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Italy

Health system review

Francesca Ferré • Antonio Giulio de Belvis
Luca Valerio • Silvia Longhi
Agnese Lazzari • Giovanni Fattore
Walter Ricciardi • Anna Maresso

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Anna Maresso (Editor), Sarah Thomson and Bernd Rechel were responsible for this HiT

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Francesca Ferré, *CERGAS Bocconi University, Milan*

Antonio Giulio de Belvis, *Università Cattolica del Sacro Cuore, Rome*

Luca Valerio, *Università Cattolica del Sacro Cuore, Rome*

Silvia Longhi, *Università Cattolica del Sacro Cuore, Rome*

Agnese Lazzari, *Università Cattolica del Sacro Cuore, Rome*

Giovanni Fattore, *CERGAS Bocconi University, Milan*

Walter Ricciardi, *Università Cattolica del Sacro Cuore, Rome*

Anna Maresso, *European Observatory on Health Systems and Policies*

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Preface

The Health Systems in Transition (HiT) series consists of country-based reviews that provide a detailed description of a health system and of reform and policy initiatives in progress or under development in a specific country. Each review is produced by country experts in collaboration with the Observatory's staff. In order to facilitate comparisons between countries, reviews are based on a template, which is revised periodically. The template provides detailed guidelines and specific questions, definitions and examples needed to compile a report.

HiTs seek to provide relevant information to support policy-makers and analysts in the development of health systems in Europe. They are building blocks that can be used:

- to learn in detail about different approaches to the organization, financing and delivery of health services and the role of the main actors in health systems;
- to describe the institutional framework, the process, content and implementation of health-care reform programmes;
- to highlight challenges and areas that require more in-depth analysis;
- to provide a tool for the dissemination of information on health systems and the exchange of experiences of reform strategies between policy-makers and analysts in different countries; and
- to assist other researchers in more in-depth comparative health policy analysis.

Compiling the reviews poses a number of methodological problems. In many countries, there is relatively little information available on the health system and the impact of reforms. Due to the lack of a uniform data source, quantitative data on health services are based on a number of different sources, including

the World Health Organization (WHO) Regional Office for Europe's European Health for All database, data from national statistical offices, Eurostat, the Organisation for Economic Co-operation and Development (OECD) Health Data, data from the International Monetary Fund (IMF), the World Bank's World Development Indicators and any other relevant sources considered useful by the authors. Data collection methods and definitions sometimes vary, but typically are consistent within each separate review.

A standardized review has certain disadvantages because the financing and delivery of health care differ across countries. However, it also offers advantages, because it raises similar issues and questions. HiTs can be used to inform policy-makers about experiences in other countries that may be relevant to their own national situation. They can also be used to inform comparative analysis of health systems. This series is an ongoing initiative and material is updated at regular intervals.

Comments and suggestions for the further development and improvement of the HiT series are most welcome and can be sent to info@obs.euro.who.int.

HiTs and HiT summaries are available on the Observatory's web site http://www.healthobservatory.eu.

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The HSPM is an international network that works with the Observatory on Country Monitoring. It is made up of national counterparts that are highly regarded at national and international level and have particular strengths in the area of health systems, health services, public health and health management research. They draw on their own extensive networks in the health field and their track record of successful collaboration with the Observatory to develop and update the HiT.

CERGAS is a multidisciplinary research centre that combines applied research on health-care management, economics and policy with investigations into a vast array of issues concerning the health and welfare of people in Italy and abroad. CERGAS research fellows use the modern tools of management, economics, accounting, organizational research and policy analysis to better understand how welfare systems work at the micro and macro levels, and how to improve them through innovative and evidence-based solutions. International and domestic comparative research is one of its major areas of interest, as well as having an integrated system of thematic observatories on NHS organizations, pharmaceutical policy and management.

The Institute of Public Health at the Università Cattolica del Sacro Cuore engages in teaching and training, research and international consulting on the protection and promotion of health, in particular health in the community. Recognizing the complexity of the problems arising in this sector and the need

for an interdisciplinary approach, the institute fosters both a global vision and one that incorporates the specific insights and skills within a range of disciplines, including the medical and biological sciences, management, physics and chemistry, the social sciences, law, ethics, operational research, epidemiology, health statistics, anthropology and sanitary engineering (town planning). Such disciplines are targeted towards specific research questions with the aim of achieving a synthesis between theoretical findings and applied solutions.

This edition of the HiT was written by Francesca Ferré, Antonio Giulio de Belvis, Luca Valerio, Silvia Longhi, Agnese Lazzari, Giovanni Fattore, Walter Ricciardi and Anna Maresso. It was edited by Anna Maresso, working with the support of Ewout van Ginneken of the Observatory's team at the University of Technology Berlin. The basis for this edition was the previous HiT on Italy which was published in 2009, written by Alessandra Lo Scalzo, Andrea Donatini, Letizia Orzella, Americo Cicchetti, Silvia Profili and Anna Maresso, and edited by Anna Maresso.

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Thanks are also extended to the WHO Regional Office for Europe for their European Health for All database from which data on health services were extracted; to the OECD for the data on health services in western Europe; and to the World Bank for the data on health expenditure in central and eastern European countries. Thanks are also due to ISTAT, the Italian National Institute of Statistics that provided data. The HiT reflects data available in June 2014, unless otherwise indicated.

The European Observatory on Health Systems and Policies is a partnership, hosted by the WHO Regional Office for Europe, which includes the Governments of Austria, Belgium, Finland, Ireland, the Netherlands, Norway, Slovenia, Spain, Sweden and the Veneto Region of Italy, the European Commission, the European Investment Bank, the World Bank, UNCAM (French National Union of Health Insurance Funds), the London School of Economics and Political Science, and the London School of Hygiene & Tropical Medicine. The Observatory team working on HiTs is led by Josep Figueras, Director, Elias Mossialos, Martin McKee, Reinhard Busse, Richard Saltman, Sarah Thomson and Suszy Lessof. The Country Monitoring Programme of the Observatory and the HiT series are coordinated by Gabriele Pastorino. The production and copy-editing process of this HiT was coordinated by Jonathan North, with the support of Caroline White, Mary Allen (copy-editing) and Pat Hinsley (typesetting).

List of abbreviations

ACN	Active Citizenship Network	
AED	Accident and Emergency Department	
AGENAS	National Agency for Regional Health Services	*Agenzia Nazionale per i Servizi Sanitari Regionali*
AIFA	Italian Medicine's Agency	*Agenzia Italiana del farmaco*
AO	hospital enterprise (public hospital)	*Aziende ospedaliere*
ASL	local health authority	*Azienda sanitaria locale*
CAM	Complementary and Alternative Medicine	
CCM	National Centre for Disease Prevention and Control	*Centro Nazionale per la Prevenzione e il Controllo delle Malattie*
CIPE	Inter-ministerial Committee for Economic Planning	
CME	continuing medical education	
DDD	defined daily dose	
DMH	Department of Mental Health	
DRG	diagnostic-related group	
EHR	electronic health records	
EU	European Union	
EU-12	Countries that joined the EU in May 2004 and January 2007	
EU-15	Countries belonging to the EU before May 2004	
EUPHN	European Health Property Network	
GDP	gross domestic product	
GNI	gross national income	
GP	general practitioner	
HIV/AIDS	human immunodeficiency virus/ acquired immunodeficiency syndrome	
HTA	health technology assessment	
ICT	information and communication technology	
IMF	International Monetary Fund	
INAIL	Italian Workers' Compensation Authority	
INN	International Non-proprietary Name	

IRAP	an earmarked corporate tax	*Imposta regionale sulle attività producttive*
IRCSS	National Hospital for Scientific Research	*Istituti di ricovero e cura a carattere scientifico*
IRPEF	personal income tax	*Imposta sul reddito delle persone fisiche*
ISTAT	National Institute of Statistics	*Istituto nazionale di statistica*
ISVAP	Private Insurance Supervisory Authority	
IT	information technology	
LEA	nationally defined basic health benefit	*Livelli essenziali di assistenza*
MOEF	Ministry of Economics and Finance	
MOH	Ministry of Health	
NHP	National Health Plan	
NSIS	New Health Information System	*Nuovo Sistema informative sanitario*
NVP	National Vaccination Plan	
OECD	Organisation for Economic Co-operation and Development	
OOP	out-of-pocket	
OTC	over-the-counter	
PPP	purchasing power parity	
RHP	Regional Health Plan	
SIMI	Computerized Infectious Disease System	
SSN	Italy's National Health Service	*Servizio sanitario nazionale*
VAT	value added tax	
VHI	Voluntary Health Insurance	
WHO	World Health Organization	

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Abstract

Italy is the sixth largest country in Europe and has the second highest average life expectancy, reaching 79.4 years for men and 84.5 years for women in 2011. There are marked regional differences for both men and women in most health indicators, reflecting the economic and social imbalance between the north and south of the country. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases. Italy's health-care system is a regionally based national health service that provides universal coverage largely free of charge at the point of delivery. The main source of financing is national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. In 2012, total health expenditure accounted for 9.2% of GDP (slightly below the EU average of 9.6%). Public sources made up 78.2% of total health-care spending. While the central government provides a stewardship role, setting the fundamental principles and goals of the health system and determining the core benefit package of health services available to all citizens, the regions are responsible for organizing and delivering primary, secondary and tertiary health-care services as well as preventive and health promotion services.

Faced with the current economic constraints of having to contain or even reduce health expenditure, the largest challenge facing the health system is to achieve budgetary goals without reducing the provision of health services to patients. This is related to the other key challenge of ensuring equity across regions, where gaps in service provision and health system performance persist. Other issues include ensuring the quality of professionals managing facilities, promoting group practice and other integrated care organizational models in primary care, and ensuring that the concentration of organizational control by regions of health-care providers does not stifle innovation.

Executive summary

Introduction

With a population of almost 61 million (in 2012), Italy is the sixth most populous country in Europe. The country is made up of 20 regions, which are extremely varied, differing in size, population and levels of economic development. Since the early 1990s, considerable powers, particularly in health-care financing and delivery, have been devolved to this level of government. The regions are subdivided into provinces, which are made up of municipalities (*comuni*). Italy has about 8100 municipalities, which range in size from small villages to large cities such as Rome.

A range of indicators shows that the health of the population has improved over the last decades. Average life expectancy reached 79.4 years for men and 84.5 years for women in 2011, the second highest in Europe (compared with 77.4 years for men and 83.1 years for women for the EU as a whole). Italy has one of the lowest total fertility rates in the world: in 2011, it was 1.4 births per woman, far below the replacement level of 2.1. The population growth rate is, therefore, very low (0.3% in 2012), one of the lowest in the EU, and immigration is the source of most of this growth.

In almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic and social imbalance between the north and south of the country. For example, there is a gap of 2.8 years in life expectancy between the longest and shortest-lived regions, for both genders. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases, while smoking and rising obesity levels, particularly among young people, are major health challenges.

Organization and governance

Italy's health-care system is a regionally organized National Health Service (*Servizio Sanitario Nazionale*, SSN) that provides universal coverage largely free of charge at the point of delivery. At national level, the Ministry of Health (supported by several specialized agencies) sets the fundamental principles and goals of the health system, determines the core benefit package of health services guaranteed across the country, and allocates national funds to the regions. The regions are responsible for organizing and delivering health care. At local level, geographically based local health authorities (*Aziende Sanitarie Locali*) deliver public health, community health services and primary care directly, and secondary and specialist care directly or through public hospitals or accredited private providers.

Patient empowerment and patient rights are not specified by a single law but are present in several pieces of legislation, starting with the Italian Constitution and the founding law of the national health system. Over the last 20 years, several tools have been introduced for public participation at all levels but no systematic strategy exists and implementation varies across the country, as does the satisfaction of citizens with the quality of health care. Over the last few years, measures have been taken to tackle excessive recourse to legal action against doctors and to prevent defensive medicine practices.

Financing

The National Health Service is largely funded through national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. In 2012, total health expenditure accounted for 9.2% of GDP (slightly below the EU average of 9.6%). While this reflects a process of upward convergence towards the EU average over the last couple of decades, part of this apparent increase is also due to relatively weak GDP growth for Italy over that period.

Public sources made up 78.2% of total health-care spending, with private spending, mainly in the form of out-of-pocket (OOP) payments (17.8%), accounting for the remainder – these OOP payments are mainly for diagnostic procedures (laboratory tests and imaging), pharmaceuticals, specialists visits and for unjustified (non-urgent) interventions provided in hospital emergency departments. Only about 1% of total health-care expenditure is funded by private health insurance. The production, distribution and pricing of

pharmaceuticals are strictly regulated by a national agency, and provisions are made progressively more complex by repeated attempts at cost-containment of pharmaceutical expenditure.

Since the early 2000s the health-care system has been undergoing a process of fiscal devolution from the central government to the regions. Within Italy there are substantial differences in funding between regions, with per capita expenditure ranging from 10.2% below the national average to 17.7% above. Although most funding is pooled at national level and redistributed to regions, there is scope for significant regional variation in tax rates (in particular through taxing corporations and a regional surcharge on income tax). The resulting financing system has an unevenly distributed tax base, smaller room for manoeuvre for poorer regions and a need for poorer regions to increase tax rates more than high-income regions, with consequent disincentives for business location, for example.

In recent years there have been attempts to place stricter controls over regions' health spending after a few incurred considerable deficits (mainly in the central and southern parts of the country). Moreover, in light of the global economic and financial crisis, tighter cost-containment measures on public health expenditure have been proposed and are being slowly implemented (e.g. caps on specific spending areas). At the same time, higher co-payments for outpatient/ambulatory care, diagnostics and drugs have been introduced, adding to private spending on health.

Health care is delivered mainly by public providers, with some private or private-public entities. Although reforms in 1992 aimed to introduce a quasi-market system with patients free to choose any provider, in practice these arrangements vary across regions and, in some regions, are barely present. Only in the regions of Lazio, Campania, Molise and Lombardy is there a relatively high level of private care, with around 30% of total hospitalization supplied by private providers.

In general, doctors employed by the National Health Service are salaried and have civil servant status, although general practitioners and paediatricians are independent professionals, paid via a combination of capitation and fee-for-services for some interventions. All salaried doctors are allowed to practise privately and can earn additional income on a fee-for-service basis; they are encouraged to do so within National Health Service facilities, and then pay a proportion of their income to that facility.

Payment rates for hospital and outpatient care are determined by each region, with national rates (determined by the Ministry of Health) as a reference. Payment for hospital care (ordinary and day hospital treatments) is based on DRG tariffs, although it is generally complemented with other payment methods (lump sum or global budget) while outpatient care is reimbursed using a tariff per unit of care. There are considerable inter-regional variations in the prospective payment system adopted by each region, such as how the fees are set, which services are included, and the tools employed to influence patterns of care.

Physical and human resources

Over the last five years, Italy has decreased investment in expensive infrastructure and has even halted some projects due to cost-cutting measures, although in 2013 the government announced 162 new capital investment plans totalling nearly €1.5 billion. In addition, in a period of increasing decentralization and recent national-level cost-containment measures, the regions have sought additional sources of funding for health infrastructure. Sources include ad hoc regional funds, European funds, self-financing by local health service organizations, traditional and non-traditional forms of financing such as mortgages or project financing.

In terms of hospital sector infrastructure, in 2012 Italy had 3.4 hospital beds per 1000 people; 80% of which are dedicated to acute care (higher than the EU average of 69%).

The importance of medical technology has generally grown over time. The number of MRI units, CT scanners and PET units is constantly rising, at least doubling over the last 10 years to become one of the highest per capita in the EU, albeit with great regional variability. E-health initiatives are promoted by the government and current development is focused on increasing online services, electronic health records (EHRs) and the digitalization of medical prescriptions and certificates.

With 3.7 practising doctors per 1000 people, Italy is slightly above the EU average of 3.4 – though the number of nurses is relatively low, at 6.3 per 1000 people, and the ratio of nurses to doctors (roughly 1:1) is among the lowest in the EU – the average is 2.5 nurses to every doctor. This is despite an increase in the number of health-care professionals over the last 25 years, especially practising nurses and midwives, with the former becoming more active in the

management of patients with chronic conditions. In terms of health worker mobility, Italy is predominantly a destination country, with higher levels of inflows for certain categories of health professionals such as nurses and care assistants (both legal and illegal), largely due to chronic nursing shortages, which have shifted attention to recruitment from abroad. In contrast, emigration mostly affects medical doctors.

Provision of services

The Ministry of Health is the main institution responsible for public health at the national level. Immunization and screening programmes are considered to be priorities. In addition to the mandatory and voluntary routine immunization programmes, pap tests, mammography and colorectal screening are offered free of charge to target populations nationally.

Primary care services are delivered by health districts, the operative branches of local health authorities. Over the last 15 years, there have been attempts to reorganize the delivery of primary care, with the objective of moving from the traditional model of GPs and other health professionals working in single practices to an integrated care model that connects different health care professionals and bridges the gap between front-line staff and patients, though change has been slow.

Inpatient care is provided through a network of accredited public and private hospitals, with general practitioners and paediatricians (who usually treat children up to the age of 6 or if parents so wish, up to the ages of 14–16) playing a gatekeeping role. In recent years there has been a progressive increase in Accident and Emergency Department admissions, some of which are due to inappropriate use by patients (e.g. for minor illnesses or prevention interventions that could have been treated by primary care physicians) for which co-payments of €25 are imposed (see above).

Medicines are grouped into three main classes: Class A are essential medicines that are reimbursable (but require a co-payment, that varies by region) and include those indicated for the treatment of severe, chronic or acute illnesses. Class C includes non-reimbursable pharmaceutical products (though some regions opt to offer some reimbursement). Class H includes pharmaceutical products delivered only within hospitals. To contain pharmaceutical expenditure, the 2012 Spending Review reduced the budget for drugs used in non-hospital settings from 13.3% of total health-care expenditure

to 11.35% in 2013. However, in the last decade, the cost of pharmaceuticals delivered by hospitals has significantly increased due to new expensive products and the delivery by hospital pharmacies of products that are then used outside hospital settings.

With regard to mental health care, the 1978 Basaglia Law marked the switch from institutional care to community mental health services. Subsequently, specific departments of mental health have been established within local health authorities. A priority remains closing the gap between the northern and southern regions with regard to the provision and quality of services, which remains a major challenge.

Health-care delivery to vulnerable or excluded groups has undergone a recent change in policy. After several years without specific regulations, legislation has now been defined to guarantee that immigrants (both legal and temporarily undocumented) are eligible to receive the same public health-care services that are available to Italian citizens.

The central issue with health service delivery is the heterogeneity of regional arrangements. In general, northern and central regions appear to keep pace with institutional, organizational and professional developments aligned with best international practices and in line with central government orientations, while southern regions appear to lag behind. The gaps between northern and southern regions mainly reflect socioeconomic and cultural factors that are far beyond the health-care system. However, it is also likely that decentralization policies introduced in the last two decades have not favoured the homogeneity of regional systems as they have provided opportunities for improvement to the best institutionally equipped regions while leaving southern regions with less central support to cope with more difficult social contexts.

Principal health reforms

The National Health Service was established with a radical reform in 1978 and modified in the 1990s and early 2000s. The first reform clearly designed an NHS-type system, fully implemented in the 1980s, that guaranteed universal access to health care. With a 1992 reform, backed by the 2001 constitutional reform that redistributed powers to the regions, the National Health Service was regionalized. Now most health policies are developed and implemented

by regions, with an increasing heterogeneity of institutional arrangements, provider payment rules and levels of performance in terms of the quantity and quality of care offered to citizens.

The 1992 reform also envisaged a quasi-market based on patients' choice and competition between public and private providers but this was mitigated over time with measures that give strong control to regional authorities over the allocation of resources between providers. Another priority was the 'managerialization' of health service organizations; here again, in the last decade regional authorities have centralized administrations, reduced the discretion of management and not fully supported management development in public organizations.

Overall, the last decade has been dominated by two intertwined issues: regional fragmentation and the need to maintain financial control within regional health systems. Italy's fiscal crisis has put the health system under strain; the central government has acted to control total health expenditures but performance in terms of health protection is increasingly governed at regional level, with large variations, mainly but not exclusively between the northern and southern parts of the country.

Assessment of the health system

Italy currently spends less than the OECD average on health care in relation to its GDP (9.2% in comparison to the OECD average of 9.3%), though public spending is increasing at a faster pace than total private spending and OOP expenditure.

Despite the country's federal structure, most regions cannot fund health care with their own resources, relying on the central transfers to compensate for the differences in regional incomes. Regions also allocate their funds differently, with some southern regions still suffering large deficits and with secondary care favoured over primary and community health services.

While equitable access to health care is one of the statutory objectives of the health system, severe inequities in health status and health-care provision appear to exist across socioeconomic population groups. A significant part of these inequities stem from geographical differences: inter-regional disparities in population wealth, health-care resources and efficiency of care are especially evident between northern and southern regions. This pattern is also substantially echoed in the geographical distribution of satisfaction levels with

the health-care system and its performance. Generally, however, over the last few years there has been a general decrease in satisfaction levels, and problems such as long waiting times for outpatient and diagnostic services exist across the country. The current system of specialists providing both public and private care might be contributing to waiting lists as well as favouring the wealthier over the poorer in terms of access to specialist care.

Life expectancy of Italians is one of the highest in the world and their mortality profile is comparable to that of the other high-income countries. Prevention policies have been successful in increasing coverage for the most important vaccinations. Estimates of avoidable mortality suggest a progressive improvement, and care for chronic conditions compares well at an international level. However, the prevalence of risk factors such as overweight and obesity is significant, and health-care outcomes are inequitable across regions, genders and socioeconomic groups.

National funds are distributed to regions using formulas that aim to ensure coverage of the full scope of public health care, including primary care, hospital care and community health services; the age structure of the local population and health needs are also considered. However, the allocation formulas have been changed frequently and further reforms are currently ongoing. Despite increasing financial controls, the costs per patient treated, per service provided and per input units (e.g. costs per hospital bed) in secondary care have not decreased over the last 25 years but have actually increased and are higher than in most other OECD countries. The best explanation available for this is the disproportionately high number of small hospitals. The median size of Italian hospitals is one-third less than that of Germany, France and Austria, and around half that of UK hospitals. This could be due to small hospitals compensating for poor community health services such as home care and long-term care, especially in non-urban areas. Data from primary care also suggest wide geographical variations in technical efficiency. The use of generic pharmaceuticals has been increasing as a result of targets but their market penetration is still lower than in most other OECD countries. Inter-regional differences in awareness among the public and general practitioners are also a hindrance to greater use of generics.

The national policy agenda has become increasingly aware that availability of data is vital to identify problems, monitor performance and ensure accountability in the health system. Accordingly, several recent interventions have been directed at improving existing information systems and making data available to the public but their implementation has been slow in the absence of systematic monitoring.

Conclusion

In the last five years the National Health Service has been targeted by a number of policies aimed at containing or even reducing health expenditure without reducing the provision of health services to patients. To date these efforts have been largely successful in that regional deficits are now under control and health services continue to be delivered according to the prescribed national benefit package. However, with current fiscal constraints putting a strain on health services, Italy also faces a number of entrenched health system challenges. These include the risk that the highly decentralized regional health systems will continue to perform differently in terms of service delivery and that the gap between the southern and the northern parts of the country will continue to widen.

In terms of health system organization and service delivery, three main issues deserve to be highlighted. The first concerns the relationship between politics and top management. While national health service organizations have experienced increasing professionalism at management level, the appointment of general managers, health directors and administrative directors still appears to be mainly driven by local and political considerations, which can constrain ambitious tasks such as the closure of small hospitals, the development of new integrated systems of care or the redesign of hospitals. A second major issue concerns primary care, which is still mainly based on solo-practice GPs or general paediatricians. The ongoing efforts to promote group practice and other organizational models based on a variety of health professionals working together in primary care teams should be promoted and incentivized. Thirdly, efforts should be made to ensure that current trends towards (re)integration of national health service facilities under regional or local control does not stifle innovation. Currently, most regional policies seem to have returned to integration, namely through the reattribution of some independent hospitals to local health authorities, the concentration of purchasing activities in regional or supra-organizational entities and the enlargement of the size of local health authorities. In addition, most regions have strengthened control over their providers, which in turn, have lost most of their organizational autonomy. While this trend is probably motivated by the search for savings as well as by the need to find better integrated care pathways and care coordination, experimenting, evaluating and disseminating good practices in this respect should be developed from the bottom up, mindful of local experiences and contexts, rather than by utilizing a top-down approach.

1. Introduction[1]

With a population of almost 61 million (2012), Italy is the sixth most populous country in Europe. The country is made up of 20 regions, which are extremely varied, differing in size, population and levels of economic development. Since the early 1990s, considerable powers, particularly in health-care financing and delivery, have been devolved to this level of government. The regions are subdivided into provinces made up of municipalities (*comuni*). Italy has about 8100 municipalities, which range in size from small villages to large cities such as Rome.

A range of indicators shows that the health of the population has improved over the last decades. Average life expectancy reached 79.4 years for men and 84.5 years for women in 2011, the second highest in Europe (compared with 77.4 years for men and 83.1 years for women for the EU as a whole). Italy has one of the lowest total fertility rates in the world: in 2011 it was 1.4 births per woman, far below the replacement level of 2.1. The population growth rate is, therefore, very low (0.3% in 2012), one of the lowest in the EU, and immigration is the source of most of this growth.

In almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic and social imbalance between the north and south of the country. For example, there is a gap of 2.8 years in life expectancy between the longest and shortest lived regions, for both genders. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases, while smoking and rising obesity levels, particularly among young people, are major health challenges.

[1] The majority of the text in this section is based on and updates Chapter 1 of the previous *Health System Review* on Italy (see Lo Scalzo et al., 2009).

1.1 Geography and sociodemography

Italy is a parliamentary republic in Southern Europe, with a population of almost 61 million in 2012, making it the sixth most populous country in Europe. The country covers 301 340 km^2 and extends from the north where it borders France, Switzerland, Austria and Slovenia to the south where it includes the Mediterranean islands of Sardinia and Sicily and a cluster of other smaller islands. The country has 20 regions (the region of Trentino-Alto-Adige is split into the Autonomous Province of Trento and the Autonomous Province of Bolzano). In addition, enclaves within mainland Italy include the countries of San Marino and the Holy See, a papal state mostly enclosed by Rome, Italy's capital (Fig. 1.1). Five out of the 20 regions (namely Valle d'Aosta, Friuli-Venezia Giulia, Province of Trento, Province of Bolzano, Sicily and Sardinia) are granted home rule; the Constitution (article 116) acknowledges their powers in relation to legislation, administration and finance. In return, these regions have to finance their health-care and education systems, and most public infrastructure through their own means. These particular institutional arrangements were designed to take into account cultural differences and protect linguistic minorities. In fact, Italian is the major language throughout the country, although there are small areas in which German (in parts of Trentino-Alto-Adige), French (in Valle d'Aosta) and Slovene (in the Trieste-Gorizia area) are spoken. The dominant religion is Roman Catholicism but the Constitution guarantees freedom of worship to religious minorities, which are primarily Protestant, Muslim and Jewish.

About 77% of the country is mountainous or hilly and 23% is forested. Northern Italy consists of a vast plain with the Alps in the north and is the richest part of the country, with the best farmland and largest industrial centres. Central Italy has great historical and cultural centres, such as Rome and Florence, and a flourishing tourist trade. Southern Italy is the poorest and least developed area (Lo Scalzo et al., 2009). Gross national income (GNI) per capita (measured in current international $PPP) in 2012 was 34 070, compared to an average of 40 613 for high income OECD countries (IMF, 2013).

Population density on average is 206.4 inhabitants per km^2 and most of the population clusters around metropolitan areas and along the coasts (urban population accounts for 69% of total population). The structure of the population changed significantly between 1980 and 2012 owing to marked declines in fertility rates (from 1.6 to 1.4 births per woman) and increases in life expectancy at birth (from 74 to 82 years). Italy has one of the lowest total fertility rates in the world: in 2011, it was 1.4 births per woman, far below the replacement

Fig. 1.1
Map of Italy

Source: www.mapsoftheworld.com, 2013.

level (Table 1.1). The average population growth rate is, therefore, very low (0.3 in 2012), one of the lowest in the European Union (EU), and immigration is the source of most of this growth (World Bank, 2013). The population is also aging quite rapidly: in 2012 the proportion of the population aged 65 or over was 20.8%.

Table 1.1
Trends in population/demography indicators, 1980–2012 or latest available year

	1980	1990	1995	2000	2005	2012
Population, total (millions)	56.4	56.7	56.8	56.9	58.6	60.9
Population, female (% of total)	51.5	51.5	51.6	51.6	51.4	51.4[a]
Population ages 0–14 (% of total)	22.2	16.5	14.9	14.3	14.1	14.0
Population ages 65 and above (% of total)	13.4	14.9	16.7	18.3	19.6	20.8
Population growth (average annual %)	0.2	0.1	0.0	0.0	0.7	0.3
Population density (people per sq km)	191.9	192.9	193.3	193.6	199.2	206.4[a]
Fertility rate, total (births per woman)	1.6	1.3	1.2	1.3	1.3	1.4[a]
Birth rate, crude (per 1 000 people)	11.3	10.0	9.2	9.3	9.5	9.0[a]
Death rate, crude (per 1 000 people)	9.8	9.4	9.7	9.7	9.7	9.8[a]
Age dependency ratio (% of working-age population)	55.3	45.8	46.2	48.3	50.9	53.5
Mortality rate, infant (per 1 000 live births)	14.3	8.4	6.4	4.7	3.7	3.2
Life expectancy at birth, total (years)	73.9	76.9	78.0	79.4	80.6	82.1[a]
Urban population (% of total)	66.6	66.7	66.9	67.2	67.6	68.6

Source: World Bank, 2013.
Note: [a]2011 data.

1.2 Economic context

Italy has an open economy and is a founding member of the EU. It is also a member of major multilateral economic organizations such as the Group of Seven Industrialized Countries (G-7), the Group of Eight (G-8), OECD, the World Trade Organization and the International Monetary Fund (IMF). In 2012, according to IMF data, Italy was the ninth largest economy in the world and the fifth largest in Europe in terms of nominal gross domestic product (GDP). Its annual GDP (in current prices) accounts for 12.1% of the European Union's total GDP. Nevertheless, per capita income (measured in current international $PPP; see Table 1.2) is 33.8% lower than in the United States and nearly 20% lower than the average among European Union countries.

Table 1.2
Macroeconomic indicators

	1980	1990	1995	2000	2005	2012
GDP (current US$), millions	459 830	1 138 091	1 131 770	1 104 009	1 786 275	2 013 263
GDP, PPP (current international $), millions	520 909	999 589	1 203 934	1 466 461	1 657 399	2 017 025
GDP per capita (current US$)	8 148	20 065	19 910	19 388	30 479	33 049
GDP per capita growth (annual %)	3.43	1.99	2.89	3.65	0.93	-2.37
GDP per capita, PPP (current international $)	9 230	17 623	21 179	25 753	28 279	33 110
Real interest rate (%)	-1.48	5.45	7.92	4.98	3.43	3.56
Central government debt, total (% of GDP)	0.00	0.00	121.12	118.67	112.80	110.89
Agriculture, value added (% of GDP)	6.02	3.48	3.29	2.78	2.19	1.90
Manufacturing, value added (% of GDP)	28.93	23.20	22.12	20.83	18.37	16.74
Industry, value added (% of GDP)	38.07	31.99	30.12	28.24	26.72	25.26
Services, etc, value added (% of GDP)	55.91	64.52	66.58	68.98	71.09	72.84
Official exchange rate (LCU per US$, period average)	856.45	1 198.10	1 628.93	n.a.	n.a.	n.a.
Labour force, total	n.a.	23 784 644	22 772 910	23 271 088	24 670 885	n.a.
Unemployment, total (% of total labour force)	7.50	9.80	11.70	10.80	7.70	8.40

Source: World Bank, 2013.
Note: n.a. = data not available

The basis of Italy's economy is processing and manufacturing goods, primarily in small and medium-sized firms. Its major industries are precision machinery, industrial machinery and equipment, transportation equipment, motor vehicles, chemicals, pharmaceuticals, electric and electronic equipment, fashion, clothing, leather, jewellery and shoes. Italy has few natural resources, with no substantial deposits of iron, coal or oil. Natural gas reserves are located mainly in the Po Valley and offshore in the Adriatic Sea. Most raw materials for industry and over 79% of energy requirements have to be imported (World Bank, 2013). In 2012, the agricultural sector employed 4.7% of the workforce, although it accounted for only 2.2% of GDP; industry employs 28.5% of the population and represents 26.7% of GDP; the service sector employs 67.8% of the population and comprises 71.1% of GDP. Tourism represents an important part of the economy, with nearly 46 million incoming visitors in 2011, an increase of 11% since 2005.

