medical schools are independent and there is no national medical examination for qualification (with the exception of the SJT, discussed previously), standardisation of quality of medical education is nonetheless a major concern. Quality assurance is the responsibility of the General Medical Council (GMC), which follows a Quality Improvement Framework (QIF), which is available publicly. Quality assurance is carried out across four domains: approval against standards, shared evidence, visits (including checks) and responses to concerns (GMC, 2010).

In the United Kingdom there has been some reflection on how to improve quality assurance, and how to match quality assurance to desired outcomes from the medical education system. For example, following the 2010 merger of two bodies responsible for overseeing medical education (the GMC and the PMETB (Postgraduate Medical Education Training Board), a review of Education and Training Regulation was carried out. Partly influenced by the wake of a number of high profile scandals within the NHS in the late 2000s, involving serious breaches of health care quality, this review asked both whether it was possible to achieve greater coherence and consistency across the undergraduate and postgraduate arenas and whether the regulator should focus less on assuring processes and more on the quality of individual trainees produced by those processes. Following the review the GMC responded with its own review of the approach to the quality assurance of medical education and training, and set out a range of steps that will be introduced to improve the quality assurance process, including new approaches to standards, sanctions, and annual specialty reports, working across regulators, and transparent and accessible reporting showing risk profiles of organisations and how evidence has used to form quality assessment judgements (GMC, 2014).

3.4. Keeping workforce quality high: Maintaining and improving professional standards through continuing medical education

Continuing medical education in Italy

Continuing medical education (CME) in Italy includes the acquisition of new knowledge, skills and approaches considered useful for developing competent and experienced medical practice. Legislation covering medical workers – all physicians and nurses, around 9 000 health personnel – sets out the ethical obligation of health care professionals to keep their practice up-to-date, and to possess the skills useful in daily practice to respond to patients' needs, and skills needed to meet the demands of the NHS, and their own professional development. According to the current legislation all health care professionals must obtain 50 CME credits per year, but there are no formal sanctions if credits are not completed; the only consequence to non-completion of CME is inadmissibility from a Head of Department post. Nonetheless, in the years 2011-13 the majority – 67% – of health care professionals for whom CME is mandatory (physicians, nurses) completed their CME requirements.

CME credits in Italy are assigned by accredited CME providers to the educational programme, according to hours of training activities, the type and characteristics of the programme. There are approximately 1 100 national CME providers, providing a total of 167 849 CME events in 2011-13. CME providers may be funded by sponsors in their training activities, with agreements between the parties, or provide a registration fee for each training event following specifications set by the Ministry of Health. Health care professionals can be sponsored by pharmaceutical companies for up to a maximum of 1/3 CME credits per year. The CoGeAPS, an organisation that gathers the National Federation of the Orders, Colleges and Associations of health care professionals participating in the programme of continuing medical education, has the role of manager of the national register of credits.

Keeping the quality of CME high

To help play a role in securing a high quality medical workforce, Italy's CME system for health care professionals needs to be functioning well. At present, it is not possible to link CME activities to quality outcomes, or variations in quality, in a meaningful way. There are a number of checks in place to regulate CME activities, either at the national or regional level. The primary means of assuring the quality of continuing medical education is through the accreditation of providers. Provider accreditation is awarded by the national body the National Commission for Continuous Education (*Commissione Nazionale Formazione Continua*), or for around 10% of providers accreditation is given by R&AP. Accreditation by R&AP only allows providers to operate only within the given region.

The National Commission for Continuous Education is chaired by the Minister of Health, and composed of 35 members who are appointed by the Ministry of Health, the R&AP, the professional orders and associations. Accreditation should recognise that the provider is active and appropriately skilled to provide CME, and qualified to organise training, and following a core set of requirements. These requirements include certain structural, organisational and qualitative requirements, for example CME providers have to provide evidence of an appropriate scientific committee, economic and financial solidity, informatics structure, and follow a quality manual which describes the procedures that providers put into practice to ensure quality of training.

Whether or not CME providers are meeting core requirements is assessed by the accrediting bodies using documentation and site visits. The National Commission for Continuous Education and the R&AP, as accrediting bodies, have responsibility checking the providers that they have accredited, as well performing screening checks of CME activities that take place within the territory. Planned annual verification visits are made to at least 10% of providers, as well as visits whenever there is evidence of violations. If there is evidence of violation of requirements, including around financing (e.g. illegitimate acceptance of sponsorship), sanctions are arranged, ranging from a warning, through to the withdrawal of accreditation temporarily or permanently, depending on the severity of the violation. The National Commission for Continuous Education makes use of experts AGENAS for scrutiny of the documents of the requirements that providers must have for accreditation, and site visits that are planned for all providers by accreditation 24 months after.

Some positive additional steps have been taken towards introducing a layer of quality assurance for CME. From the 1st January 2008 all *administrative* functions for CME were passed to AGENAS (from the National Commission for Continuous Education) as part of an attempt to harmonise different standards for CME provision in different regions, in particular through improving information collection. AGENAS has already signed specific agreements with ten regions around CME standards, involving the implementation of the programme for the accreditation of regional providers, which requires the use of the software needed for administrative tasks. For nationally accredited CME providers, which make up the majority of providers, a series of biennial administrative checks – staffing, building infrastructure, checks by a scientific committee – are carried out by the National Commission for Continuous Education, which can be followed up with unplanned inspections. AGENAS can also push providers to provide CME that meets some of the key challenges of the health care systems (further detailed in the following text) – for example maternal health, or sexual health – but take-up of CME relies upon professional choice.

Maximising the impact of Italy's CME system

There are some ways that Italy could look to maximising the impact of the existing CME system, even without making significant changes to the structure of CME delivery, or surrounding requirements and legislation. To have a real impact on care quality, CME should match with identified shortcomings in the health system, as well as helping to address areas of weakness of individual health professionals, and should be delivered in such in way so as to maximise positive impact.

In terms of providing CME that matches with identified shortcomings in the health system some efforts are already in place in Italy. The educational objectives, national and regional, defined by the National Commission, are used to guide some of the content of continuing education programmes offered to health professionals. These objectives have to be traced back to health and social care activities related to essential levels of care (LEA) (see Chapter 1), and have to take account of health programmes as defined by the *Patto per la Salute*, in addition to promoting the improvement of professional skills in specific technical areas and promote and maintain the knowledge and the skills necessary and appropriate to improve the standards of effectiveness, appropriateness, safety and quality of services. For example, in 2013 the educational objectives were centered around maternal health, sexual health, and preventative health, on which providers had to offer a certain percentage of their training events. However, there is no national requirement for health professionals to follow particular training courses, and CME uptake relies mostly on individual professionals' choice, although in some local contracting of health professionals there is a requirement to demonstrate the attendance or completion of some specific training events linked to career progression. There may be scope to incentivise the uptake of certain CME activities which are judged to meet the health system's needs, for example by increasing the number of CME credits attributed to these activities.

At present there is no link between individual health professionals' performance evaluation, either systematic self-evaluation or evaluation by peers, and CME accreditation. Across Europe, assessment of standards of care, by either self-assessment, by peer review or by more systematic analysis or audit of activities, is increasingly seen as an essential part of CME. Systematic reviews of practice can disclose weaknesses or educational needs, which can then be used to target CME uptake more effectively. Italy may want to explore ways of rewarding physicians who undertake training in areas of identified weakness in their practice, giving preferential weighting to certain credits, or some other incentive, to CME programmes which encourage more active evaluation of quality performance and care provision. In general, tools that facilitate physician self-evaluation and reflection upon practice should be further encouraged, and have already been as part of some CME practice, for example within the general practitioners' scientific society *Società Italiana di Medicina Generale* (SIMG). Such approaches should also be promoted for nurses' CME.

In local contracting agreements with health care professionals there is already sometimes a need for demonstration of having done some specific training events to link to career progression, and this could be pushed further. Individual physician contracts could also be used more actively to encourage quality improvement, and push physicians towards following CME that matches well with areas for improvement in their practice or knowledge. Contracts could also be sensitive to the particularities of the given health care setting, patient group or physician specialism. For example, the contract of a nurse who will be working with low income communities and children could be required to take a CME programme on health promotion or prevention of obesity or childhood obesity, issues that are growing concerns in Italy and known to be associated with poorer income groups.

Improving the quality of CME offered

There is some evidence which suggests that – as for undergraduate education, discussed above – certain ways of delivering CME are more effective than others. In a comprehensive review of evidence on the effectiveness of various forms of CME, Bloom (2005) found that interactive ways of delivering CME – audit/feedback, academic detailing/outreach, and reminders – were the most effective in terms of changing physician care, and patient outcomes. Marinopoulos et al. (2007) suggest that multiple techniques be combined. Didactic presentations and the distribution of printed information were found to have little or no beneficial effect. Other research has also found that traditional lectures and presentation-based CME is largely ineffective in changing the performance of health professionals and in improving patient care, and interactive forms of CME to be more effective (Davis et al., 1999; Macy Foundation, 2007).

Some of these more interactive forms of improving medical knowledge and skills are sometimes distinguished from traditional learning forms with the description of continuing professional development, which is discussed in more depth in Section 3.5.

Different forms of CME are recognised and eligible for award of credits in Italy, including some of those judged by academic studies to be more or most effective, for example interactive platforms and feedback. Efforts could be made to encourage these types of CME which are understood to be more effective. This could mean weighting such programmes with more CME credits, but could also include supporting and encouraging such efforts in other ways. It may be possible to provide support, for example in the form of grant funding, for CME providers looking to develop more interactive models of CME, especially if backed up by evidence of efficacy, or with an evaluation process built-in or planned. Internet- and computer-based methods of learning have also been gaining popularity, and can be a good way of making effective models of CME available even in more isolated areas, or even to the health workforce at-large. Time pressures and expense are often anecdotally reported as obstacles to completing CME activities, and computer – or internet-based learning methods could offer health professionals greater flexibility in following CME programmes which they may find valuable.

3.5. Focus on continuing professional development: International experiences and examples

The basics of good quality improvement mechanisms for Italy's medical workforce appear to be in place, and functioning well, even if more could be done to maximise the impact of existing education and continuing medical education systems. However, Italy may not be keeping up with other OECD countries in taking steps towards a more modern, rigorous system of workforce quality assurance. Internationally, there is a growing realisation that the historical organisation of the medical professional, and reliance upon self-governance and individual physician integrity and responsibility, is not sufficient or appropriate for new models of health care delivery, and medical practice, and additional checks and standards need to be introduced. There are some areas in which Italy could take action – drawing on examples from other OECD countries – and in doing so drive improvements in the quality of care delivered by medical professionals.

Changing approaches to quality assurance mechanisms for the medical profession

A distinction is often made between more traditional instruments of quality assurance for the medical profession – for instance education, disciplinary procedures, or audits imposed upon doctors by insurance companies – and newer approaches to quality insurance, including peer review or medical audit (van Herk et al., 2001).

Box 3.1. "Modern" approaches to self-regulation of the medical profession

Peer review or medical audit

Often used interchangeably, these instruments review and address the clinical practice style of a physician by a peer group. These reviews can use implicit criteria, e.g. read through patient records and provide feedback on the diagnostic and therapeutic approach, or explicit ones, e.g. apply criteria that reflect standard medical practice and check for compliance. Assessment and recommendations are usually provided, based on the review results.

Recertification

Rather than maintaining a physician's licensure status indefinitely or until incompetence is proven, professional institutions may require regular renewal of the license and base renewal on set requirements, for example obtaining a certain number of CME credits and maintaining a minimum practice volume.

Confidential use of quality indicators and benchmarking

Quality indicators are measures for the technical quality of medical care and mainly reflect compliance with medical standards (process indicators) and success of treatment (outcomes indicators). In internal quality improvement, indicators are usually reported back to clinicians and compared to a peer group as benchmark. Full confidentiality is maintained. This process can be regarded as automation of medical audit based on explicit criteria.

Confidential reviews of incidents and perceived problems

Review and discussion of isolated care problems, or patterns of such problems, have a long tradition in medical care, for example in Morbidity & Mortality Conferences. Incident review is a formalised approach which builds on this tradition. Sometimes referred to as root cause analysis, it employs a structured investigation to determine the immediate and underlying causes of a problem. The goal is usually not to place blame on an individual but to identify and correct systems failures that lie at the heart of the observed problem, and to avoid further mishaps. Because of the sensitive nature of these events, and the risk that punitive approaches might discourage reporting, there is a tendency for governments not to interfere with these proceedings.

Source: Adapted from: Mattke, S. (2004) "Monitoring and Improving the Technical Quality of Medical Care: A New Challenge for Policy Makers in OECD Countries", *Towards High-Performing Health Systems: Policy Studies*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264015609-en.

The 2004 OECD publication *Towards High-Performing Health Systems* detailed the traditional forms of professional self-regulation: standards of codes and ethics, education, training and knowledge dissemination; licensing and registration; arbitration panels and medical court; guidelines and clinical pathways; and decision support systems (either passive systems which make information readily available upon request, such as internet-based journal search, or active systems are embedded in the workflow and provide real-time decision support, such as reminders and alerts) (Mattke, 2004). More recent developments include peer review or audit, recertification, confidential use of data and benchmarking, and confidential use of reviews of incidents and problems (see Box 3.2).

Mattke (2004) suggests that the development of structural standards for care and external supervision both mark a watershed in monitoring and improving care. These are instruments that involve an external authority imposing or supporting agreed standards of practice, in various forms. Such approaches include external practice review and audit, external incident investigation, and release of quality indicators and benchmarking results to regulators or purchasers.

Box 3.2. Towards external supervision of quality for the medical profession

External practice review and medical audit

Similar to the profession-driven medical audits, such reviews entail assessment of care decisions, usually based on reviews of medical records, but the assessment is provided by external reviewers on behalf of regulators or purchasers. For example, utilisation reviews look at appropriateness of indications for procedures and quality reviews investigate whether certain key quality criteria have been met. In an extension of the audits to check compliance with regulatory standards, inspections can be applied to clinical care processes as well. This is usually done through site visits combined with staff interviews, and reviews of medical records and other documents. Inspectors can, for instance, look at compliance with treatment guidelines.

External incident investigation

While the external practice review and medical audit are used routinely to assure quality of care, incident investigation is event-driven. Incidents of a defined severity, like wrong site surgery, trigger a comprehensive external review of procedures and practice patterns.

Quality-based contracting

Providers write quality provisions into their contracts with providers, for example that a hospital has to decrease its infection rate by a certain percentage in a year. Contract terms can address structural requirements (equipment, staffing requirements) or explicit quality targets.

Release of quality indicators and benchmarking results to regulators or purchasers

Regulators or purchasers may require the reporting of measures for quality of care that reflect processes and outcomes. Similarly, league tables rank providers according to their performance along a particular measure of quality. Scoring methods group providers into several categories of relatively homogeneous performance levels. This approach is more amenable to incorporating descriptive information than ranking methods, such as league tables.

Source: Adapted from: Mattke, S. (2004) “Monitoring and Improving the Technical Quality of Medical Care: A New Challenge for Policy Makers in OECD Countries”, *Towards High-Performing Health Systems: Policy Studies*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264015609-en.

At present, Italy is mostly relying on the traditional forms of quality assurance for the medical workforce – standards of codes and ethics, education, training and knowledge dissemination, licensing and registration, arbitration panels and medical court, guidelines and clinical pathways. It would be valuable for Italy to consider introducing some of the more modern approaches to quality assurance in a widespread way, and there are a number of OECD countries from which Italy could draw inspiration.

Beyond CME: Re-licensing and the shift to CPD

Moving beyond a strengthening of the existing CME system, Italy would do well to consider the experiences of countries which have introduced re-certification or re-licencing protocols for physicians. The link between demonstration of continuing professional development and revalidation or reaccreditation is variable, although is becoming formalised in an increasing number of countries, with the aim of consistently assuring the public of a clinician's fitness to practice. Revalidation has been in place in Australia, Canada, New Zealand and the United States for some time, and has been increasing in Europe (Merkur, 2008).

Re-licencing is increasingly seen as an important workforce quality assurance measure, backed by the argument that the awarding of a licence to practice at the end of medical education is not sufficient to ensure high quality care across a career of 50 years or more, particularly considering the rapidly changing nature of health care delivery (for example changing evidence bases for treatments, pharmaceuticals, new technologies). Revalidation is a way of checking that the competency of health professionals is up to the required standards, and a way of promoting continuing improvements in practice. In some cases moves towards additional regulation of health care professionals have been triggered by political or social changes or events. In the United Kingdom a number of high profile scandals involving health professionals challenged public trust in physicians, providing some of the back drop to the introduction of a system of physician revalidation and peer review.

In a number of countries completion of CME activities has been linked to relicensing as a means of enforcing CME participation. For Italy, interesting examples are found in the Netherlands and in the United Kingdom, where highly comprehensive systems of re-licencing have been introduced. These re-licencing procedures include more rigorous appraisal aspects such as comprehensive peer review, the requirement that physicians have reflected upon and changed their practice through training activities, and that physicians can demonstrate that they have reflected upon feedback from patients and colleagues. Such systems could be seen as examples for Italy to learn from and follow in coming years (Boxes 3.3 and 3.4).

Box 3.3. Re-licensing and peer review in the United Kingdom

In the United Kingdom, a system of five-yearly revalidation has recently been introduced. Participation in CPD activities has long been required for doctors working in the United Kingdom, a condition of employment in the NHS and later a condition of participation in the royal collages (speciality schools) for physicians (Merkur, 2009). In September 2013 the Nursing and Midwifery Council also committed to introducing a system of revalidation by the end of 2015.

In 2010 the Department of Health set out that a system of revalidation, which had previously been proposed by the General Medical Council (GMC), should be in place from 2012. This revalidation covers all physicians working in all fields. The royal colleges have a role in supporting recertification, as they have traditionally been responsible for setting standards within their field and for supervising the training of doctors. The GMC is responsible for quality control of over the appraisal process for relicensing.

Revalidation involves the appraisal of a doctor's performance in the workplace, against national standards set by the GMC, across a range of domains (for example, knowledge, skills and performance; safety and quality; communication). Evidence required in doctors' portfolios differs across domains, and may include proof of training or assessment of skills, continuing medical education, audit (a quality improvement process), or validated tools for feedback about doctors' practices and anonymous records (Villanueva, 2010).

Doctors are required to submit an annual portfolio of evidence showing how they meet these professional standards, have changed their practice through CPD activities and have reflected upon feedback from patients and colleagues. The portfolio is appraised by a peer – a senior doctor, typically working within the same organisation – and five successful appraisals lead to revalidation of a doctor's entry on the medical register with approval from the GMC.

Source: Merkur, S. et al. (2008), "Physician Revalidation in Europe", *Clinical Medicine*, Vol. 8, No. 4, pp. 371-376; General Medical Council (2012), *Ready for Revalidation: Supporting Information for Appraisal and Revalidation*, available at: www.gmc-uk.org/Supporting_information__for_appraisal_and_revalidation.pdf_48977650.pdf, accessed 20 August 2014; Nursing and Midwifery Council (2013), "Background to Revalidation", website of the Nursing and Midwifery Council, available at: http://www.nmc-uk.org/Nurses-and-midwives/Revalidation/Background-to-revalidation/, accessed 20 August 2014; Villanueva, T. (2010), "Revalidation Wave Hits European Doctors", *Canadian Medical Association Journal*, Vol. 182, No. 10.

Box 3.4. Physician re-licensing in the Netherlands

In the Netherlands, physicians must undergo revalidation every five years in order to maintain their place on the medical register. Revalidation is for both GPs and specialists, and is led by the Central College of Specialists together with the government organisation the Central Information Centre for Professional Practitioners in Healthcare. Supervision of revalidation was previously split for GPs and hospital specialists, but now both are overseen by a combined committee of the Central College of Specialists together with the government organisation the Central Information Centre for Professional Practitioners in Healthcare.

Requirements for revalidation include participation in continuing medical education (CME) and other training activities, a minimum level of participation in peer review activities, and an assessment by a visiting team of three doctors. To meet the requirements of doctors must have completed a minimum number of hours of accredited training activities in the period prior to revalidation, and doctors are free to choose CME according to their personal interests, and not necessarily gaps in their knowledge and skills. Moving beyond this requirement, though, there has been an emphasis on continuing professional development (CPD) as a more deliberate approach to maintaining and improving competence, and a range of "competence-based training" is offered in the Netherlands (Schäfer et al., 2010). The Central College of Medical Specialists (Centraal College Medische Specialismen, CCMS) is responsible for the national roll-out of competence-based training for all specialties, and the range of required competences is defined by the National Federation of Academic Medical Centres and is based on standards set by the Royal College of Physicians and Surgeons of Canada. The review visit prior to revalidation would include discussion of these activities, of competencies, and reflection on how the doctor's practice has changed as a result of CME or CPD activities.

If doctors fail to comply with loan requirements they can be struck off the registry, although this is reported as generally unusual (Villanueva, 2010). If doctors fail to comply with revalidation requirements, there is also the option for physicians to re-educate themselves, either by working as a trainee again, or working under the supervision of another physician. Some serious cases may end up in legal action, and being settled in court.

Source: Schäfer, W. et al. (2010), "The Netherlands: Health System Review", *Health Systems in Transition*, European Observatory on Health Systems and Policies, Vol. 12, No. 1; Villanueva, T. (2010), "Revalidation Wave Hits European Doctors", *Canadian Medical Association Journal*, Vol. 182, No. 10.

A distinction is made in some scientific literature, and in some policy documents and guidance, between continuing medical education and continuing professional development (CPD). While the distinction is not universally used, CPD activities generally refer to ways in which the skills and quality of care offered by health professionals are actively improved and built-up, filling in gaps in competence. This can be contrasted with CME, which might be seen as "topping up" or "updating" medical knowledge, rather than developing professional practice (although the reality is that CME varies, and has beyond the traditional medical subjects and knowledge updates) (Chan, 2002; du Boulay, 2000).

Whether considering CME or CPD, it is increasingly recognised that demonstration of continuing medical learning and development must move on from counting points to measuring the impact of continued learning, through more demanding methods incorporating personal reflection and analysis of learning needs, peer review, external evaluation, and practice inspection (Miller et al., 2008; Parboosingh, 2000).

Using information (data) to drive quality improvement for medical professionals

One further challenge that Italy faces, and that medical professionals practicing in Italy face, is a lack of data that tells authorities or individual physicians anything about the quality of care that they are delivering. At present no physician-level quality or outcome indicators are collected. A very small number of physicians are participating in outcome indicator collection as part of initiatives launched by scientific societies or research institutes, as part of which they get feedback on their performance. More widespread collection of physician-level or practice-level quality and outcome indicators would be highly desirable, if challenging to introduce. There are obvious anxieties about ranking of practitioners, and exposure to criticism, blame and legal liability.

There are avenues for Italy to explore in this respect, for example the partial anonymisation of practitioner-level data, or use of data privately but not publically. Whilst physicians may feel anxious about such collections, in other countries – for example a very impressive data collection and benchmarking scheme in primary care in Denmark (see Box 3.5) – doctors have in fact been pleased with the availability of data that allows them to reflect upon their own practice, and compare it to that of their peers. Indeed, availability of outcomes data, and transparency of data, can help practitioners with self-reflection and improvement in their own care.

More comprehensive data collection could benefit both patients and the Italian health system, as a quality improvement measure, but also physicians, if they are encouraged and supported in reflecting on their own results in a productive way.

Box 3.5. Using physician-level outcome data to improve quality of care in Denmark

Denmark has developed a system of automatic data capture from primary care records – DAMD –, which allows GPs to access quality reports from their own practice for over 30 areas. The data include diagnoses, procedures, prescribed drugs and laboratory results. Most data is collected automatically, limiting any additional burden on GPs themselves, although annual data checks and specific research projects may request additional data via occasional pop-up screens. As well as being able to identify individual patients that are sub-optimally treated, the system allows them to benchmark their practice against other practices at municipal, regional, and national levels. DAMD also produces weekly quality reports.

This system was set up voluntarily in 2006, and from April 2011 was practice is obliged to start participate in the two years that followed. In 2013 just over 70% of practices were participating. Data are sent to the Danish General Practice Database (DAMD) hosted by the University of Southern Denmark.

Without a control group it is difficult to say whether DAMD has a significant positive effect on care quality, although a smaller randomised trial in one municipality prior to the nation-wide roll-out of DAMD did report a positive impact upon prescribing practices.

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

3.6. Conclusions

The relatively good results that Italy's health system is delivering suggest that the medical workforce is, in general, delivering care of a high quality. Indicators such as low avoidable hospital admissions for asthma, COPD and diabetes, and lower than the OECD average for mortality following hospital admission for stroke and AMI, and relatively low rates of surgical complications (OECD, 2011), reflect well on the quality of both the primary care and specialist workforce. While there are some workforce shortages, and some regional disparities in workforce supply, these positive indicators likely speak to a well-skilled workforce, and reflect well on Italy's medical education system.