Since the end of the Second World War, Italy's economic structure has completely changed from being agriculturally based to industrially based, with about the same total and per capita output as France and the United

Kingdom. Italy experienced its 'economic miracle' from 1958 to 1963 when industrial output peaked at over 19% per year, investment levels reached 27% of GDP (in 1963) and the country enjoyed full employment. The country did, however, suffer considerably from the two economic crises of the last quarter of the 20th century. After 1963, the economy slowed down, and after 1973, it experienced a severe downturn. The oil shocks of the 1970s hit Italy's economy particularly hard, given the reliance on foreign sources of energy. An extended period of high inflation and large budget deficits ensued during the 1980s, as the industrial complex restructured to meet the challenges posed by the new context. In addition, during the international economic crisis of the early 1990s, the rate of GDP growth decreased markedly, unemployment rose and inflation peaked, increasing to more than 6%. Severe financial unrest forced monetary officials to withdraw the lira (its legal tender prior to joining the single European currency) from the European monetary system when it came under extreme pressure in currency markets (Lo Scalzo et al., 2009).

From 1992, after learning that Italy might not qualify to join the European Economic and Monetary Union, the authorities made a significant effort to address the most pressing economic issues. Economic policies were launched to tackle the fiscal and monetary imbalances that had developed over the previous years, aiming to re-establish an environment of sound finance, a stable currency and low interest rates. The government adopted fairly strict budgets, ended its highly inflationary wage indexing system and started to reduce its social welfare programmes, specifically focusing on pension and health-care benefits. In addition, the private sector was increasingly emphasized as the primary engine of growth: to this end, a broad array of deregulation measures was enacted, and from 1994, a massive privatization programme for state-owned enterprises was implemented to reduce the presence of the state, which, at the time, played a major role in the economy by owning large industrial and financial companies. The most significant effect of such initiatives was a progressive, continuous decrease in inflation rates throughout the 1990s. In addition, unemployment declined and GDP growth rates increased substantially during the mid-1990s, although they were somewhat reversed during the late 1990s. The success of the corrective action undertaken during the 1990s led to Italy adopting the common European currency, the Euro, from its introduction on 1 January 1999 (Lo Scalzo et al., 2009).

Some of the most remarkable, specific weaknesses of Italy's economy in the late 1990s were related to its labour market structure. In 2000, for instance, 27.5% of all unemployed people were younger than 25, one of the highest proportions in the EU (18.1% on average). Although it decreased to 20.3% in

2007, it started increasing again in 2009 and reached 35.3% in 2012 (OECD, 2014a). Total unemployment – expressed as percentage of the total labour force – was 8.7% in 2012. Currently, women only account for 39% of the workforce (latest data are from 2010), one of the lowest rates among EU countries and, above all, a percentage that sharply declines with movement up the hierarchical scale, with top positions both in the public and private sectors usually being the domain of the male workforce. In addition, temporary jobs continue to play an increasingly important role within Italy's economy, primarily in the south. There is also a major underground economy that accounts for an estimated 14–20% of GDP. This includes many nominally unemployed people, as well as undocumented immigrants, especially in difficult agricultural work in the rural south.

In the 2000s, priorities for the Italian economy included the need to address proposed fiscal reform, revamp its communication system, reduce pollution in major industrial centres and adapt to the new competitive environment related to the ongoing process of economic integration and expansion of the EU (Lo Scalzo et al., 2009). Following the onset of the global economic crisis in 2008, Italy's economy went into recession in early 2009 and has continued to struggle with achieving economic growth. At the time of writing, the most recent data show that Italy's economy was still stagnating in 2014, with an estimated GDP growth rate of 0.7% (IMF, 2014). Priorities now include reversing sharp decreases in investment and export markets, tackling rising unemployment (8.7% in 2012) and implementing cut back measures in the public sector to manage a widening public debt.

1.3 Political context

The Italian state is a parliamentary, democratic republic with a multi-party political system. Italy has been a democratic republic since 2 June 1946, when the monarchy was abolished by popular referendum. The political system is based on the 1948 Constitution. The Chamber of Deputies (630 members) and the Senate (315 members) form the bicameral parliament, whose members are directly elected for five years by universal suffrage. The President of the Republic is elected for seven years by a joint session of the Chamber and Senate and is the formal head of the state. The Prime Minister must be endorsed by, and have the confidence of, both parliamentary houses and is ultimately nominated by the President. The Prime Minister is usually the leader of the party that has

the largest representation in the Chamber of Deputies. The judiciary system is independent of the executive and the legislative branches and is headed by the High Council of the Judiciary.

Italian politics has been characterized by high levels of government turnover since the beginning of the republic; indeed, there have been 62 governments since 1946. From 1948 until the late 1970s the Prime Minister was consistently from the Christian Democratic Party. Coalition governments with roughly the same party configurations promoted a relative period of continuity and stability to Italy's political situation during much of the post-war period, with the clear intention of keeping the Italian Communist Party (PCI) out of power in order to maintain Cold War equilibrium in the region. During 1976–1979, the Communist Party voted in support of the government (which included the Christian Democratic Party, the Socialist Party, the Social Democratic Party and the Republican Party) for the first time, although it did not formerly enter the government coalition.

Starting in 1979, a new alliance was formed, also headed by the Christian Democrats. As part of the formation of this government (known as the five-party coalition), the Communist Party ceased to support the government and the minority rightist Liberal Party was incorporated. The Minister for Health was from the Liberal Party during most of the 1980s and until 1993 (Lo Scalzo et al., 2009). During the early 1990s, persistent government instability, mounting economic pressure and especially a series of corruption scandals implicating all governing parties in illegal party financing prompted a profound political crisis. By September 1993, many political leaders were under criminal prosecution (known as the 'Clean Hands' (*Mani Pulite*) investigation) by the courts and the whole power structure faltered. Seemingly indestructible parties, such as the Christian Democrats and the Socialist Party, disbanded; the Communist Party changed its name to the Democratic Party of the Left and took the role of the previous Socialist Party as the country's main social democratic party. A non-partisan ('technocratic') government, led by the former president of the Bank of Italy (Carlo Azeglio Ciampi), was put in charge of ruling the country during the transition period, which lasted until March 1994.

This transition period was followed by the so-called Second Republic. From 1992 to 1997, Italy faced significant challenges, as voters, disenchanted with past political paralysis, massive government debt, extensive corruption and organized crime's considerable influence demanded political, economic and ethical reforms. Major political parties beset by scandal and loss of voter confidence underwent far-reaching changes and the proportional electoral system was reformed into a majoritarian system. New political forces and new

alignments of power emerged in the March 1994 national elections. This election saw a major turnover in the new parliament, with 452 out of 630 deputies and 213 out of 315 senators elected for the first time. The new parties developed around two poles: the conservative coalition 'Pole of Liberties' was formed by the leading Forza Italia party, the regionalist Lega Nord (Northern League) party and the radical right-wing group Alleanza Nazionale (National Alliance) and on the other hand, several centre-left, leftist and green parties (including the ex-communists) joined to form an alliance initially called the Progressives and later L'Ulivo (the Olive Tree). For nearly 15 years, governments tended to alternate between these two poles. Since 1995 the alternation between centre-right and centre-left coalitions corresponded to the succession of four governments led by Silvio Berlusconi and five by the centre-left (led by Romano Prodi twice, Massimo D'Alema twice and Giuliano Amato). A political crisis occurred in November 2011 following the resignation of the then Prime Minister, Silvio Berlusconi, as well as parliamentary approval of austerity measures designed to meet the severe challenges of the economic crisis facing the Italian economy. A technocratic government led by Mario Monti steered the administration for 18 months before elections were held in early 2013. Italy was then governed by a grand coalition government led by Enrico Letta,[2] and following his resignation in early 2014, Italy's current prime minister is Matteo Renzi.

The Constitution organizes Italy's territory into 20 regions, which are extremely varied. They differ in size (Piedmont is 25 000 km^2, while Valle d'Aosta is only 3000 km^2), population (Lombardy has 15% of the total population, whereas Molise has less than 1%) and levels of economic development. The regions also differ in population age distribution. For example, an average of 20.8% of Italy's population is aged 65 years or older; southern Italy has fewer (19.5%) and central and northern Italy has more (22.4%). Each region is governed by an Executive and a Regional Council, both of which are democratically elected. The regions have exclusive legislative power with respect to any matter not expressly reserved under national law (Constitution article 117). Yet their financial autonomy is quite modest: they hold 20% of all levied taxes, mostly used to finance the regionally based health-care systems. This is the result of the reform passed in 1997 – known as the Bassanini Law – that significantly extended the powers transferred to regions through the principle of subsidiarity. In particular, responsibility for regulating, planning and organizing health-care

[2] A snap general election was held in February 2013, without any party emerging as the clear winner. Votes were divided into three parts: the Centre-left alliance (29.5% in the Chamber of Deputies), the Centre-right Coalition (29.1%), and the new anti-establishment Five Star Movement (25.5%), whose leader is Beppe Grillo, a popular activist, comedian and blogger.

delivery has been transferred to the regions, and the central government retains responsibility over the basic principles and institutional rules of the system and as such functions by approving the National Health Plan, allocating funding and defining clinical and accreditation guidelines. The gradual devolution of political power during the 1990s runs parallel to the fiscal reform passed in 2000, which (in theory) granted regions significant autonomy over revenue in the regional budget and complete autonomy over the allocation of funds (Constitutional Law N. 3/2001) (see Chapters 3 and 7). However, the autonomy over revenue has been modest so far.

The 20 regions are subdivided into 110 provinces. The provinces are led by a president and a council, both of which are elected by city mayors and city council representatives of the respective provinces. Provincial councils comprise a minimum of 24 members and a maximum of 45 depending on population density. In addition, each province has a prefect who represents – and is appointed by – the national government. The basic unit of local government is a municipality (*comune*), which may range in size from a small village to a large city such as Rome. Italy has about 8100 municipalities, many of which are small villages with an ancient tradition of independent self-government; only 8% of total municipalities have more than 15 000 inhabitants. A council elected for a five-year term by universal suffrage governs each municipality and mayors of cities and towns are also elected.

1.4 Health status

The majority of the Italian population has a high standard of living and quality of life resulting, in part, from well-established health policies and welfare measures. Over the last four decades, the health status of Italians has improved, with a particularly remarkable increase in life expectancy at birth, which, after Switzerland, is the second highest in Europe (2011). On average, life expectancy has increased by about 12 years since 1960 and currently stands at 84.5 years for women and 79.4 years for men (Table 1.3) – compared with 77.4 years for men and 83.1 years for women for the EU as a whole (Eurostat, 2014). These results can be attributed to multiple factors such as improved standards of living, more widespread education, better-quality health care and increased access to health services. However, there is still a substantial gender difference in life expectancy (+5.1 years for women compared to men) and a high variability among regions (with a gap of 2.8 years, for both genders, between the highest and lowest performing region).

Table 1.3

Mortality and health indicators, selected years

Indicators	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Life expectancy at birth										
Female	83.0	82.8	83.7	83.5	84.0	84.0	84.1	84.1	84.5	84.5
Male	77.1	77.2	77.9	77.8	78.4	78.7	78.8	79.0	79.4	79.4
Mortality rate										
Female adults (per 10 000 inhabitants)	77.1	80.0	71.3	72.9	68.7	69.4	69.5	69.3	–	–
Male adults (per 10 000 inhabitants)	127.0	129.5	118.5	119.4	112.6	111.9	110.9	109.4	–	–

Sources: Osservatorio Nazionale sulla Salute nelle Regioni Italiane, selected years; ISTAT, 2013a.

Over the last 30 years (between 1980 and 2010) mortality has decreased by 53%. The highest contribution to this large reduction is due to the falling incidence in cardiovascular diseases, with a decrease for both men (127.00 vs 109.41 per 10 000) and women (77.05 vs 69.31 per 10 000) in the period 2002–2009 (Ministero della Salute, 2012a). Cancer has emerged as the most frequent cause of death for people under 64, followed by circulatory diseases (Table 1.4). While breast cancer is still the most common cancer among women in Italy (42%), breast cancer mortality trends showed a decreasing rate between 1989 (38.59 per 100 000) and 2010 (23.62 per 100 000).

Table 1.4

Main causes of death (people aged 19–64, per 10 000 inhabitants), selected years

Causes	2006	2007	2008	2009	2010
Malignant neoplasm					
Female	8.0	8.0	7.9	7.9	7.7
Male	11.5	11.1	10.8	10.5	10.2
Circulatory diseases					
Female	2.1	2.0	1.9	1.8	1.8
Male	6.1	5.8	5.8	5.5	5.2
Violent causes					
Female	0.9	0.8	0.8	0.8	0.8
Male	3.8	3.8	3.6	3.5	3.2
Digestive diseases					
Female	0.6	0.6	0.6	0.5	0.5
Male	1.6	1.5	1.5	1.4	1.4

Sources: Osservatorio Nazionale sulla Salute nelle Regioni Italiane, selected years; ISTAT, Indagine sui decessi e cause di morte, selected years.

Italy has low infant and neonatal mortality rates, with a significant decrease over the last 40 years compared with other European countries, eliminating the existing gaps and reaching levels of excellence (see Table 1.1). Biological determinants and skilled assistance at delivery are particularly significant in explaining the trend in neonatal mortality.

The sharp decline of the total fertility rate over the last 30 years is a matter of concern in Italy, as for other Western countries. In the last decade a reversal has been observed, partially due to the effect of immigration, and fertility rates have gradually increased. However, in 2012 the fertility level was 1.4 births per woman (Table 1.1), still below the 2.1 replacement level. The reasons behind this process are complex and could be explained by the delay in transition to adulthood and the difficulties experienced by Italian women in combining work and raising children (Rosina & Caltabiano, 2012). At the end of 2010, foreign nationals accounted for 7.5% of the Italian population. The number of legal documented (regular) immigrants showed an increasing trend and varied across the country with higher numbers in northern and central regions and smaller numbers in the south. The largest foreign communities, for both genders, are represented by Romanians, Albanians and Moroccans. There has been a steady increase over time of births in which either one or both parents are foreigners.

In 2011, more than one-third of the adult population (35.8%) was overweight, while 1 out of 10 (10%) was obese (Table 1.5), with a higher prevalence registered in the southern regions. At national level, 2011 data seem to be stable compared to 2010. Moreover, the proportion of overweight or obese people increases proportionally with age, before declining slightly among the elderly.

The proportion of smokers among the population aged 15 and over was 22.3% in 2011. In 2003, before the approval of Law 3/2003 to ban smoking in public spaces, the prevalence rate was 23.8%. Smoking cigarettes was found to be more common in young adults, particularly in the 25–34 age group and more prevalent among men (28.7%) than women (16.7%). Data for non-smokers and former smokers are inversely distributed among the two genders. Thus, there is a higher prevalence of non-smokers in females (65.1%) than in males (39.4%), while the percentage of former smokers among men is almost double (30.5%) that of women (16.7%).

In terms of alcohol consumption, prevalence rates for those drinking a standard number of units per week show a significant gap between genders (11.53% for men vs 2.72% for women aged over 15 who consume alcohol more than once a week) and geographical differences (lower values in the south and Italy's islands).

Table 1.5

Morbidity and factors affecting health status, selected years

Indicators	2002	2009	2010	2011
Obese (%) (people aged 18+ years)				
Female	8.2	9.3	9.6	9.4
Male	8.7	11.2	11.1	10.7
Overweight (%) (people aged 18+ years)				
Female	25.4	27.7	27.6	26.7
Male	44.2	45.2	44.3	45.5
Smokers (%) (people aged 15+ years)				
Female	17.2	17.1	17.1	16.7
Male	31.3	29.9	29.5	28.7
*Alcohol consumers (%) (people aged 15+ years)**				
Female	2.6	2.6	2.7	2.7
Male	12.0	10.8	11.3	11.5

Source: ISTAT, selected years.
Note: *people aged 15 or older who consume alcohol more than once a week.

Notwithstanding the important results gained in health status, geographical differences remain in terms of health conditions and lifestyles, as well as in the supply and quality of services. Southern regions still score lower in life expectancy, lifestyles, access to care and quality of services. Moreover, many concerns are being raised on the sustainability of the system as Italy is undergoing an economic and financial crisis, which requires cost containment and resources reallocation policies. These measures are expected to have a marked impact on health care in the years to come, possibly generating inequalities in access to care, sharpening existing differences in the quality of care among regions and affecting the most vulnerable groups of the population.

2. Organization and governance

Italy's health-care system is a regionally organized National Health Service (*Servizio Sanitario Nazionale*, SSN) that provides universal coverage largely free of charge at the point of delivery. At national level, the Ministry of Health (supported by several specialized agencies) sets the fundamental principles and goals of the health system, determines the core benefit package of health services guaranteed across the country and allocates national funds to the regions. The regions are responsible for organizing and delivering health care. At local level, geographically based local health authorities (*Aziende Sanitarie Locali*) deliver public health, community health services and primary care directly, and secondary and specialist care directly or through either public hospitals or accredited private providers.

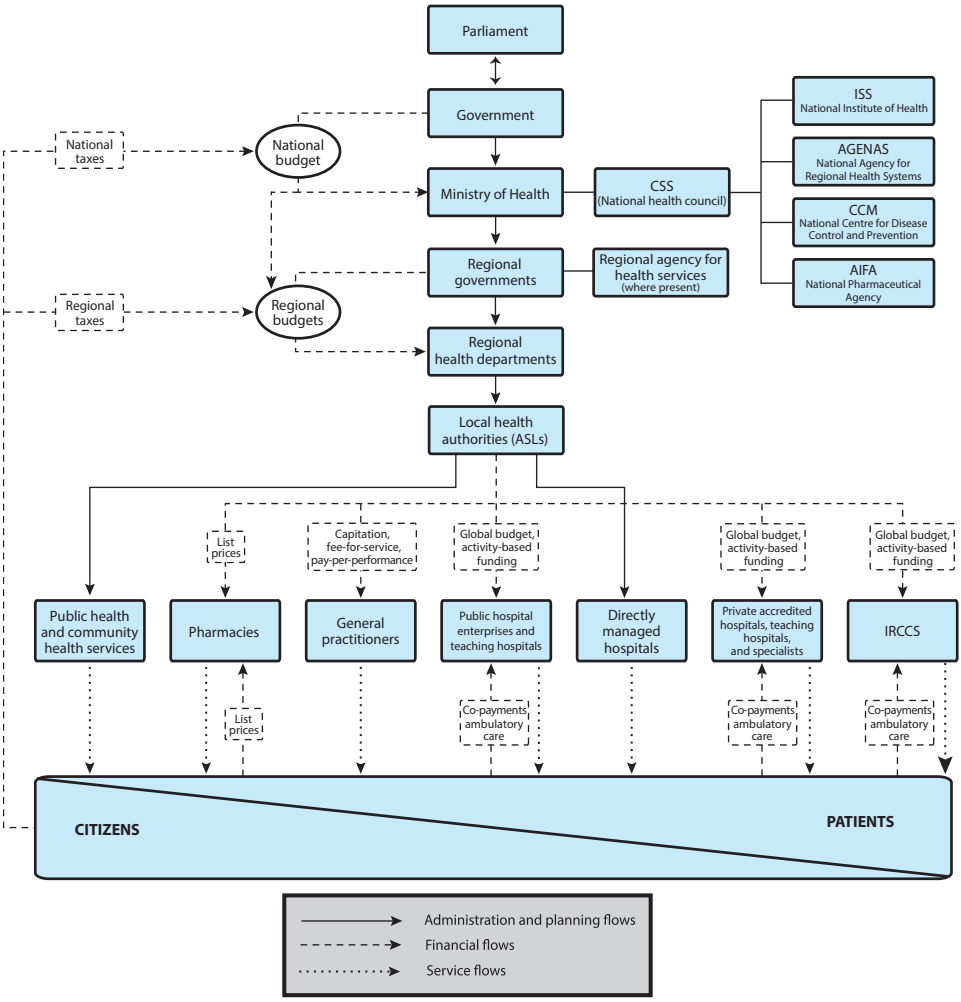
Patient empowerment and patient rights are not specified by a single law but are present in several pieces of legislation, starting with the Italian Constitution and the founding law of the national health system. Over the last 20 years, several tools have been introduced for public participation at all levels but no systematic strategy exists and implementation varies across the country, as does the satisfaction of citizens with the quality of health care. Over the last few years, measures have been taken to tackle excessive recourse to legal action against doctors and to prevent defensive medicine practices.

2.1 Overview of the health system

Italy's health-care system is a regionally based National Health Service (*Servizio Sanitario Nazionale*, SSN) that provides universal coverage, largely free of charge at the point of service. The system is organized into three levels: national, regional and local. The national level is responsible for ensuring the general objectives and fundamental principles of the SSN. Regional governments, through their regional health departments, are responsible for ensuring the

delivery of a package of benefits through a network of population-based 'local health authorities' (*aziende sanitarie locali*, ASLs) and public and private accredited hospitals. Fig. 2.1 summarizes the main organizational actors and the relationships between them.

Fig. 2.1
Overview of the Italian health-care system



2.2 Historical background

The 1978 reform (Law No. 833/1978) that created the SSN introduced universal health-care coverage for Italian citizens and those legally residing in Italy. It established human dignity, health needs and solidarity as the guiding principles of the system. The main aims of the reform were to guarantee everyone equal access to uniform levels of care, irrespective of income or location; to develop disease prevention schemes; to control health spending; and to guarantee public democratic control. A mixed financing scheme was established that combined general taxation and statutory health insurance contributions, progressively moving to a fully tax-based system. The new health-care system was partly decentralized, with national, regional and local administration levels. The central government was responsible for financing, namely defining the criteria for the distribution of funds to the regions, attempting to progressively reduce regional imbalances and distributing funds; it was also responsible for planning through a three-year National Health Plan (*Piano sanitario Nazionale* – PSN). Regional health authorities were responsible for local planning according to health objectives specified at the national level, for organizing and managing health-care services and for allocating resources to the third tier of the system, then known as 'local health units' (*Unità Sanitarie Locali* – USLs). The USLs were operational agencies responsible for providing services through their own facilities or through contracts with private providers. They were run by management committees elected by assemblies of representatives from local governments.

However, this structure created jurisdictional conflicts between the different levels of authority. Responsibility was not clearly divided and health care was not planned consistently at the national and regional levels. Above all, regional governments considered the resources they received from the central government to be insufficient to satisfy the health-care needs of their populations. As a result, regional public deficits mounted and the central government had to cover the accumulated debts. The separation between central financing responsibilities and regional and local spending powers was seen as the main cause of constantly rising health-care expenditure. Moreover, health care was markedly different in the north and the south of the country, causing concern about the capacity of the health-care system to guarantee equal rights to citizens across the country. In addition, health-care management suffered from excessive politicization, as political party representatives managed USLs according to their electoral strength.

Faced with these problems, the government set out new reforms to the health-care system with Decrees 502/1992 and 517/1993, that combined universal coverage with new financing mechanisms. Incentives and competition among

providers would improve efficiency and responsiveness to consumers at the micro level, while containing costs and ensuring equity at the macro level. The 1992 reform introduced managerial principles into the SSN and began concerted efforts to devolve health-care powers to the regions. USLs and major hospitals were transformed into autonomous bodies and made more independent of political influence. The USLs were thus transformed into public entities, the ASLs; major hospitals became semi-independent public enterprises – 'public hospital enterprises' (*aziende ospedaliere*, AOs); and both ASLs and AOs were made directly accountable to the regions.

In 1998, dissatisfaction with the effects of the 1992–1993 reforms prompted the government to reorganize the SSN. Changes involved the relationship between levels of responsibility and management, the roles of actors such as managers, doctors and local institutions, and the balance between economic constraints and the principles of universalism and equity of access. The resulting reform was launched by Decree No. 229/1999, which extended regionalization and strengthened the role of municipalities, distributing responsibilities more clearly between levels of government. This reform also softened the previous shift to quasi-market and internal competition, promoting cooperation among health-care providers and partnerships with local authorities for health promotion and community care. To tackle the previously unresolved issue of the relationship between health care and social services, it created a more integrated framework for delivering health care to disadvantaged people such as the elderly, the poor and those with reduced autonomy.

As a step towards decentralizing fiscal powers so as to give more financial responsibilities and powers to each region, a Decree in 2000 (No. 56/2000) set out a timetable to eventually abolish the National Health Fund, which was used to collect and distribute central resources to regional health-care systems.[3] Various regional taxes became the sources of health care funding. Regions unable to provide the basic package of health services with their own resources would receive additional funding from a newly created National Solidarity Fund. Money from this fund is allocated annually based on criteria recommended by the government and the Standing Conference on the Relations between the State, the Regions and the Autonomous Provinces (or the State-Regions Conference, for short). Table 2.1 summarizes the main historical landmarks in the development of Italy's health-care system.

[3] However, due to continuing stalemates between the central government and the regions over resource allocation criteria, the National Health Fund is still in operation. See Chapter 3.

Table 2.1
Historical background and recent reforms in Italy's health-care system

1861–1920	Autonomous mutual aid associations are established for artisans and workers; the Catholic Church and charitable institutions establish several health-care providers; provincial and municipal networks provide social assistance to the needy and disabled.
1898	Insurance for occupational accidents becomes compulsory for the first time.
1904, 1917	Insurance becomes compulsory in industry and agriculture, respectively.
1923	The right-to-hospital care for the needy, indigent population is guaranteed for the first time.
1925	A national body in charge of insurance for the employees of local authorities is created (INADEL).
1926	A small number of centres for cancer diagnostic testing are created.
1927	Provincial authorities for tuberculosis treatment are created, and tuberculosis insurance becomes compulsory.
1926–1929	Health-care provisions for workers become mandatory for the government to approve collective labour force agreements.
1942	A national body is created to guarantee social insurance and health care for public employees (ENPAS).
1943	A national body for private employees' health care insurance is created (INAM).
1958	An independent Ministry of Health is created.
1968	Public institutions providing hospital care are established as autonomous entities (Law 132/1968).
1974–1975	Responsibility for hospital management is transferred to the regions (Laws 386/1974 and 382/1975).
1978	A national health service (SSN) is established by Law 833. Health insurance funds are abolished (First reform of Italian health care).
1992–1993	Second reform of the SSN (Legislative Decrees 502/1992 and 517/1993). Devolution of health care to regions begins; managerial autonomy granted to local health authorities (ASLs) and hospitals (AOs); elements of an internal market are introduced.
1994	First National Health Plan (1994–1996). The plan defines national health targets and establishes that a uniform core benefit package ('essential levels of assistance' – LEAs) should be guaranteed to all citizens.
1997	Further steps towards federalism: Law 51/1997 devolves some key political powers to the regions; Law 446/1997 initiates the process of fiscal federalism.
1998	Second National Health Plan (1998–2000).
1999	Third reform of the SSN (Decree 229/1999). Further development of devolution; strengthening of cooperation and regulation to partially reorient the internal market; establishment of tools to define the core benefit package; regulation of the introduction of clinical guidelines for quality in health care.
2000	Decree 56/2000 replaces (in theory) the National Health Fund with a National Solidarity Fund; plan for fiscal federalism to be operative in 2013.
2001	Constitutional Law No. 3 modifies the second part of the Italian Constitution (Title V), giving regions with more powers. Law 405/2001 introduces new regional governance tools and stronger responsibility in the control of health-care expenditure.
2003	Third National Health Plan (2003–2005).
2005	Memorandum of understanding between the state and the regions reforms the health-care financing system and introduces new mandatory financial rules.
2006	Fourth National Health Plan (2006–2008). In June the newly formed Centre-left government outlines the policy programme, A New Deal for Health. National Budget Law 2007 introduces financial turnaround (recovery) for regions with deficits
2009	Law 42/2009 provides the framework for fiscal federalism. In the following years, a series of decrees defines the distribution of local taxes to the tiers of government and the criteria for central equalization and redistribution of funds.
2012	A spending review of the national budget includes cuts to health spending and a reduction of hospital beds per inhabitant.
2012	Decree 158 ('Balduzzi Law') modernizes the SSN on several levels: continuity of care; selection by merit of general directors and head physicians; simplifications for homeopathic and innovative pharmaceuticals; rationalized pharmaceutical and capital spending.

2.3 Organizational overview

2.3.1 National level

The national Government, through the Ministry of Health, takes the lead in health-care planning, including the definition of the benefit package (LEAs, see section 2.4) and the setting of long-term goals; financing, with the distribution of available funds to the regional health systems; monitoring of the SSN; and the general governance of the National Institutes for Scientific Research (IRCCS).

The ministry is currently organized into three independent and specialized departments, each comprising several directorates:

1) Department of Public Health and Innovation.
   - Prevention
   - Health and biomedical research
   - European and international relationships
   - Communication and institutional relations.

2) Department of Planning and Organization of the SSN.
   - Health-care planning
   - Health statistics and information system
   - Health professions and SSN human resources
   - Medical devices, pharmaceutical service and safety of care.

3) Department of Veterinary Care, Food Safety and Collegial Organs for Health Protection.
   - Veterinary care and pharmaceuticals
   - Food and nutrition safety
   - Collegial organs for Health Protection.

The Ministry is supported in its functions by several permanent government agencies:

- The National Institute of Health (ISS) carries out scientific research, surveillance and promotion of public health, and dissemination of knowledge. It has an advisory role to the ministry with a significant degree of independence, including its own research facilities.

- AGENAS (National Agency for Regional Health Services) works at the interface between the Ministry of Health and the regional authorities, helping them ensure organizational quality, efficiency and efficacy in the delivery of care. It carries out monitoring activities in these areas and supports both the ministry and single regional health-care systems in planning and implementing organizational reforms.
- CCM (National Centre for Disease Prevention and Control) was established to liaise between the Ministry of Health and regional governments in surveillance, prevention and health emergency response. Over the years its role has expanded to include designing evidence-based national strategies for disease prevention, health promotion and equity in access to care. It provides assistance to the regional technical working groups in public health programmes, and maintains relationships with large international epidemiology and public health networks.
- AIFA, the national authority for pharmaceutical regulation (see section 2.8.4).
- IRCCSs (National Institutes for Scientific Research), tertiary care and research centres; and the IZSs (Experimental Zooprophylactic Institutes), which regulate and control animal livestock and food of animal origin.

The single most important technical and consultative body to the Ministry of Health is the National Health Council (CSS). It consists of 50 members and a president, and it brings together representatives of the national government agencies listed above as well as scientists, physicians and other recognized experts.

The State-Regions Conference was established in 1983 to provide a permanent interface for consultation and communication between the state and the regions in the domains of public policy where their mandates overlap.

2.3.2 Regional level

The 19 Regions and 2 Autonomous Provinces share planning and financing responsibilities with the central government in the State-Regions Conference, and are exclusively responsible for delivering public health and health-care services through their regional health-care systems.

Each region, through its elected Regional Council, carries out legislative activity, which was enlarged in scope by the 1999 SSN reform and currently includes:

- general principles and organization of the regional health-care system, including the general rules about the roles of the regional authority, ASLs and AOs (public providers) and private providers;
- criteria for financing public and private health-care providers;
- technical and management guidelines for service provision and planning, including assessment of the need for new hospitals.

The executive functions of the regional government in health care, mainly carried out through the regional Department of Health, include drafting the three-year Regional Health Plan; defining the criteria for authorizing and accrediting public and private health-care providers and monitoring the quality of their care; coordinating health and social care through a Standing Conference for Regional Health and Social Care Planning; and managing ASLs and AOs by defining their geographical boundaries, allocating resources to them, and appointing their directors.

Eleven regions, mainly northern ones, currently have a regional agency for health responsible for both supporting the regional health department itself in its executive functions and providing technical and scientific support to the ASLs and hospitals.

2.3.3 Local level

Within each region, responsibility for the organization and delivery of services rests on geographically and population-defined institutions, the ASLs. These Local Health Authorities directly depend on the government of their region, which funds them according to financing schemes that vary from region to region (see Chapter 3). They provide preventive medicine and public health services, primary care – including family medicine and community services – and secondary care. The territory of each ASL is further divided into Districts, the institutional level that directly controls the provision of public health and primary care services. Each district is statutorily set to have a coverage population of approximately 60 000 inhabitants. As of 2012, there were 143 ASLs and 826 Districts in the SSN.