Looking to secure this high performance for the decades to come, and push back against any regional disparities in quality and outcomes, Italy has been taking important steps towards ensuring nationally cohesive workforce training programmes. The recent steps to standardise accreditation for continuing medical education (CME) providers across regions is, in particular, an encouraging move. A recent move to change the entry process for specialist schools could also be an interesting development.

However, going forward, good medical education and nationally standardised CME may not be enough to secure a high quality, high performing medical workforce. There is scope to look to the scientific literature, and the experiences of other OECD countries, to try to maximise the impact of medical education, from the undergraduate level and beyond. There is some evidence about different ways to select entrants into medical school, and in teaching approaches within medical schools, that could provoke further reflection in Italy. There are also opportunities to maximise the positive impact of Italy's existing CME programme, for instance by incentivising the uptake of certain CME activities which are judged to meet the health system's needs, or encouraging more active and interactive forms of CME.

Going a step further, Italy should also look to develop more modern models of workforce quality insurance, pushing practitioners to play a more active role in evaluating their own care – for example, through more active use of data and outcome indicators – and could learn from other OECD countries in developing more pertinent quality assurance mechanisms for the medical workforce. The international models of workforce quality promotion presented in this chapter, for instance of medical recertification, could provide key learning examples for Italy.

Bibliography

Azer, S.A. (2013), "Enhancing Learning Approaches: Practical Tips for Students and Teachers", *Medical Teacher,* Vol. 35, No. 6, pp. 433-443.

Bloom, B.S. (2005), "Effects of Continuing Medical Education on Improving Physician Clinical Care and Patient Health: A Review of Systematic Reviews", *International Journal of Technology Assessment in Health Care*, Vol. 21, No. 3, pp. 380-385.

Boulay, C. du (2000), "From CME to CPD: Getting Better at Getting Better?", *British Medical Journal,* Vol. 320, p. 393.

Chan, K. (2002), "Medical Education: From Continuing Medical Education to Continuing Professional Development", *Asia Pacific Family Medicine* Vol. 1, pp. 88-90.

Cleland, J. et al. (2012), *Identifying Best Practice in the Selection of Medical Students*, General Medical Council, available at www.gmc-uk.org/about/research/25036.asp, accessed 1 August 2014.

Davis, D. et al. (1999), "Impact of Formal Continuing Medical Education. Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes?", *Journal of the American Medical Association*, Vol. 282, No. 9, pp. 867-874.

Department of Health (2004), *Medical Schools: Delivering the Doctors of the Future*, Department of Health, London.

Elmore, L., J. Skelley and T. Woolley (2014), "Impact of Adapted Team-based Learning Methods on Student Self-assessment of Professionalism, Teamwork, and Skills in a Self-care Course", *Currents in Pharmacy Teaching and Learning*, Vol. 6, No. 4, pp. 488-493.

Ferguson, E., D. James and L. Madeley (2002), "Factors Associated with Success in Medical School: Systematic Review of the Literature", *British Medical Journal*, Vol. 324, No. 7343, pp. 952-957.

Fragstein, M. von et al. (2008), "UK Consensus Statement on the Content of Communication Curricula in Undergraduate Medical Education", *Medical Education*, Vol. 42, No. 11, pp. 1100-1107.

Freeman, M. (2012), "To Adopt or Not to Adopt Innovation: A Case Study of Team-based Learning", *International Journal of Management Education*, Vol. 10, No. 3, pp. 155-168.

General Medical Council (1999), *Tomorrow's Doctors: Recommendations on Undergraduate Medical Education*, available at www.gmc-uk.org/Tomorrows_Doctors_1993.pdf_25397206.pdf, accessed 1 August 2014.

General Medical Council (2009), *Tomorrow's Doctors: Education Outcomes and Standards for Undergraduate Medical Education,* available at www.gmc-uk.org/Tomorrow_s_Doctors_0414.pdf_48905759.pdf, accessed 1 August 2014.

General Medical Council (2010), *Quality Improvement Framework for Undergraduate and Postgraduate Medical Education and Training in the UK*, available at www.gmc-uk.org/Quality_Improvement_Framework_0414.pdf_48904974.pdf, accessed 20 August 2014.

General Medical Council (2012), *Ready for Revalidation: Supporting Information for Appraisal and Revalidation,* available at www.gmc-uk.org/Supporting_information__for_appraisal_and_revalidation.pdf_48977650.pdf, accessed 20 August 2014.

General Medical Council (2014), *Report of the Review of Quality Assurance of Medical Education and Training*, available at www.gmc-uk.org/06___Report_of_the_Review_of_Quality_Assurance_of_Medical_Education_and_Training.pdf_55154276.pdf, 1 August 2014.

Herk, R. van et al. (2001), "Medical Audit: Threat or Opportunity for the Medical Profession. A Comparative Study of Medical Audit Among Medical Specialists in General Hospitals in the Netherlands and England, 1970-1999", *Social Science and Medicine,* Vol. 53, pp. 1721-1732.

Husbands, A. et al. (2014), "Predictive Validity of the UK Clinical Aptitude Test in the Final Years of Medical School: A Prospective Cohort Study", *BMC Medical Education,* Vol. 14, No. 88.

Irdes – Institut de recherche et documentation en économie de la santé (2005), "Questions d'économie de la santé : Issues in Health Economics", *Health Economics Letter No. 95*, June.

ISTAT – Italian National Institute of Statistics (2013), *Annuario Statistico Italiano 2013*, Italian National Institute of Statistics, available at www.istat.it/en/files/2013/12/ASI_2013.pdf, accessed 13 August 2014.

Koles, P.G. et al. (2010), “The Impact of Team-based Learning on Medical Students’ Academic Performance”, *Academic Medicine*, Vol. 85, No. 11, pp. 1739-1745.

Lia, C. di and G. Cavaggioni (2013), “L’iter di selezione nella Facoltà di Medicina: l’utilità di una valutazione psicoattitudinale” [The selection process in the Faculty of Medicine: the usefulness of a psychological and aptitude assessment], *La Clinica Terapeutica,* Vol. 164, No. 1.

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

Lumb, A.B. and A. Vail (2004), “Comparison of Academic, Application Form and Social Factors in Predicting Early Performance on the Medical Course”, *Medical Education*, Vol. 38, pp. 1002-1005.

Lumsden, M.A. et al. (2005), “Assessment of Personal Qualities in Relation to Admission to Medical School”, *Medical Education*, Vol. 39, No. 3, pp. 258-265.

Macy Foundation (2007), “Continuing Education in the Health Professions”, Proceedings of a conference sponsored by the Josiah Macy Jr. Foundation, 28 November to 1 December 2007, Bermuda, available at http://macyfoundation.org/docs/macy_pubs/pub_ContEd_inHealthProf.pdf accessed 20.08.2014.

Marinopoulos, S.S. et al. (2007), *Effectiveness of Continuing Medical Education*, Evidence Report Technology Assessment No. 149*,* Agency for Healthcare Research and Quality, Rockville, United States.

Mattke, S. (2004), “Monitoring and Improving the Technical Quality of Medical Care: A New Challenge for Policy Makers in OECD Countries”, *Towards High-Performing Health Systems: Policy Studies*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264015609-en.

McManus, I.C. et al. (2013), “The UKCAT-12 Study: Educational Attainment, Aptitude Test Performance, Demographic and Socio-economic Contextual Factors as Predictors of First Year Outcome in a Cross-sectional Collaborative Study of 12 UK Medical Schools”, *BMC Medicine*, Vol. 11, No. 244.

Merkur, S. et al. (2008), “Physician Revalidation in Europe”, *Clinical Medicine,* Vol. 8, No. 4, pp. 371-376.

Miller, S.H. (2008), "Continuing Medical Education, Professional Development, and Requirements for Medical Licensure", *Journal of Continuing Education in the Health Professions*, Vol. 28, No. 2, pp. 95-98.

Ministry of Health (2011), *Health System Personnel 2011* [Il Personale del Sistema Sanitario Italiano 2011], Direzione Generale del Sistema informativo e statistico sanitario e Direzione Generale delle Professioni sanitarie e delle Risorse Umane del SSN, available at www.salute.gov.it/imgs/C_17_pubblicazioni_2191_allegato.pdf, accessed 13 August 2014.

Nursing and Midwifery Council (2013). "Background to Revalidation", website of the Nursing and Midwifery Council, available at www.nmc-uk.org/Nurses-and-midwives/Revalidation/Background-to-revalidation/, accessed 20 August 2014.

OECD (2013a), *Health at a Glance 2013: OECD Indicators*, OECD Publishing, Paris, http://dx.doi.org/10.1787/health_glance-2013-en.

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

OECD (2004), *Towards High-Performing Health Systems: Policy Studies*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264015609-en.

Parboosingh, J. (2000), "Credentialing Physicians: Challenges for Continuing Medical Education", *Journal of Continuing Education in the Health Professions*, Vol. 20, pp. 188-190.

Park, H. et al. (2014), "Effects of Team-based Learning on Perceived Teamwork and Academic Performance in a Health Assessment Subject", *Collegian,* http://dx.doi.org/10.1016/j.colegn.2014.05.001.

Patterson, F., V. Ashworth and D. Good, (2012), *Situational Judgement Tests: A guide for applicants to the UK Foundation Programme*, Work Psychology Group and Medical Schools Council, available at www.foundationprogramme.nhs.uk/downloads.asp?file=SJT_monograph.pdf, accessed 1 August 2014.

Schäfer, W. et al. (2010), "The Netherlands: Health System Review", *Health Systems in Transition*, European Observatory on Health Systems and Policies, Vol. 12, No. 1.

Spencer, J.A. and K. Jordan (1999), "Learner Centred Approaches in Medical Education", *British Medical Journal*, Vol. 318, No. 7193, pp. 1280-1283.

Thompson, B.M. et al. (2007), "Team-based Learning at Ten Medical Schools: Two Years Later", *Medical Education*, Vol. 41, pp. 250-257.

Villanueva, T. (2010), "Revalidation Wave Hits European Doctors", *Canadian Medical Association Journal*, Vol. 182, No. 10.

Database references

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

Chapter 4

Measuring and improving quality in Italy's regionalised health system

Whilst it cannot be said that any one region delivers consistently "poor" health care, it appears that some regions struggle to provide the same quality as others. Italy has established a number of mechanisms to try and ensure an evenness of approach to quality measurement and improvement. These include activities to ensure dialogue between national and regional authorities as well as professionally led initiatives to measure quality consistently. While it would be unrealistic and undesirable to seek complete homogeneity in how regional health systems are configured, more can be done to achieve a more even approach to quality measurement and improvement across R&AP.

Key priorities are to develop a more consistent approach to using information to manage performance and strengthen local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important. Actions that strengthen the regional approach to health care governance and delivery in Italy are also needed. Developing the responsibilities and capacities of the national authorities whose role is to support the R&AP should continue. Reframing governance as a whole such that quality improvement is emphasised as much as financial control is also necessary.

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.

4.1. Introduction

Italy is a very heterogeneous country, in both social and economic terms. The autonomous province of Bolzano has a GDP per capita more than double that of Campania and the difference in unemployment rate between these two areas is almost five-fold. Such heterogeneity is reflected in the health system. Since the reforms federalising health care delivery a decade ago, 21 distinct health systems have developed – with markedly divergent patterns of care and outcomes. Such variation in activity and outcomes across regions and autonomous provinces (R&AP) is both inefficient and inequitable, a reality which is not lost on the public judging by the large number of patients crossing R&AP in search of health care.

How should Italy respond to the challenge of a regionalised health system that appears to be delivering very different levels of quality from region to region? How can the advantages of decentralised governance be balanced against the needs to ensure equitable quality of care? This chapter explores actions that could be taken to assure and improve the quality of health care across Italy's regionalised structure. The focus is on national and regional governance, since these are the most important levels of government in terms of policy making for quality of care issues in Italy. Issues of supra-national and sub-regional governance (i.e. Europe and local health services) are not considered.

The chapter opens by describing the organisation and governance of health care in Italy and highlights the *Piani di Rientro* (financial recovery plans) as a special instance of how federalism has operated in Italy. Section 4.3 describes recent initiatives that have sought to improve performance and quality across the R&AP and Section 4.4 exhibits the regional differences in health system performance and performance management which nevertheless exist. The chapter closes with policy recommendations and concludes that, whilst it would be unrealistic and undesirable to seek complete homogeneity in how R&AP plan and deliver services, there is significant scope to achieve a more consistent approach to quality governance across Italy's regional health system.

Actions are needed both to improve health care quality and health care outcomes in poorer performing R&AP and to strengthen the governance underpinning Italy's regionalised model of health care. In terms of the former, priority actions include developing a more consistent approach across R&AP to performance management and strengthening local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important. Key actions to strengthen the model of regional health care delivery will include resolving any tensions or misalignments in centre-regional governance arrangements and reframing governance such that quality improvement is emphasised as much as financial control.

4.2. Organisation and governance of Italy's regionalised health system

The federal nature of health care delivery in Italy can only be understood within the broader trajectory of political, financial and regulatory decentralisation in the country. This section provides that context and describes the federal nature of health care responsibilities in more detail. Crucially, the point is made that the far-reaching constitutional reforms of 2001, which devolved greater competence to the R&AP, were not underpinned by sufficiently effective mechanisms for central oversight and steering. As a consequence, the *Piani di Rientro* (Recovery Plans) of recent years represent an abrupt rebalancing of central versus regional authority in financial terms. It remains to be seen whether steering and governance driven by quality imperatives will be given equal prominence.

Italy's R&AP vary markedly in their social and economic characteristics

Italy is composed of twenty one R&AP. The smallest, and also least densely populated of these, is the Valle d'Aosta with an area of 3 263 km^2 and population density of 39 people per km^2. The most densely populated R&AP are Lombardia (with its capital Milan), Campania (Naples) and Lazio (Rome). Five R&AP (Sardegna, Sicilia, Trentino-Alto Adige, the Valle d'Aosta and Friuli-Venezia Giulia) have special constitutional status that recognises linguistic and cultural differences and gives them wider legislative and administrative powers.

Significant economic heterogeneity characterises the Italian R&AP, with the poorer regions clustering in the south. The province of Bolzano near the Austrian border has a GDP per capita of USD 39 170 (2010), more than double that of Campania's USD 17 120 (OECD*,* 2013a). The difference in unemployment rate between these two areas is even more stark, at 4.1% and 19.3% respectively. In a neighbouring southern region, Calabria, unemployment amongst 15-24 year-olds reached 53.4% in 2012.

Figure 4.1. The Italian regions and autonomous provinces

Governance reforms of 2001 significantly deepened the regional nature of Italy's health system

The Italian National Health Service (INHS) was established in 1978 to grant universal access to a uniform level of care throughout Italy, free at the point of use, financed by general taxation. Italy's decentralisation process, however, can be traced back to the constitution of 1948, which included several federalist elements, and to the creation in 1970 of a fully-fledged regional level above the provinces and municipalities. In 1997, in the wake of an economic crisis and Italy's bid to join the euro area, the country passed the "Bassanini reforms", which devolved a set of spending and regulatory powers to sub-central governments. Although some taxing power was delegated to the R&AP, in line with new spending responsibilities, the revenue side remained much more centralised than the spending side. This institutional set-up required sizeable intergovernmental transfers, which were mainly determined by negotiations between the central government and individual R&AP, but was based on historical cost and lacked objective allocation criteria. In the second half of the 1990s, the northern regionalist movement started to claim that the generous transfer system was straining the resources of the economically rich north and discouraging economic development in the south, and it began to seek more autonomy (Blöchliger and Vammalle, 2012).

A decisive shift toward greater federalisation occurred with reforms to Chapter V of the Constitution in 2001. Radically, these state that the Italian state was "composed" of regions, provinces and communes (rather than "divided into" them) and listed the competencies of central government. The reform also clarified spending roles, the principle of financial autonomy and, in more general terms, how the transfer system and equalisation should work. R&AP were granted "concurrent legislative powers" alongside those of central government on several areas, including the organisation and delivery of health care. Of note, central government retained responsibility for ensuring "essential levels of services needed to ensure civil and social rights throughout the territory" and given the power to assure these, overriding regional authority in instances where an essential level of service could not be delivered. As will be made clear in this chapter, however, the new Chapter V "required detailed enabling laws to make a reality out of its many provisions, as well as a fundamental shift in administrative organisation and practice, neither of which was to emerge over the ensuing decade" (Keating, 2010).

National authorities set overall framework for the health system's funding and objectives

Within Italy's federal arrangements, the Ministry of Health fulfils the function of the overall steward of the health system. Key departments within the ministry are the Department for Planning and Organisation which sets overall policy, manages national health information systems and distribution networks for pharmaceuticals and devices; and the Department of Public Health and Innovation, which has a health protection function, liaises with international bodies and promotes research. The ministry also defines the *livelli essenziali di assistenza* (or essential level of care – LEA) to be delivered across the country and operates the *Griglia LEA*, through which regional performance in delivering the LEA is monitored. Interestingly, the Ministry of Health also monitors veterinary functions although this, as well as overall ministry functions, is currently under review.

Other ministries also play a role. The Ministry of the Economy and Finance determines the overall budget available for health services. The Ministry of Social Affairs maintains strategic oversight of the social services delivered within the health system. In addition, a number of national arms-length bodies contribute to policy making and monitoring. Amongst the most important of these are the National Health Council (*Consiglio Superiore di Sanità*) that provides scientific and technical advice to the Ministry of Health; the National Institute of Health (*Istituto Superiore di Sanità*) that conducts publically-funded clinical and health services research; and the Italian Pharmaceutical Agency (*Agenzia Italiana del Farmaco*) that co-ordinates the pricing, reimbursing and distribution of pharmaceuticals, as well as undertaking linked research.

Responsibility for service design and delivery, however, sits at regional level

The national authorities outlined above set the broad parameters for health service performance. Beyond this, the R&AP are responsible for the actual planning and delivery of services. Articulation between central government’s steering role and regional government’s delivery role is expressed in the *Patto per la Salute*. This is a three-year plan that emanates from the conference between the state, regions and autonomous provinces.

The most basic requirement expected from R&AP is to ensure that the positive list of services defined in the LEA is provided to the local population. Under reforms dating from 1999, the Italian R&AP have considerable legislative, executive and evaluation functions to enable this role. An important partner in this are each region’s network of Local Health Authorities (*Azienda Sanitaria Locale* – ASL) and hospital trusts (*Azienda Ospedaliera* – AO) to whom executive functions are largely delegated. The ASL provide primary care, secondary care, public health, occupational health and health care related to social care at local level, with the R&AP providing technical support.

Regional governments directly set the resources to be allocated across the ASL and AOs, define their geographical boundaries and appoint their managers. They also accredit and authorise the AOs operating in their area, and monitor the efficiency, effectiveness and appropriateness of the services provided by accredited public and private organisations. A degree of autonomy at the level of ASLs and AOs is nevertheless encouraged, and the R&AP establish the regulatory framework around this and support ASL and AO managers in their strategic planning. R&AP can provide non-LEA services to their residents if they are able to finance them with their own revenues.

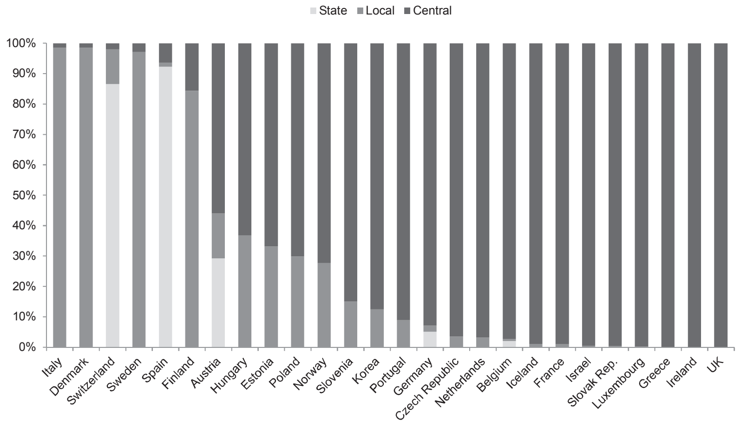
Based on the *Patto per la salute* and on local needs, the R&AP are also responsible for designing a local three-year health plan and monitoring activities on health care delivery across the territory. Regional governments, mainly through their departments of health, outline three-year regional health plans. These plans are used, based both on the *Patto per la Salute* and on assessed regional health care needs, to establish strategic objectives and initiatives, together with financial and organisational criteria for managing health care organisations. They are also responsible for co-ordinating health care activities through a standing conference for regional health and social care planning.

Italy is one of the few OECD countries where health spending is almost entirely decentralised

In Italy, revenues for the health system are raised through general taxation at both central and local level. Seventy-eight per cent of total health expenditure is raised in this way (slightly more than the OECD average). R&AP may apply out-of-pocket payments for specialist care, pharmaceuticals and diagnostic procedures, and 18% revenue comes from this route. Although around 15% of the population have private health insurance plans, private health care constitutes a very small part of the Italian health system (accounting for about 1% of revenue).

As implied by the foregoing discussion of the distribution of functions, almost 100% of public revenues are devolved to the R&AP since they are largely responsible for the planning and delivery of services. Italy is unusual amongst OECD countries in this regard. In most countries, decisions on the bulk of health care spending are made by central government (Figure 4.2).

Figure 4.2. Participation of each level of government in health spending, 2009



Source: OECD National Accounts, http://dx.doi.org/10.1787/na-data-en.

In addition to revenue raised by regional taxes, the R&AP receive EUR 2 000 per resident from central funds to provide health care. Adjustment to this capitation is made within a 6% margin, based on local measures of need. Since the 1990s, this adjustment has been made using a formula which gives most weight to differences in the age structure of regional populations. Southern regions have younger populations, meaning that they receive fewer funds than they might if other measures of need, such as deprivation, were given more weight. This risk is recognised and to some extent mitigated by supplementary funds from a central government pool and in-kind resources given to poorer performing R&AP, usually linked to new initiatives.

R&AP are responsible for any deficits incurred, but in practice the central government bails out the R&AP along with conditions that require cost containment measures and additional regional financial revenues (Torbica and Fattore, 2005). The consequences of this arrangement in the years following the 2008 crisis is discussed next.

The **Piani di rientro** *represent a dramatic rebalancing of governance across central and regional authorities*

When federalism was established in 2001, sufficient information or financial infrastructure to adequately monitor and control regional performance was not in place. Many regional health budgets quickly ran into deficit, requiring central authorities to impose *Piani di rientro* (financial recovery plans) on Piemonte, Liguria, Abruzzo, Molise, Lazio, Campania, Puglia, Calabria, Sicilia and Sardegna. Armeni and Ferré (2013), using Ministry of Health and Finance data, report that the average per capita deficit was EUR 667 over 2001 and 2012, with Lazio and Molise reaching deficits of over EUR 2 000 per capita.

It is important to note that the *Piani di Rientro* signalled the introduction of a dominant new player in national health care policy – the Ministry of Finance. This ministry is actively involved in designing and approving health care delivery in R&AP subject to budget recovery plans. Its priority, naturally, is to ensure a balanced budget. It collaborates with the Ministry of Health in the national system for the monitoring and control of public health care known as *Sistema nazionale di Verifica e controllo sull'Assistenza Sanitaria* (SiVeAS). As well as monitoring adequate access to the *livelli essenziali di assistenza*, SiVeAS aims to promote more cost-effective and patient-centered treatments as well as more efficient purchasing and workforce practices. Encouraging providers to evaluate their own efficiency and performance is another line of activity.

The *Piani di rientro* were very successful at reducing regional deficits. Between 2006 and 2011, the regional health systems subject to recovery plans reduced expenditure in real terms by 0.6%, compared to an increase of over 9.4% in other R&AP (de Belvis et al., 2012). Nevertheless, the focus of this abrupt resumption of central control has thus far been financial, with priority actions including reducing length of stay, hospital bed numbers and pharmaceutical expenditure. Whether quality-based governance will be given equal prominence alongside financial governance remains to be seen.

4.3. Initiatives seeking to ensure an even approach to quality measurement and improvement across the Italian regions and autonomous provinces (R&AP)

Against this diverse background, Italy has established a number of mechanisms to try and ensure an evenness of approach to quality measurement and quality improvement across its regional health systems. These include activities to co-ordinate approaches across R&AP and ensure dialogue between national and regional authorities. An evident trend is for central government and other national authorities to be adopting an increasingly prominent role in the governance of local health systems. This is trend that is being observed across most other OECD health systems.

A number of standing conferences enable policy discussion across different levels of government

The amendments introduced to the Constitution in 2001 established the transfer of legislative and regulatory competences from the state to the R&AP. The main mechanism to achieve co-ordination across levels of government within these new constitutional arrangements is the "Conference system", based on three co-ordination bodies:

- The *Conference between the State, Regions and Autonomous Provinces* was established in 1988 to co-ordinate governance and activity as the devolution process unfurled. Its composition includes the Prime minister or the Minister of Regional Affairs as President of the Conference, the presidents of the R&AP, and other ministers according to the issues under discussion.
- The *Conference between the State, Municipalities and other Local Authorities* was established in 1996 and its functions include co-ordinating the relations between states and local authorities, as well as analysing and serving as a forum for discussion of issues of interest for local authorities. Its composition involves the Prime minister as President of the Conference, several other ministers

including those of the Interior, Regional Affairs, and Treasury, the President of the Association of Italian Provinces as well as representatives of other towns and communities.