The providers of all health and social care services have different relationships with ASLs, ranging from direct dependency (in-house provision of services) to commissioning:

- Preventive medicine and public health services are delivered by the Department of Prevention, present in every ASL. ASLs of different sizes may have several additional departments that may take on more public health services.
- A network of general practitioners (GPs) provides family medicine services and acts as a gatekeeper to higher levels of care. They work for the regional health system and coordinate with the activities of the Districts. However they are not salaried employees of ASLs as the terms of their work are set out in a national agreement between the State-Regions Conference and (since 2001) the association of health professionals with a contract with the SSN, SISAC (*Società Interregionale Sanitari Convenzionati*).
- Community services include primary medical and nursing care, home and residential care for the elderly and the disabled, and hospice care.
- Secondary care can be either delivered directly by the ASLs through the hospitals they own or by public hospital enterprises, the AOs (*Aziende Ospedaliere*). In the latter case, the ASLs work as purchasers of services in a quasi-market system. It is up to the individual regions to choose whether to opt for purchaser–provider separation.
- Accredited private hospitals and specialists.
- Social care and social welfare services are delivered by municipal authorities, with varying degrees of integration and coordination with ASLs.

2.4 Centralization and decentralization

The national level has exclusive authority in determining the core benefit package (*Livelli Essenziali di Assistenza* – LEA), that must be guaranteed throughout the country free or with cost sharing, using the resources collected through general taxation. The delivery of LEA is organized into three levels: public health; community health medicine and primary care; and hospital care. A specific National Commission for the definition and updating of the LEA is requested to follow three criteria: efficacy, appropriateness and consistency with the functions and goals of the SSN.

Regions have exclusive authority in execution-level planning and delivery of health care, as well as health protection and health-related disciplines such as labour safety, organization of professions, food safety and scientific research. Since 2001, agreements between the national level and the regions have become

the main instrument for planning and organization of public health care in Italy. In fact, different regions have made different choices on how to use their increasing autonomy. For instance, Tuscany decided to keep the system heavily centralized, with most hospitals remaining under ASL control and only a handful becoming AOs. At the other extreme, Lombardy opted in 1998 for a fully fledged experiment in which all hospital and specialist services are delivered by AOs or private providers. The region's main hospitals were converted to AOs, free to negotiate financing terms with ASLs – although controlled on the quality of services provided – and citizens were given full freedom of choice between ASLs, hospitals and even social care services. While a part of these features was repealed in subsequent years, the basic configuration is still the same. Since 2006, 'financial recovery plans' (*Piani di Rientro*) have further affected the level of decentralization of policies (see section 3.3.3).

Because of these regional differences in policies and financing, a large vertical fragmentation exists in the extent and the quality of such strategies between regions or ASLs of excellence, which are mainly found in the northern part of the country, and areas where self-directed initiatives are scant. In addition, horizontal fragmentation undermines the continuity of care for chronic diseases, as integration between actors of social care (municipalities) and health care (ASLs) varies across the country and is mostly incomplete.

The process of decentralization was set to end with the full implementation of fiscal federalism, set in motion in 2009 (Law 42/2009). However, this reform has stalled. The uncontrolled increase of regional health-care spending since 2001 and the international financial and economic crisis that began in 2008 have led policy-makers to reconsider full fiscal decentralization.

2.5 Planning

2.5.1 National level planning

The main instrument for national level health-care planning is the National Health Plan (NHP). Drafted by the Ministry of Health following consultations with the regions, it is then approved by the government in agreement with the State-Regions Conference, and covers three years. The first NHP was released in 1994. Within a flexible structure, such plans set the fundamental principles and values of the health system, the general goals of the SSN and the strategic directions for quality improvement, evaluation of the system's

efficiency and efficacy, and for scientific research. The single most important part of the NHP is the LEA, the main instrument for planning, priority setting and assuring equity.

The NHP for 2011–2013 defines at all levels (prevention, diagnosis, care, rehabilitation):

- the LEA;
- criteria for ensuring that the financing of regional health care is adequate to guarantee the LEA (see Chapter 3);
- criteria for resource allocation of regional funds across the individual ASLs;
- economic sustainability;
- criteria for adapting national goals with the epidemiological features and health needs of regional populations.

The NHP also compares the predicted annual number of new graduates in the health professions and the estimated number of health professionals that will be needed, also considering the average age of the workforce. It discusses the potential impact and the administrative effects of newly introduced provisions, including fine-tuning of education and training policies; and specifies the provisions included in the yearly National Financial Laws that are relevant to health and health care.

2.5.2 Regional level planning

The main health-care planning instrument at the regional level is the Regional Health Plan (RHP). Every region adopts one within 150 days of the introduction of the NHP and forwards it to the Ministry of Health to receive feedback on its consistency with the national plan. The RHP is generally more detailed than the NHP. It includes details such as the distribution of beds in secondary, emergency and long-term care, size and location of hospitals, measures to ensure balance between primary and secondary care, integration between health and social care, and continuous improvement. Approaches to regional planning widely vary: some regions regularly issue plans while other have rarely used formal planning to steer the system.

2.5.3 Local level planning

Although there are great intra- and inter-regional variations, every ASL generally plans on three levels: Managing Board, Department Directors and single professionals.

The Managing Board performs long-term strategic planning and monitoring, which includes the following stages:

- definition of long-term institutional goals;
- analysis of the external environment (needs and demands, indications from regional and national planning, features of other organizations with a similar mandate) and the internal environment (SWOT analysis at the organizational and the technological level);
- definition of critical success factors;
- formulation of strategy with specific goals;
- implementation plans;
- definition of strategic control functions, consisting of monitoring and correcting actions.

The Department Directors draft the budget for the medium term, which includes:

- budgeting, which defines specific and concrete sub-goals leading to the attainment of the general goals defined through strategic planning, and accountabilities; and assigns sufficient resources to each goal;
- reporting, which sets up a periodic comparison between set goals and actual achievements.

Health-care professionals at the management level carry out short-term operational planning and monitoring.

2.6 Intersectorality

Compared to similar institutions in other countries, the Italian Ministry of Health has much wider 'horizontal' administrative competences. In addition to health financing and planning, its mandate includes protecting citizens' health through the preventive control of industrial production (e.g. biotechnologies and health and safety at work) and agriculture (e.g. veterinary public health and food safety), the exchange of several goods (e.g. manufacturing and marketing of medicines, medical devices and cosmetics), and human international mobility. Moreover, enforcement of certain environmental health standards (e.g. air and water quality) also fall within the remit of the ministry, as does the control of their implementation through the structures of the SSN.

The Ministry of Health links closely to the Ministry of Economy and Finance, especially with regard to the definition of the health-care budget, and the Ministry of Welfare and Social Affairs, in the coordination of social services with SSN infrastructures. Table 2.2 lists the main actors responsible for health-related issues in several public policy domains.

Table 2.2

Main actors responsible for health-related issues in public policies

Domain	Responsible authority	Activities
Agriculture and food safety control	Ministry of Agriculture, Regions, ASLs (Veterinary Division, Food and Nutrition Hygiene Division) Customs offices and port bureaus of the Ministry of Health	Enforcement of EU regulations (1997 European Commission Green Paper on the General Principles of Legislation in the field of Food, 2000 White Paper on Food Safety, 2002 General Food Law, 2006 Hygiene Pack with Regulations 852, 853, 854, 882/2004 and Directive 2002/99. Biochemical and microbiological controls on food production, labelling, distribution, import and export, yearly reports.
Workplace safety, occupational hazards	Ministry of Health, Directorate-General of Prevention[a] Municipal fire brigades Municipal police	Specialized doctors in Labour Medicine are authorized by the ministry to prevent and diagnose work-associated health hazards and diseases. Employers must comply with workplace safety standards set by law and monitored by local fire brigades and police officers. Employees must follow safety training and are entitled to care by Labour Medicine doctors.
Road Safety	Ministry of Public Works Ministry of Transport and Navigation Ministry of Economic Development ISS	Enforcement of relevant legislation: the 1999 National Plan for Road Safety (*Piano Nazionale Sicurezza Stradale*) and its three implementation programmes (2002, 2003, 2007), the latter still ongoing. The ISS runs a permanent observatory on road safety.
Emergency response	Prime Minister's Office, Department of Civil Protection, ASLs	The Civil Protection Department is responsible for responding to seismic, volcanic, hydrogeological, fire, nuclear, environmental, industrial, and terrorism-related large-scale risks. It has its own workforce and equipment.
Environment	Ministry of Environment, Regional Environmental Authorities (ARPA) Municipal fire brigades	Safety of industrial sites handling dangerous substances.
Water, air	Ministry of Environment, ASLs, Regional Environmental Authorities (ARPA)	Quality control of drinking water and bathing water.
Veterinary Health	Ministry of Agriculture, ASLs, Veterinary Health Service, IZS (Experimental Zooprophylactic Institutes)	Controls on industrial and non-industrial farming.
Smoking, alcohol and drugs	Ministry of Health, Ministry of Economic Development, ASLs, Municipal social care services, Provinces	Health promotion campaigns, addiction treatment and rehabilitation.

Note: [a]In 2010, following an institutional reorganization, the National Institute for Prevention and Safety at Work (*Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro*, ISPESL) was disbanded and its roles assigned to existing government agencies.

In 2007, the CCM (see Section 2.3.1) adopted the evaluation tool in the WHO's *Health in all Policies* strategy. The evaluation involved the fields of mobility and transport, work, identification of social and environmental health determinants, poverty and health, and urbanization and health. However, the *Health in all Policies* principles were not systematically applied by the Ministry of Health or regional governments. In 2011, the Health Committee of the State-Regions Conference created a National Working Group to act upon the European Commission's Communication (of October 2009) 'Solidarity in health: reducing health inequalities in the EU'. In 2012, the Group submitted to the Conference the draft of a White Paper on health inequalities in Italy that is currently being discussed by citizens' and patients' associations and other relevant stakeholders.

2.7 Health information management

2.7.1 Information systems

Collection, processing and dissemination of data relevant to the statutory health-care system and to citizens' health status fall within the mandate of the Ministry of Health's General Directorate of Health-care Statistics (Statistics Office). ASLs collect data and send them to regions, which in turn, forward them to the Office.

Specific data flows originate locally, from GPs and ASL departments. The surveillance data flow for infectious diseases, the SIMI (*Sistema Informativo Malattie Infettive*), collects notifications filed by doctors on cases of 47 infectious diseases. Each ASL forwards them to the Regional Public Health Agency, which warns the Ministry of Health and the National Health Council; these can notify international organizations (EU, WHO). An annual Epidemiological Bulletin collects the data by month and by location. A similar data flow exists for occupational hazards and work-related accidents.

One of the most important databases is the national database on hospitalizations (*Sistema Informativo Ospedaliero* – SIO). This database is based on the Hospital Discharge Form (*Scheda di Dimissione Ospedaliera* – SDO), introduced in 1991, that reports all details of each hospitalization in secondary care structures, classifying diseases based on the most recent revision of the International Classification of Diseases and listing the services provided to patients. Other notable data flows are the information system on accidents and emergencies (*Sistema Informativo Emergenza Sanitaria* – SIES);

the Register of Delivery Certificates (*Certificato di Assistenza al Parto* – CeDAP), which collects details on every birth in all regions (since 2008); and the data on organ donations and transplants collected by the National Centre for Transplants.

General demographic statistics with relevance to health, such as general mortality, child mortality and mortality of live births, are produced by the National Institute of Statistics (*Istituto nazionale di Statistica* – ISTAT), which supports all ministries and central government agencies. Financial and organizational data are also collected and analysed by the State General Accountant (*Ragioneria Generale dello Stato*).

Over the last few decades, several steps have been taken to coordinate local, regional and national information systems. The Health-care Information System (*Sistema Informativo Sanitario* – SIS) was established in 1984 within the Ministry of Health to coordinate and manage SSN data flows. Since 2001, a centralized national information system for storage and management of health and health-care-related data, the New Health Care Information System (*Nuovo Sistema Informativo Sanitario* – NSIS), has been under development. Common and interoperable languages have already been developed for its subcomponents (pharmaceutical distribution database; monitoring of care networks; information system on mental health; observatory of public investments in health care; national information system on addictions; traceability of pharmaceuticals; emergency and urgency; home care; residential and semi-residential care; hospital drug consumption; information system for the monitoring of health care errors).

2.7.2 Health Technology Assessment (HTA)

The first evaluations of medical technologies were carried out by clinical engineers at the ISS in the 1980s, and they spread to teaching hospitals at the beginning of the 1990s. After the 1993 meeting of the International Society of Technology in Health Care (ISTAHC), held in Italy, interest grew in public regional institutions, especially with regard to opportunities for price control. HTA units were set up in several teaching hospitals and through regional health care agencies; Emilia-Romagna was the first region to produce HTA reports. With the publication of the first research grants in HTA by the Ministry of Health, the Italian Network of Health Technology Assessment was formed in 2003, and the Italian Society of HTA (SIHTA) in 2006. In the same year, the

regions of Emilia-Romagna and Veneto, and the Catholic University of Rome, entered the EUnetHTA project, aimed at building a European HTA network (Favaretti et al., 2009).

The first official mention of HTA at the institutional level was in the 2006–2008 National Health Plan, which described the recognition of its tools as a priority. Following this statement, the State-Regions Conference assigned AGENAS (see section 2.3.1) the task of supporting the regions to develop HTA activities. Through an ad hoc working group, AGENAS started to publish reports for the General Directorate of Medical Devices.

So far, Italy has not established a national HTA governmental agency; HTA activity by central agencies has been conducted by AGENAS in the field of medical devices and by AIFA for pharmaceuticals. However, five regions out of 21 have taken action to structurally include HTA in their health-care decision-making processes: Veneto (the forerunners), Emilia-Romagna, Lombardy, Piedmont and Tuscany (CSA, 2012). Their experience is quite heterogeneous. The involvement of industry only occurs in Emilia-Romagna, and involvement of patients only in Piedmont; the other three regions do not provide a role for either. The degree of centralization is low in Veneto, where many bodies share responsibilities and play a role in the decision-making process, while it is high in the remaining four regions. On the other hand, research and decision-making are assigned to different bodies only in Emilia-Romagna. Inter-regional differences also exist in the application of HTA: in 2012, of the 18 regions that reported conducting some HTA activity, 14 applied it to both medical devices and pharmaceuticals, and 4 – concentrated in central-southern Italy – exclusively on medical devices.

2.8 Regulation

2.8.1 Regulation and governance of third-party payers

Until 1992, only the central government could raise taxes and allocate funds to the regions, while the regions funded the ASLs and their hospitals. Funding was based on past spending, and the ASLs had no incentives to contain costs. Therefore, most ASLs overspent their budgets, and the central government funded their deficits. In the 1990s, a series of reforms was introduced, underpinned by the principles of managerialism, regionalization and managed competition. Managerialism gave ASLs greater independence but required them to improve their performance and encouraged them to adopt governance

techniques similar to those of private companies (Cantú, Ferré & Sicilia, 2010). It also made it possible for hospitals to become independent from ASLs by taking on the legal form of a Hospital Enterprise (*Azienda Ospedaliera* – AO), with their own managing board. Reimbursements to providers are based on activity-related funding: diagnosis-related groups (DRGs) for hospitals and a capitation (partially combined with fee-for-service) for GPs and outpatient specialist services (see Chapter 3).

Regionalization has progressively transferred full jurisdiction on health care to the regions. They carry out goal-setting and planning; fund their spending with regional taxes and user charges (even though a national equalization fund still compensates for cross-regional differences in fiscal capacity); and are free to decide whether to keep the purchasing role for themselves or transfer it to the ASLs. As a result, since the 1990s different regions have been experimenting with different organizational and funding models, thus resulting in great diversity:

- Most regions use an 'ASL-centred template', with each ASL acting as both provider and (to a limited extent) as purchaser of services from a limited number of AOs. This template partly resembles a quasi-market, as ASLs are financially penalized if residents seek care from providers other than theirs, as they have to pay them.
- A few smaller regions in northern and central Italy adopt a 'region-centred template', where most purchasing concentrates at the regional level, while ASLs act mostly as providers. These regions directly control most public providers and they accredit only a limited number of private providers.
- Lombardy is the only region that has carried out a complete purchaser–provider split. Most hospitals have been taken out of ASL control and established as AOs. ASLs purchase services from public and private providers, while the region has a regulatory role. The incentive for ASLs to ensure financial control by limiting provision balances the incentive for providers to increase volumes by attracting patients who have full freedom of choice. However, inadequate governance of demand makes ASLs act more often as third-party payers than purchasers, and volume-driven profits have led hospitals to increase demand artificially. Though a significant part of the reform that introduced the model was withdrawn in the early 2000s, Lombardy remains the region with the greatest emphasis on freedom of choice and a tendency towards a purchaser–provider split.

2.8.2 Regulation and governance of providers

Health-care providers can be either public or private. Public health-care providers are either under direct control of their ASL or are independent organizations (AOs, University Hospitals and Public Research Institutes – IRCCSs), though under a regional planning, financial and control scheme. On the other hand, private providers, both for-profit or non-profit, cooperate with public ASLs and regional authorities in ensuring the supply of services. However, several provisions exist to ensure they meet minimum structural, organizational and operational standards; the main ones are: authorizations, institutional accreditation and contracts.

Authorization procedures concern the minimum structural, technological and organizational criteria required under Italian law to operate in the health-care sector and concerns individual professionals and facilities. Authorization applies to any subject operating in Italy, even if its activities are completely outside those of the SSN.

SSN accreditation is a form of public licensing necessary for providing health care on behalf of the SSN, which is quite different from voluntary accreditations issued by organizations such as the Joint Commission International or the International Organization for Standardization. SSN accreditation hinges on more extensive quality criteria than authorization. It encompasses management of human and technical resources, as well as consistency of the provider's activity with regional health planning, and evaluation of the activities already conducted and the results achieved. The standards for the accreditation procedure were first set in 1997 by the National Accreditation Act. The Constitutional reform of 2001 gave regions the freedom to set their own accreditation criteria and procedures, as long as the LEA is guaranteed. At present, significant variability exists in regional accreditation policies.

Lastly, *contracts* between private providers and regional authorities (on behalf of the SSN) specify the financing conditions that will apply to that provider. Contracts qualify them as 'SSN providers', thus allowing them to begin to operate on behalf of the SSN, as authorization and accreditation alone are not enough for that purpose. Regional health authorities, in cooperation with ASLs, define the details of the contract agreements. Contracts also specify the operational and financial information the provider must supply to the ASL and region, the terms for supervision and monitoring, the maximum yearly volume or mix of care, and the financial and administrative sanctions if the

provider exceeds or does not reach the targeted volume (Cantú, Ferré & Sicilia, 2010). These contracts for private providers are the equivalent of the formal agreements ASLs establish with public providers.

2.8.3 Registration and planning of human resources

Every region determines its annual requirements for medical specialists by means of an ad hoc algorithm. The algorithm combines, per specialty, the overall turnover rate of SSN doctors according to the latest annual state budget with the variation of the number of specialists that each region needs for that year. These data express regional needs for the three categories of medical specialties, surgical specialties and medical services specialities.

Every three years, the State-Regions Conference determines the number of medical residencies allotted to each region. The annual requirement for medical specialists turned in by each region is matched with financial resources made available by the Ministry of Finance. If these resources are not enough to finance all the residencies needed, the regions can fund the remaining ones through regional or private funds.

2.8.4 Pharmaceuticals

Governance of pharmaceuticals rests with the AIFA, the Italian Agency for Pharmaceuticals. AIFA approves the pharmaceuticals that can be produced, used and marketed in Italy, and authorizes clinical trials.

Pharmaceuticals are divided into three categories, with different reimbursement regimes. Class A (*Classe A*) includes pharmaceuticals that are reimbursed by the SSN with or without co-payment and distributed either by pharmacies or by hospitals. Regions are free to impose a share of co-payment on their price, mainly used for cost-containment purposes or as a disincentive against inappropriate drug use. These shares can be dependent on parameters such as the patient's health status, income, age or employment status, and the number of regions introducing them has been on the increase over the last decade (see section 5.6). Class H (*Classe H*) includes pharmaceuticals that are fully reimbursed by the SSN, but can only be distributed by hospitals. Class C (*Classe C*) includes drugs that are entirely paid for by patients, except when regional health departments include specific drugs in reimbursement schemes. Class C pharmaceuticals are divided, in turn, into medicines with compulsory medical prescription and medicines not requiring a compulsory medical prescription. The latter are over-the-counter (OTC) pharmaceuticals against minor, mild or intrinsically transient conditions or symptoms, suitable

for self-medication. Off-label use of a pharmaceutical – defined as the use in clinical practice of a registered pharmaceutical with a therapeutic indication or administration forms different from what the AIFA registration specifies – is strictly regulated. In principle, it is only allowed when no alternative exists and enough scientific evidence for its efficacy is available.

Until 1992, the Ministry of Health had a statutory power to decide which pharmaceuticals were publicly reimbursed and to determine their prices. After a series of corruption scandals, the role of reimbursement and marketing regulation was taken up by several different independent committees, until AIFA was established in 2003. The prices of Class A and H drugs are determined by a negotiation process between AIFA and the producer. The producer must file an application, including evidence proving a positive cost–effectiveness ratio or otherwise show that the pharmaceutical is of interest to the SSN. The prices of all Class C drugs are determined by the producer but with some constraints. The price must be the same across the country; it can only be increased every two years; and the increase cannot be higher than expected inflation. AIFA monitors the market to check that these conditions are met. The prices of OTC drugs are freely determined by the producer.

Italian law distinguishes, for patent purposes, between branded pharmaceuticals and generic or equivalent pharmaceuticals. Branded drugs are pharmaceuticals sold with specific names and packages, either within patent or after the patent has expired. Generic or equivalent pharmaceuticals are not covered by patent but have the same composition, pharmaceutical form and dosing. Generic drugs are usually identified by the International Non-Proprietary Name (INN). They can be produced and sold following an authorization to enter the market (*Autorizzazione all'Immissione in Commercio* – AIC) by the Ministry of Health. However, their price must be at least 20% lower than the price of the matching branded pharmaceutical previously covered by patent. Reimbursement of pharmaceuticals not covered by patent – that is, either with an expired patent or a generic – is regulated by national provisions that specify a minimum reduction in price and even leave single regions free to set their reimbursement price as the price of the cheapest matching generic pharmaceutical available under regional distribution.

An incentive exists for generic substitution: pharmacists have to ask patients whether they would like to replace a patented pharmaceutical with the cheapest equivalent drug. If the doctor explicitly states that the prescribed pharmaceutical cannot be replaced or the patient refuses the replacement, the patient must pay the difference between the price of the prescribed pharmaceutical and the

price of the matching generic. Over the last few years, more cost-containment measures have been introduced. Since 2011, AIFA has set a maximum reimbursement price for equivalent Class A drugs. This reimbursement cap is based on a survey of current prices in other European Union countries, and must be enough to determine a predetermined yearly saving for regions. The first deliberation (March 2011) used Germany, UK, France and Spain as reference countries and determined a maximum reimbursement of 40%.

2.8.5 Regulation of medical devices and aids

Regulation of medical devices and aids falls within the remit of the Ministry of Health's General Directorate for Medical Devices, Pharmaceutical Services and Care Safety. Its duties include surveillance of the production of medical devices, their commerce and their use within the SSN, in line with Italian and the European regulations. It oversees surveillance, provides the forms and the contacts for notifications of malfunctions or accidents connected to medical devices, and checks the requirements for correct notifications. With AGENAS and AIFA, it coordinates HTA activities (see section 2.7.2). Since 2010, an information system has been active to monitor medical devices bought or used by all public health providers. This information system is connected to the NSIS (see section 2.7.1). In 2012, the directorate began a reorganization, which is ongoing.

2.8.6 Regulation of capital investment

The first investment plan for buildings and technologies was introduced in 1988. In 1998, the investment framework for public resources was changed and since then health-care infrastructure is no longer regulated through the same administrative pathways that regulate other public spending. Instead, single ministries are responsible – mostly the Ministry of Health. For this purpose the ministry created the Centre for Evaluation and Verification of Public Investments. The regions also obtained the main responsibilities for planning. The centre consists of professionals drawn from the ministry, regions and ASLs, and its composition is changed every three years. It advises on all proposed investments, deliberates on the use of European Funds in health care, monitors annual data on infrastructure planning and implementation sent by the regions to the ministry, and supports projects that come across difficulties. The centre also cooperates with the European Health Property Network (EUPHN). The Inter-ministerial Committee for Economic Planning (CIPE) is a public agency that supervises all public capital investments, ensures financing and prevents illicit use of investments.

2.9 Patient empowerment

There is no single law or code on patient empowerment or patient rights in Italy. Patient rights and the participation of patients in the statutory health system or in their own care are enshrined in a broad diversity of legislation, conventions and case law. Despite the lack of systematic programmes or initiatives, the SSN reforms of the last 20 years have progressively recognized these principles and provided a number of tools for their implementation at several levels.

2.9.1 Patient information

The Health Services Charter that all health-care providers have been required to adopt since 1995 gives citizens the right to consult health planning documents at all levels. In 2010 the Ministry of Health produced a set of guidelines to improve online communication by health-care providers, within the framework of health promotion. However, no system is in place to monitor compliance with the guidelines, nor is any institution charged with overseeing their implementation. A 2012 study analysing all 245 websites of the country's AOs found that compliance with the guidelines was low. The most critical area was availability of health information (Vanzetta et. al., 2012).

Since 2009, the National Health Outcomes Programme has evaluated hospitals' care outcomes; today, it represents an official tool to assess the SSN. The data include post-intervention mortality at 30 days from hospitalization or intervention for ischaemic heart disease, heart failure, stroke, COPD, upper gastrointestinal haemorrhage, cholecystectomy, major cancer surgical interventions and femur fracture. In addition, inappropriate hospitalizations are reported per ASL, in an attempt to evaluate quality of local primary care and community care services in chronic disease management. These indicators included hospitalizations for acute complications of chronic diseases such as diabetes or COPD, or for conditions such as influenza, childhood gastroenteritis or childhood asthma. In addition to outcome indicators, the last edition of the programme (2013) includes a set of volume indicators for the conditions with available evidence of an association between volume and outcome. Data from the National Health Outcomes Programme are not publicly accessible (PNE, 2013). However, in late 2013 a research-driven initiative to publicly report health outcomes data was started (see: http://www.doveecomemicuro.it/index.php).

2.9.2 Patient choice

Within the SSN, patients are free to seek health care from any public health-care provider (even outside their ASL or region) and any private provider accredited to offer care on behalf of the SSN. Providers must describe their equipment and tariffs for the most relevant services (Law 502/1992, art. 14). Patients are free to choose their GP and paediatrician for children under 14 from among those working in their ASL. People cannot switch GPs for at least 12 months, and their current registration is automatically extended if there is no explicit withdrawal. However, GPs and paediatricians must accept all patients and can only refuse a patient or remove them from their list due to exceptional and proven reasons of incompatibility. Patients are also free to choose providers of specialized and secondary health care among the available SSN-accredited public or private providers, in any Italian region. As with the choice available for GP services, this choice is also limited by capacity constraints. Patients are free to choose any accredited hospital but do not have the right to choose hospital specialists. To promote freedom of choice, the 1992 reform placed a statutory duty on the Ministry of Health to publish and regularly update the list of all public and accredited providers of specialized care.

2.9.3 Patient rights

Personal rights are one of the mainstays of the Italian Constitution. The fundamental right to self-determination, the liberty to dispose of one's body and the right to health are the subject of explicit references and underpin diffuse legislation.

The principles and the strategies proposed by international consensus documents such as the WHO 1994 Declaration on the Promotion of Patients' Rights in Europe and the 2000 Charter of Fundamental Rights of the European Union were not implemented through a systematic strategy in Italy. In 2002, the European Charter of Patients' Rights was drafted under the auspices of the Active Citizenship Network, the international department of the Italian NGO *Cittadinanzattiva* ('Active Citizenship'). The charter directly stemmed from the 2000 Charter of Fundamental Rights, and 16 European consumer associations adhered to it. It identifies and describes 14 patient rights: the right to preventive medicine, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment, complaint and compensation (see Active Citizenship Network, 2007).

Legislation on privacy and protection of personal data has been collected in the Code on the protection of personal data. The Code specifies the criteria for informed consent and the conditions for use of data on personal health status, including genetic data. It gives a mandate to the Authority for Protection of Personal Data (*Garante per la protezione dei dati personali*) to monitor its implementation and also decide on specific cases.

2.9.4 Complaints procedures

In Italy, there are three main ways that a patient can seek redress for malpractice or service failure: administrative complaint procedures; judicial procedures; and professional responsibility.

Patients, their relatives, and/or regionally accredited volunteer and consumer associations can lodge comments, concerns, and complaints at the Public Liaison Office (*Ufficio Relazioni con il Pubblico* – URP) of every AO and ASL within 15 days of the event or of realizing there is a valid reason to complain. This administrative procedure brings the case to the attention of the General Director of the ASL and AO, who has a duty to react within a further 15 days, after consulting the Medical Director.

A judicial procedure can be pursued through recourse to the ordinary public judicial system. The Italian legal system is based on civil or continental law, in which criminal law and civil law have markedly different features. Medical malpractice cases follow the general rules of contractual liability, part of civil law, as health-care relationships originate from a contract (Nuti et al., 2007; Traina, 2009). However, a medical malpractice case may also be pursued with a criminal law procedure in cases of proved 'negligence injury', described by the Italian criminal law code as 'an event that, even if it occurred without intention, occurred due to negligence, imprudence, lack of skill or failure to comply with laws, regulations, orders and disciplines' (art. 43, Italian Penal Code). In this case, the accused are prosecuted by a public attorney and punishments are more severe, including prison. A civil procedure and a criminal procedure may co-exist. In a 2010 Eurobarometer survey (European Commission, 2010), Italy was shown to be the European country with the highest share of its citizens believing that legal action taken against the responsible health-care facility was a possible form of redress in their country in cases of harm received during the provision of health care, while other forms of redress such as financial compensation or an investigation into the case were less known in Italy than the EU average. Over the last few years, measures have been taken to tackle

excessive recourse to legal action against doctors and to prevent defensive medicine practices. In 2010, the instrument of conciliation was introduced in an attempt to reduce the number of cases reaching the judicial level.

In 1980, *Cittadinanzattiva*, one of the largest Italian citizens' associations, created the Tribunal for Patient Rights (*Tribunale per i diritti del malato*) whereby a network of around 10 000 citizens and professionals are organized in 300 local sections. The association collects complaints from users of health-care services, publishes reports and undertakes action to ensure patient participation in health-care policy. In 2001, *Cittadinanzattiva* established the Active Citizenship Network (ACN) along with 70 citizens' associations of 30 EU or EU-candidate countries, to compare experiences and strengthen cooperation with national and European institutions (see *Tribunale per i diritti del malato*, 2013).

Professional responsibility falls within the mandate of the Orders and Colleges of Health Professions. They can carry out their own investigations, even in cases not deemed relevant by public courts, and take disciplinary action against their members. This action can take the form of a reprimand, a fine, temporary suspension from the register, partial restriction of the professional's licence to practise or permanent removal from the register.

2.9.5 Public participation

The founding law of the SSN included statements of principles on patient participation in health care but their implementation has been unsystematic and is still far from complete. The predecessors of the ASLs – the USLs – were managed by local health authority management committees (*Comitati di Gestione delle USL*) that included municipal representatives. They were the only legitimate channel for citizens' involvement.

The law enforcing the 1992 reform devoted a whole article to citizens' rights (Law 502/1992, art. 14). It placed a statutory duty on local SSN bodies to take measures for the collective involvement of patients through volunteers and community group representatives, and the use of patient satisfaction surveys. At the national level, it specified that the Ministry of Health, together with patients' and citizens' associations, would establish a set of indicators for this purpose. In addition, both the 1992 and the 1999 reforms required regions and ASLs to develop formal channels for consultation with volunteers' and patients' associations in health policy planning and evaluation. An example of such tools is the Conference of Health Services, a conference open to the public where

the administrators of the statutory health-care services, health-care workers and citizens´ organizations meet to evaluate the relationship between ASLs and citizens.

Regions have shown different degrees of commitment in the implementation of these statutory and non-statutory instruments. Emilia-Romagna and Tuscany, in particular, have emphasized the role of standing committees, which include members from citizens' associations, while the Veneto Region has focused on systematic patient satisfaction surveys.