- The *Unified Conference between the State, Regions, Municipalities and Local Authorities* was established in 1997 as the institutional mechanism to co-ordinate the relationships among the central government, R&AP and local authorities. Its composition includes all the members of the previous two conferences. It is a key forum which works on issues such as administrative simplification, probity, quality of services, impact analysis and feasibility studies.

As mentioned earlier, one of the most important mechanisms through which the R&AP and central authorities engage with each other is discussion and ratification of the *Patto per la Salute*. The *Patto* for 2014-16 has recently been approved: as discussed in Chapter 2, a core focus will be shifting care away from hospitals and into primary and community care.

The National Outcomes Programme and Griglia LEA allow benchmarking and comparison of regional performance

The *Programma Nazionale Esiti* (National Outcomes Programme – PNE) is a professionally led initiative that monitors health care outcomes across hospitals and municipalities in Italy. The programme began in the 1980s looking at outcomes in cardiac care and has since expanded to cover over 120 indicators across a range of clinical areas. Indicators are selected to reflect clinical outcomes as far as possible (rather than inputs or processes) and are chosen in conjunction with professional and scientific societies, to ensure robustness and utility. Most indicators pertain to hospital care although a few, such as rate of hospital admission for asthma or COPD, relate to the quality of primary care – an area of work that the PNE is looking to expand. Methodological research around improving data quality, comparability, case-mix adjustment etc. is another significant area of work.

The PNE has been instrumental in quality improvement work (Fusco et al., 2012). Data are released annually via a navigable web platform; examples of the information made publically available are shown later in Section 4.4 of the chapter. Of note, both regional averages as well as within-region variation is shown and R&AP’ names are shown (hospitals are also named on the individual R&AP’ charts). Rates of timely surgery after hip fracture have shown significant improvement over recent years (both in terms of improved regional averages and reduced variation). In Sicilia, PNE demonstration of high mortality rates in two cardiology centres (which also had low patient volumes), was used as the basis to close them and concentrate practice in a well-performing centre, with higher patient volumes, nearby.

In addition, there are other monitoring frameworks sets that apply uniformly across the country. Among the most important of these is the *Griglia LEA*, which monitors provision of the LEA. Its primary purpose is to monitor the provision of minimum standards of care in the R&AP; hence it only contains 31 indicators. Nevertheless, many of these, such as rates of caesarean section, case-fatality rates following acute myocardial infarction and timeliness of surgery after hip fracture, can be considered as measures of quality of care. National targets for each indicator and results can be disaggregated by region.

AGENAS is a key organisation that co-ordinates quality improvement activity across levels of government

The National Agency for Regional Health care (*Agenzia Nazionale per i Servizi Sanitari Regionali* – AGENAS) is instrumental in co-ordinating activity across levels of government. AGENAS's responsibilities include supporting national and regional health planning with analyses of need and supply, assessing the costs and effectiveness of health care nationally and across R&AP, supporting innovation, evaluation and disseminating good practices and, finally, supporting R&AP subject to *Piani di Rientro* to comply with financial consolidation requirements whilst maintaining the accessibility and quality of services.

A particularly good example of AGENAS's work concerns patient safety. AGENAS has established an Observatory for Good Practices for Patient Safety, whose objective is to improve patient safety across the country through a cyclic model of collecting, classifying and disseminating safety improvement activities across R&AP. Every year, the Observatory issues a call for good practices, and provides a standard platform in which to report their content, outcomes and costs. Practices that have an evidence base, that have been evaluated in accordance with the principles of continuous quality improvement and that are sustainable, are disseminated in an annual publication and searchable database.

Two features of the Observatory make it a good demonstration for how co-ordinated action which transcends institutional boundaries should occur. First, the Observatory was designed with the input of multiple stakeholders: central authorities, regional authorities, professional and scientific groups. Second, the underpinning philosophy of the Observatory is that top-down and bottom-up actions are complementary in the quest to improve patient safety.

Similar to other OECD countries, central authorities are adopting an increasingly prominent role in health system governance

As set out in Chapter 1, central authorities are adopting an increasingly prominent role in the quality governance of health care in Italy. This role is not filled solely by central government, but by arms-length bodies or civil society actors at national level as well. There are several valid reasons for this, including better information and technological capacity to benchmark local performance, more demanding central accountability regimes and social trends that make differences in health care quality of across R&AP less tenable.

One example concerns accreditation. As described in Chapter 1, the accreditation of health care providers is mandatory to be eligible for funding from the national health system. Accreditation is a regional responsibility; increasingly, however, central authorities are adopting an expanded role to support R&AP in the systematisation and standardisation of this function. Against a background of 21 different accreditation models, AGENAS was asked in 2010 to identify a framework of common standards to underpin accreditation. To support practical implementation of this content, AGENAS also created a platform which R&AP can use to manage their accreditation of providers. Currently, ten R&AP use this resource. Of note, however, a national inspectorate of health still does not exist.

There are also professionally led examples of quality improvement work taking place at national or cross-regional level. The *Società Italiana di Medicina Generale* (Italian Society of General Medicine and Primary Care – SIMG) is a national scientific society for Italian GPs, set up in 1982. It has around 7 500 members, some 15% of the GP workforce; 5 000 of these participate in a quality monitoring initiative where data on activity and outcomes is pulled automatically from patients' records. Care for diabetic patients, for example, is measured through ten indicators. The information gathered is used for audits and issuing real time reports to individual GPs.

Whilst these nationally led initiatives are welcome, tensions may arise between the need for centrally set standards and benchmarking systems on the one hand and the need to safeguard local responsiveness and decision making in those countries which value strong local government on the other hand, as described in Box 4.1.

Box 4.1. OECD experience in balancing health system governance across national and regional authorities

Governance refers to how a system of care is steered and managed at a macro level. The tasks of governance include setting out the values and ambitions of a health system, allocating responsibilities and defining accountabilities, monitoring progress, encouraging and rewarding excellence, as well as correcting failures. Effective governance is an essential element in ensuring consistently better quality of care and improving outcomes. Exactly how governance should be organised, however, is a complex policy question. This is particularly the case for health care, which is often the focus of national debate and scrutiny, but is almost always delivered locally.

OECD countries present practically every conceivable model of intergovernmental relations, ranging from highly decentralised federal systems, as in the United States, Canada, and Switzerland, to highly centralised unitary state systems, as in Ireland, Greece, and Portugal. Between these polar models are recently created regional systems (as in France, Italy, and Spain), and unitary states with traditions of strong local government, such as the Scandinavian countries (Charbit, 2011). Such diversity in governance is reflected in how health systems are managed. Local management is believed to bring several advantages, including service priorities that reflect local preferences; tailored policy solutions to local problems thanks to a strong, in-depth local knowledge and policy innovation, driven by competition and comparison between local governments in the provision of services.

4.4. Variation in performance and performance management of regional health systems

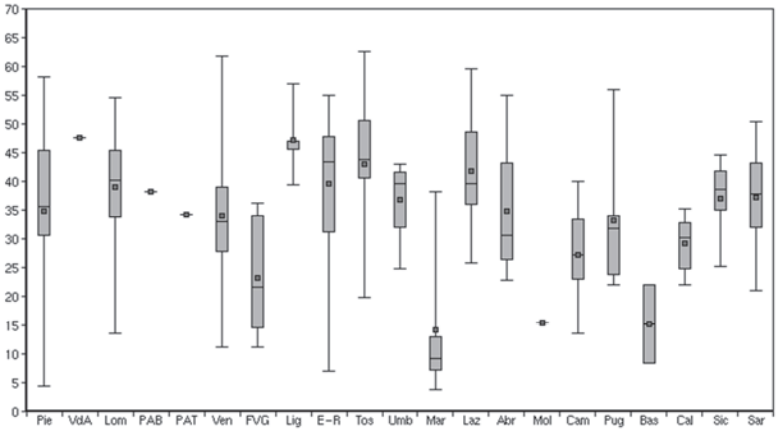
Despite the quality strategies outlined above, regional differences in health care quality across Italy remain significant. This section reviews regional differences in some indicators of quality, to contextualise the policy analysis and recommendations that follow. The review is deliberately brief, given that such differences have been extensively documented elsewhere, such as the annual *Rapporto annuale sui ricoveri ospedalieri*, published by the Ministry of Health each year which analyses hospital discharges by disease and by region. Furthermore, the review focuses on indicators of health care *quality* rather than more "distal" measures such as mortality or self-rated health (since these are determined by a broad range of socio-economic factors that lie beyond the health system).

Whilst it cannot be said that any one region has consistently "poor" health care, a typical pattern that emerges is of relatively poorer health care quality and outcomes in southern R&AP (Toth, 2014). As a result, large numbers of Italians move between R&AP in search of health care, with northern R&AP being net importers of patients. Another striking feature is that variation observed *within* a region is often greater than cross-regional variation. This underlines the importance of strong performance management of hospitals and clinicians at regional level. The approach to performance management varies greatly across R&AP however. Some R&AP have developed multidimensional, automated reporting, disseminating the results to multiple users with the clear aim of influencing policy. Other R&AP approach performance management as a technical exercise involving few stakeholders and with the primary aim of managing resources.

Regional variations in the health care practice and outcomes are significant, across R&AP as well as within them

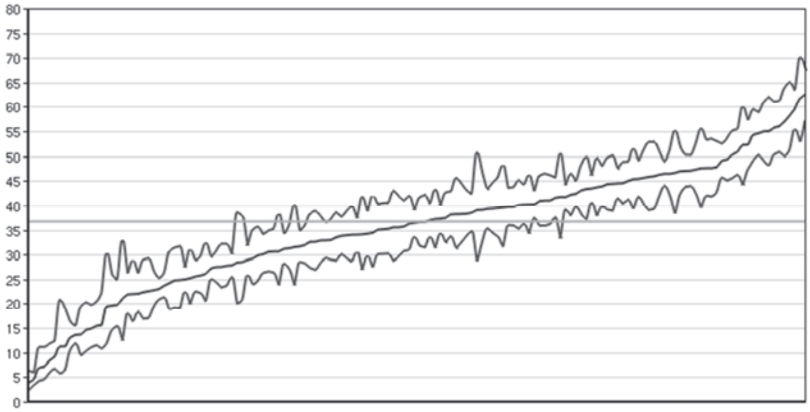
Results from the National Outcomes Programme (PNE) allow an assessment of national variation in the quality and outcomes of care, by ASL or by region. For several important areas of care, variation is marked. The proportion of patients receiving coronary angioplasty within 48 hours of a heart attack, for example, varies from ~15% in Marche, Molise and Basilicata to almost 50% in Valle d'Aosta and Liguria (Figure 4.3). Variation *within* R&AP is even more profound: Figure 4.4 shows how the same indicator ranges from ~5% to over 60% when disaggregated to ASL-level. Thirty-day mortality, disaggregated to ASL level, is shown in Figure 4.5 and ranges from ~5% to 18% with a national mean of 10%.

Figure 4.3. Proportion of cases of acute myocardial infarction (AMI) treated with percutaneous transluminal coronary angioplasty (PTCA) within 48 hours, disaggregated to R&AP



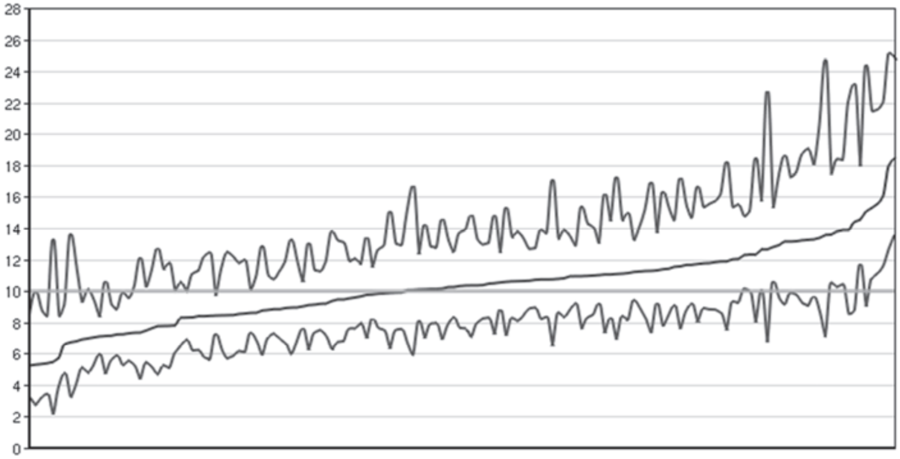
Source: Programma Nazionale Esiti ed. 2013, SDO 2005-2012, available from http://95.110.213.190/PNEed13/index.php, accessed 5 August 2014.

Figure 4.4. Proportion of cases of acute myocardial infarction (AMI) treated with percutaneous transluminal coronary angioplasty (PTCA) within 48 hours, disaggregated to ASLs



Source: Programma Nazionale Esiti ed. 2013, SDO 2005-2012, available from http://95.110.213.190/PNEed13/index.php, accessed 5 August 2014.

Figure 4.5. Acute myocardial infarction (AMI) – 30-day case fatality



Source: Programma Nazionale Esiti ed. 2013, SDO 2005-2012, available from http://95.110.213.190/PNEed13/index.php, accessed 5 August 2014.

Similar patterns are seen in other PNE indicators of the quality of acute hospital care. Thirty-day mortality after a stroke, for example, varies from ~7% in Bolzano to almost 20% in Molise. After hip fracture, patients wait

Figure 4.6. Hospital medical admission rates, across and within OECD countries, 2011 (or latest year)

	Belgium	France	Israel	Germany1	Switzerland	Germany2	Spain	Italy	England	Australia	Finland	Portugal	Canada
Crude rate	10 337	8 802	11 878	13 342	7 047	13 342	5 244	7 403	10 276	10 986	8 168	5 277	4 376
Std rate	9 723	8 805	12 755	12 102	7 662	12 267	5 121	6 370	10 585	12 033	8 962	5 245	5 717
Coeff. of variation	0.08	0.11	0.12	0.12	0.13	0.14	0.14	0.15	0.19	0.20	0.20	0.21	0.34

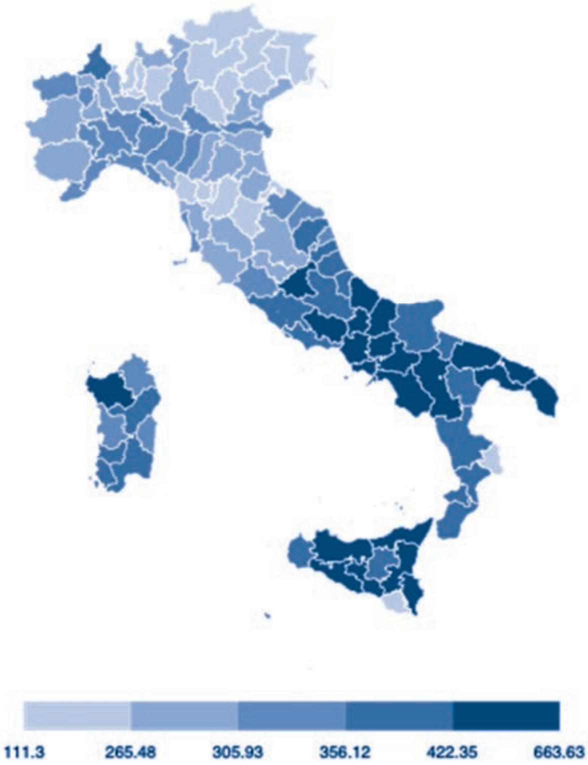
Source: OECD (2014), *Geographic Variations in Health Care: What Do We Know and What Can Be Done to Improve Health System Performance?,* OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264216594-en.

Caesarean sections are associated with an increased risk of maternal death and puerperal complications, so use should be restricted to a few well-defined indications such as dangerous placental or foetal position. The World Health Organisation estimates that no more that 10-15% of deliveries are associated with a medically justifiable reason for a caesarean section. In Italy, the national rate estimated from PNE data is around 25%. Bolzano (13.6%) and Trento (14.5%) have the lowest rates, whilst Campania has a rate just over 45%. Caesarean sections become increasingly common as one moves south, as illustrated by Figure 4.7.

Data submitted to the OECD's MPV project show that this geographic variability is greater than elsewhere (Figure 4.8). At provincial-level, the coefficient of variation in Italy is 0.29, the highest co-efficient among the group of countries represented. Between 2007 and 2011, the national rate of caesarean sections was stable, with only a 3% decrease in the last year and an identical coefficient of variation.

Further analysis has demonstrated that units delivering low numbers of women (<500/year) have the highest rates, some approaching 70% (Ministry of Health, 2011). A recent national regulation states that units delivering less than 1 000 women/year must close or merge in an attempt to address this phenomenon.

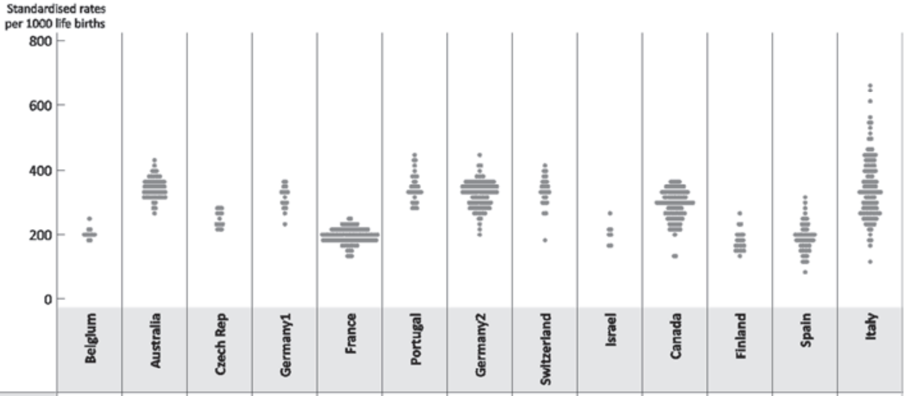
Figure 4.7. Caesarean section rates in Italy by province, age-standardised, per 1 000 women, 2011



Source: Analysis of the National Hospital Discharge Database, Ufficio VI, DG Programmazione, Ministero della Salute, Italy.

Italy displays more variation than other countries for other MPV indicators as well. Italy's CV for cardiac catherisation after a heart attack, for example, is higher than any other country. It is much less reasonable, however, to interpret this indicator as a measure of quality or access. In particular, a substitute procedure exists (coronary artery bypass grafting) where the Italian CV is similar to other countries. Similarly, for other MPV metrics such as rates of knee arthroscopy, knee replacement or diagnostic imaging, there is no easily-defined international clinical consensus around appropriate use or an "ideal" rate, limiting their utility as an internationally comparable measure of quality or access.

Figure 4.8. Caesarean section rates, across and within OECD countries, 2011 (or latest year)



	Belgium	Australia	Czech Rep	Germany1	France	Portugal	Germany2	Switzerland	Israel	Canada	Finland	Spain	Italy
Crude rate	194	323	237	314	196	328	314	332	185	270	161	170	369
Std rate	206	343	243	311	194	349	324	332	207	292	181	189	346
Coeff. of variation	0.09	0.10	0.11	0.11	0.12	0.13	0.13	0.15	0.16	0.16	0.18	0.25	0.29

Source: OECD (2014), *Geographic Variations in Health Care: What Do We Know and What Can Be Done to Improve Health System Performance?,* OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264216594-en.

The way the performance of health systems is managed varies markedly across R&AP

Additional analyses of MPV have demonstrated that variation *within* a region is often greater than cross-regional variation. This observation underlines the importance of strong performance management of hospitals and clinicians at regional level. Very different approaches are taken to performance management and quality improvement across R&AP, however. Whilst all R&AP are developing increasing interest in continuous quality improvement and performance management, the approach and implementation of these strategies varies markedly across R&AP.

There are a variety of performance management systems across Italy, of variable strength. In a survey of twelve R&AP following the European Ministerial Conference on Health Systems in Tallinn in 2008, a mix of approaches including balanced scorecards and automated multidimensional reporting was noted (Carinci et al., 2012). Toscana's application of performance management is particularly well known and has been adopted by other R&AP (see Chapter 1 for a description). Eight R&AP did not report development of any local performance management system, relying solely upon the Ministry of Health's monitoring of the *Griglia LEA* to assess the quality of services. Several of these R&AP have rich databases of health care activities, outcomes and patient satisfaction, but appear to have not yet harnessed them in a way that allows continuous quality monitoring and improvement.

The extent of professional and public involvement also varied. Emilia Romagna, Lombardia, Toscana and Umbria reported incorporating professionals’ and civic input in a structured way when assessing and planning local services; others reported more ad hoc involvement. Similarly, the use and dissemination of findings also differed. Emilia Romagna, Umbria and Toscana reported regular publication of structured performance reports, whilst irregular or less structured reporting appears to occur in most other regions. Marche and Piemonte only produce occasional statistical and epidemiological reports.

Not all R&AP reported having units dedicated to performance management and using findings to influence policy. Lombardia, Marche, Sicilia, Trento, Umbria, Valle d’Aosta, Basilicata and Toscana used local quality of care information in a systematic fashion, including using performance metrics in their contracting with service providers. The R&AP’ infrastructures included specific offices for performance evaluation, sometimes linking to external organisations (such as universities) for expert technical support (see, for example, Agabiti et al., 2010). Other R&AP use local performance measures in a more ad hoc fashion. Abruzzo, Calabria, Campania, Molise and Piemonte (all of which were subject to *Piani di rientro*) did not have a unit dedicated to performance evaluation at the time of the survey, for example. These R&AP would mainly use health data for epidemiological purposes, with infrequent use of quality and outcome measures to inform local policy debate or negotiation with service providers.

Another important difference across R&AP concerns the capacity to link data. Linking data on individuals from two or more sources (such as an administrative database containing details of procedures or waiting times and a clinical database containing details of diagnoses and outcomes) is increasingly recognised as a capacity that agencies should develop in order to build a richer picture of the quality and outcomes of individuals’ care, subject to appropriate protection of data privacy (OECD, 2013b).

Data linkage in Italy is theoretically possible, given the existence of a unique identifier given to all Italian citizens (the *codice financiale,* or tax file number). Yet R&AP vary greatly in their capacity to track an individual’s use of health care services across a period of time, indeed, may R&AP have no capacity to do so at all. Part of the explication for this heterogeneity lies in an on-going confusion about the ownership of data. Whilst central government is responsible for the management of all standardised data collection, responsibility to provide actual data lies with the R&AP, who request this data from their constituent ASLs. According to the latest interpretation of the national privacy legislation, ASLs may be regarded as the ultimate owners of all health care information and the only entities fully entitled to access and link individual data across different domains. ASLs are small entities, however, and are unlikely to have the technical capacity to undertake data linkage and analysis of linked data in a consistent manner. Even if these issues were to be resolved, an outstanding issue would be how to link health system data to clinical registry data, most of which are operated by professional associations.

Many Italians leave their region for health care, with northern R&AP being net importers of patients

Levels of patient satisfaction vary markedly across Italy. In 2009, the share of patients who declared themselves to be "very satisfied" with hospital care was over 50% in Trentino-Alto Adige, Veneto and Emilia-Romagna, and less than 20% in Sicilia and Puglia. No doubt linked to this, the substantial flow across regional borders of individuals seeking health care is well-recognised in Italy. Data from the Ministry of Health show the southern regions of Campania, Calabria and Sicilia lose at least 30 000 patients a year in search of health care (and attract far fewer; the inflow/outflow ratios for these regions being 11.7, 34.0 and 13.6, the highest in Italy). Northern R&AP are net importers of patients: Toscana had a net inflow of 22 230 patients in 2010 (inflow/outflow ratio 0.3), Emilia Romagna 48 891 patients (ratio 0.2) and Lombardia 61 399 patients (ratio 0.2).

Patients may opt for health care in another region for several reasons, such as to be nearer to family, and little qualitative data exists on why patients move. Nevertheless, it is widely accepted that the main reason why patients move from south to north is to seek better quality care (France et al., 2005; Ministry of Health, 2011).

4.5. Securing a greater quality dividend from Italy's regional health systems

In order to achieve consistently high quality health care across all Italy's R&AP actions are needed in two broad areas: first, actions to improve health care quality and health care outcomes in poorer performing R&AP. Key actions here would include developing a more consistent approach across R&AP to using information to manage performance and strengthen local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important. Second, actions that strengthen the regional approach to health care governance and delivery in Italy are also needed. This would consist of resolving any tensions or misalignments in centre-regional governance arrangements and reframing governance as a whole such that quality improvement is emphasised as much as financial control.