2.9.6 Patients and cross-border health care

Italy has converted into national law EU Directive 24/11 on the application of patients' rights in cross-border health care. The SSN's system of international mobility primarily ensures health-care coverage to both Italian citizens who move within the borders of the EU, Switzerland and the European Economic Area (EU countries plus Norway, Iceland and Lichtenstein) and those who are in other countries with which Italy has active cross-border health-care agreements. At present, before going abroad for health care Italian patients ought to contact their relevant health services provider to obtain information about the following: the required procedures to obtain coverage of the expenses that they will incur, whether prior authorization is required and how to ask for it, if the cost of care will be paid directly by the regional health-care system or if the patient will need to first pay in full and then be reimbursed, and if so, what proportion will be refunded. To receive health care in these other countries, Italian residents must make available the documents issued by their ASL of residence. They will receive the same care as local citizens. In the case of third-party payment arrangements, the Italian Ministry of Health will pay the foreign providers, charging the patient's ASL of residency in Italy. The balance between international debts and credits for each ASL is considered when assigning resources to the regions.

3. Financing

The National Health Service is largely funded through national and regional taxes, supplemented by co-payments for pharmaceuticals and outpatient care. In 2012, total health expenditure accounted for 9.2% of GDP (slightly below the EU average of 9.6%). While this reflects a process of upward convergence towards the EU average over the last couple of decades, part of this apparent increase is also due to relatively weak GDP growth for Italy over that period.

Public sources made up 78.2% of total health-care spending, with private spending, mainly in the form of OOP payments (17.8%), accounting for the remainder – these OOP payments are mainly for diagnostic procedures (laboratory tests and imaging), pharmaceuticals, specialist visits and for unjustified (non-urgent) interventions provided in hospital emergency departments. Only about 1% of total health-care expenditure is funded by private health insurance. The production, distribution and pricing of pharmaceuticals are strictly regulated by a national agency, and provisions are made progressively more complex by repeated attempts at cost containment of pharmaceutical expenditure.

Since the early 2000s the health-care system has been undergoing a process of fiscal devolution from the central government to the regions. Within Italy there are substantial differences in funding between regions, with per capita expenditure ranging from 10.2% below the national average to 17.7% above. Although most funding is pooled at national level and redistributed to regions, there is scope for significant regional variation in tax rates (in particular through taxing corporations and a regional surcharge on income tax). The resulting financing system has an unevenly distributed tax base, smaller room for manoeuvre for poorer regions and a need for poorer regions to increase tax rates more than high-income regions, with consequent disincentives for business location, for example.

In recent years there have been attempts to place stricter controls over regions' health spending after a few incurred considerable deficits (mainly in the central and southern parts of the country). Moreover, in light of the global economic and financial crisis, tighter cost containment measures on public health expenditure have been proposed and are being slowly implemented (e.g. caps on specific spending areas). At the same time, higher co-payments for outpatient/ambulatory care, diagnostics and drugs have been introduced, adding to private spending on health.

Health care is delivered mainly by public providers, with some private or private-public entities. Although reforms in 1992 aimed to introduce a quasi-market system with patients free to choose any provider, in practice these arrangements vary across regions and, in some regions, are barely present. Only in the regions of Lazio, Campania, Molise and Lombardy is there a relatively high level of private care, with around 30% of total hospitalization supplied by private providers.

In general, doctors employed by the National Health Service are salaried and have civil servant status, although general practitioners and paediatricians are independent professionals, paid via a combination of capitation and fee-for-services for some interventions. All salaried doctors are allowed to practise privately and thus can earn additional income on a fee-for-service basis; they are encouraged to do so within National Health Service facilities and then pay a proportion of their income to that facility.

Payment rates for hospital and outpatient care are determined by each region, with national rates (determined by the Ministry of Health) as a reference. Payment for hospital care (ordinary and day hospital treatments) is based on DRG tariffs, although it is generally complemented with other payment methods (lump sum or global budget) while outpatient care is reimbursed using a tariff per unit of care. There are considerable inter-regional variations in the prospective payment system adopted by each region, such as how the fees are set, which services are included and the tools employed to influence patterns of care.

3.1 Health expenditure

In Italy, as in most OECD countries, health expenditure has steadily increased over time, making its containment a major issue for governments. However, it is noteworthy that public health-care expenditure remained virtually unchanged between 2010 and 2012 (with a +1.1% average yearly change). The recent history of health-care expenditure is marked by attempts to place stricter control over

regions' health spending after a few regions incurred considerable deficits. To address this financial failure, the government introduced a special regime for overspending regions that requires the adoption and implementation of formal regional 'financial recovery plans' (*Piani di Rientro*). Since 2007, ten[4] out of the twenty-one regional health systems have adopted these plans, which include actions to address the structural determinants of costs. All subsequent dynamics of public spending for health care must be seen in light of these provisions. The overall effect of this regime has been a decrease in the yearly level of overspending. In 2012, the total deficit of the public health-care sector was €1.04 billion, declining by 77% since 2006 (€4.48 billion) (Armeni & Ferré, 2013).

Total health expenditure (public and private) exceeded €140 billion in 2012 (9.2% of GDP) (Table 3.1), growing at a yearly average[5] of 4.7% from 2000 to 2009 and by only 0.9% from 2009 to 2012. Since 2000, total health-care expenditure has increased by 1.3 percentage points of GDP (from 7.7% in 2000 to 9% in 2010), mainly because the public component has experienced rates of increase that are substantially higher than GDP. Only in the last three years (2010–2012) has the increase in public health-care expenditure been radically contained; thus, the ratio of total health-care expenditure to GDP has been stabilized.

Table 3.1

Trends in health expenditure in Italy (1990, 1995, 2000, 2005, 2009–2012)

	1990	1995	2000	2005	2009	2010	2011	2012
Total expenditure on health per capita (PPP International $)[a]	–	1 494.08	2 028.6	2 478.8	3 037.0	3 025.7	3 016.8	3 040.1
Total health expenditure in € (millions)	50 173	66 051	92 813	121 793	136 944	138 580	140 669	140 770
Total health expenditure as % of GDP	5.6	7.6	7.7	8.5	9.0	8.9	8.9	9.2
Mean annual real growth rate in GDP (%)	–	-2.9	5.7	2.8	-3.5	2.1	1.7	-0.8
Public expenditure on health as % of total expenditure on health	82.6	73.8	75.6	79.5	80.5	80.3	80.2	80.8
Private expenditure on health as % of total expenditure on health	17.4	26.2	24.4	20.5	19.5	19.7	19.8	19.2
Government health spending as % of GDP	4.6	5.6	5.9	6.7	7.3	7.2	7.1	7.3
OOP payments as % of total expenditure on health	–	–	23.10	19.00	17.69	17.52	18.00	17.84
VHI as % of total expenditure on health	–	–	0.9	0.9	1.0	1.0	1.0	0.9

Sources: Armeni & Ferré, 2013, using Ministry of Health and Finance data; [a]WHO Health For All, 2014.
Notes: GDP: gross domestic product; 2011 and 2012 public health expenditures include depreciation expenses.

[4] Piedmont, Liguria, Abruzzo, Molise, Lazio, Campania, Puglia, Calabria, Sicily and Sardinia.

[5] In this chapter yearly or annual average growth rates are calculated as CAGR (compounded annual growth rate).

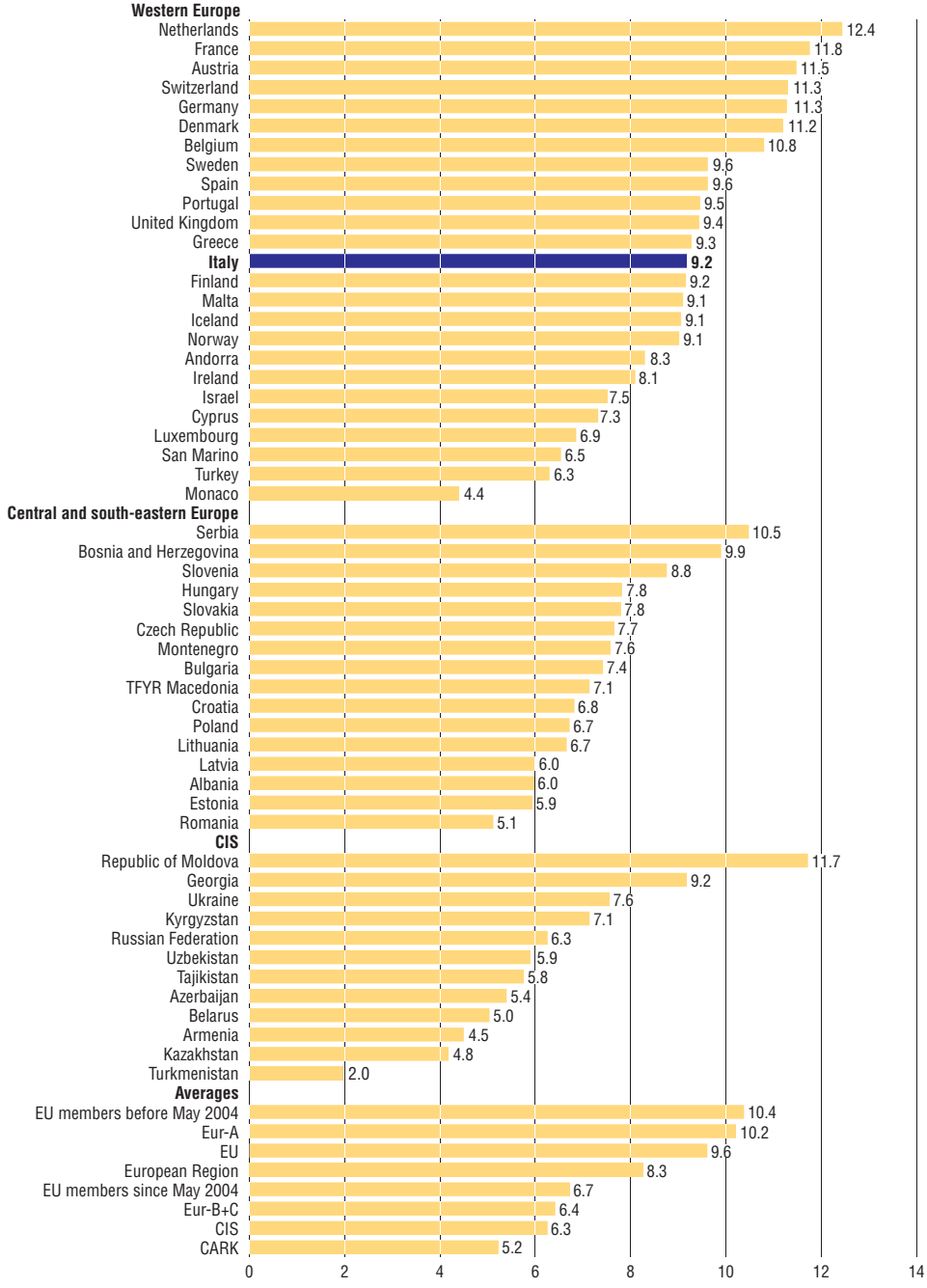
Using WHO Health for All data, Fig. 3.1 shows Italy's position with regard to health-care expenditure as a percentage of GDP compared with other countries in the WHO European Region. In 2012, the country's health spending (9.2%) was almost on a par with the EU average (9.6%). Fig. 3.2 shows this trend more concisely by comparing Italy's total health expenditure and that of a selection of Western European countries from 1990 to 2012. For much of this period, Italy was one of the lowest spenders, along with Spain and the United Kingdom but since 2009, most of the countries in the group have seen a decline in expenditure and have converged around the EU average. It is important to highlight that since the early 1990s Italian GDP has grown substantially less compared to the rest of Europe. Consequently, important increases in the share of GDP for health care were driven by moderate increases in absolute spending. Per capita health expenditure among countries in the WHO European Region is shown in Fig. 3.3 where Italy positioned itself at $US 3040 PPP in 2012, below the EU average of $US 3346 PPP.

In 2012, €112.6 billion in public funding was made available for health care. Overall public expenditure on health was €113.6 billion, with a modest growth rate of 0.8% compared to the previous year, and confirming the marked deceleration since 2005 (Armeni & Ferré, 2013). From 2006 to 2012, the average annual public health-care expenditure growth rate was 2.2%, compared to 6.6% during 2000–2005. Although volatile, private health-care expenditure also appears to be stable in the long term with an annual average increase of 2% between 2000 and 2005 but with a lower growth rate in the last six years (+0.8%). In 2010 and 2011 the level of private expenditure rose more than that of public expenditure (1% and 1.3% in public expenditure vs 1.9% and 2.2% in private expenditure). These changes may reflect two contrasting forces: on the one hand, the economic crisis has reduced households' disposable income and, thus, demand for private health care; on the other, because of cost-containment policies in the public sector, patients may be forced to pay higher co-payments or to go fully private due to longer waiting times or other forms of implicit and explicit rationing. In this respect, it is interesting to note the emergence of low-cost initiatives in the private sector (e.g. for dental and eye care), which are mainly provided in the form of discounted services (Del Vecchio & Rappini, 2011).

During 2007–2009, the central government had increased its efforts to contain costs, especially through policies aimed at increasing the efficiency of public spending. The main strategy was to make regions more accountable in their provision of the benefit package by keeping within financial constraints.

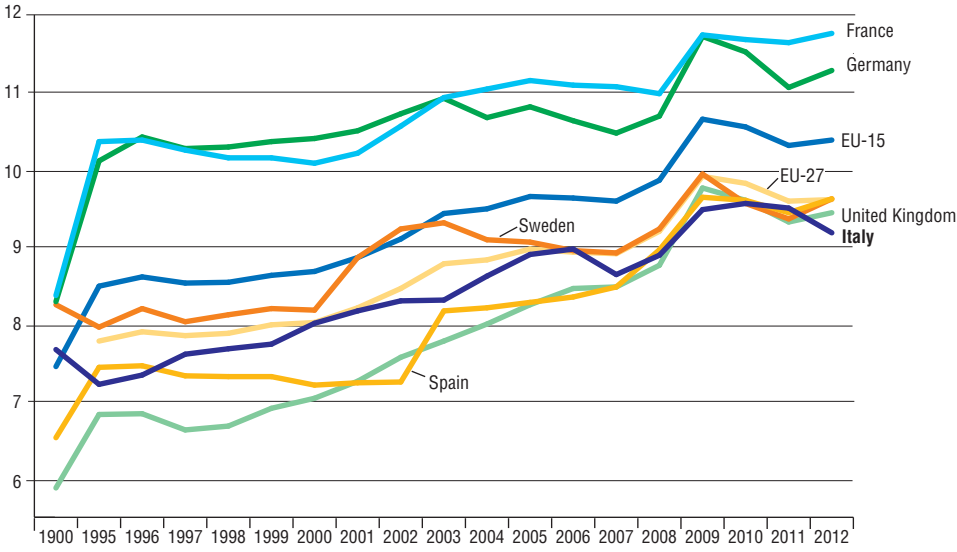
Fig. 3.1

Health expenditure as a share (%) of GDP in the WHO European Region, latest available year, 2012



Source: WHO Health For All, 2014.
Notes: CIS: Commonwealth of Independent States; TFYR Macedonia: The former Yugoslav Republic of Macedonia.

Fig. 3.2
Trends in health expenditure as a share (%) of GDP in Italy and selected countries, 1990 to latest available year (2012)



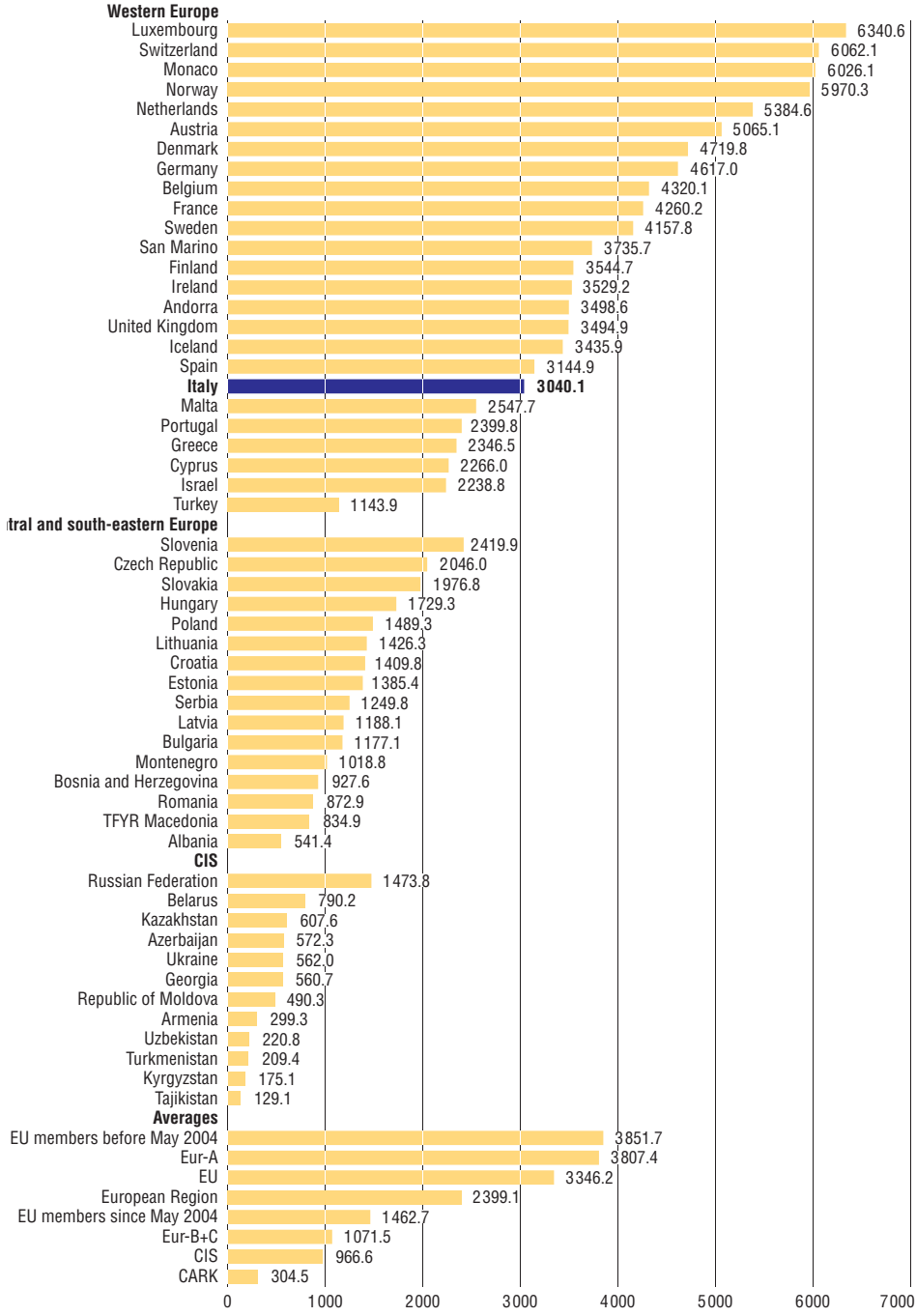
Source: WHO Health For All, 2014.

More recently, more stringent cost-containment measures have been introduced, including the requirement to reduce the number of hospital beds (to 3.7 beds per 1000 population versus 4 previously), promoting lower hospital admissions (by increasing the use of appropriateness criteria to avoid unnecessary admissions) and also reducing the average length of stay. In addition, in response to the financial crisis and the stricter public budget imperatives of the European Commission and the European Central Bank, the national government cut central transfers to regions and local governments for disability, childhood, migrants and other welfare policies.

The 2012 'Spending Review' (Decree Law n. 95/2012), the 'Stability Law' (*Legge di Stabilità*, Law n. 228/2012) and the '*Decreto Salva Italia*' (Decree Law n. 201/2011) reduced total public health financing by €900 million in 2012, €1.8 billion in 2013 and a further €2 billion in 2014. This reduction in central funding was compensated for primarily by higher co-payments (see section 3.4) and cost-saving measures to reduce pharmaceutical expenditures. Cost-containment measures also targeted the expenditure side: the government decreased outsourcing expenditures to accredited private providers by 0.5% in

Fig. 3.3

Health Expenditure in $PPP per capita in the WHO European Region, 2012



Source: WHO Health For All, 2014.
Notes: CIS: Commonwealth of Independent States; TFYR Macedonia: The former Yugoslav Republic of Macedonia.

2012, 1% in 2013 and 2% in 2014 (compared to the 2011 level). The budget for regions' pharmaceutical spending, introduced in the late 1990s to force regions to implement effective cost-containment initiatives was also revised, reducing the budget cap that is in place by 0.2% from 13.3% in 2011 to 13.1% in 2012 and 11.35% in 2013 on drugs used in non-hospital settings (patient co-payments are excluded from the budget cap). A budget cap for medical devices expenditure was also introduced: 4.8% of regional budgets in 2013 and 4.4% in 2014. Moreover, for 2012 the government imposed a 5% reduction in the value of purchasing contracts for medical goods and services signed by public health organizations (including medical devices but excluding pharmaceuticals). The measure places great emphasis on homogenizing the prices of medical goods and services across the country, allowing public ASLs and AOs to roll over or withdraw contracts if large price differences exist for the same good/service (difference >20% of the reference price) among regional health systems.

Finally, a main feature of the health-care system is regional variation in the distribution of health-care expenditure and in the supply and utilization of services. Table 3.2 shows the evolution of per capita regional health-care expenditure for selected years. While per capita public health expenditure varied widely in 1990 between Calabria (€586) and Emilia Romagna (€856), by 2012 regional differences had narrowed to between -10.2% and +17.7% of the national average. In general, regions in the centre and north were above the national average, and southern regions were below. Part of the differences in regional public expenditure are related to the different age structure of the population, with some regions having a larger share of elderly citizens than others. Such differences are also taken into account as the main adjustment to per capita funding in the allocation formula to calculate the fair amount of resources that each region should have to provide the LEA. Public health-care expenditure tends to be lower in less affluent and less economically developed regions, and in Italy such regional differences have persisted despite allocation formulas aimed at equalizing the distribution of financial resources. Nevertheless, these differences are getting smaller.

Table 3.2
Per capita health-care expenditure (in €) in Italy's regions, selected years

	1990	1995	2000	2005	2009	2010	2011	2012
North								
Piedmont	688	828	1 300	1 661	1 883	1 903	1 897	1 914
Valle d'Aosta	756	875	1 392	1 829	2 076	2 170	2 236	2 224
Lombardy	709	868	1 185	1 573	1 766	1 813	1 872	1 870
A.P. Bolzano	722	995	1 589	2 059	2 134	2 183	2 234	2 259
A.P. Trento	731	907	1 318	1 722	2 044	2 088	2 209	2 229
Veneto	746	861	1 249	1 609	1 769	1 788	1 782	1 823
Friuli Venezia Giulia	730	868	1 234	1 650	1 958	1 979	2 076	2 095
Liguria	841	957	1 342	1 837	2 026	2 006	2 043	1 983
Emilia R	856	975	1 282	1 699	1 906	1 920	1 926	1 983
Centre								
Tuscany	788	891	1 240	1 647	1 919	1 899	1 914	1 945
Umbria	766	865	1 251	1 629	1 807	1 806	1 841	1 850
Marche	834	886	1 237	1 544	1 744	1 795	1 793	1 800
Lazio	788	891	1 283	1 919	2 011	1 971	1 965	1 950
South								
Abruzzo	724	761	1 281	1 729	1 757	1 743	1 751	1 773
Molise	678	776	1 145	2 033	2 072	2 070	2 037	2 035
Campania	692	743	1 150	1 670	1 747	1 719	1 710	1 692
Puglia	671	783	1 109	1 515	1 751	1 772	1 731	1 730
Basilicata	603	707	1 071	1 505	1 753	1 796	1 818	1 816
Calabria	586	721	1 130	1 423	1 741	1 719	1 697	1 686
Sicily	700	747	1 054	1 559	1 666	1 688	1 717	1 727
Sardinia	695	860	1 163	1 632	1 826	1 874	1 932	1 951
ITALY	730	840	1 208	1 648	1 825	1 836	1 850	1 859
Coefficient of variation (%)	**9.5**	**9.8**	**10.0**	**10.1**	**7.7**	**8.1**	**9.3**	**9.3**

Source: Armeni & Ferré, 2013, using Ministry of Health and Finance data.

3.2 Sources of revenue and financial flow

In Italy, public financing accounted for 78.2% of total health spending in 2012, while 21.8% was privately financed, through OOP payments (17.8%), especially for pharmaceuticals, outpatient care and dental services, voluntary health insurance coverage (0.9%) and non-profit institutions serving households (3.1%) (Table 3.3).

Fig. 3.4 highlights that the majority of funding among EU countries comes from public sources (on average 76%). Based on this WHO data, in 2012 Italy ranked just higher than the EU average (with 78.8%) in terms of the share of

Table 3.3

Sources of financing as a percentage of total public health expenditure on health, 2000–2012

Source of financing (%)	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
General government	74.2	75.9	75.9	76.2	77.4	77.9	78.2	78.3	78.9	78.9	78.5	77.8	78.2
Private insurance	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.0	1.0	1.0	1.0	1.0	0.9
Out-of-pocket	23.1	21.1	21.0	20.8	20.1	19.0	18.6	18.8	18.5	17.7	17.5	18.0	17.8
Other[a]	1.8	2.2	2.2	2.1	1.7	2.2	2.3	1.9	1.6	2.4	3.0	3.2	3.1

Source: OECD, 2014a.
Notes: [a]Includes non-profit institutions serving households (charities, relief or aid agencies) (OECD glossary). Data on general government sources of financing vary slightly from the figures shown for public expenditure on health in Table 3.1 due to differences in data sources.

public funding devoted to total health-care expenditure. Data from the OECD shows a slight increase in this public share of health funding by 0.9 percentage points in 2012 compared with 2011 (see Table 3.3). According to national, OECD and WHO data the share of private expenditure as a percentage of total health-care expenditure decreased between 2000 and 2009, before increasing again – especially the OOP share – at the onset of the economic crisis. Conversely, the public share of total health-care expenditure, which was 74.2% in 2000, kept rising until 2009 when it reached 78.9% and then fell between 2010 and 2012 by an average of 0.2 percentage points. This decrease can be partially explained by the recent series of cost-containment policies adopted by the national government, aimed at containing public health-care expenditure, reducing overcapacity and improving efficiency.

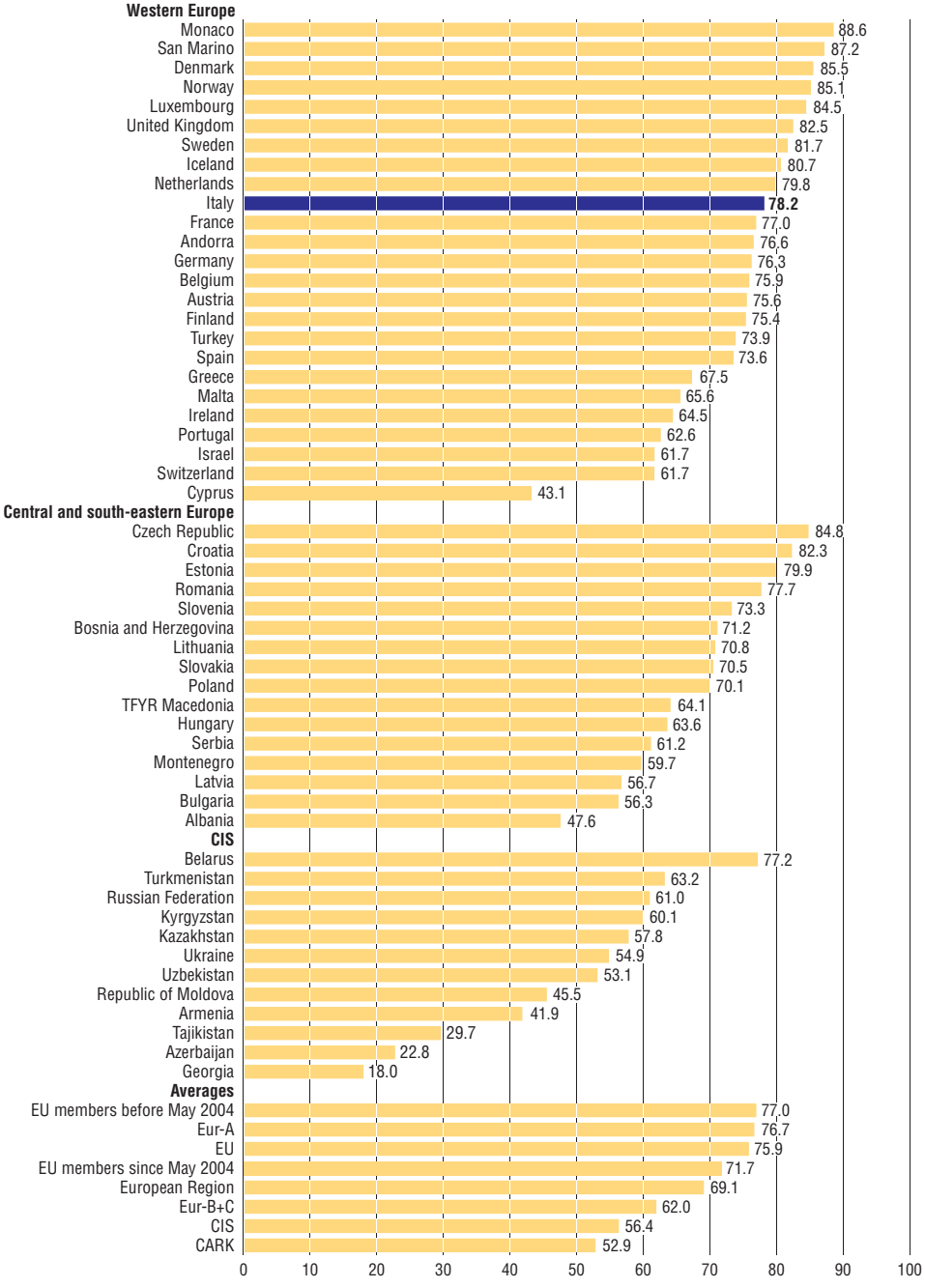
Fig. 2.1 (in Chapter 2) provides a snapshot of the financial and service flows within the Italian health-care system, more details of which are given below.

The public health-care system is financed primarily through (Table 3.4):

- An earmarked corporate tax (IRAP) on the value added of companies and on the salaries paid to public sector employees. The tax is pooled nationally and allocated back to the regions. The tax base rate is set at 3.9% of value-added produced by a company (i.e. the difference between operating revenues and costs before interest income and expenses) and regions have the flexibility to raise the level by 0.92% depending on the industry, thus leading to inter-regional differences in the corporate tax base.
- A regional surcharge on the national income tax (*addizionale* IRPEF). The tax base rate is set at 1.23% (increased in 2012 from 0.99%) and regions have the flexibility to raise the level by an additional 0.50%. The tax is either applied by regions on a regressive (flat rate) or progressive basis (adjusted for income brackets).
- A fixed proportion of national value-added tax (VAT) revenue collected by the central government to be used the national equalization fund. It is used to provide resources to regions unable to raise sufficient resources to provide the core health benefit package (LEA). Currently, 38.5% of VAT is used to fund health care.

Fig. 3.4

Health expenditure from public sources as a percentage of total health expenditure in the WHO European Region, latest available year, 2012



Source: WHO Health For All, 2014.
Notes: CIS: Commonwealth of Independent States; TFYR Macedonia: The former Yugoslav Republic of Macedonia.

Table 3.4
Distribution of main sources of health financing, 2012

Sources of financing	% of total financing
IRAP and additional IRPEF	35
VAT and other excise taxes (Decree Law n. 56/2000)	47
Other transfers from public and private organizations	9
Health organizations' revenue and other income	3
National Health Fund and Restricted National Funds	4
Other	2
Total	100

Source: Armeni & Ferré, 2013, using Ministry of Health and Finance data.

IRAP and IRPEF rate levels can be further increased by regions that are facing health-care budget deficits since regions are financially responsible for covering with their own resources any deficits incurred (see section 3.3.3). An additional 0.15% on IRAP and 0.30% on the IRPEF maximum rate can be applied by overspending regions that do not achieve health-care planning and expenditure goals expressed in their financial recovery plans. For instance, the regions of Molise, Campania and Calabria apply the highest IRAP rate 4.97% (3.9%+0.92%+0.15%) and also have the highest IRPEF tax rate.

Currently, the financing system appears to have an unevenly distributed tax base, smaller room for manoeuvre for poorer regions and the need for poorer regions to increase tax rates more than high-income regions, with subsequent negative incentives for business location. Moreover, every region is allowed to generate its own additional revenue, leading to further inter-regional financing differences (e.g. revenues from motor vehicle tax and other taxes[6]). Other sources of financing include other unrestricted resources generated by public and private organizations within regional health systems, health organizations' revenue and restricted national health funds.