Work to develop a more consistent regional approach to performance management should be prioritised

Differences in how R&AP use currently available information on the quality and outcomes of health care (and/or gather additional regional quality indicators) is a key weakness in Italy's regional approach to health service delivery. As evident in the survey work undertaken for the implementation of the Charter signed at the 2008 Tallinn conference on health systems, some R&AP have developed more sophisticated and demanding performance management regimes than others. While it is understandable that national authorities have avoided imposing one or other model, there is scope to work toward a more consistent national approach. At present, the *Griglia LEA* is strikingly limited in the scope and depth of indicators it collects. Whilst the *PNE* is more ambitious in scope, the information it contains is not used as extensively as it should be to drive health competition and continuous quality improvement across R&AP.

A more consistent and ambitious approach would encourage all R&AP to see performance management as a collective exercise that influences policy and leads to continuous quality improvement, rather than as a technical problem that involves few stakeholders and leads to few policy-relevant outputs. Performance management should be multidimensional, focus on outcomes and equity (rather than activities and outputs), be widely disseminated and supported by a dedicated performance management unit within each R&AP. Consistency along these lines would still allow ample scope for a regionally tailored approach, guided by local priorities.

Denmark offers a model that may be applicable here. As in Italy, Danish health system governance is decentralised and the Danish regions are primarily responsible for delivering health care. Nevertheless, a uniform approach to performance management has been agreed. The *Danske Regioner* (the organisation of Danish regions, www.regioner.dk) have together formed a "quality agenda" with the overall objective to improve the quality of care in the Danish health care system. Each region has its own staff is in charge of monitoring quality of care in local health services and initiating programmes for quality improvement. Although national legislation increasingly sets out requirements on topics such as waiting times, safety of pharmaceuticals and adverse event reporting, more detailed regulation is carried out through the agreement between the national level, the regions, and the municipalities. Quality targets are an increasing feature of these agreements. The agreement on the regional budget for 2013, for example, stipulates a 10% decrease in hospital standardised mortality rate and a 20% decrease in adverse events for the next three years. Although these agreements are not legally binding, they are considered to be an important mechanism to govern the Danish health care system, whilst leaving sufficient room for regional and local adaptations according to needs (OECD, 2013c).

The Italian Ministry of Health, together with the Italian R&AP and other key national agencies such as AGENAS should work together to define a more consistent regional approach to the performance management of health systems. Key themes to address would be the extent to which performance metrics are used in contracting with hospitals, other providers and their management boards, and the extent to which performance metrics are made available for public scrutiny and open comparison. One issue to be overcome in this regard is the fragmented nature of the information infrastructure underpinning the Italian health system, as discussed in Chapter 1. Responsibilities for collecting, analysing and publishing health system metrics is currently scattered across several bodies, including the Ministry of Health, AGENAS, AIFA, ISS, regional departments/agencies, ASLs and public health observatories. Italy lacks a single national institute for health system information (as seen in a number of other OECD countries). This lack of co-ordination has held back public dissemination. Overall, public availability of quality indicators is very limited in Italy compared to other OECD countries.

Some steps have been taken recently to improve this situation. Early in 2013, the Conference of the State and the R&AP agreed that "Portal for the Transparency of Health Services" (Conferenza Stato Regioni, 2013), on which results of quality of care and performance evaluation shall officially be disclosed to the public on a regularly basis, starting in 2014. The Ministry of Health and AGENAS are also working toward creation of a national framework of performance evaluation (Di Stanislao et al., 2012). This kind of work is much needed and should be continued. Finland offer possible models to follow. There, the National Institute for Health and Welfare (www.thl.fi/en) is a single institute that is responsible for collecting, analysing and disseminating an extensive range of health and social welfare statistics. A large number of areas are covered, including ageing, mental health, environmental health and health workforce statistics. Many of its publications are oriented toward the public. At the same time, it is able to produce data to an impressive degree of refinement and policy relevance. Mortality rates after a named health care episode at 7, 30, 90 and 365 days are available for example.

Finances should also be used to incentivise quality improvement

Better use of financial resources and incentives should be used alongside better use of information to improve the quality of care in Italy's poorer performing R&AP. Italy's poorer R&AP from time to time receive additional block grants to support particular needs or finance new initiatives. These grants should be used to incentivise quality improvements where possible. This could be through ensuring that each grant has a ring-fenced element for impact evaluation, or includes specific resources to extend the quality-improvement infrastructure or personnel, or making some, or all, of the grant conditional upon achieving certain targets or implementing new processes.

Sweden demonstrates deployment of both informational and financial incentives during its recent reforms to drive better integrated, community-based care. National strategies are coupled with rich data on local results, which act as an information-based incentive. The *Quality and Efficiency in Swedish Health Care* publication is an example of this, it is extensively and creatively used to drive policy debate in a way that Italian data (whether the *Griglia LEA* or PNE) are not. In 2010, central government also began to use performance-based incentives to encourage quality in elderly care. This is a change with respect to previous arrangements, where central government transfers to local governments had been based on historical trends. In 2011, for example, the government allocated SEK 325 million (EUR 35 million, USD 47 million) to counties that demonstrated a statistically significant improvement in reducing unnecessary hospitalisations. Monetary rewards are given to counties that reduce the use of inappropriate drugs, reduce the inappropriate combinations of drugs and the use of psychotropic drugs among elderly people in institutional care (OECD, 2013d).

A second aspect concerns the regional resource allocation formula. This is currently under discussion, particularly in light of the work underway to create a national price schedule for health care activities, and the desire to uncouple resource allocations from historic patterns of service use in each region, which are known to be a poor measure of need. Clearly, it is important that regional allocations are matched to need as closely as possible, and reward efficiency. Box 4.2 describes how other OECD countries are tackling this challenge. Equally important, though, regional allocations should support and reward quality. Less efficient R&AP are likely to see their budgets being squeezed – whilst efficiency gains are being sought, adequate safeguards should be in place to ensure that access to care and the quality of care do not suffer. An important action in this regard would be to monitor the impact of financial consolidation on the health of vulnerable individuals and communities.

Box 4.2. Regional resource allocation in other OECD health systems

In single-payer systems, resource allocation (RA) attempts to distribute resources from a central fund to local providers (or purchasers) of care in a way that enables them to meet local population health needs adequately and without waste. A key challenge is to appropriately measure need, as opposed to the demand for health care. There are several ways in which local health needs can be measured or proxied. These most often include:

- broad demographics of the locality (e.g. head count, age, sex, standardised mortality ratios)
- broad socio-economic characteristics of the locality (e.g. deprivation index)
- historical service utilisation patterns in the locality.

There is extensive evidence that demographics by themselves do not adequately reflect health needs. In some settings, for example, areas with a greater proportion of elderly residents may be wealthier than younger areas. Poorer areas typically have greater population health needs and so using simple demographics alone here would lead to a mismatch between allocated resources and local need. Standardised mortality ratios (particularly premature mortality ratios, i.e. deaths under 75 years of age) are likely to be a better measure of need. This was the approach adopted by the United Kingdom's Resource Allocation Working Party in the 1990s (Buck and Dixon, 2013).

The potential impact of incorporating area-based socio-economic characteristics is demonstrated using data from England (Barr et al., 2014). In 1999, the English RA formula was changed to give more weight to area deprivation measures. Between 2001 and 2011, the gap in rates of amenable mortality in people aged less than 75 years between wealthier and poorer areas decreased (from 95 to 54 male deaths and from 47 to 28 female deaths per 100 000). Barr et al. estimate that 85% of this reduction can be explained statistically by the increase in resources allocated to deprived areas.

Historical utilisation patterns are also flawed measures of need given that patterns of utilisation are based on a variety of factors such as supply and physician or patient preferences which may be poorly correlated to actual need (OECD, 2014c; Asthana and Gibson, 2008). Nevertheless, historic utilisation/spending patterns may need to be included in some form or other in RA formulas to reflect unavoidable regional differences in input or capital costs, such as higher wage rates in capital cities.

International comparison of resource allocation formulae reveals that all are characterised by a mix of demographic, socio-economic and service utilisation measures (Penno et al., 2013). The choice and balance of components and, in particular, the prominence given to socio-economic characteristics is often as much of a political as a technical decision, however. Buck and Dixon (2013) point out that socio-economic measures are more prominent if governments see RA as a means to tackle health inequalities rather than merely meet health care needs.

Box 4.2. Regional resource allocation in other OECD health systems *(cont.)*

More recently, attempts have been made to move from broad demographics to person-based measures of need. Compiling individual diagnoses intuitively appeals as an accurate and explicit means to determine health care need and several compilation algorithms have been developed. Most emanate from research to achieve efficient risk-equalisation across insurance schemes, a problem that is largely synonymous to the regional RA problem. Algorithms include the *Johns Hopkins Adjusted Clinical Group (ACG) System* (Weiner et al., 1996), the *Chronic Disease and Disability Payment System* (Kronick et al., 2000)*, Clinical Risk Groups* (Hughes et al., 2004)*,* and the *Clinically-detailed Risk Information System for Cost* (Kapur et al., 2003). The ACG system is the oldest and perhaps the best known. This allocates individuals to one of six Resource Utilisation Bands, based on their age, sex, diagnoses, severity of illness, duration and other factors.

Although person-based measures of need demand an advanced information infrastructure, an increasing number of OECD countries have this capability in the form of electronic patient records or other systems. Applying risk-equalisation algorithms to the RA challenge has shown encouraging results. In Sweden, for example, application of the ACG algorithm to primary care was shown to increase explanation of the variance in health care costs from 14% to 63% compared to a model that only used broad demographics (Zielinski et al., 2009). Within Italy, the Liguria region uses DRG-based measures of need to derive a cost-profile for each citizen to support its health service planning.

An important caveat to bear in mind when using ACG or similar systems is that diagnoses are not free of endogeneity and are likely to have been determined, to some extent, by supply and historical patterns of service utilisation. One way around this is to use health survey data, which has the potential to triangulate self-reported symptoms and/or clinical measurements against a selected set of diagnoses. Modelling in Wales and England has shown this to be a promising approach (National Assembly of Wales, 2001; Asthana et al., 2007).

Strengthening and clarifying the role of national authorities, whilst redefining mutual accountabilities between the centre and the R&AP, will be important

The regional structure of Italy's health service is well established and should be valued. Indeed, the first two recommendations to use information and financial resources more effectively to monitor and improve quality are intended to strengthen R&AP' role in delivering Italian health care. At the same time, however, there is scope to develop the responsibilities and capacities of some national authorities, particularly those whose role is to support the R&AP in their performance management of local hospitals, clinics and professionals. The roles and responsibilities of central government and other national authorities need to be clearly defined rather than assumed or adopted by default. Even in highly decentralised systems, it is clear that central authorities have several important roles and functions. These include:

- *producing overviews* of current knowledge, current practice or current performance, both nationally and internationally
- *setting standards,* on performance or performance reporting, for example
- *developing tools* such as evaluation frameworks, IT platforms, deep dive teams to visit and support areas with special needs
- *levelling out resources and workload*, particularly for small, remote or under-resource localities
- *encouraging local innovation* and evaluation of differences in approach
- *providing a platform or forum* for contact and exchange between localities.

The Norwegian Association of Local and Regional Authorities (*Kommunesektorens organisasjon* – KS, www.ks.no) is a national interest association for municipalities, counties and public enterprises which demonstrates many of these functions. All 428 Norwegian municipalities and 19 counties among others are members of KS. KS have regular contacts with central authorities to advocate the interest of its members. The government and KS have entered into several agreements. The 2012-15 agreement, for example, aims at promoting quality initiatives in local primary health care service, with an emphasis on patient participation, prevention, rehabilitation and the use of new technologies. These are all priorities for Italy´s health system as well. KS actively communicates with the members, disseminates information and facilitates the exchange of experience (OECD, 2014a).

In Italy, AGENAS appears as the national agency that most naturally offers itself as a corollary to the *Danske Regioner* described earlier or KS. It already undertakes some key activities linked to the recommendations outlined above. Regarding the better use of information, for example, AGENAS in collaboration with the Ministry of Health and the R&AP, supports dissemination of PNE results through a series of events and regional workshops organised throughout the country, through which the assessment of results is shared with relevant stakeholders in order to pursue the realisation of a continuous cycle of quality improvement. There is scope to consider developing the role of AGENAS more fully, modelling it on equivalent organisations in other countries such as *Danske Regioner* in

Denmark, or the KS in Norway. Examples of quality improvement work which AGENAS is well placed to undertake include:

- development of a nationally consistent approach to performance management and quality improvement cycles across R&AP;
- thought-leadership around developing a more consolidated national health information infrastructure, for example, on how a national institute for health information might be created;
- technical advice to support national planning, including possible revision of the formula used to allocate regional resources;
- thought-leadership around the next phase of minimum quality standards, including extensions to the *Griglia LEA* and development of a more rigorous health inspectorate function, at national or regional level.