3.3 Overview of the statutory financing system

3.3.1 Coverage

The SSN covers all citizens and ordinarily resident foreign nationals. Coverage is automatic and universal. Since 1998, undocumented immigrants have been granted access to basic services. Temporary visitors from countries outside the

[6] From 2010 petrol excise is no longer a source of funding for health care (Legislative Decree 6/10/2010).

European Union can receive health services by paying for the costs of treatment, while since October 2013 European Union citizens have been able to obtain free cross-border health-care provision[7] (EU Directive 24/2011). Modelled after the British National Health Service, the SSN replaced a Bismarckian system of health insurance funds from 1978. Complementary and supplementary private health insurance are also available (see section 3.5).

Health-care services provided within the SSN (i.e. the LEA) are identified by positive and negative lists using criteria related to medical necessity, effectiveness, human dignity, appropriateness and efficiency in delivery (Lo Scalzo et al., 2009). Positive lists exist for community care services (primary care, emergency care, pharmaceuticals, specialist outpatient care, integrated care, prosthesis care, ambulatory and home care, residential and semi-residential care and thermal therapy), hospital services and public health and occupational health services (Torbica & Fattore, 2005). For the latter, there is a list of general community and individual levels of preventive services that are covered, including hygiene and public health, immunization and early diagnosis tools. Dental care – specifically orthodontics and dental prostheses – is generally not covered[8] and is paid for out of pocket (see section 3.4). Negative lists include ineffective services; services that are covered only on a case-by-case basis, such as orthodontics and laser eye surgery; and inpatient services for which ordinary hospital admissions are likely to be potentially inappropriate (e.g. cataract surgery and carpal tunnel release). For the latter category, regions should provide substitute treatment at other levels of the health-care delivery system, such as day hospital and ambulatory care.

Currently, the Ministry of Economics and Finance and the State-Regions Conference are discussing an update of the health benefit package. Despite heavy cuts to health-care spending (*Spending Review*), the proposed revision promotes the inclusion of 110 rare diseases and five major chronic conditions (bronchopneumopathy, chronic osteomyelitis, chronic renal diseases, polycystic kidney disease and sarcoidosis) in the positive list of treatments covered by the SSN.

Regions can choose to offer non-LEA services, but must finance these themselves. The health benefit package does not include a specific list of mental health services. Rather, national legislation creates an organizational framework for these services, and local health authorities are obliged to define the diagnostic, curative and rehabilitative services available at each level of

[7] Long-term care services and vaccination programmes are excluded.

[8] Some limited care is available to special groups of patients defined according to age and specific clinical conditions.

care. Nor does the health benefit package explicitly define rehabilitative and long-term care services that are covered by the SSN. Instead, they are broadly referred to as services to be delivered as part of a standard, inpatient curative care program (Donatini, 2012).

3.3.2 Collection

The main source of finance for the Italian SSN is a mix of taxes applied at both regional and national level (see section 3.2). Thus, collection is performed partially at national and partially at regional level, although pooling of funds is managed at national level.

3.3.3 Pooling of funds

Historically the allocation of resources for the SSN has been a source of contention between the central government and individual regions and among regions themselves, resulting in delays in the assignment of regional shares for health care. Substantial difficulty arises in the allocation of funds due to the large geographical differences in levels of economic development, size and age of populations and long-term patterns in the availability of services. To address these issues, in 1997, the government implemented a weighted capitation system that took into consideration the current demand for health services, age,[9] geographical distribution, social deprivation and health condition of the population based on the mortality rate.

The capitation rate should, theoretically, represent the resources needed to finance services included in the LEA and represents on average 97% of total health-care resources available to regions. The remaining 3% of resources are integrated by the regional systems with additional own sources of funding; this is often the case of the five regions granted greater autonomy (home rule) (see section 1.1). It is also the responsibility of the Ministry of Health to propose the allocation of resources to each region: the proposal is then discussed by the State-Regions Conference, which must approve or reformulate it.

Under Ministry of Health specifications, annual health-care funding should be allocated to three different health-care categories as follows:

- community health care (district-level, which includes primary care services) (50%);

[9] On average, the percentage of the population aged over 65 exceeds 20%, with the highest level registered in Liguria (27.3%) and the lowest in Campania (16.6%) (ISTAT, 2012b).

- hospital health care (45%);
- public health services and preventive medicine (5%).

According to these categories, individual regions are then free to reallocate the funds received within different programmes and assign spending duties to local health authorities.[10] Thus, the percentages fixed by the Ministry of Health can be modulated at the regional level in accordance with regional planning targets (Lo Scalzo et al., 2009). In fact, while the central government regulates the health benefit package for citizens and controls the distribution of tax revenue, each region is individually responsible for the organization and delivery of services within its jurisdiction.

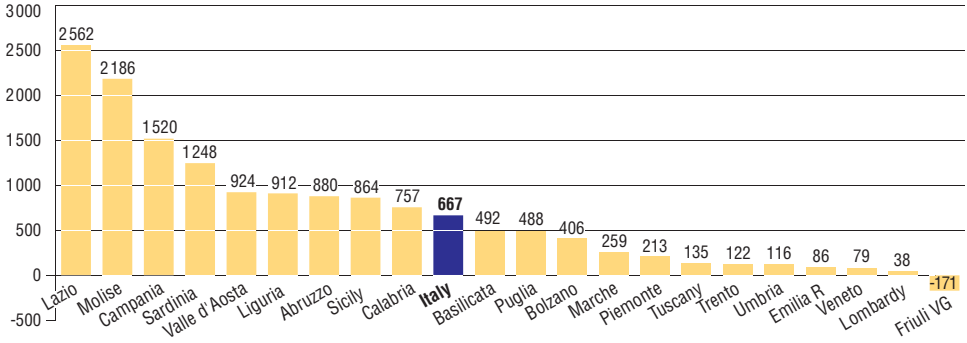
The aims of the devolution reform of 2001 have been two fold: to increase microeconomic efficiency and to increase regions' financial responsibility. From this perspective, however, there is still a notable trend for the national government to assume an increasing steering role and oversight of regional financial performance. This is illustrated by two recent developments. The first is the establishment of financial recovery plans. In 2006 it emerged that several regions suffered from severe financial deficits (Fig. 3.5) because of their health-care spending (annual deficits above 7% of total funding). Negotiated financial recovery plans were instigated to restore financial stability and to address the structural determinants of the organizational failures and cost over-runs. Additional regional resources to cover deficits are then tied to the achievement of health-care planning and expenditure goals expressed in the financial recovery plan. Thus, this process sets out a new collaborative agenda between national government and the respective regions, with disciplinary consequences for non-compliance. It has also enabled increased central government interference in regions' autonomy to fund and plan health-care services.

A second development is emerging but is not yet implemented[11] and involves significant innovation with respect to the current resource allocation formula for the regions. The basic idea is to adjust the age-weighted per capita formula with criteria that would fund hospital and community services according to 'standard costs' identified as the lowest cost registered by regions (Pamolli & Salerno, 2010; Caruso & Dirindin, 2012; Citoni & Solipaca, 2013). How to combine these two criteria has not yet been clarified. Moreover, the scheme is highly controversial because many feel that is not feasible and does not respect regional powers in the internal allocation of resources. In addition, the use of

[10] Local health authorities are funded mainly through capitated budgets.

[11] Legislative Decree n. 68/2011, implementing Law n. 42/2009 on fiscal federalism.

Fig. 3.5
Per capita health care deficits (in €) by region, 2001–2012



Source: Armeni & Ferré, 2013, using Ministry of Health and Finance data.

efficiency criteria to allocate funds is seen as risking – at least in the short term – the re-allocation of resources in favour of the northern regions and thus of increasing the existing resource gap between the south and the north.

3.3.4 Purchasing and purchaser–provider relations

Legislation approved in 1992 and 1993 (Legislative Decree n. 502/1992 and subsequent modifications) introduced a quasi-market system where both public and private providers were expected to be paid according to DRGs (for hospital care) and fee-for service (for specialist outpatient care) and could compete for patients who are free to choose any provider. However, the legislation did not make clear reference to purchasing per se. Subsequently, Legislative Decree n. 229/1999 (Bindi reform) introduced measures aimed at regulating and promoting purchasing. In general, regions may either directly purchase services or delegate the function to ASLs. Thus, depending on regional arrangements and local purchasing strategies, services can be purchased from public, private or private–public entities, potentially in competition with each other, and thus producing incentives for specialization.

On the basis of the 1992 reform, regions have to set accreditation criteria to identify providers (public and private) that respect minimum quality criteria/rules of compliance (accreditation). Private accredited providers sign a contractual agreement stating the volume, price and quality of the services to be delivered (usually renegotiated every year). The initial assumption of the purchaser–provider relationship was that regions would simply set the fundamental rules of compliance, with market incentives guiding the behaviour

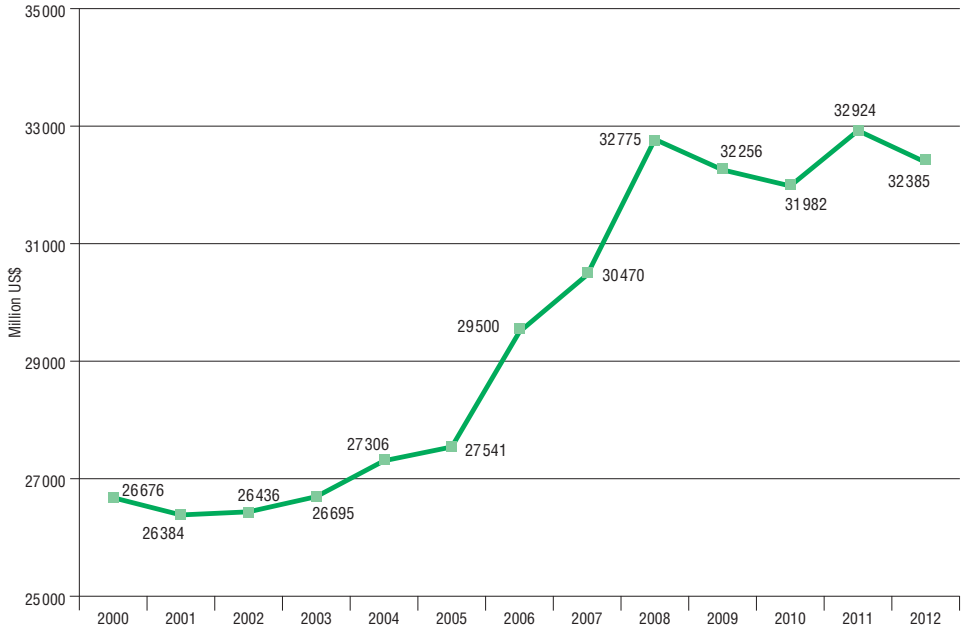
of public and private providers. Since the beginning of 1997, regions have gradually reinforced 'hierarchies' and 'institutions' to supplement and correct market incentives (Anessi Pessina, Cantu & Jommi, 2004). Since 2008 there has been a good deal of concern over the balance between public and private provision and regional turnaround plans have been introduced. For example, regions are now playing a more stringent role in differentiating fees across classes of providers (i.e. between public and private providers or between teaching and non-teaching hospitals) and introducing provider-specific funding ceilings to contain expenditure and limit incentives for volume increases for specific sets of services. Regional health systems have gradually included planning and control systems – as supplementary managerial tools to contacting – to predefine the volumes, mix, prices and possibly other features, such as waiting times and quality, to be offered by each provider. Over time, these systems have become increasingly top-down, with a more stringent regulatory framework, and focused on the financial dimension of performance due to budget constraints.

Quasi-market arrangements vary across regions and in some regions are barely present. Regions appear to be predominantly public-service based with the introduction of some internal markets mechanisms, i.e. separating the responsibility of buying health care from the provision of services within the regional health service itself. Among the 21 regional health systems, only Lazio, Campania, Molise and Lombardy present a rather high level of private acute care, with 30% of total hospitalization supplied by private providers (Ministero della Salute, 2010a). Moreover, mixed networks of public–private partnerships are developing as alternative arrangements to financing and delivering public health-care services.

3.4 Out-of-pocket payments

Out-of-pocket (OOP) payments play a significant role in Italy: between 17% and 19% of total health expenditure between 2005 and 2012 (Table 3.3), which is in line with the OECD average. In 2012, a total of more than US$32 million PPP was paid by patients for health-care services in the form of cost-sharing for services covered by the SSN or direct payments outside the SSN (Fig. 3.6).

Fig. 3.6
OOP expenditure (US$ millions) in Italy, 2000–2012



Source: OECD, 2013.

3.4.1 Cost-sharing (user charges)

Cost-sharing mainly refers to co-payments for diagnostic procedures (laboratory tests and imaging), pharmaceuticals, specialist visits and for unjustified (non-urgent) interventions provided in hospital emergency departments. Primary and inpatient care are totally free at the point of use for everyone. Co-payments for pharmaceuticals were first introduced in 1978 and are regulated at both national and regional level; co-payments for specialist visits and other outpatient services were established in 1982 and are regulated by national legislation with some regional variations. Since their introduction both have undergone several extensive changes (Lo Scalzo et al., 2009). Co-payments on medicines are applied in 15 of the regions as a flat rate or percentage of the price (pursuant to Legislative Decree n. 98/2011) (Osservatorio Farmaci, 2013).

Turning to prescriptions for diagnostic procedures and specialist visits, the co-payments structure varies among regions and has a rather long history. Since 1993, patients have paid for the total cost per visit up to a ceiling determined by law. The ceiling currently stands at €36.15 per prescription. Therefore, a patient

who receives two separate prescriptions (e.g. a magnetic resonance imaging scan and a laboratory test) after a visit has to pay the first €36.15 on each prescription. To address the public finance crisis, in July 2011 (Legislative Decree n. 98/2011) the government introduced an additional €10 co-payment for each 'prescription'. Co-payments have also been introduced for the 'unwarranted' use of hospital emergency services – that is, instances deemed to be noncritical and non-urgent (although some regions have not enforced this co-payment). Public providers, and private providers under a contractual agreement with the SSN, are not allowed to charge above the scheduled fees. Notwithstanding the centralized nature of these interventions, the national government allowed regions to decide whether to apply the co-payment in full or to enact regional rules that allow for varying co-payments according to gross family income or service tariffs. As a result, co-payments differ among the regions.

Total exemptions from cost-sharing are applied to people aged 65 and over; children aged 6 and under; the unemployed; patients who live in households with a gross income below a certain threshold (approximately €8263 for single and €11 362 for larger households); people with severe disabilities; and prisoners. People with chronic or rare diseases, people who are HIV-positive, and pregnant women are exempt from cost-sharing for treatments related to their condition. Most screening services are provided free of charge.

The introduction and increase in co-payments/user charges are emerging health policy responses to the economic and financial crisis in Europe (Mladovsky et al., 2012). However, there is a general concern about their efficiency (e.g. shifting and increasing spending in other areas of care), effectiveness (e.g. reducing the use of needed care services and thus worsening health outcomes) and increased inequity in access.

3.4.2 Direct payments

Direct payments refer to payments by users to purchase health-care services and OTC medicines that are not covered by the SSN. These services may be offered either by public or private facilities. Most private accredited hospitals also offer services to patients who directly pay for them or are covered by voluntary health insurance (VHI). A few private hospitals in Italy are not accredited by the SSN and thus work only with private patients. Services outside SSN coverage can be offered by SSN facilities within the *intra-moenia* framework i.e. where SSN professionals, mainly specialists, can also offer their services to privately paying patients within SSN facilities as part of their (part-time) private practice (see also section 3.7.2 and footnote 17). Private health-care services refer mostly to dental services, OTC medicines, diagnostic services (if not

during a hospital admission) and specialist visits. The most recent estimate using the national ISTAT survey reports that 56.8% of total specialist visits in 2005 were paid fully by patients, 27.8% applied a co-payment and the remaining 15% were free of charge (Cislaghi & Giuliani, 2008). Dentist[12] and gynaecology outpatient visits are the most common privately paid visits outside the SSN. In Italy there is a common perception that in order to ensure faster access and/or enhance consumer choice of providers, people are encouraged to opt for privately paid services. This is especially true for diagnostic and laboratory examinations (PiT Salute, 2012). Moreover, as an incentive to increase private-sector utilization, and to help families bear the burden of co-payments, private health expenditure is eligible for a tax credit: 19% of medical expenses (no caps on OOP spending) can be deducted from individual taxable income (there is a deductible of €129) (see section 3.5.3).

3.5 Voluntary health insurance

3.5.1 Market role and size

Spending on voluntary health insurance (VHI) accounted for 0.9 % of total health expenditure in 2012, with no significant change since 2000. Premiums are mainly paid by employers as fringe benefits to their employees or are requested by individuals for being affiliated to professional groups. In nominal terms, it steadily increased from 2000 to 2009 and then declined with the outset of the economic crisis (Fig. 3.7).

The VHI market plays a double role: (1) a complementary role,[13] covering user charges and co-payments required within the SSN, expenditures associated with hospital stays (per diems for private rooms or rehabilitation) or services excluded from the public system or partially covered such as dental care, home care,[14] cosmetic treatments, thermal therapy and alternative medicine; (2) a supplementary[15] role to ensure faster access and/or enhance consumer

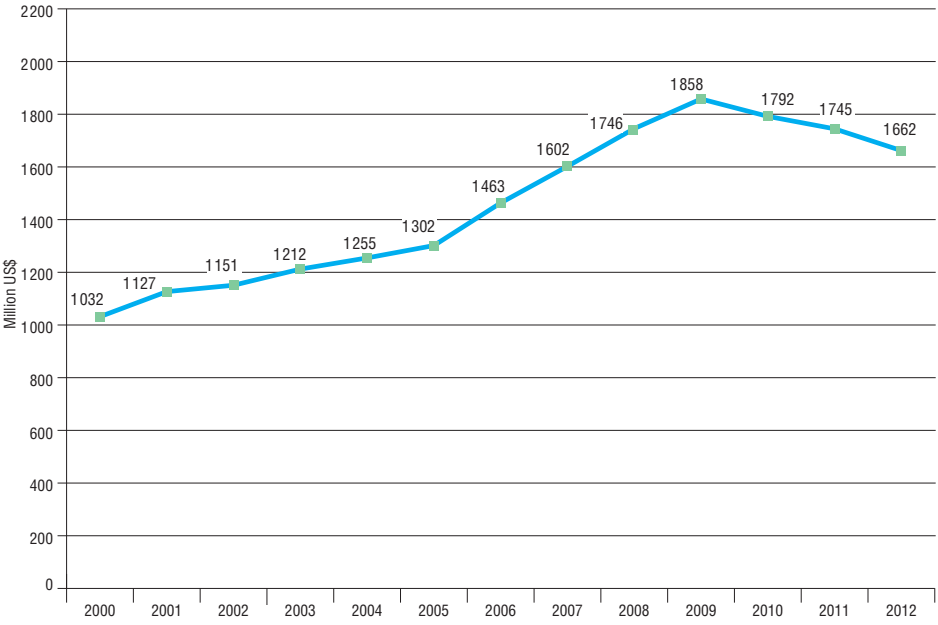
[12] Dental care is generally not covered by the SSN and is paid for out of pocket.

[13] Complementary insurance refers to services not covered by the statutory system, co-payments required or other forms of payments related to the disease episode (e.g. for a day of hospitalization).

[14] Residential long-term care is still rarely covered.

[15] Supplementary insurance refers to coverage of services covered by the SSN but for which the patients decides to go privately due to perceived better quality in the private sector, freedom of choice of the specialist and shorter waiting time.

Fig. 3.7
VHI expenditure (US$ millions) in Italy, 2000–2012



Source: OECD, 2014b.

choice of providers (i.e. intra-moenia services[16]) (De Pietro & Cavazza, 2011, 2012). Full substitutive VHI does not exist as it is not possible to opt out of the public system. There are two types of VHI plans: group plans purchased by companies to cover their employees and sometimes also their families; and individual plans purchased by individuals for themselves or for their families. Policies differ in the degree that they are complementary and/or supplementary to the public system. Survey data suggest that people mainly buy VHI to jump waiting lists for treatment (Thomson & Mossialos, 2009) and in some cases to obtain better quality of care. The availability of, and waiting times for, public and accredited health services vary across regions and areas of care. For example, the average waiting time for some diagnostic tests and specialist consultations[17] is over 7.5 months (Fattore, Mariotti & Rebba, 2013).

[16] Since 1999, doctors working in the public sector have been required to choose between public and private practice but with the possibility of working privately within a public hospital ('intra-moenia') both in the area of inpatient and outpatient specialist care. Most physicians have chosen to remain in the public sector and opted for intra-moenia practice.

[17] The longest waiting times are reported for major imaging tests such as OCM-Osseous Computerized Mineralography (15 months), mammograms (12 months), echography (8.5 months), MRI, PET and CT scans (10 months on average). Regarding specialist consultations, longer waiting times are reported for urology, ophthalmology and cardiology consultations.

In 2010 around 5.5% of the population had VHI coverage (1.33 million families), a 0.5% increase compared to 2008. Insurance take-up is concentrated in higher socio-economic groups (16.3% of the families in the highest quintile vs 1.4% in the lowest quintiles) and among middle-aged groups compared to younger and older age groups (Bank of Italy, 2012). There is also a geographical variation in the diffusion of VHI: families in the north and centre of the country are more inclined to have VHI (7.6% and 7.2% respectively) compared to those living in the south (1.3%). Education is another determinant of VHI take-up, with people with higher education being more likely to be insured (Bank of Italy, 2012).

3.5.2 Market structure

VHI plans are sold by collective complementary private insurance funds (called Integrated Health Funds or *Fondi integrativi del SSN*) and private insurance companies. Integrated Health Funds are for-profit or not for-profit private health insurance funds that are, after the SSN (first pillar), considered to be the second pillar of health insurance. Integrated Health Funds may provide both complementary and supplementary cover. They are allowed to reimburse user charges, services provided privately within public facilities and expenditures for services that are complementary with respect to 'SSN essential services', i.e. not included in the SSN benefit package and supplied only by accredited private structures integrated with the SSN or by SSN providers themselves. Table 3.5 outlines the different kinds of VHI providers.

Table 3.5
Types of VHI providers in Italy

VHI provider	Profit status	Types of plans offered	Details	Number of providers (2010)[a]
Fondi Aziendali	Not-for-profit	Corporate (firm-specific insurance funds)	Employer-specific insurance funds; provided by companies such as FIAT, ENI and Luxottica; can be managed internally by the companies themselves or by commercial insurance companies on their behalf; people over 75 are usually not eligible for such schemes but they cover retired people provided that they were enrolled for a minimum time span before retiring.	n.a.
Fondi di categoria	Not-for-profit	Collective	Insurance funds managed by organizations of categories of professional workers; they cover retired people provided that they were enrolled for a minimum period before retiring.	n.a.
Società di mutuo soccorso	Not-for-profit	Individual or collective policies	Insurance funds organized in the form of mutual aid societies	3
Commercial insurance companies	For-profit	Corporate and individual	Non-life health insurance companies; the biggest eight account for 50% of the commercial health insurance market (ANIA, 2012)	65

Sources: authors compilation and [a]ISTAT, 2012b.
Note: n.a., data not available.

The Private Insurance Supervisory Authority (ISVAP) (primarily) and the Ministry of Health are the bodies responsible for regulating and monitoring the VHI market. In addition, commercial insurance companies are regulated by the Code for Private Insurance established in 2005.

3.5.3 Market conduct

Historically, there have been differences between the for-profit and not-for-profit VHI sectors. For instance, for-profit insurers apply individual risk rating for both individual and group policies, while in the non-profit sector the biggest funds use community rating (Giannoni, 2009). In addition, tax treatment varies depending on the type of insurer. VHI has been subsidized through various forms of tax incentives. Currently, 19% of medical expenses can be deducted from individual taxable income, even if part or all of these expenses are covered by a VHI policy (there is a deductible of €129). For workers' associations, Integrated Health Funds and mutual organizations VHI contributions are deductible up to a limit of €3615.2 per worker per year.

Private insurers are not vertically integrated with providers. People with VHI coverage can usually seek treatment by private and public providers within the intra-moenia framework. Several insurers, both profit and non-profit, operate selective contracting and incentivize patients to use closed lists of providers.

3.5.4 Public policy

Traditionally, VHI was seen as a marginal sector for a small and affluent segment of the population and received little attention from the government. However, since 1992 VHI, and especially the Integrated Health Funds, were introduced and promoted in order to manage the growth of private health-care expenditure, without forgoing the key features of solidarity and universality of the SNN system. Since 2010 the government has required insurance companies that provide complementary policies to be listed in the national register of Integrated Health Funds (complementary insurers/*Fondi Integrative Sanitari*) and to allocate at least 20% of premiums to dental care and social care (i.e. mainly long-term care) for subscribers who are not self-sufficient (in terms of age and physical impairment) in order to gain fiscal benefits. In the future, such complementary SSN insurance funds could gain greater relevance to secure financial sustainability of the SSN and to promote integration between health and social care.

3.6 Other financing

Other sources of financing are not relevant in the Italian context as almost all financing comes from public funds (78.8% of total expenditures), direct payments from patients (OOP 17.8%) or forms of complementary private insurance (0.9%). For instance, there is no parallel health system providing services for certain categories of employees and public officials as is the case for some European countries such as Portugal. In June 2008, penitentiary health care was transferred to the responsibility of the SSN. The only exception is a parallel health-care system for active military personnel funded by the Department of Defence. Minimal external funding comes from bilateral/multilateral organizations or donations, mainly for providing services to undocumented immigrants. Italian regions can apply for European Structural Funds for capital investments, human development and cross-border cooperation within the health-care sector. Moreover, Italy attracts some (competitive) international grants from the European Commission for specific health research projects.

Social care services for the elderly and people with disabilities (e.g. community home care) are not the responsibility of the Ministry of Health but are dealt with by local authorities (mainly municipalities) and volunteer associations or non-profit social service cooperatives. Unlike residential and semi-residential care (see section 5.8), community home care is not designed to provide physical or mental care services, but rather to enhance a patient's autonomy by providing additional assistance throughout a course of treatment or therapy.

3.7 Payment mechanisms

3.7.1 Paying for health services

Payment rates for hospital and outpatient care are determined by each region, with national rates (determined by the Ministry of Health) as a reference. More specifically, payment for hospital care (ordinary and day hospital treatments) is based on DRG tariffs, although this method is generally complemented with other forms of payments (see below) and is not applied to hospitals run directly by local health authorities. National tariffs are used to set inter-regional hospital patient mobility rates. DRG tariffs are set at the national level, presumably based on average production costs, and then regions can modify the tariffs implemented in their own health systems. Consequently, there is considerable

inter-regional variation in the prospective payment system, the frequency of fee schedule updates, their value, how to deal with innovation and the tools employed to monitor providers and patterns of care. Since 2009 regions have adopted the ICD-9-CM (International Classification of Diseases, 9th revision, Clinical Modification) classification and DGR version 24. In addition, in all regions, a portion of funding is administered outside the prospective payment system (e.g. funding of specific functions such as emergency departments, teaching programmes, organ transplants, blood and tissue banks). All regions have mechanisms for cutting tariffs once a spending threshold for the hospital sector or even each provider is reached, in order to contain costs and offset incentives to increase admissions (Fattore & Torbica, 2006). The only two forms of hospital treatment for which a bed-day rate still applies are for rehabilitation and long-term care. These two types of hospital care have a progressive rate reduction scheme to prevent the unnecessary lengthening of a hospital stay. A length-of-stay longer than a set limit (usually 60 days) triggers a 40% reduction in the bed-day rate (psychiatric care does not follow this rule). Moreover, budgets for specific care services (e.g. emergency services, oncology treatments, hospital-teaching activities) are not based on DRG tariffs but are paid on the basis of global budgets.

Reimbursement for outpatient specialist care, diagnostic services and imaging is based on tariffs defined by unit of service. Specialist/ambulatory care is generally provided by local health authorities or by public and private accredited hospitals under contractual agreement with a local health authority. Once referred, patients are given free choice of any public or private accredited hospital. Across regions there is great variation in nomenclature (coding and classification systems) used to list outpatient services. In addition, there are inter-regional differences on the tariffs adopted since regions are allowed to set their own reimbursement rates (using national rates as maximum). In general, cost assessment to define tariff levels are not conducted regularly and based on a gross costing approach in which the total costs for ambulatory care services is first allocated to different specialty areas and then to specific services; there are very few cases of cost assessment using a micro-costing approach (Fattore & Torbica, 2006).

Primary/ambulatory care is managed by GPs and is paid via a combination of capitation and fee-for-service, sometimes related to performance, and is regulated under national and regional contracts. Capitation is adjusted for age. The majority of GPs operate in solo practices, although the state and most regions have offered economic incentives to encourage group practice, to foster greater integration between GPs and social care and to promote home care and

health education (see section 5.3). Moreover, regional health-care systems are developing integrated services for non-acute care involving GP groups as the principal agents to respond to post-acute and chronic care needs. An innovative example in delivering and paying for chronic care is found in Lombardy (CReG – chronic related group) where, for a few conditions, the region sets a predetermined amount of resources needed for each pathology – similar to the DRG mechanism for acute care reimbursement – and defines an annual amount of resources available for each chronic patient according to the severity of the condition. The prospective payment system covers all ambulatory, prosthesis, pharmaceutical and home care expenses that are needed for the appropriate clinical and organizational management of patients' chronic conditions. CReG tariffs are applied to accredited providers (public and private health-care providers and physician groups) that deliver services in coordination with ASLs. Overall, Lombardy is redesigning the medical practice of chronic care with expected improvement in the quality of life of chronic patients through enhanced access to primary care, and long-term savings resulting from fewer hospital admissions, visits to hospital emergency departments and specialist physician consultations.

Paying for long-term care and residential or semi-residential services where health care and rehabilitation are provided (see section 5.8) is based on cost-sharing between the patient and his/her municipality with important variations across regions and even municipalities. The level of cost-sharing is generally determined by patient income.

Mental health care is provided by the SSN in a variety of community-based, publicly funded settings, including community mental health centres, community psychiatric diagnostic centres, general hospital inpatient wards and residential facilities (see section 5.11). New admissions to mental health hospitals were banned by legislation enacted in 1978 (Law 180/1978) and currently no such specialized hospital is operating in Italy. Flat co-payments apply to diagnostic procedures, pharmaceuticals and specialist visits. In relation to pharmaceutical care, payment is differentiated according to product classes (A, H and C class):

- Class A includes essential products and those intended for chronic diseases and are fully reimbursed by the SSN.
- Class H includes products that are only fully reimbursed in hospital.
- Class C includes other products that do not have the characteristics of Class A and are not reimbursed.

3.7.2 Paying health workers

In general, doctors employed by the SSN are salaried and have civil servant status (including physicians or specialists providing mental health services), with the exception of GPs and paediatricians who are independent professionals with a special contract with the SSN. GPs and paediatricians delivering primary care and preventive medicine are paid via a combination of capitation (with a ceiling for the number of patients[18]) and fee-for-services for some interventions. All the doctors employed by ASLs and AOs work and are compensated according to national contracts that generally define monthly salaries and performance-related payments administered at local level.

More specifically, GPs and paediatricians are paid via a combination of capitated payments adjusted for patient characteristics (e.g. age and chronic conditions in some regions), and fee-for-service, sometimes related to performance. Delivery and payment of primary care workers are regulated under national, regional and ASL-based contracts. A national contract (*Accordo Collettivo Nazionale*) is usually negotiated every two to three years between the government and union representatives (the more prominent are FIMG, SNAMI and SMI) and determines the tasks and functions of primary care physicians as defined by the benefit package and the capitation rate. The last national collective bargaining agreement was signed in July 2010. Regional agreements (*Accordo Integrativo Regionale*) adjust the national contract to the regional context. Finally, ASL-based contracts (*Accordo Attuativo Aziendale*) detail projects and activities required in each local setting for the implementation of national and regional contracts and provide further scope for local initiatives.

The majority of GPs run solo practices, although national contracts and regional agreements encourage group practices by offering supplements to capitation, extra resources for the practice, including nursing and staff support. A share of GP income comes from extra payments for participation in special programmes (such as the development of electronic patient records) or achievement of specific policy targets (such as improving prescription appropriateness). Financial rewards exist for providing additional services such as home care, care for the aged in residential homes and vaccination of special groups, such as flu shots for the elderly. A few services are paid on a fee-for-service basis, including certificates of good health, disability statements and services provided during night or non-working hours. Physicians providing

[18] 1500 patients maximum for GPs and 800 for paediatricians.

primary care at night and during weekends when GPs and paediatricians are not on duty and other specific categories of physicians working on specific projects/ activities receive an hourly rate determined at national level.

Hospital-based physicians are salaried employees and their level of payment is contracted at national level with a separate contract subject to review every 3–5 years. Salary is a function of grade and performance, related to locally defined annual targets. Since 2007, freezing doctors' salaries and periodic across-the-board hiring freezes have been commonly implemented policy tools in the public health-care sector.

All salaried doctors are allowed to practise privately and thus can earn additional income on a fee-for-service basis. A 1999 reform (Decree Law 229/1999) created attractive incentives for private practice within SSN facilities (intra-moenia) versus activities carried out in private settings (extra-moenia). Employment contracts set forth a scheme of incentives and bonuses, including up to a 20% increase in salary and career promotion for those who chose intra-moenia practice. Doctors had to choose one or the other scheme, and a survey conducted in early 2000 recorded that most doctors (91.6%) and other SSN professionals chose the intra-moenia option (France, Taroni & Donatini, 2005). In 2004, a change in legislation (Decree Law 81/2004) allowed public-hospital physicians to decide – on an annual basis – between an exclusive employment relationship and independent practice outside the SSN and abolished the career advantages tied to choosing the first option. Doctors choosing independent practice must register with the relevant ASL, indicating the place and hours of their private service. All public physicians choosing to conduct private care within public hospitals pay a proportion of their extra income to the hospital. Recent legislation (Law 189/2012) promotes the creation of ad hoc facilities within public hospitals to practise intra-moenia activities.

Dentists working within the SSN come under the category of specialists and are paid a salary. In addition, pharmacists employed by the SSN managing pharmaceutical care within public facilities are paid with a monthly salary.[19] As with other public health workers, nurses and other staff are paid according to national collective agreements negotiated every three years by representatives of the trade unions and government.

[19] Pharmaceuticals are distributed to the public via a network of pharmacies, on average, one for every 3293 inhabitants. The bulk of pharmacies are private (16 425), with a small number of public pharmacies (1614) owned and operated mainly by local authorities (Federfarma, 2012). The regions are responsible for licensing and regulating pharmacies, which are remunerated with a nationally negotiated percentage margin of SSN drug retail prices.

4. Physical and human resources

Over the last five years, Italy has decreased investment in expensive infrastructure and has even halted some projects due to cost-cutting measures, although in 2013 the government announced 162 new capital investment plans totalling nearly €1.5 billion. In addition, in a period of increasing decentralization and recent national-level cost-containment measures, the regions have sought additional sources of funding for health infrastructure. Sources include ad hoc regional funds, European funds, self-financing by local health service organizations, and traditional and non-traditional forms of financing such as mortgages or project financing.

In terms of hospital sector infrastructure, in 2012 Italy had 3.4 hospital beds per 1000 people; 80% of which are dedicated to acute care (higher than the EU average of 69%).

The importance of medical technology has generally grown over time. The number of MRI units, CT scanners and PET units is constantly rising, at least doubling over the last 10 years to become one of the highest per capita in the EU, albeit with great regional variability. E-health initiatives are promoted by the government and current development is focused on increasing online services, electronic health records (EHRs) and the digitalization of medical prescriptions and certificates.

With 3.7 practising doctors per 1000 people, Italy is slightly above the EU average of 3.4 – though the number of nurses is relatively low, at 6.3 per 1000 people, and the ratio of nurses to doctors (roughly 1:1) is among the lowest in the EU – the average is 2.5 nurses to every doctor. This is despite an increase in the number of health-care professionals over the last 25 years, especially practising nurses and midwives, with the former becoming more active in the management of patients with chronic conditions. In terms of health worker mobility, Italy is predominantly a destination country, with higher levels of

inflows for certain categories of health professionals such as nurses and care assistants (both legal and illegal), largely due to chronic nursing shortages, which have shifted attention to recruitment from abroad. In contrast, emigration mostly affects medical doctors.

4.1 Physical resources

4.1.1 Capital stock and investments

Until 1988, a proportion of the National Health Fund was earmarked for capital investment in the health sector (including new buildings, renovations, purchasing of technologies), with a central committee approving which projects to fund. This funding stream provided a stable flow of resources and procedural stability that allowed regional planners to implement projects in the medium to long term. The programme was renewed in 1998 with the approval of new investment plans (€17.5 billion) to improve health-care infrastructure. During this second term, this source of funding was replenished with ad hoc funding allocated by the central government. For example, in 2000 a lump sum was allotted to the promotion and modernization of radiotherapy facilities; and again in 2001 for the expansion of structures reserved for physicians working intra-moenia (see section 3.7.1). Again, in 2008 the Financial Law renewed the investment plan, raising the funds to nearly €20 billion. To coordinate the capital investment plan and monitor its implementation across the country, the government set up an independent assessment body to evaluate the implementation of publicly funded facilities' investment (*Nucleo valutazione e verifica investimenti pubblici*).

Given the increased autonomy and responsibility of regions, they also activated additional sources of funding for health infrastructure. Several sources have been explored, including ad hoc regional funds, European Union funds, self-financing by ASLs and AOs (such as mortgages, budget advances and the sale of assets) and non-traditional forms of financing (such as project financing). Over the last five years, Italy has decreased investment in expensive infrastructure and has even halted some projects due to cost-cutting measures. In 2012, the central government approved a €1 billion reduction in hospital building and technology investments. Some commentators consider this measure to be a high risk one in relation to health workers' and patients' safety, given that the mean age of Italian hospitals is 70 years (De Belvis et al., 2012).

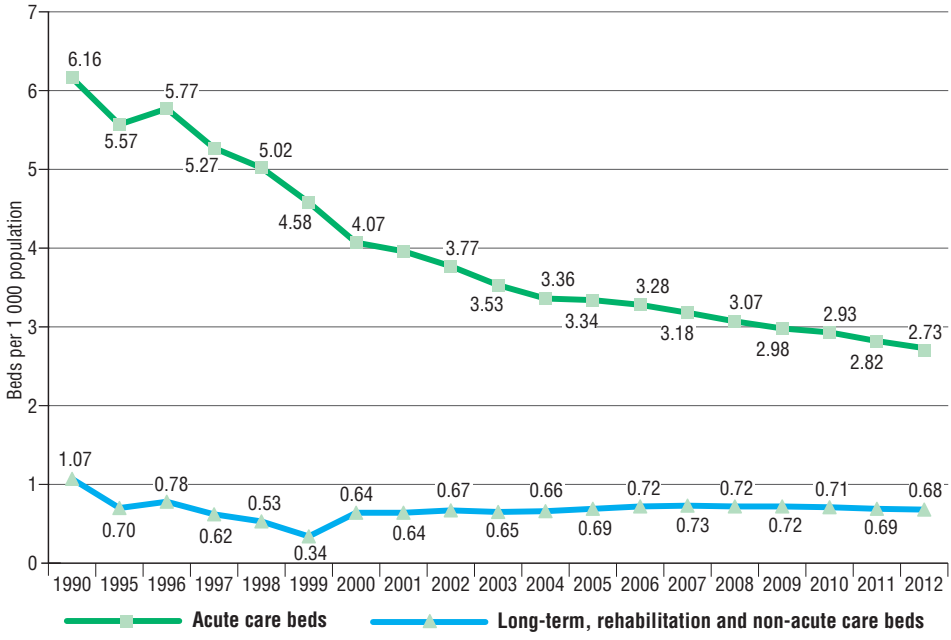
4.1.2 Infrastructure

In 2012, Italy had a total of 202 676 hospital beds (including general hospital, mental health and other specialized hospital beds) (OECD, 2014b) of which 80% were dedicated to acute care and the remaining to rehabilitation and long-term care activities. On average, 68.4% of hospital beds are public while the remaining are in private facilities accredited by the SSN, with a high concentration of private accredited beds in the regions of Lazio, Campania and Lombardy (OECD, 2014b).

Fig. 4.1 shows the declining trend in the overall number of beds from 1990 to 2012, totalling 3.4 beds per 1000 people in 2012. In particular, the number of acute hospital beds per 1000 population decreased from 6.16 in 1990 to 2.73 in 2012. This figure does not include day-care or non-acute care beds (see also section 5.4.3). The current legislative targets are 3.7 beds per 1000 population of which 0.7 should be for non-acute care beds. However, interregional variability exists.

Fig. 4.1

Mix of beds in acute care hospitals, psychiatric hospitals and long-term care institutions, 1990–2012

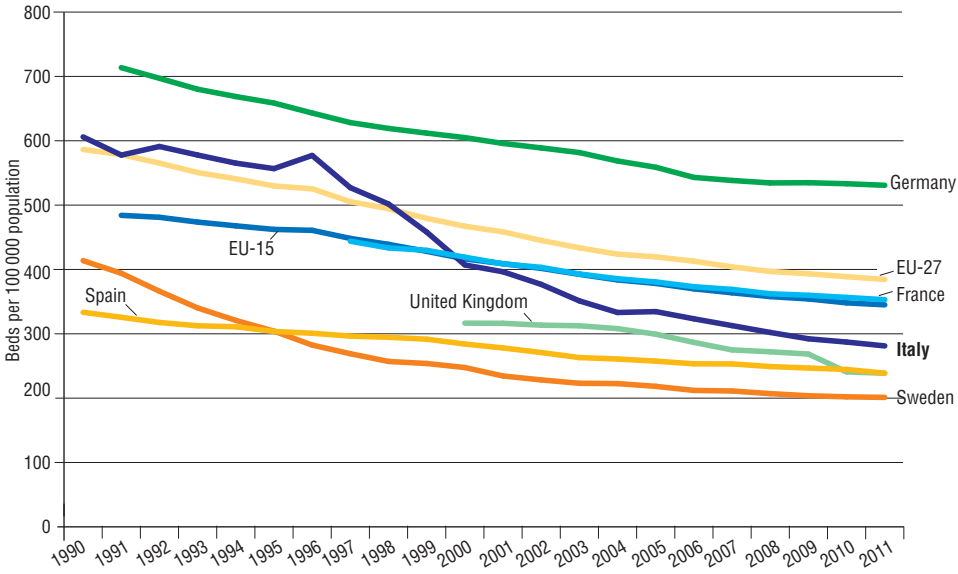


Source: OECD, 2014.

Fig. 4.2 clearly shows that the trend over time for acute care hospital beds per 100 000 population in Italy is comparable to the overall trend of other European countries. In Italy there was a sharp decrease in bed supply particularly between 1996 and 2000, from 577 beds per 100 000 to 407 beds per 100 000. In addition, the bed occupancy rate has been increasing steadily since 2003 (Fig. 4.3); it is higher than that of the other countries, except for Germany and the United Kingdom, and is higher than the EU average. The average length of stay in Italy has been falling steadily since 1990, comparable to the EU-15 average, along with Spain and the United Kingdom; it is considerably lower than in Germany (Fig. 4.4).

Fig. 4.2

Beds in acute hospitals per 100 000 population in selected countries, 1990 to latest available year

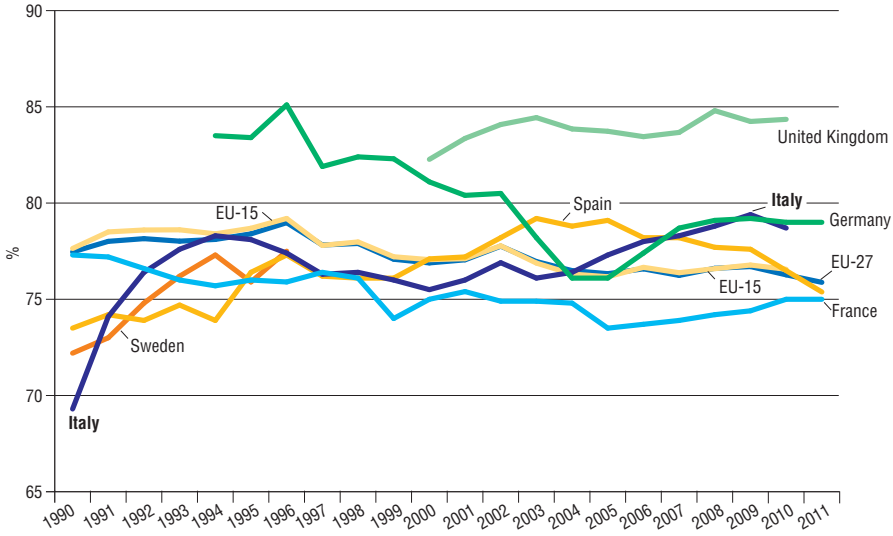


Source: WHO Health For All, 2014.

In Italy, the change in bed utilization over time is an expected result of the policies aimed at controlling health expenditure, increasing hospital efficiency and reducing waste. Therefore, on the one hand, there has been a consistent reduction in bed numbers, in compliance with national guidelines, including the target of 160 hospitalizations per 1000 inhabitants of which 25% should be provided in day-hospital settings (Decree Law 95/2012); on the other hand, there has been a reduction in the number of health-care facilities particularly via

Fig. 4.3

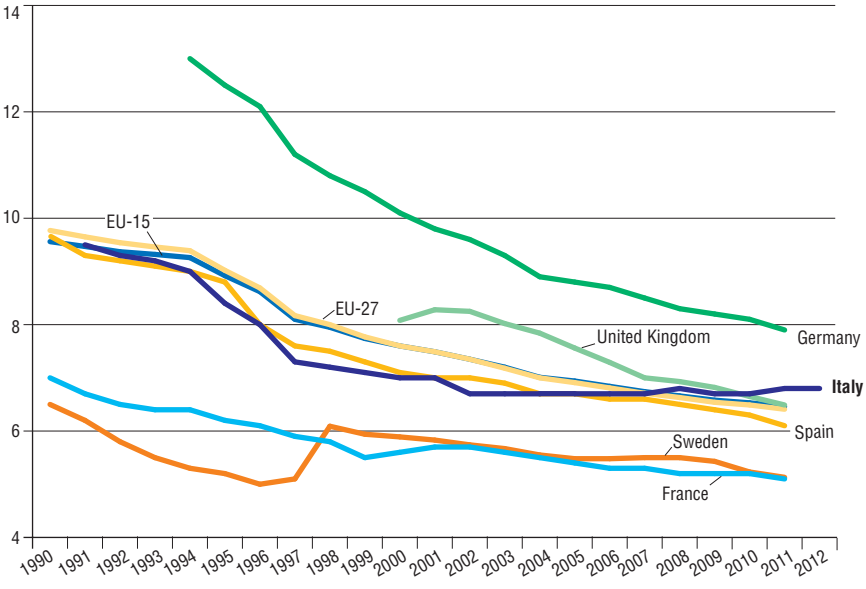
Bed occupancy rate (%) in acute care hospitals only, in Italy and selected countries, 1990, latest available year



Source: WHO Health For All, 2014.

Fig. 4.4

Average length of stay (days), in acute care hospitals only, in Italy and selected countries, 1990, latest available year



Source: WHO Health For All, 2014.

the closure of small hospitals or the transformation of acute care facilities into other types of services to meet changing needs (for example, to provide care for those with chronic diseases or care for the frail and elderly).

Nowadays, many hospitals are no longer organized along the lines of clinical specialties or departments; instead, the use of space and beds is determined by managers, while multidisciplinary teams of clinicians treat patients according to the level of care required. Adoption of lean management techniques is also developing in Italy, where hospitals are encourage to think in terms of systems and process management (Carbone et al., 2013). An example of this is the Careggi Hospital in Florence, where clinical activities are performed in 10 clinical departments created on the basis of health needs (Rechel et al., 2009). The new health-care environment has resulted in other innovative approaches to capital assets and working practices. For example, some hospitals are now open only Monday to Friday ('week hospital') for elective surgery and other planned treatments so patients are discharged before the weekend. Evaluation of this experimental model is ongoing and is part of a planned network of care in a few regions (Piedmont and Tuscany). These are some of the regions that have moved away from a hospital-centred form of regional planning towards one that integrates primary and community health services and encompasses the whole spectrum of health-care services.

4.1.3 Medical equipment

The importance of medical technology has generally grown over time. The number of MRI units, CT scanners and PET units is constantly rising, doubling between 2000 and 2011 in the case of CT scanners and more than tripling in the case of MRI units (Table 4.1). In 2011 there were 30.4 CT scanners per million population and almost 20 MRI units per million population available in hospital (including public, private accredited and non-accredited providers) and ambulatory settings (public and private accredited providers) (OECD, 2014b). However, the diffusion of medical technology is not evenly distributed across the country. Some regions, such as Liguria, the central regions, as well as Molise, Basilicata and Sardinia have high levels (higher than the national average) of technologies available in public facilities while others in the south have constantly lower levels (Campania, Puglia, Calabria and Sicily).

Table 4.2 highlights this uneven distribution with the number of total MRI units ranging from 7.2 units per million population (Campania) to 31.2 (Molise) and CT scanners ranging between 20.2 (Friuli-Venezia Giulia) and 43.8 (Molise). PET units are available only in high density regions, with the highest available number in Friuli-Venezia Giulia.

Table 4.1

Number of MRI units, CT scanners, PET per million population, 1990–2011

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
MRI units	4.11	5.82	6.25	7.76	9.07	10.83	11.84	13.98	14.84	16.73	18.48	19.72
CT scanners	14.80	18.01	18.99	21.13	23.01	24.00	23.80	26.01	27.52	28.89	30.06	30.44
PET	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.77	2.01

Source: OECD, 2014.
Note: OECD data includes equipment in public as well as private SSN-accredited and non-accredited facilities; n.a., not available.

Table 4.2

Number of MRI units, CT scanners, PET per million population in public and private-accredited hospitals and ambulatory settings, Italy 2011

	Public			Private accredited		
	MRI	CT	PET	MRI	CT	PET
North						
Piedmont	10.1	19.3	–	4.3	3.4	–
Valle d'Aosta	23.4	31.2	–	–	–	–
Lombardy	11.2	17.5	0.2	5.3	5.0	0.1
A.P. Bolzano	9.8	15.8	–	3.9	3.9	–
A.P. Trento	7.6	20.8	–	5.7	5.7	–
Veneto	12.4	17.0	0.2	2.0	1.4	–
Friuli Venezia Giulia	8.1	17.8	1.6	4.0	2.4	–
Liguria	19.2	22.3	–	–	–	–
Emilia R	9.5	19.0	0.2	6.8	3.6	0.2
Centre						
Tuscany	13.3	20.5	0.8	1.6	2.7	–
Umbria	12.1	23.2	–	1.1	2.2	–
Marche	14.7	21.7	–	4.5	3.8	–
Lazio	18.2	21.5	–	5.6	6.8	–
South						
Abruzzo	8.9	17.9	–	8.9	7.4	–
Molise	28.1	34.4	–	3.1	9.4	–
Campania	3.6	13.7	0.3	3.6	8.7	0.2
Puglia	7.6	17.1	0.5	2.9	5.1	–
Basilicata	11.9	23.8	–	1.7	1.7	–
Calabria	6.5	18.9	–	5.0	9.4	–
Sicily	6.9	19.4	0.2	4.6	9.7	0.2
Sardinia	9.5	17.9	0.6	3.0	4.2	–
ITALY	**10.6**	**18.6**	**0.2**	**4.2**	**5.2**	**0.1**

Source: Ministero della Salute, 2013a.
Note: The difference in the total numbers of medical imaging technologies between Table 4.1 and Table 4.2 is due to differences in data collection. In Table 4.1, the OECD source includes public facilities as well as private-accredited and private non-accredited providers in the national total. In Table 4.2 data by the Ministry of Health includes public facilities and only private-accredited facilities.

Purchasing of medical technology differs between type of technology (e.g. drugs, prosthesis or diagnostic devices). In general, medical technologies are purchased through open public tender procedures. Negotiations take place at the local level between health providers and manufacturers/wholesalers even though there is a tendency to centralize purchasing as a way to strengthen market power and reduce hospitals' administrative costs (Cappellaro, Fattore & Torbica, 2009). For instance, various types of voluntary and compulsory consortia to centralize technical and administrative activities between health providers have been established (called *centrali d'acquisto*).

4.1.4 Information technology

The use of information and communication technologies in the health-care sector is increasing in Italy as in other European countries. E-health initiatives are promoted by the government and current development is focused on the overall plan to implement the New Health Care Information System (NSIS, *Nuovo Sistema Informativo Sanitario*), which is an information system and governance tool to assist, monitor and oversee all primary levels of health-care services (see section 2.7.1). Another relevant initiative is included in the *E-Government Plan 2012*, which aims to encourage government innovation within the entire public sector, including health care, where the focus is on increasing online services, developing EHRs and digitalizing medical prescriptions and certificates.

In 2010 approximately 86% of Italian GP practices used a computer. Overall, 71% of Italian GP practices are connected to the Internet and broadband connections can be found in almost half the practices (49%) (Tamburini et al., 2010). With regard to the use of eHealth applications (e.g. EHR or digitalization of medical prescriptions), the best results are achieved for the storage of administrative data (patient summary) and the use of computers for consultation purposes. However, the exchange of electronic patient data is not yet well established: only 3% of GPs exchange administrative data with other care providers and just about 1% of GP practices use electronic exchange of prescriptions (e-prescription) (Tamburini et al., 2010).

At regional level, many patient summary pilots are running and are highly developed; some regions, such as Lombardy and Emilia Romagna, have already fully deployed a patient summary that includes administrative data and medical history (Tamburini et al., 2010). Italy is also involved in the European epSOS (European patients Smart Open Services) project where the Italian initiative – IPSE – focuses on the transregional transfer of medical data and the

establishment of a patient summary as well as e-prescription. Regional pilots for e-prescription have run in Italy since 2002. In the region of Emilia Romagna, 'SOLE – Online Healthcare' programme[20] aims to develop an integrated (inter-operational) telematic network of hospitals and health-care professionals, including the electronic management of prescriptions.

Italy's background in telemedicine includes the €50 million (TELEMED) initiative in 1991 that for 10 years represented a focal point for several applications. Many telemedicine pilots and projects are currently ongoing, including the 'Renewing Health' European funded project,[21] which started at the beginning of 2010, coordinated by the Veneto Region. This project aims to promote the adoption of remote patient monitoring and treatment for those suffering from chronic conditions.

4.2 Human resources

4.2.1 Health workforce trends

In 2010 the SSN employed a total of 646 236 health-care personnel, of which 70.2% are health staff, 18.1% technical staff and 11.7% administrative staff. Among health staff, 23.7% are physicians and dentists, 58.3% are nurses and the remaining 18% include other health professionals (pharmacists, biologists, physiologists and veterinarians[22]) (Ministero della Salute, 2013b). Almost 64% of SSN employees are women, with a marked concentration in nursing, rehabilitation and administrative (Ministero della Salute, 2013). Overall, the number of health-care professionals increased from 1990 to 2011, especially with regard to practising nurses and midwives. In the last ten years an increase of 18% in the number of nurses and midwives has been registered (Table 4.3).

The number of active physicians grew during the 1990s and early 2000s, declining to the minimum of 3.65 physicians for every 1000 population in 2006. The trend is now stable at around 4 active physicians per 1000 population. Over the same period, dentists also increased with a peak in 2006 (0.63 per 1000 population). The number of active pharmacists is available from 2004 only and here too there is an increase up to 2008 followed by a small decline.

[20] Also known as Emilia Romagna Digitale.

[21] See http://ec.europa.eu/information_society/apps/projects/factsheet/index.cfm?project_ref=250487.

[22] In Italy, veterinarians working in local health authorities are counted as health professionals. The veterinary activities of local health authorities are divided into two functional areas: one dealing with animal health and hygiene of animal farming and production, the other with production and trade of food of animal origins.

Table 4.3

Health-care personnel in Italy per 1000 population, 1995–2011

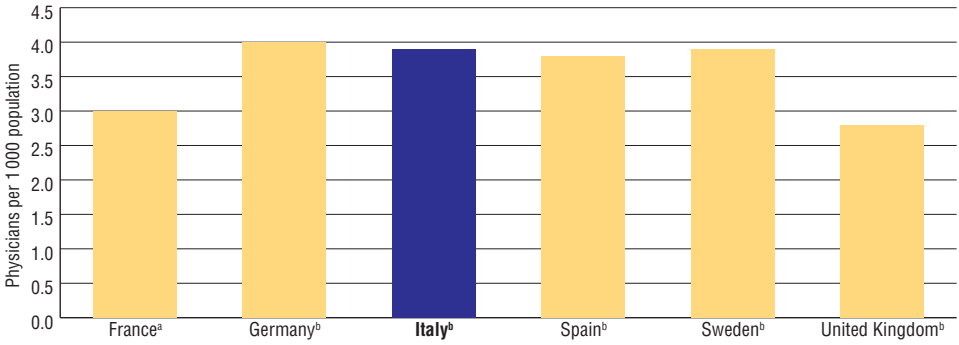
	1995	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Active physicians	3.89	4.16	4.37	4.43	4.11	4.15	3.79	3.65	3.84	4.13	4.10	3.92	4.00
Practising nurses and midwives	n.a.	n.a.	n.a.	13.15	13.22	13.67	14.26	14.13	14.31	14.79	14.97	15.2	15.50
Active dentists	0.40	0.56	0.54	0.54	0.54	0.57	0.60	0.63	0.57	0.48	0.52	0.56	0.58
Active pharmacists	n.a.	n.a.	n.a.	n.a.	n.a.	0.91	0.85	0.75	0.93	1.00	0.88	0.86	0.95

Source: OECD Health Data, 2014.
Note: Break in the series; n.a = data not available.

By way of comparison Fig. 4.5 shows OECD data on the number of active physicians per 1000 population in Italy and selected European countries in 2012 or the latest available year. The rate in Italy (4.1) is on a par with that of Sweden and Germany and higher than the rates in France, Spain and the United Kingdom. (Other OECD data on practising physicians shows 3.7 practising doctors per 1000 people in Italy, which is slightly above the EU average of 3.4).

Fig. 4.5

Number of physicians per 1000 population in Italy and selected European countries, 2011 or latest available year

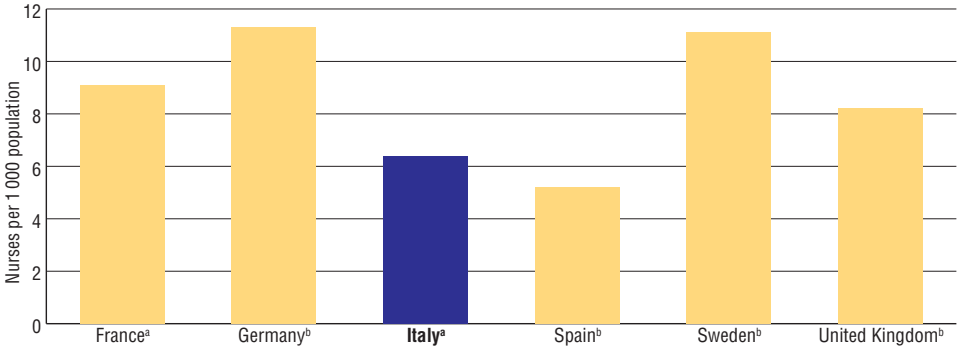


Source: OECD, 2014b.
Notes: [a]Data refer to professionally active physicians, which include practising physicians plus other physicians working in the health sector as managers, educators, researchers, etc. (adding another 5–10% of doctors); [b]data refer to practising physicians, which are defined as those providing care directly to patients.

Conversely, compared to these countries the number of nurses (not including midwives) per 1000 population is considerably lower in Italy, with the exception of Spain (Fig. 4.6). Interestingly, the nursing profession in Italy is currently experiencing an enhancement of its role, especially with regard to the management of patients with chronic conditions with the introduction of formal or informal nurse-led professional groups in primary settings (see Chapter 5). In terms of the combined number of physicians and nurses per 100 000 population, WHO data show that Italy is roughly in line with the European Union average with around 1092 of these health-care professionals compared with an average of 1182 (Fig. 4.7).

Fig. 4.6

Number of nurses per 1000 population in Italy and selected European countries, 2011 or latest available year



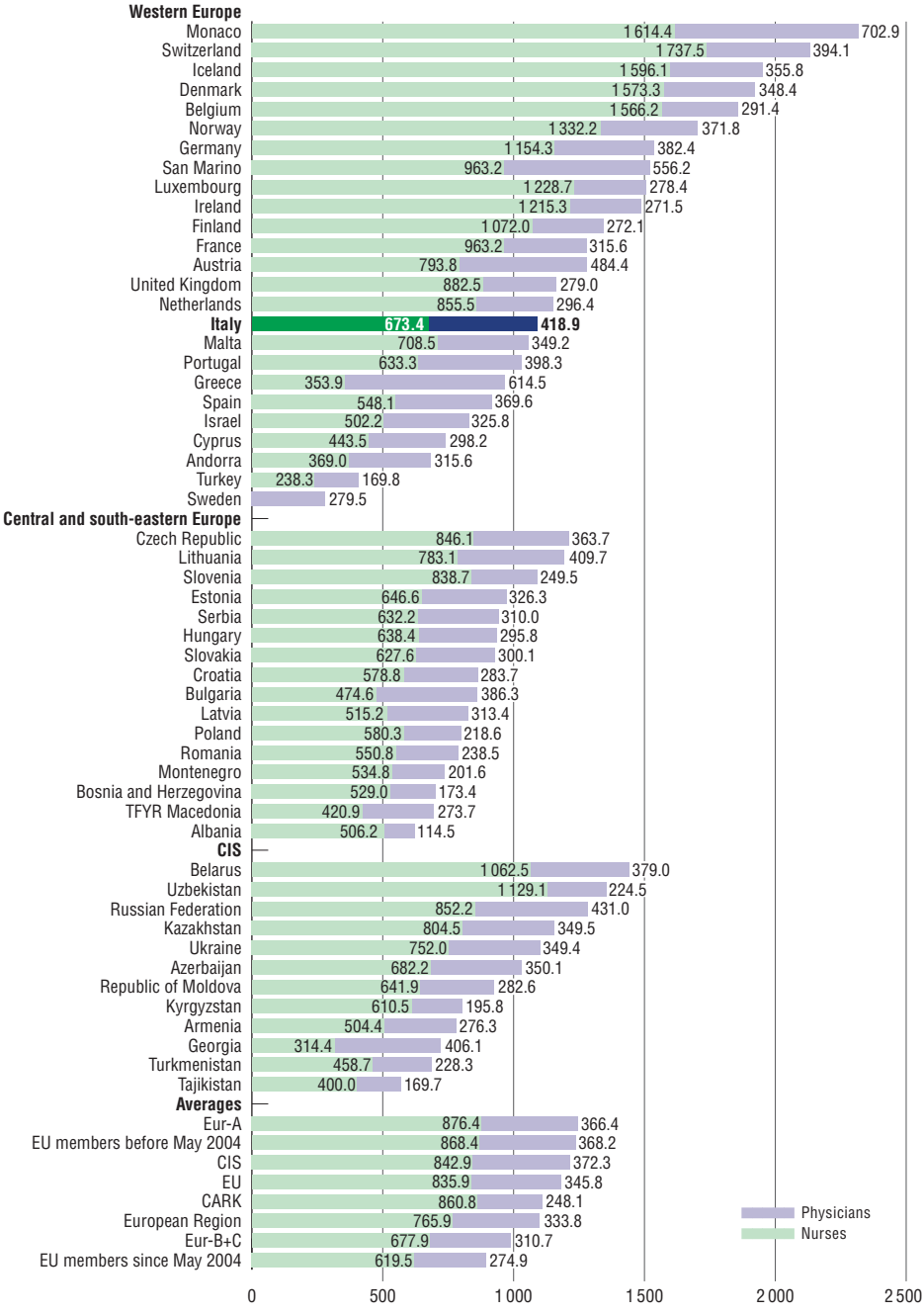
Source: OECD, 2014b.
Notes: [a]Data refer to professionally active nurses, which include practising nurses plus other nurses working in the health sector as managers, educators, researchers, etc. (adding another 5–10% of nurses); bdata refer to practising nurses, which are defined as those providing care directly to patients.

Fig. 4.8 shows in greater detail the trend in the number of dentists per 100 000 population over the last 20 years or so in a selection of countries. Europe registers a steady increase in the available number of dentists over time, with the exception of France and Sweden. In Italy the trend is rather unstable with peaks (1999 and 2006) and declines (1995, 2003 and 2008).