Identify and resolve tensions and inefficiencies in the multi-level governance structure

Strengthening and clarification of the role of central authorities in supporting the performance management of regional health care delivery in Italy is appropriate, and is aligned with the direction of travel seen across OECD health systems. Whatever the starting-point in terms of governance structures, whether federalised or centralised, central authorities are adopting an increasingly prominent role in the quality governance of local health systems (OECD, 2014b). This is likely to be due to a number of reasons, particularly greater informational capacity to benchmark and compare regional variation in performance.

Although there may be sound reasons for adoption of more prominent role by central authorities, it may lead to tensions and inefficiencies in governance, particularly in multi-level governance systems such as Italy's. Box 4.1 sets out some of the gaps or inefficiencies that may arise, in terms of information, capacity, funding or accountability.

Italy needs to be alert to these risks, and identify and resolve any tensions that arise. It starts from a strong position, in that accountabilities are already well defined (R&AP are clearly responsible for the totality of health service provision), resource-flows match accountabilities (almost 100% of health spending is under R&AP' control) and there are well-established mechanisms to ensure regular centre-regional dialogue (such as the standing conferences described in Section 4.3).

Drawing on the series of *OECD Health Care Quality Reviews*, it seems clear that the most important elements in balancing governance are agreeing mutual accountabilities, information sharing and effective dialogue, and matching accountabilities with the right resources and incentives to enable delivery. Together, these elements can go a long way to close gaps in information, capacity, funding or accountability.

Shifting governance from a financial focus to give equal prominence to quality improvement needs to happen at all levels of government

Underpinning all of the earlier recommendations must be a commitment from both national and regional authorities to equal commitment to quality improvement as to financial control. In particular, the *Piani di Rientro* (Recovery Plans) of recent years represent an abrupt rebalancing of central versus regional authority in financial terms. It is essential that governance driven by quality imperatives is given equal prominence. The scaling-back of performance management capacity in some R&AP as a result of the crisis underscores the importance and timeliness of this argument. Although this shift is needed at all levels of government, clear leadership from central authorities will be essential.

The Ministry of Health could develop a stronger operational role around monitoring health care quality and outcomes. For example, the Ministry of Health uses the *Griglia LEA* as its performance monitoring tool, but this is a limited set of 31 indicators with targets that most R&AP achieve easily. Although the ministry considers PNE results, this data is not "operational" in the sense that no action can be taken on low performers. The ministry is considering bringing some PNE indicators (such as timeliness of surgery after hip fracture) into the *Griglia LEA*, but progress is slow. Advancing this work would give a clear signal that quality improvement is a priority.

The same priority needs to be reflected at regional level. Whilst some R&AP do this already, as earlier described, other R&AP need targeted support to build robust and effective quality governance. AGENAS is well placed to offer this, particularly since it can broker support and knowledge-transfers from other R&AP, as well as internationally. In particular, R&AP should be encouraged or required to publish regular quality improvement plans with specific goals and milestones, along the lines of the *Danske Regioner* described earlier.

Portugal offers a good model here. Although subject to tough requirements to find savings and efficiency gains as a result of the 2008 crisis and Troika intervention, the country has continued building ambitious quality monitoring and improvement programmes. A particularly successful area of reform has been the reduction in spending on pharmaceuticals and medical devices through the promotion centralised purchasing, national formularies, and incentives to use generic drugs. Doctors receive regular, automated and individualised feedback on their prescribing patterns, alerting them, for example, on the extent to which they prescribe outside the national formulary. Quality and efficiency gains have also been realised by concentrating services. Portugal has reduced its number of hospitals from 650 hospitals in 1970 to 73 in 2005. Hospitals with fewer than 200 beds were required to close their emergency departments. This reduced the number of acute hospitals to 40, which are further grouped in to 25 clusters, enabling additional efficiency gains. Primary care has also been the focus of major reforms, with the introduction of new contracting models which reward quality and outcomes, multidisciplinary teams and task-shifting (OECD, forthcoming).

4.6. Conclusions

Italy is a country characterised by significant socio-economic heterogeneity. The provision of health care services reflects this heterogeneity, being a fully regionalised system. Although regional systems have much in common, there are marked differences in the quality, outcomes and performance management across them. Whilst it cannot be said that any one region has consistently "poor" health care, a typical pattern is of relatively poorer health care quality and outcomes in southern R&AP. As a result, large numbers of Italians move between R&AP in search of health care, with northern R&AP being net importers of patients. Another striking feature is that variation observed *within* a region is often greater than cross-regional variation. This underlines the importance of consistently effective performance management of hospitals, clinics and professionals at regional level.

Italy has established a number of mechanisms to try and ensure an evenness of approach to quality measurement and quality improvement across its regional health systems. These include activities to co-ordinate approaches to performance management across R&AP, as well as ensure dialogue between national and regional authorities, and activities that are statutory as well as professionally led. Whilst maintaining these activities, more could be done to achieve consistently high quality health care across all Italy's R&AP.

Actions are needed in two broad areas: first, actions to improve health care quality and health care outcomes in poorer performing R&AP. Key actions here would include developing a more consistent approach across R&AP to using information to manage performance and strengthen local accountability. Ensuring that regional resource allocation has a focus on quality, and is linked to incentives for quality improvement, will also be important. Second, actions that strengthen the regional approach to health care governance and delivery in Italy are also needed. This would consist of resolving any tensions or misalignments in centre-regional governance arrangements, emphasising in particular that the role of national authorities should not be to performance manage R&AP per se, but to support R&AP in their performance management of local hospitals, clinics and clinicians. Reframing governance as a whole, such that quality improvement is emphasised as much as financial control, will also be fundamental.

Bibliography

Agabiti, N. et al. (2010), “Profiling Hospital Performance to Monitor the Quality of Care: The Case of COPD”, *European Respiratory Journal*, Vol. 35, No. 5, pp, 1031-1038.

Armeni, P. and F. Ferré (2013), “La Spesa Sanitaria: Composizione ed Evoluzione”, in CERGAS (eds.), *Rapporto OASI 2013*, Egea, Milan.

Asthana, S. et al. (2007), *Review of the Weighted Capitation Formula on behalf of the East of England Strategic Health Authority*, University of Plymouth and Eastern Region Public Health Observatory, England.

Asthana, S. and A. Gibson (2008), “Health Care Equity, Health Equity and Resource Allocation: Towards a Normative Approach to Achieving the Core Principles of the NHS”, *Radical Statistics*, Vol. 98, pp. 6-26.

Barr, B., C. Bambra and M. Whitehead (2014), “The Impact of NHS Resource Allocation Policy on Health Inequalities in England 2001-2011”, *British Medical Journal*, Vol. 348.

Belvis, A.G. et al. (2012), “The Financial Crisis in Italy: Implications for the Healthcare Sector”, *Health Policy*, Vol. 106, No. 1, pp. 10-16.

Blöchliger, H. and C. Vammalle (2012), *Reforming Financial Federalism and Local Government: Beyond the Zero-Sum Game*, OECD Financial Federalism Studies, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264119970-en.

Buck, D. and A. Dixon (2013), *Improving the Allocation of Health Resources in England*, The King’s Fund, London.

Carinci, F. et al. (2012), “Performance Measurement in Response to the Tallinn Charter: Experiences from the Decentralized Italian Framework”, *Health Policy*, Vol. 108, No. 1, pp. 60-66.

Charbit, C. (2011), “Governance of Public Policies in Decentralised Contexts: The Multi-level Approach”, *OECD Regional Development Working Paper*s, No. 2011/04, OECD Publishing, Paris, http://dx.doi.org/10.1787/5kg883pkxkhc-en.

Conferenza Stato Regioni (2013), “Deliberazione del progetto interregionale ‘Portale della trasparenza dei servizi per la salute’”, available at www.statoregioni.it/Documenti/DOC_039309_20%20%20csr%20punto%2017%20odg.pdf, accessed 11 September 2013.

Di Stanislao, F. and F. Carinci (2012), "Verso un sistema nazionale di valutazione della qualità dell'assistenza sanitaria", *Monitor*, Vol. 30, AGENAS, Rome, pp. 8-21.

France, G., F. Taroni and A. Donatini (2005), "The Italian Health-care System", *Health Economics*, Vol. 14, No. 1, pp. 187-202.

Fusco, D. et al (2012), "Il Programma Nazionale di valutazione Esiti (PNE). Breve guida alla consultazione", *Monitor*, Vol. 30, pp. 8-21, AGENAS, Rome.

Hughes, J.S. et al. (2004), "Clinical Risk Groups (CRGs): A Classification System for Risk-Adjusted Capitation-Based Payment and Health Care Management", *Medical Care*, Vol. 42, No. 1, pp. 81-90.

Kapur, K. et al. (2003), "Medicare Calibration of the Clinically Detailed Risk Information System for Cost", *Health Care Financing Review*, Vol. 25, No. 1, pp. 37-54.

Keating, M. and A. Wilson (2010), "Federalism and Decentralisation in Italy", PSA Conference Paper, available from http://scienzepolitiche.unical.it, accessed 29 October 2013.

Kronick R. et al. (2000), "Improving Health-Based Payment for Medicaid Beneficiaries: Chronic Illness and Disability Payment System", *Health Care Financing Review*, Vol. 21, No. 3, pp. 29-64.

Keating, M. and A. Wilson (2010), "Federalism and Decentralisation in Italy", PSA Conference Paper, available from http://scienzepolitiche.unical.it, accessed 29 October 2013.

Lo Scalzo, A. et al. (2009), "Italy: Health System Review", *Health Systems in Transition,* European Observatory on Health Systems and Policies, Vol. 11, No. 6.

Ministry of Health (2011), "Sistema di valutazione e monitoraggio della qualità dell'assistenza e delle performance dei sistemi sanitari", *Relazione sullo stato sanitario del Paese 2009-2010*, Ministero della Salute, Roma, available at www.rssp.salute.gov.it/rssp/paginaParagrafoRssp.jsp?sezione=risposte&capitolo=valutazione&id=2677.

National Assembly of Wales (2001), *NHS Resource Allocation Review – Targeting Poor Health: Professor Townsend's Report of the Welsh Assembly's National Steering Group on the Allocation of NHS Resources*, National Assembly of Wales, Cardiff.

OECD (2013a), *OECD Regions at a Glance 2013*, OECD Publishing, Paris, http://dx.doi.org/10.1787/reg_glance-2013-en.

OECD (2013b), *Strengthening Health Information Infrastructure for Health Care Quality Governance: Good Practices, New Opportunities and Data Privacy Protection Challenges*, OECD Health Policy Studies, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264193505-en.

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

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

OECD (2014b), *OECD Reviews of Health Care Quality: Norway – Raising Standards*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264208605-en.

OECD (2014c), "Lessons from the Health Care Quality Reviews: Balancing Governance for Health Service Performance Across Central and Local Authorities", *OECD Health Committee Paper*, DELSA/HEA(2014)4, June 2014 (available on request).

OECD (2014d), *Geographic Variations in Health Care: What Do We Know and What Can Be Done to Improve Health System Performance?*, OECD Health Policy Studies, OECD Publishing, Paris http://dx.doi.org/10.1787/9789264216594-en.

OECD (forthcoming), *OECD Reviews of Health Care Quality: Portugal – Raising Standards*, OECD Publishing, Paris.

Penno, E., R. Gauld and R. Audas (2013), "How Are Population-based Funding Formulae for Healthcare Composed? A Comparative Analysis of Seven Models", *BMC Health Services Research*, Vol. 13, No. 470.

Quaderni AGENAS (2008), "I sistemi di valutazione dei servizi sanitari", *Quaderno di Monitor n.1*, ASSR, Rome, available at: www.agenas.it/images/agenas/monitor/quaderno/pdf/3_I_SISTEMI_DI_VALUTAZIONE.pdf.

Torbica, A. and G. Fattore (2005), "The 'Essential Levels of Care' in Italy: When Being Explicit Serves the Devolution of Powers", *European Journal of Health Economics*, Vol. 6, No. 1, pp. 46-52, http://dx.doi.org/10.1007/s10198-005-0318-x.

Toth, F. (2014), "How Health Care Regionalisation in Italy Is Widening the North–South Gap", *Health Economics, Policy, and Law*, Vol. 9, No. 3, pp. 231-249.

Weiner, J.P. et al. (1996), "Risk-Adjusted Medicare Capitation Rates Using Ambulatory and Inpatient Diagnoses", *Health Care Financing Review*, Vol. 17, No. 3, pp. 77-100.

Zielinski, A. et al. (2009), "Validation of ACG Case-mix for Equitable Resource Allocation in Swedish Primary Health Care", *BMC Public Health*, Vol. 9, No. 347.

Database references

OECD National Accounts, http://dx.doi.org/10.1787/na-data-en.

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