Fig. 4.9 provides a snapshot of the trend in number of pharmacists per 100 000 population across Europe. On average, for EU-15 countries, the number has increased but the trend is not steady for all the countries featured, particularly Spain and Italy. The few data available for Italy indicate a sharp reduction in 2006 (-12 professionals available per 100 000 population in one year) followed by a significant increase in 2008 (+25 professionals available per 100 000 population in two years), and then a decline again before a new rise. These fluctuations are the outcome of intermittent employment freezes on public pharmacists imposed by national and regional level cost-containment measures and possibly of poor quality of available data (see Chapter 3).

Fig. 4.7

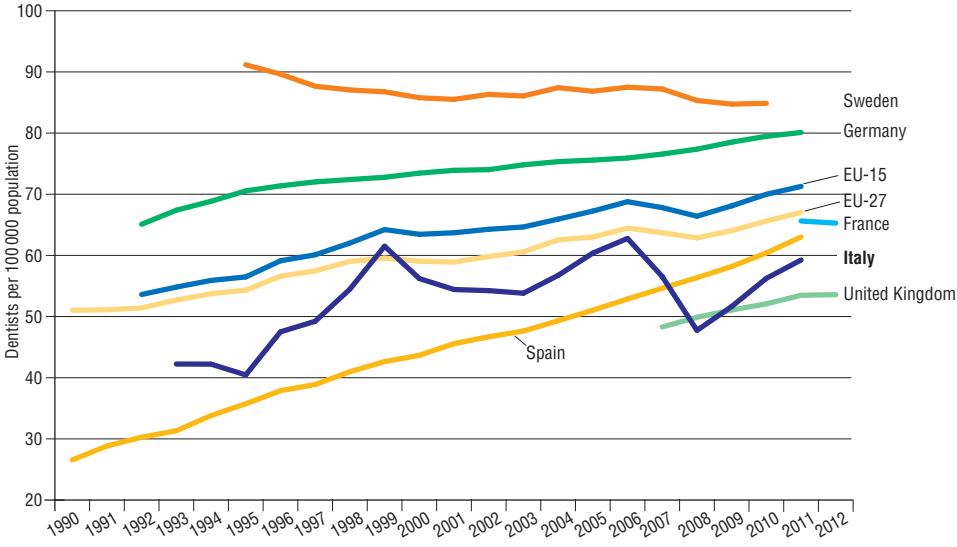
Number of physicians and nurses per 1000 population in the WHO European Region, 2012 or latest available year



Source: WHO Health For All, 2014.
Notes: CIS: Commonwealth of Independent States; TFYR Macedonia: The former Yugoslav Republic of Macedonia.

Fig. 4.8

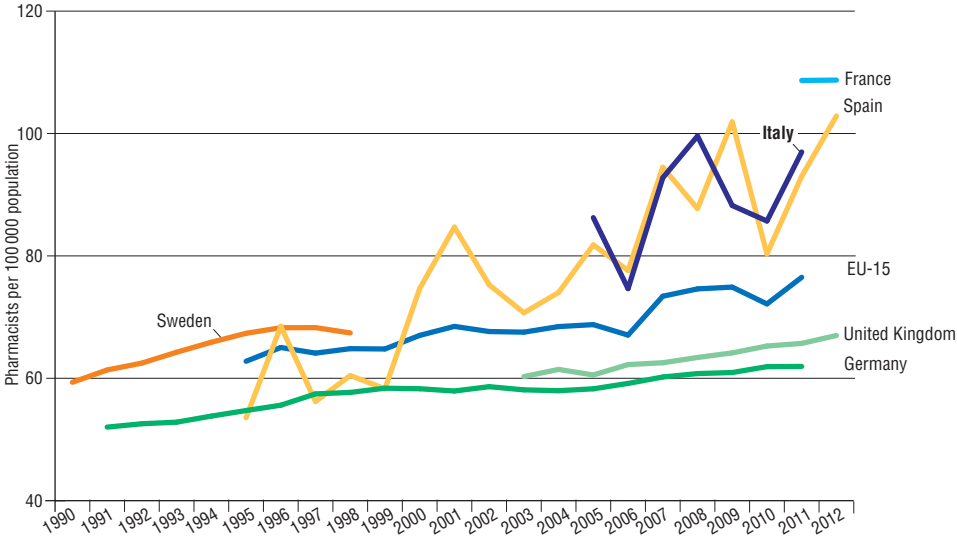
Number of dentists per 100 000 population in selected countries, 1990 to latest available year



Source: WHO Health For All, 2014.

Fig. 4.9

Number of pharmacists per 100 000 population in selected countries, 1990 to latest available year



Source: WHO Health For All, 2014.

4.2.2 Professional mobility of health workers

Few data at national level map the mobility (outflows and inflows) of health workers in Italy, especially with regard to personnel working outside hospital settings (e.g. informal care workers). Since 2007 the National Federation of Nurses (Federazione Nazionale Collegi Infermieri – IPASVI) has been monitoring the flow of nurses and reporting on the composition of the workforce; there are no reliable national data on the mobility of medical doctors or care workers.

Estimates report that Italy has a relatively low reliance on foreign medical doctors – less than 5%, when compared to UK, Ireland and Switzerland where such rates range between 22.5% and 36.8% (Wismar et al., 2011). Currently, the country is facing a freeze on medical doctor turnover as well as health care-professionals turnover in general. In addition, it is difficult for both foreign-trained and domestically trained foreign medical doctors to find stable employment. Consequently, medical doctors tend to leave, rather than enter, the country. On the other hand, nursing shortages have led to high inflows of foreign nurses. In fact, one in ten nurses is of foreign origin. The largest groups are from the European free-movement area, including Romania (25%), Poland (10.7%), Switzerland (7%), Germany (5.6%), France and Spain (around 3.5% each), and a significant number are from South America (Peru 5.3%) (Wismar et al., 2011). The majority of foreign nurses have migrated to central and northern Italy. In addition, the elderly care and home-care sectors rely heavily on foreign carers, who nevertheless are mainly undocumented workers working in the grey economy. The demand for informal care workers (*badanti*) is estimated to be three times higher than the demand for nurses (Chaloff, 2008). The increasing demand for assistance for elderly people is the main driver influencing international health professional mobility. Recent legislation has sought to regularize the immigration status of care workers and partly reflects the needs of the health and long-term care systems; entry requirements for nurses also have been eased. However, health professionals from non-EU countries cannot hold permanent public sector positions and are thus disproportionally affected by less favourable working conditions.

To encourage health workforce mobility and strengthen education and capacity building within the health professions, bilateral agreements have been developed at regional and local level. Regions and health-care units have primarily agreed bilateral programmes with foreign nursing institutes, especially with Eastern European partners, to guarantee the recruitment of qualified professionals (e.g. through distance learning programmes).

4.2.3 Training of health workers

The educational pathway to achieving and maintaining professional status for doctors includes basic medical training, which occurs primarily at a public university (5–6 years). The initial years are dedicated to pre-clinical/basic science and later years to clinical rotation (university based). Before entering postgraduate specialization, medical graduates take a state examination in order to be listed in the national register and be granted the authorization to practise as physicians. Postgraduate education consists of a minimum two years of residency depending on speciality and is often much longer. Physicians wishing to become GPs must be registered on a national list. Ranking on the list depends not only on the number of educational and academic qualifications achieved but also, as of 1 January 1995, on successful participation in a two-year GP training course. Legislative Decree No. 256/1991, which implemented the EU directive on GP training, made participation in this two-year course compulsory to practise family medicine.[23] There are lifelong continuing medical education (CME) requirements for public and private sector employees.

Since 1999, to limit the number of training positions available in the medical field, enrolment in university medical education programmes (medicine and surgery, veterinary science and dentistry) has been based on a competitive assessment exam. For the 2013–2014 cycle, there are 9897 slots available for medicine and surgery training, 825 slots for veterinary science and 984 slots for dentistry. There are also restrictions on advancement to postgraduate levels. However, it is worth noting that despite these efforts to control the national supply of medical doctors, there is still an over-supply in the country, resulting in an outflow to other EU countries, especially the UK and Germany, where they find more stable employment conditions (Wismar et al., 2011).

In 2001 the training programmes for qualified nurses changed to encourage more qualified personnel to enter the health-care workforce. Currently, nursing training occurs at university level (3 years) and includes foundation courses and clinical rotation at the end of which candidates are required to take a national examination. This is in line with EU Directive 85/595/ECC on the upgrading of the nursing profession. Some nurses continue with specialization programmes in fields such as public health, paediatrics, mental health and psychiatry, and geriatrics, taking a first or second level Masters degree or a two-year graduate degree. Doctoral programmes also are available.

[23] In accordance with Legislative Decrees Nos. 256/1991 and 368/1999, certificates issued by other EU Member States to practise as a GP are equivalent to those issued in Italy and therefore are valid for practising in Italy (Lo Scalzo et al., 2009).

Both doctors (GPs and specialists) and qualified nurses are registered in their national registries (*Albo Porfessionale*) that are available by specialities. Moreover, there is mutual recognition of medical qualifications gained in other EU Member States, Switzerland, Norway, Iceland and Lichtenstein for the purpose of practising in Italy.

In general, CME is recommended for continuing certification and career development for all health professionals. The National Programme on Continuing Education in Medicine (NPCEM) was established by the Ministry of Health in 2002 and from 2008 its coordinating body is the National Agency for Regional Health Services – AGENAS (see Chapter 2). All health professionals are currently required to earn 150 CME credits every three years (minimum 25 and maximum 75 credits per year), including comprehensive knowledge upgrades in management and leadership skills. Regardless of the profession or training level, in order to offer CME credits, institutions typically require accreditation by central or regional governments as part of quality assurance requirements.

Ancillary staff, such as laboratory technicians or nurses' aids, are often trained through some specialized courses not associated with a university.

5. Provision of services

The Ministry of Health is the main institution responsible for public health at the national level. Immunization and screening programmes are considered to be priorities. In addition to the mandatory and voluntary routine immunization programmes, pap tests, mammography and colorectal screening are offered free of charge to target populations nationally.

Primary care services are delivered by health districts, the operative branches of local health authorities. Over the last 15 years, there have been attempts to reorganize the delivery of primary care, with the objective of moving from the traditional model of GPs and other health professionals working in single practices to an integrated care model that connects different health-care professionals and bridges the gap between frontline staff and patients, though change has been slow.

Inpatient care is provided through a network of accredited public and private hospitals, with general practitioners and paediatricians (who usually treat children up to the age of 6 or if parents so wish, up to the ages of 14–16) playing a gatekeeping role. In recent years there has been a progressive increase in Accident and Emergency Department admissions, some of which are due to inappropriate use by patients (e.g. for minor illnesses or prevention interventions that could have been treated by primary care physicians) for which co-payments of €25 are imposed (see above).

Medicines are grouped into three main classes: Class A are essential medicines that are reimbursable (but require a co-payment, that varies by region) and include those indicated for the treatment of severe, chronic or acute illnesses. Class C includes non-reimbursable pharmaceutical products (though some regions opt to offer some reimbursement). Class H includes pharmaceutical products delivered only within hospitals. To contain pharmaceutical expenditure, the 2012 Spending Review reduced the budget for

drugs used in non-hospital settings from 13.3% of total health-care expenditure to 11.35% in 2013. However, in the last decade, the cost of pharmaceuticals delivered by hospitals has significantly increased due to new expensive products and the delivery by hospital pharmacies of products that are then used outside hospital settings.

With regard to mental health care, the 1978 Basaglia Law marked the switch from institutional care to community mental health services. Subsequently, specific departments of mental health have been established within local health authorities. A priority remains closing the gap between the northern and southern regions with regard to the provision and quality of services, which remains a major challenge.

Health-care delivery to vulnerable or excluded groups has undergone a recent change in policy. After several years without specific regulations, legislation has now been defined to guarantee that immigrants (both legal and temporarily undocumented) are eligible to receive the same public health-care services that are available to Italian citizens.

The central issue with health service delivery is the heterogeneity of regional arrangements. In general, northern and central regions appear to keep pace with institutional, organizational and professional developments aligned with best international practices and in line with central government orientations, while southern regions appear to lag behind. The gaps between northern and southern regions mainly reflect socioeconomic and cultural factors that are far beyond the health-care system. However, it is also likely that decentralization policies introduced in the last two decades have not favoured the homogeneity of regional systems as they have provided opportunities for improvement to the best institutionally equipped regions while leaving southern regions with less central support to cope with more difficult social contexts.

5.1 Public health

The main institution responsible for public health at the national level is the Ministry of Health, which undertakes a stewardship role and sets the general policies targeting health improvement and prevention. Public health policies are implemented by the regions through their Departments of Health and ASLs, the remits of which include protection of the population's health, health promotion,

preventing diseases and disability, and improving quality of life. The main areas of activity are: public hygiene, occupational health, food and nutrition and veterinary health care.

5.1.1 Communicable diseases control programmes: vaccinations

The reduction or elimination of the burden of vaccine-preventable diseases is considered a priority of the public health service. The routine immunization programme includes diphtheria, tetanus (DT) and poliovirus (oral poliovirus vaccine – OPV) vaccinations, which have been mandatory by law since the early 1960s for all newborns under 24 months. The hepatitis B vaccine was added in 1991, introducing universal vaccination of infants and children (up to 12 years of age). Vaccinations against pertussis, measles, mumps, rubella, *Haemophilus influenzae* type b (Hib), meningococcal C and pneumococcal meningitis, chickenpox and HPV are non-mandatory vaccinations but are recommended by the Ministry of Health. Compulsory and recommended vaccinations are included in the benefit package and are provided free of charge for all Italian and foreign children living in the country.

Regions are in charge of organizing and implementing their own vaccination strategy, based on the National Vaccination Plan (NVP). In 2012 a new NVP – NVP 2012–2014 – was released, which emphasizes the right to vaccination, defines the specific objectives to be reached for the population and certain risk groups and sets the standards for vaccination coverage (Ministero della Salute, 2012b). ASLs and the Ministry of Health are responsible for implementing the activities outlined in the plan. Childhood vaccinations are routinely provided through a well-established and organized network of public facilities and are usually administered by specific departments within ASLs. Moreover, primary care paediatricians are the key contacts for counselling and information; they verify that children have received vaccinations and can administer vaccines themselves.

To evaluate the efficacy of vaccination programmes, national and sentinel surveillance systems are used to collect data and provide information on the incidence of infectious diseases and vaccination coverage. SIMI (Computerized Infectious Disease System) is the statutory notification system, administered by the National Institute of Health, in collaboration with the Ministry of Health. Remarkable progress has been achieved in terms of coverage rates for the compulsory vaccinations, reaching an average of 96% and meeting the target of 95% set by the National Vaccination Plan, in accordance with World Health Organization guidelines. With regard to the recommended vaccinations for

measles, mumps and rubella, coverage (89.9%) has increased significantly over the last 10 years, even if further efforts are needed to meet the target of 95% and a certain degree of heterogeneity still persists, at both the regional and local level (Table 5.1).

Table 5.1

Mandatory and some recommended vaccination coverage per 100 newborns under 24 months, 2011

Regions	POL3	DTP3	DT-DTP3	EpB3	MPR1-MPRV	M-MPR1-MPRV	Hib3
Piedmont	95.9	95.9	96.0	95.9	92.2	92.2	95.4
Valle d'Aosta	95.6	95.2	95.3	94.8	86.2	86.4	94.9
Lombardy	97.0	96.9	97.1	96.2	93.9	94.6	95.9
Bolzano-Bozen	89.0	89.9	89.9	89.6	72.4	72.4	90.5
Trento	95.9	95.7	95.8	95.5	89.0	89.1	95.1
Veneto	95.3	95.3	95.3	95.1	92.3	92.5	94.7
Friuli Venezia Giulia	96.0	96.2	96.7	95.4	91.6	91.6	95.0
Liguria	96.7	96.7	96.7	96.7	85.6	85.7	96.3
Emilia Romagna	96.5	96.2	96.6	96.3	92.8	92.9	95.4
Tuscany	96.2	95.8	98.6	95.9	92.1	92.2	95.2
Umbria	97.8	97.8	97.8	97.4	94.7	94.7	97.5
Marche	97.2	97.1	97.1	97.1	92.3	92.4	97.1
Lazio	96.6	96.5	96.5	99.9	90.0	90.0	96.8
Abruzzo	99.1	99.1	99.1	99.1	91.9	91.9	99.1
Molise	99.0	99.0	99.0	99.0	89.7	89.7	99.0
Campania	91.9	91.9	93.5	90.2	86.5	86.5	88.1
Puglia	96.9	96.9	96.9	96.9	92.7	92.7	97.2
Basilicata	98.6	98.6	98.6	98.6	92.4	92.4	98.6
Calabria	95.9	95.9	95.9	95.9	85.8	85.8	95.9
Sicily	94.8	94.8	94.8	94.8	90.1	90.1	94.8
Sardinia	96.1	91.4	96.0	96.0	92.7	95.8	96.0
Italy	**96.1**	**95.8**	**96.3**	**96.0**	**89.9**	**90.1**	**95.6**

Source: Ministero della Salute, 2012c.
Notes: POL3, three doses of polio vaccine; DTP3, three doses of diphtheria–tetanus vaccine; DT-DTP3, three doses of diphtheria–tetanus–pertussis vaccine; EpB3, three doses of hepatitis B vaccine; MPR1-MPRV, measles, rubella, mumps and chickenpox; M-MPR1-MPRV, measles, rubella, mumps and chickenpox; Hib3, three doses of *Haemophilus influenzae* type b vaccine.

5.1.2 Occupational health

Driven by EC Directives, the occupational health sector has made significant progress in recent years. The Italian Occupational Health and Safety Act (Legislative Decree 81/2008) provides the legal framework, setting out the rights and duties of all parties in the workplace and harmonizing previous legislation. Due to spending cuts, in 2010 the National Institute for Occupational Safety and Prevention (ISPESL) was absorbed within the Italian Workers' Compensation

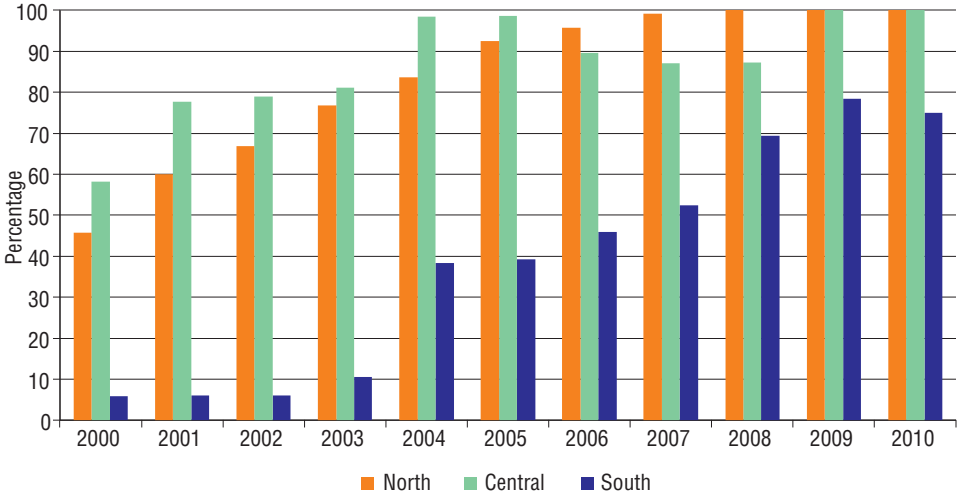
Authority (INAIL). This organization is responsible for the administration of the compulsory insurance scheme related to work/industrial accidents and occupational illnesses. Public funds are the main source of funding and are set through the National Health Fund, along with additional finance that can be provided by the regions and the European Commission. In all workplaces where workers can be exposed to specific risks an occupational health specialist must be appointed by law for medical check-ups of employees and education information activities.

5.1.3 Screening programmes

Since 2001, the government has adopted a series of measures to promote the widespread and uniform adoption of screening policies and guiding principles at the national level. Secondary cancer prevention has been included in the benefit package. To improve screening coverage and following the EU's recommendation on cancer screening (December 2003), several plans have been developed with the aim of strengthening the diffusion of active programmes: National Health Plan (2003–2005), National Screening Plans (2004–2006 and 2007–2009) and National Prevention Plan (2005–2007). Moreover, Law 138/2004 contains a commitment to reduce the gap between the target and the screened population, allocating €50 million.

Important progress in the extension of screening programmes has been made in recent years (for example, see Fig. 5.1) Cervical Pap tests, mammography and colorectal screening are offered free of charge to target populations nationally. For cervical cancer the Pap test is offered every three years to women aged 25–64, in accordance with European Union guidelines. Mammography screening is offered every two years to women aged 50–69. As for colorectal screening, current guidelines recommend two screening tests: the majority of programmes use the faecal occult blood test (FOB) in subjects aged 50–69/74, while others (mainly those in the Piemonte and Veneto regions) have adopted flexible sigmoidoscopy (FS) once in a lifetime (or with a frequency of at least 10 years) in patients aged 58 or 60. The screening programmes are regulated and organized at the regional level through the ASLs, which actively invite the target population to have preventive tests (mammography, Pap test, FOB) free of charge. Participation in screening programmes is voluntary and several indicators are calculated to monitor screening invitations and uptake, which impacts on the efficacy of programmes in reducing cancer mortality. The National Centre for Screening Monitoring (*Osservatorio Nazionale Screening*) was created in 2002 and was charged by the Ministry of Health with monitoring and promoting screening programmes nationwide.

Fig. 5.1
Nominal extension of breast cancer screening, 2000–2010



Source: Osservatorio Nazionale Screening, 2012.

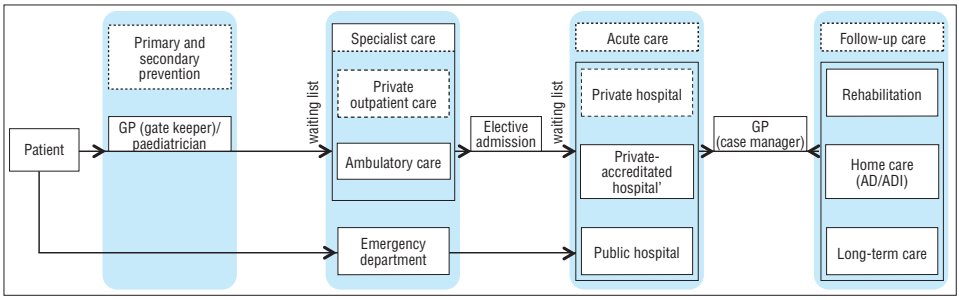
5.1.4 Smoking bans

It is worth mentioning that, as a major national public health measure to reduce the prevalence of tobacco usage, the introduction of a general ban of smoking in all public and working places was implemented in 2012. This ban, approved by parliament after a long history of attempts, was implemented rapidly (Mele & Compagni, 2010).

5.2 Patient pathway

Fig. 5.2 represents a typical patient pathway for non-emergency health care. The different levels consist of GPs, ambulatory care, hospital care and primary care follow-up after discharge. In practice, a patient's first contact with the health-care system occurs when their health problems are explicitly manifest. In these cases, the severity and type of the health problem drives the patient towards the main points of access to care. Most of the time, GPs play a gate-keeping role and represent the first point of contact for patients. Every patient has access to free visits and freedom of choice in terms of registering with a GP. Generally speaking, when GPs provide a referral, they can recommend a certain organization, taking into account the patients' special needs in terms of urgency of care, proximity to where they live and quality of services.

Fig. 5.2
Typical patient pathway



Source: Based on Ministero della Salute, Direzione Generale del Sistema Informativo e Statistico Sanitario, 2012.

For specialist care, patients can choose both public and private providers, according to their willingness to pay and to wait. After preliminary contact with a GP, patients can enter ambulatory care through public facilities located either in a hospital or in ASLs. The required intervention can be requested via a central booking point (*Centro Unico di Prenotazione* – CUP), in most cases by calling a special telephone number. CUP operators can suggest providers where the service would be available sooner, thus reducing waiting times. Such information about waiting lists covers both public and private accredited hospitals that provide reimbursable services. Services provided in public or private-accredited facilities require a referral and are covered by the SSN (apart from any co-payments due for outpatient services). For those who want to skip waiting lists or choose an individual specialist, and are ready to pay, care is also available outside statutory coverage through private providers or SSN specialists operating intra-moenia (who also have their own information systems for bookings and waiting lists). In such cases (private visits), patients have direct access to the facility without a referral from a GP and pay the total cost without any reimbursement from the SSN.

If further care is needed, the next step in the care pathway may involve an inpatient (acute) hospital admission. In the case of surgical interventions, one-day pre-admissions for patient preparation are increasingly common in order to reduce the length of stay; day hospital and day surgery rates are also growing (see section 5.4). Once treated in the acute setting, a patient pathway is expected to move into integrated home care (*Assistenza Domiciliare Integrata* – ADI) if the patient needs post-acute care. Usually the discharging hospital will refer the patient to a specific provider for rehabilitative care or if appropriate, to local residential care (*Residenza Sanitaria Assistenziale* – RSA) for long-term care.

In the case of out-of-hours emergency care, or where a consultation with a GP is not possible, care is provided by 'continuous care physicians' (*Medici di Continuità Assistenziale* – MCA – formerly called emergency doctors). Continuous care, designed according to effective integrated models, has been reformed at national and regional level over the last 20 years in order to guarantee 24 hour coverage, 7 days a week.[24] Where the situation requires urgent attention, a free ambulance service to the closest hospital is provided by calling the Emergency System number 118 or patients can go directly to the nearest hospital emergency department to obtain necessary treatment. Charges can be applied if patients use emergency services inappropriately. Further details on emergency care pathways are provided in section 5.5.

5.3 Primary/ambulatory care

According to the National Health Plan (2011–2013), primary care represents the 'hub' for delivering general practice at the first point of contact with the SSN and is responsible for providing continuity of care through appropriate coordination. Thus, the primary care network promotes the maintenance of health, health education, diagnosis and treatment of acute and chronic disease in different settings, from ambulatory care to home care (Damiani & Ricciardi, 2010). This section focuses on ambulatory care provided outside hospital by GPs and specialists.

GPs and paediatricians (who usually treat children up to the age of 6 or if parents so wish, up to the ages of 14–16) have a gatekeeping role. They are responsible for prescribing medication and, after diagnosing a health problem, referring patients to specialist consultations or further levels of care if needed. GPs are self-employed and independent doctors, paid on the basis of a capitation fee on the number of registered patients (up to 1500; see Chapter 3) augmented by a fee-for-service component for specific activities (e.g. home visits) and additional payments according to specific performance indicators (typically managed at regional and local level). In order to practise, GPs must complete specialist training consisting of a three-year professional training course in general medicine. Recent legislation has promoted a revision of the criteria governing fitness to practise for both GPs and paediatricians (Law 189/2012), as negotiated during the National Labour Contract for General Practice (*Accordo Collettivo Nazionale* – ACN) (see also section 3.7.2). The profile of paediatricians is quite unusual as they are both specialist independent doctors and physicians

[24] Legislative Decree 502/92; National Health Plan 2010–2012; Legislative Decree 158/2012.

who are fully integrated within the SSN and responsible for guaranteeing the first level of care for children aged up to age 14–16. Alternatively, if no paediatrician is available or when a child reaches 6 years of age, parents can choose to register him or her with a GP. Paediatricians can have a maximum of 800 registered patients in their lists (up to 880 with a special dispensation).

Organizationally, both GPs and paediatricians are included within Health Districts, the operative branches of ASLs that are responsible for guaranteeing the provision of primary care services. Each Health District is expected to plan and deliver health and social care based on population needs. Multidisciplinary teams of professionals (GPs and paediatricians, specialists, nurses, social assistants, social care staff and other technical and administrative staff) work within Health Districts to provide different types of services to meet community needs (e.g. GP and specialized ambulatory care, maternal–infant care, frail care, mental health care, etc.).

Over the last 15 years, there have been attempts to re-organize the delivery of primary care, with the objective of moving from the traditional model of GPs and other health professionals working in single practices to an integrated care model that connects different health-care professionals and bridges the gap between front-line staff and patients. In 2000, the National Labour Contract for GPs represented a milestone for primary care reorganization, introducing economic incentives for group practice and integration between primary care physicians and Health District services (e.g. social and home care, environmental health, etc.). In particular, three different models were introduced with increasing degrees of integration: 'base-group practice', 'network group practice' and 'advanced group practice' (see Longo, 2007; Fattore et al. 2009; Lo Scalzo et al., 2009; Armeni, Compagni & Longo, 2014 for details about organizational developments in primary care). Further developments for group practice occurred in 2005, with the introduction of Primary Care Territorial Units (*Unità Territoriali per l'Assistenza Primaria* – UTAP) and in the 2009 National Labour Contract for GPs, which established an additional compulsory framework known as a Complex Primary Care Unit. More recently, in 2012, the Balduzzi Decree Law n. 189/2012 has promoted the voluntary formation of group practice in primary care, particularly to foster continuity of care and greater integration of care. In particular, given that GPs play an important 'liaison' role in the management of chronic care patient pathways they make a key contribution in defining the best care programme and delivery setting for a patient. Currently, GPs, paediatricians, continuous care physicians (MCAs) and ambulatory specialists are urged to supply 24-hour continuous care, 7 days a week by organizing their group practice according to the organizational

models mentioned above. In terms of implementation, different models have been adopted in different districts and regions but with an observed decline nationally in single and base-group practice and a slow evolution towards more complex aggregative working models (Osservasalute, 2012). Table 5.2 provides a summary of the different types of group practice models currently available, even though in practice solo practice still dominates.

Table 5.2
GP group practice models

Simple models		Complex models	
Functional	**Structural**	**Functional**	**Structural**
Base group practice (*Medicina in associazione*)	Advanced group practice (*Medicina di gruppo*)	Functional territorial collective practice (*ATF – Aggregazioni funzionali territoriali*)	Complex Primary Care Unit (*UCCP – Unità Complesse di Cure Primarie*)
Network group practice (*Medicina in rete*)			Primary care territorial unit (UTAP) formally introduced by ACN in 2005

Source: Damiani & Ricciardi, 2010.

Notwithstanding these efforts to encourage multi-professional group practice, it remains the case that comprehensive management in primary care settings still requires a stronger integration between health services and social care, which in Italy are still split into two sectors: all social care services are the responsibility of municipalities while all health-related services are covered by the ASLs. Only a few regions (e.g. Veneto, Emilia Romagna, Tuscany, Marche) have really implemented effective governance tools to integrate these two areas in terms of merged management and financing.

5.4 Specialized ambulatory care/inpatient care

5.4.1 Specialized ambulatory care

Ambulatory activities consist of complex specialist services, such as visits, diagnosis, laboratory services, curative therapy and rehabilitation care for patients who do not require hospitalization (Ministero della Salute, 2012d). In particular, they include specialized care services within the SSN that are accessible only with a GP's referral, except for dental care, obstetric and

gynaecological services and paediatric care, which are services that can be directly accessed. Direct access is also guaranteed for private (*intra-moenia*) specialist services.

Specialized ambulatory medical services, including diagnostic imaging and laboratory tests, are coordinated by the ASLs, which can either provide them directly through health district clinics and hospital (outpatient) ambulatories and diagnostic laboratories or purchase these services through accredited public and private suppliers. Specialized ambulatory care experiences long waiting lists – a common phenomenon in Italy that is often related to unsatisfactory quality of care. A few regions, such as the Veneto region, have experimented with a proactive waiting list management system, dedicated to patients expected to wait more than three months for ambulatory visits, resulting in a significant reduction in patients voluntarily 'dropping out' of the waiting list for publicly provided services (de Belvis et al., 2013). Overall, however, given the existence of such waiting lists, people often seek care within the private sector and significant inter-regional mobility of patients takes place, especially from southern to northern regions in order to access care faster. Currently, a new National Plan for the Governance of Waiting Lists (2014–2016) has been produced with key support from the National Agency for Regional Healthcare (Agenas), which plays an essential role in promoting and implementing a framework to monitor ambulatory care waiting lists at regional and national level.

5.4.2 Inpatient/secondary care

Inpatient hospital care is delivered through a network of hospitals, which can be either public or private institutions. These structures can provide both outpatient care and inpatient care and are formally categorized (by legislation) into:

- *Aziende Ospedaliere* (AOs) (Hospital Trusts): these are quasi-independent public agencies that are accountable to the regions and provide tertiary care with a high level of specialization;
- *Aziende Ospedaliere Universitarie* (Teaching Hospital Trusts) and *Policlinici Universitari* (Academic University Hospitals);
- *Istituti di ricovero e cura a carattere scientifico* (IRCCS) (National Hospitals for Scientific Research);
- *Presidi Ospedalieri* (District General Hospitals), which are directly managed by ASLs;
- Single-specialty hospitals, such as for maternity services or orthopaedics;

- Religious hospitals (so called *Ospedali classificati*);
- *Residenza Sanitaria Assistenziale* (residential facility with long-term care beds).

More generally, Italy's hospital network has been organized according to the level of specialization and capacity to treat emergency cases. Thus, hospitals can be categorized according the following functional levels:

- *Basic hospitals*: cover a catchment area of between 80 000 and 150 000 inhabitants and have emergency services with a set of limited specialties, with a network of emergency care on call.
- *Level I hospitals*: have a catchment area of between 150 000 and 300 000 inhabitants and host a first-level Accident and Emergency Department. These structures provide a large number of specialty medical services available on call. Radiology services with CAT and ultrasound, laboratory service and immune transfusion services have to be available 24 hours a day, either in situ or connected through web-based applications.
- *Level II hospitals*: have a catchment area of between 600 000 and 1.2 million inhabitants.[25] They are equipped with facilities corresponding to Level II Accident and Emergency Departments and mainly comprise Hospitals Trusts, University Hospitals and IRCCS. They share the same characteristics as Level I hospitals but in addition are equipped with departments and facilities that are able to deal with more complex health conditions.

Since the 1990s, the reorganization of the country's hospital network has focused on promoting the clinical and organizational appropriateness of hospital care and has aimed, first and foremost, to reduce the number of beds and hospital admissions. The standardized number of beds per acute care facility (both public and private accredited) was originally defined by Law 405/2001 and revised by the *2010–2012 Healthcare Pact*. The latter set the regional standard for the average number of beds at 4 beds per 1000 inhabitants, including 0.7 beds (per 1000) for rehabilitation and long-term care. These interventions basically aimed to promote the shift from ordinary admissions to day hospital and from day hospital to ambulatory care, as well as to favour home and domiciliary care for the elderly requiring long-term care. At national level the average number

[25] In regions with fewer than 600 000 inhabitants, access to Level II hospitals can be obtained via an interregional agreement with neighbouring regions.

of all beds in acute wards fell from 3.5 beds per 1000 inhabitants in 2010 to 3.3 beds per 1000 inhabitants in 2011, with a national average of 324 beds per institution in 2011 (a slight increase over the 2009 figure of 315).

The overall distribution of acute beds by region in 2011 is described in Table 5.3. Further changes have been brought about by the Spending Review Decree issued in 2012 (Decree 95/2012) that set a target to reduce the number of hospital beds by 7389 units nationally.

Table 5.3

Distribution of acute beds in public structures and private-accredited hospitals wards in 2011 and Spending Review impact on the number of acute-care beds

Regions	Number of beds in acute care wards, 2011			Expected effect of Spending Review on the number of acute-care beds		
	Public	Private accreditated	Total	1 January 2012	After Spending Review	Variation
Piedmont	12 733	1 392	14 125	13 706	14 155	449
Valle d'Aosta	445	0	445	450	363	-87
Lombardy	28 925	492	33 845	31 938	30 512	-1 426
PA Bolzano	1 722	62	1 784	1 795	1 436	-359
PA Trento	1 652	110	1 762	1 751	1 533	-218
Veneto	15 612	794	16 406	16 125	14 900	-1 225
Friuli Venezia Giulia	4 471	500	4 971	4 679	3 989	-690
Liguria	5 963	79	6 042	5 677	5 442	-235
Emilia Romagna	13 835	2 791	16 626	16 673	14 666	-2 007
Tuscany	11 265	1 364	12 629	12 301	12 195	-106
Umbria	2 597	239	2 836	2 827	2 921	94
Marche	4 938	502	5 440	5 293	4 867	-426
Lazio	16 759	2 546	19 305	18 734	17 090	-1 644
Abruzzo	3 759	604	4 363	4 234	4 026	-208
Molise	1 097	104	1 201	1 146	1 047	-99
Campania	12 854	4 816	17 670	16 963	15 253	-1 710
Puglia	1 134	1 815	13 155	12 326	11 436	-890
Basilicata	1 745	56	1 801	1 804	1 697	-107
Calabria	5 023	1 572	6 595	6 327	5 387	-940
Sicily	1 185	361	1 546	15 036	14 118	-918
Sardinia	521	1 065	6 275	6 137	4 846	-1 291
Italy	**173 795**	**28 941**	**202 736**	**195 922**	**181 879**	**-14 043**

Source: Authors' elaboration on data from Ministero della Salute, Direzione Generale del Sistema Informativo e Statistico Sanitario, 2012.
Note: Acute-care wards do not include the following disciplines: residual asylum, spinal unit, recovery and functional rehabilitation, long-term care, neurorehabilitation, palliative care/ hospice.

Law 135/2012 (which converted the Spending Review Decree into law) set a new target for an overall national average of 3.7 beds per 1000 inhabitants, of which 0.7 must be dedicated to rehabilitation and long-term care and 3.0 for

acute patients. As of 1 January 2012, there were 231 707 hospital beds, including day-care and non-acute beds (3.82 per 1000 inhabitants), of which 195 922 were in acute care (3.23 per 1000 inhabitants) and 35 785 were dedicated to post-acute care (0.59).

At national level, the standardized hospitalization rate (considering only acute admissions and excluding day hospital and non-acute admissions) decreased from 120 discharges per 1000 residents in 2009 to 108 in 2011. Regions such as Calabria, Friuli Venezia Giulia, Apulia and Campania showed an even more pronounced reduction. In particular, the hospitalization rate in 2011 was the lowest in Friuli Venezia Giulia (74 per 1000) while the rates for Veneto and Calabria were under 100 (92 and 94 per 1000 respectively) (Ministero della Salute, 2012e).[26] By international comparison and using OECD data, Italy's hospital discharge rate for the period 2009–2011 is lower than the EU-24 average, and in 2011 stood at the very end of the ranking, with 13 544 discharges per 100 000 population (OECD, 2014b).

5.4.3 Day care

Day care services are considered to be activities provided to acute patients during the day, without an overnight stay. They were introduced for the first time in 1985 (Law No. 595) with the term Day Hospital as an alternative to traditional hospitalization. In fact, Day Hospital refers to hospitalizations and access to hospital services during one part of the day, preferably during daytime hours, for the delivery of a variety of health care, multi-professional and specialist services, including diagnostic, therapeutic and rehabilitation activities (e.g. chemotherapy, radiotherapy, physiotherapy).

Subsequent measures have further regulated the operating model and encouraged the development of other forms of hospital care specific to surgical activities, such as day surgery, one day surgery and week hospitals. Day surgery refers to surgical diagnostic procedures and/or invasive/semi-invasive procedures performed during daytime hours and delivered by public or private hospitals. It does not normally involve an overnight stay (e.g. cataract surgery, vein ligation and stripping) but exceptionally, according to regional guidelines, it can refer to day care that includes an overnight stay. All day care services consist of hospital admissions (one or a set of admissions) that are accessible through hospital clinicians and ambulatory specialists (both public and private) or through a GP's referral. The most frequent day care procedures are medical

[26] These data reflect the hospitalization rates of residents, including admissions in hospitals in regions other than those of a person's residence.

(the average number of day hospital admissions at national level equals 3.79), while surgical services have a lower average admissions rate (1.60). Finally, the week hospital has been implemented in some acute structures as a new organizational model which, circumventing the logic of clinical departments, develops elective surgical intensive care in homogeneous areas within the working week (from Monday to Friday).

According to Ministry of Health data, the overall trend for day hospital admissions from 2001 to 2010 is decreasing, thus suggesting more appropriate delivery of services is provided in ambulatory/outpatient settings. In particular, in 2010, day hospital for acute care fell by 5% (that is, by 160 000 admissions compared to 2009), with a parallel reduction in ordinary admissions (-2.8%); on the other hand, day hospital for rehabilitation fell by -2.8% with a contrasting growth in ordinary admissions for rehabilitation (+1%) (Ministero della Salute, 2013c).

5.5 Emergency care

The SSN has exclusive responsibility to provide the emergency care system and to guarantee uniform delivery of services throughout the country (Presidential Decree, 27 May 1992). In accordance with the Guidelines for the Health Emergency System (1996), which set organizational and functional requirements, the emergency care system is composed of:

- an emergency number (118) system that citizens can call in case of health emergencies and accidents. The system operates throughout the country and is organized at the regional level. Coordination of interventions/responses is carried out by the Central Operations Centre;
- a system of rescue vehicles: ambulances, mobile intensive care units and helicopters;
- first-aid care, known as the *pronto soccorso*, where the health emergency is solved or the patient is stabilized before being transferred to more specialized facilities;
- Accident and Emergency Departments (AEDs), which are open 24 hours a day, 7 days a week, in hospitals to provide immediate care and treatment for patients presenting with life-threatening medical conditions, trauma or accidents. Depending on their complexity and type of operative units, these departments can be classified into two groups; Level I AEDs include first-aid care, a reanimation unit, brief length-of-stay, observation

unit, general medicine diagnostic–therapeutic interventions, general surgery, orthopaedics, stroke units and laboratory tests. Level II AEDs provide the same services as Level I AEDs as well as highly specialized functions such as cardiac and vascular surgery, treatment for acute coronary syndrome, trauma and paediatric, gynecological and obstetric emergencies, along with technologically advanced diagnostic services.

When arriving at the AED, the patient's level of urgency will be evaluated and a Triage code will be given to establish the priority of access to treatment (the color codes are red, yellow, green and white in decreasing order of severity).

Emergency care is provided free of charge to everyone. In recent years there has been a progressive increase in AED admissions, many of which are due to inappropriate use by patients, i.e. for minor illnesses and primary care that do not require emergency treatment, and has contributed to driving up costs and increasing inefficiencies, such as longer waiting times. To cope with this issue, patients who are assigned white or green codes are required to make a co-payment of €25 (Law n. 296/2006) and, depending on regional regulations, a further €25 should specialized care be required.

5.6 Pharmaceutical care

5.6.1 Pharmaceutical provision and reimbursement

The SSN is responsible for providing pharmaceutical care and accounts for the majority of total pharmaceutical spending. Drugs are dispensed through two channels: community and hospital pharmacies. Community pharmacies can be either publicly or privately owned and deliver prescriptions and OTC drugs to citizens living in the community. Hospital pharmacies are in charge of purchasing, stocking and delivering drugs to hospitalized patients. According to the Italian legislation, hospital pharmacies have a discount on the nominal price of pharmaceuticals of at least 50%. This discount and the desire to closely monitor the delivery and administration of certain categories of drugs (e.g. anti-retroviral drugs for HIV and AIDS patients) motivated legislation that makes it possible for hospital pharmacies to deliver certain categories of drugs to patients that then use them in the community. More recently, agreement between the SSN and pharmacies has made it possible that community pharmacies deliver drugs to patients 'on behalf of the SSN', which means that these drugs are purchased by the SSN (with the relative discount) but delivered by community pharmacies.

Class A medicines

As illustrated earlier (see sections 2.8.4 and 3.7.1), Class A includes essential medicines for the treatment of severe, chronic or acute illness. They are partially reimbursed by the SSN and involve a modest co-payment that varies across regions. These reimbursable medicines are listed in the National Pharmaceutical Formulary (*Prontuario Farmaceutico Nazionale* – PFN), which is administered nationally by the Italian Medicines Agency (*Agenzia Italiana del Farmaco* – AIFA) and updated every year, or every six months if community public pharmaceutical expenditure as a percentage of total public health-care expenditure exceeds a 13% ceiling. Three main criteria determine inclusion in this class: clinical efficacy that must be proven by an evidence-based literature review, relevance of the disease and cost. AIFA's Technical Scientific Committee is responsible for assessing new drugs for inclusion in the PFN. For each medicine the PFN provides detailed information on commercial name, active ingredients, dosage instructions, price, manufacturer, etc. Drugs in Class A are available only through a medical prescription. They can be prescribed by a GP or a paediatrician, an on-call doctor, A&E doctor, ambulatory specialist or hospital physician working within the SSN. Some medicines in this class have prescription limitations (known as 'AIFA notes') that make them eligible for reimbursement only for patients with specific conditions.

Class C medicines

Class C includes non-reimbursable pharmaceutical products acquired either with or without prescription. The latter group include 'without prescription' medicines ('*farmaci senza prescrizione*' – SP) and OTC drugs (known in Italy as Class C-bis drugs). SP medicines do not require a prescription and cannot be advertised, while OTC drugs also do not require a prescription but can be advertised. This group of pharmaceuticals is not reimbursed by the SSN but at national level, where the physician recognizes the therapeutic benefit for the patient (Law n. 203/2000); those receiving war pensions are exempt from payment. In addition, regions are free to decide whether to fund with their own resources the partial reimbursement of Class C drugs, thus resulting in variations in access at regional level.

Class H medicines

Class H includes pharmaceutical products delivered only within hospitals under specialist supervision and they cannot be purchased in pharmacies. The PFN lists these medicines as it may also determine that only certain categories of centre can administered these drugs.

Every month AIFA publishes a 'transparency list' of off-patent drugs that are available on the Italian market, listing both the original medicine and its equivalent substitute (generic), with equal composition in active ingredients, same pharmaceutical form, method of administration, number of units and dosage unit. According to the reference price system introduced in 2001, the SSN reimburses the lowest price among the off-patent pharmaceuticals. For prescription drugs the pharmacist is required to deliver the product with the lowest price and can substitute the original branded medicine unless the physician specifies 'no substitution' and if the patient agrees. In cases where the doctor or the patient wants a product with a higher price, the patient pays the difference between the price of the selected product and the reference price.

Off-label use

Where no alternative therapy is available, patients may have access to treatments (under Law No. 648/1996) in the following cases:

- innovative medicines already authorized in other countries, but not yet in Italy;
- drugs under clinical investigation, but with recognized benefits;
- off-label use.

For inclusion in these special cases an application must be submitted to AIFA's Technical Scientific Committee, supported by a scientific dossier. Medicines approved under Law No. 648/1996 are reimbursable and funded by the 'AIFA Fund', which has been in operation since 2005.

5.6.2 Price setting

Price setting applies only to medicines that are reimbursed by the SSN and is administered at the central level by AIFA through its Pricing and Reimbursement Committee. In 2004, the regulatory scheme for determining pricing and reimbursement at drug launch changed and the Average European Price (AEP) was replaced by a negotiation model, applicable to all products (Fattore & Jommi, 2008).[27] This measure was introduced to contain pharmaceutical expenditure, promote competitiveness among companies and secure lower prices for consumers. Price setting of reimbursed pharmaceuticals involves negotiations between AIFA and manufacturers and is strictly linked

[27] Previously, only the prices of medicines authorized under an EU procedure were set by negotiation.

to a product's reimbursement classification, following assessment by AIFA's Technical Scientific Committee on whether it should be included in the PFN (see section 5.6.1).

The following criteria are taken into account to fix the reimbursement price[28]:

- positive cost–effectiveness ratio of the medical product, where no alternative therapy exists;
- favourable risk-benefit ratio compared to drugs available with the same therapeutic indications;
- evaluation of the financial impact on the SSN;
- costs of the therapy per day, in comparison to products of comparable efficacy;
- expected sale volumes;
- prices and consumption in other European countries.

The Technical Scientific Committee is responsible for assessing the negotiation outcome between AIFA's Pricing and Reimbursement Committee and pharmaceutical companies, while AIFA's Management Board is charged with giving final approval. Prices are determined at ex-factory level and are usually fixed for 24 months. If no agreement on the price can be reached, the original reimbursement decision made by the Technical Scientific Committee to include the product in the PFN is amended and the medicine is reclassified as non-reimbursable (Class C) and, thus, excluded from the positive list.

For non-reimbursable medicines (Class C), prices are freely determined (with some limitations) by manufacturers and monitored by AIFA. Reductions in price are allowed at any time, while increases are permitted in January of odd years.

5.6.3 Pharmaceutical expenditure per capita and defined daily dose consumption

Pharmaceutical expenditure is a significant component of public health expenditure and there is concern about its sustainability in future years. Two driving factors are of particular concern:

[28] The Inter-ministerial Committee on Economic Planning (CIPE) Resolution No. 3, 1 February 2001 regulates the negotiation procedure and sets the criteria.

- the significant growth of the elderly population and the subsequent prevalence of comorbidities, resulting in an expansion of drug consumption;
- the introduction of innovative medicines, which are usually more expensive.

To contain pharmaceutical expenditure regulatory measures were introduced in 2002, setting a spending ceiling of 13% of overall health-care expenditure (Law No. 326/2003), both at national and regional level. This limit was subsequently modified in 2009 and set at 13.3% (Legislative Decree No. 78/2009). The expenditure cap does not include hospital pharmaceutical expenditure. Furthermore, the Spending Review in 2012 reduced the budget for drugs used in non-hospital settings (Law No. 135/2012) from 13.3% of total health-care expenditure to 13.1% in 2012 and 11.4% in 2013. Meanwhile, in 2013, hospital pharmaceutical expenditure was allowed to increase from 2.4% of the total budget to 3.5%. From 2013 the regions (50%) and industry (50%) will cover any excess expenditure (over the ceiling) for drugs used in hospital settings.

In 2011 total expenditure on pharmaceuticals reached €26.3 billion, with a share of 75% reimbursed by the SSN and distributed mainly by public and private pharmacies (AIFA, 2011). Pharmaceutical expenditure per capita (including SSN-reimbursed drugs dispensed by public and private pharmacies and co-payments) increased overall by 2.5% in the period 2001–2010. A difference between northern and southern regions is evident, with all southern regions presenting higher levels than the national average of €215 per capita.

Average national consumption by defined daily dose (DDD) of products reimbursed by the SSN is 952 (per 1000), having increased by 2.8% in the period 2009–2010 and by 41.3% compared to 2001 (Montilla et al., 2011). Data analysis by age group reveals that drug use by people aged 75 and over is 17 times higher than the group aged 25–34 (Osservasalute, 2012), highlighting that age is the most predictive factor of drug consumption. Furthermore, drugs acting on the cardiovascular system are the most frequently prescribed (47.4% of total consumption). The consumption of generics (by DDD) has more than tripled in the period 2002–2010, increasing from 14.0% to 51.5% (of the total consumption of SSN). In parallel, during the same period, expenditure on generics increased from 7.0% to 30.4% of total pharmaceutical expenditure. Finally, analysis of antibiotic consumption shows that Italy is among the European countries with the highest use – 27.3 (DDD/1000) in 2010 (Cangini et al., 2011). The wide variability between northern and southern regions is also worth noting, with higher rates in the south.

5.6.4 Pharmacies

Both individual pharmacists and the government can be owners of a pharmacy. New requirements were set in 2012, foreseeing one pharmacy per 3300 citizens, a ratio far lower than the previous target (one pharmacy per 4000 citizens in areas with more than 12 500 inhabitants and per 5000 citizens in areas with fewer than 12 500 inhabitants). In 2012, at the national level, a single pharmacy served an average of 3364 inhabitants (Table 5.4), which is in line with the European average (Pharmaceutical Group of the European Union, 2012). The number of inhabitants per pharmacy is relatively low in mountainous regions or large rural communities. These regions have deviated from the national targets by opening pharmacies in small municipalities to try to adequately provide pharmaceutical care. The Autonomous Province of Bolzano is an exception, having the highest inhabitants per pharmacy ratio.

Table 5.4

Distribution of public and private pharmacies, 2012

Region	Number of pharmacies			Inhabitants per pharmacy
	Total	Private	Public	
Piedmont	1 538	1 438	100	2 898
Valle d'Aosta	49	43	6	2 617
Lombardy	2 837	2 382	455	3 496
Bolzano-Bozen	124	118	6	4 095
Trento	165	141	24	3 209
Veneto	1 331	1 221	110	3 710
Friuli Venezia Giulia	385	361	24	3 210
Liguria	597	573	24	2 708
Emilia-Romagna	1 245	1 036	209	3 560
Tuscany	1 122	889	233	3 342
Umbria	271	219	52	3 345
Marche	505	424	81	3 100
Lazio	1 491	1 331	160	3 842
Abruzzo	503	465	38	2 669
Molise	170	164	6	1 881
Campania	1 617	1 559	58	3 608
Puglia	1 108	1 080	28	3 692
Basilicata	206	202	4	2 852
Calabria	759	758	1	2 650
Sicily	1 424	1 411	13	3 547
Sardinia	574	565	9	2 919
Italy	**18 021**	**16 380**	**1 641**	**3 364**

Source: Federfarma, 2012.

5.7 Rehabilitation/intermediate care

Intermediate care and rehabilitation refer mainly to services used by frail or chronically ill people in a home care setting who have a high risk of avoidable hospital admission and to services for post-acute patients for rehabilitative interventions and health-care support not requiring an acute hospital setting. These types of care involve a range of services designed to link primary care, acute care and social care in an integrated patient pathway. ASLs are responsible for coordinating and delivering rehabilitation and intermediate care, dealing with high-complexity medical and non-medical components and coordinating a set of multidisciplinary activities aimed at switching the care setting from hospital to home care, reducing the length of hospital stay, as well as preventing hospitalizations and inappropriate readmissions.

Physiatrists or rehabilitation medicine specialists, together with other health-care professionals, support disabled people through the definition and implementation of an Individual Rehabilitation Programme. The Individual Rehabilitation Programme is provided on the basis of a comprehensive multidisciplinary assessment of each individual's health and social care profile in order to outline the required treatments and the most appropriate treatment setting(s) for an active recovery. If ASLs are not able to directly deliver the set of services required by the rehabilitation programme, they must contract with public or private hospitals to provide them.

The 1998 Guidelines for Rehabilitation Care issued by the Ministry of Health (Ministero della Salute, 1998) attempted to clarify the difference between what is known in Italy as 'intensive care' and 'extensive care' (also called 'intermediate care'). The former refers to services provided in the post-acute phase of a disease that are usually delivered in hospitals while the latter refers to all other non-intensive interventions, generally provided in long-term hospitals, outpatient settings, nursing homes and residential and semi-residential homes (see section 5.8). In practice, public hospital, equivalent hospital and extra-hospital facilities for intensive rehabilitative care have been developed differently by the regions, with marked variations in how such services are organized. Moreover, there has been a tendency for 'extensive' rehabilitation initiatives to be confused with long-term care or social care interventions.

In 2010, the Ministry of Health issued a *Strategic Plan for Rehabilitation* (Ministero della Salute, 2010c) that reaffirmed rehabilitation as an integrative component of prevention and therapy within an effective integrated patient pathway. The persisting problems at regional level associated with differing

classifications of rehabilitative structures, pathways and interventions were highlighted and the Strategic Plan proposed the establishment of Rehabilitation Departments within ASLs to uniformly co-ordinate the provision of care and guarantee better integration with providers. To date, implementation differs from region to region and from ASL to ASL.

5.8 Long-term care

Long-term care should be analysed taking into account demographic trends, which show constant increases in both the average age of the population and its mean life expectancy. The 12.5 million Italians who were over 65 in 2012 are mostly affected by conditions such as osteoarthritis and arthritis, arterial hypertension and osteoporosis (women only). The over-80s are estimated to account for 9% of the total population by 2030 (ISTAT, 2009). In the context of Italy's rapidly ageing population long-term care represents one of the main areas where effective integration between health and social care is needed more than ever. However, long-term care is still characterized by multiple providers and delivery methods. Historically, local municipalities have been in charge of providing social care services and ASLs have been considered responsible both for health-care services and some social care. Thus, the provision of long-term care is something of a 'jungle' where many different actors play according to different rules within different care models. In between, GPs act as the essential guide for patients, helping them to navigate the different options available when dealing with chronic diseases. While legislation has aimed to improve integrated care (see section 5.3), effective integrated long-term care is still a long way off.

Residential or semi-residential facilities (*Residenze Sanitarie Assistenziali* – RSA) and community nursing homes (*case protette*) represent the usual institutional setting for caring for elderly and disabled people, including those with mental health conditions (see section 5.11). RSAs generally care for patients who require more intensive use of health-care resources, whereas less critical patients are directed towards community nursing homes. In 2011 there were 333 091 elderly and disabled patients living within residential facilities, with the elderly making up 84% of the total (Osservasalute, 2012). Despite the strong financial restrictions of the Spending Review (2012), at national level the number of post-acute care beds (in hospitals and including those in residential and semi-residential facilities) increased marginally (37 252 beds in 2011 compared to 37 153 in 2009) (Ministero della Salute, 2011a). In 2011,

the discharge rate for long-term beds remained stable in comparison to the previous year, with 1.6 admissions per 1000 inhabitants. The bed rate for elderly and disabled patients was 567.8 per 100 000 inhabitants in 2010, with strong variations between northern and southern regions: rates are higher than 776.8 (per 100 000) in the north, while in the south the lowest rate is recorded in Campania (180.3 per 100 000) and the highest in Molise (601.0 per 100 000) (Osservasalute 2012).

An example of integrated service delivery is represented by the home care model (*Assistenza Domiciliare Integrata* – ADI), which is part of the benefit package. The ADI care model is based on the formulation of a Personal Care Plan (*Piano Assistenziale Individualizzato* – PAI), according to an individual's care needs. Once discharged from hospital or in line with a GP's request, a multidisciplinary unit (*Unità di Valutazione Multidimensionale* – UVM) of different health-care professionals (GPs, medical, nursing and rehabilitative staff) is activated to assess the patient's needs. Home care, in terms of timetables, services, service providers and responsibilities within the team, is defined within the plan and a case manager, who is in charge of tracking the patient's overall health status and treatment, is nominated. Nationally, 597 151 people received home care services in 2010; 990 cases per 100 000 were patients receiving services under ADI, representing an increase of 11.7% compared to 2009. There is considerable regional variability in the implementation of ADI (Osservasalute, 2012).

Financial support and vouchers for both home care and residential facilities (including disabilities support) vary considerably across regions and municipalities, where these funds count for 61% of their social expenditures. Municipalities spend, on average, €5198 per person to support long-term care: typical examples include €2136 per person for home care services and €1665 per person for benefits vouchers. In particular, social expenditure for residential care can vary hugely from €954 per person in Molise to €21 753 per person in Valle d'Aosta; home care financial support ranges from €1000 per person in Calabria to €4001 per person in the Autonomous Province of Trento (Osservasalute, 2012).

5.9 Informal and formal carers

Informal care, defined as the provision of unpaid care-giving activities, is not an area of focus in terms of specific national policies, although there is increasing attention about its fundamental role and implications. The traditional social

and culture features of the Italian population makes the role of informal carers, mainly women, extremely relevant in the care of fragile elder patients. As a matter of fact, a large part of the population, mainly family members, provide informal health care without receiving any kind of subsidy from the government and professional support (e.g. training). Many patients' organizations try to cope with this deficiency by collecting funding and delivering services to patients and informal care-givers.

More recently, the phenomenon of 'Badanti' (paid carers) has grown across the country, where care for the elderly or the disabled is mainly provided by immigrants or women on very low incomes. Quite often such carers do not have any formal training to provide appropriate care and they may also incur occupational-related problems such as working long hours, and incurring back injuries and mental strain. The state provides some cash benefits for disabled people, including the elderly, to support care at home, but too often these services are paid partially or fully out of pocket by families. Benefits in kind and cash benefits are also provided by local municipalities.

5.10 Palliative care

The development of a palliative care policy in Italy is relatively recent. The National Health Plan 1998–2000, for the first time, devoted attention to the implementation of a national palliative care programme and Law 39/1999 was approved to implement its objectives by earmarking funds to the regions to establish residential facilities. More recently, Law 38/2010 introduced broader access to palliative care and pain management, which is also based on local services managed by ASLs. The most common model is the palliative care unit, which operates within the hospital structure to provide care for all types of patients (including paediatric patients) suffering from chronic and degenerative diseases. The palliative care network involves outpatient care, home care services, day hospital, hospitalization in dedicated beds and, mainly, residential facilities for terminal patients, mostly suffering from cancer, called hospices. In particular, hospice facilities have been developed to provide long-term admissions and medical care for dying patients in the last months of their disease. However, there is still significant inequality between regions regarding the distribution of hospices and the funds allocated for palliative care generally.

5.11 Mental health care

In 1978, the ground-breaking psychiatric reform law (the 'Basaglia Law' No. 180/78), marked the switch from institutional care to community mental health services, changing the main features of the Italian mental health system. The principal element of the reform was the definition of a new approach to mental health, adding momentum to prevention and promotion and reducing public intervention in terms of control and segregation of people with mental health disorders. In addition, the Italian system made a clear distinction between mental health care for adults and children, with the former falling under the responsibility of general psychiatrists and the latter to other specialists trained as infant neuropsychiatrists.

The legislation established a shift away from hospitalization towards outpatient care and can be summarized by the following features:

- New admissions to mental health hospitals were prohibited and thus discontinued.
- All mental health hospitals were closed down.
- General hospitals were generally required to have psychiatric wards so that acute and post-acute care were delivered in general hospital settings.
- Community-based care for mental disorders was promoted.
- Compulsory 'health treatment' was regulated. In order to reduce inappropriate admissions to mental health facilities, treatment in hospital wards was made compulsory only in the event of mental disturbances requiring urgent interventions not accepted by the patient, to safeguard patient and community safety and if there is no alternative care option.

Notwithstanding the relevance of this new orientation in the provision of mental health services, the lack of strict guidelines and the transfer of responsibility to the regions to set up hospital-substitute services resulted in different levels of implementation across the country.

The reform was phased in over a period of time but at the same time the process of deinstitutionalization often led to a lack of effective care for people with mental health disorders and increased the burden of responsibilities on families.

To overcome these shortcomings, in the mid-1990s, the Ministry of Health launched a strategy for the protection of mental health (*Tutela Salute Mentale 1994–1996*), establishing a network of services to ensure a continuum of care at

the primary care level. Departments of Mental Health (DMHs) were established within ASLs to guarantee the promotion and coordination of mental health prevention, treatment and rehabilitation, and to deliver outpatient and inpatient care. They comprise a complex of integrated facilities and services spread throughout the country with a defined catchment area, usually corresponding to an ASL, and include different health professionals such as psychiatrists, psychologists, nurses, social workers and educators. Patients can have direct access or with a GP referral. A few years later, an updated mental health strategy (*Tutela della salute mentale, 1998–2000*) highlighted some critical aspects of the system such as the low specialization of the DMHs, which were limited to adult psychiatry, the lack of services targeted to child psychiatry and to alcohol and drug abuse, and the need for better coordination between different health professionals. The updated strategy tried to address these issues, devoting more attention to children's and adolescents' mental health, promoting active participation of patients in the community with parental involvement, and fostering the integration of care pathways within multidisciplinary teams.

DMHs provide four type of services (see Fattore et al., 2000 for an example):

1. Community Mental Health Centres (CMHCs). These units cover all activities related to adult psychiatry for outpatient care, coordinating interventions across different facilities and settings.
2. Semi-residential facilities for mental health day care services (day hospital and day centre).
3. Residential facilities responsible for therapeutic–rehabilitation and socio–rehabilitation of mental health patients.
4. Psychiatric units within hospitals, with up to 15 beds, for acute admissions. They provide short/medium-term care for urgent interventions and are closely linked with the CMHCs to ensure continuity of care.

In 2010 there were 144 DMHs, corresponding to the number of ASLs in each region (except for Bolzano and Sicily), and 1464 CMHCs (Ministero della Salute, 2013d). In addition, mental health care was provided by 2297 residential facilities and 1279 semi-residential facilities nationally, with a higher prevalence of private accredited providers. In Italy only a small percentage of people receive specialist care and a low percentage of the adult population contacts DMHs.

According to the National Health Plan for 2011–2013 the priorities for the mental health system are:

- to close the gap between northern and southern regions with regard to the provision and quality of services, which remains a major challenge;
- to develop and reinforce services targeted towards children and adolescents throughout the country;
- to ensure an adequate flow of information on mental health and to provide high quality data.

5.12 Dental care

There is very little public provision of dental care, with limited SSN resources allocated to reimbursable services. A minimum set of services is included in the benefit package. These are preventive and diagnostic services, treatments for caries and associated complications, periodontal diseases, dental occlusion and dental bone-related complications and emergencies. In order to access these services, co-payments are necessary, with exceptions granted to children aged 0–14 and vulnerable groups (patients on low incomes or those suffering from chronic diseases). Most dental treatments are purchased privately, OOP, by patients. Oral health care is provided mainly by private dentists and dental hygienists, organized in self-owned and small-size practices or bigger organizations involving different specialists, laboratories and technicians.

5.13 Complementary and alternative medicine

Complementary and alternative medicine (CAM) treatments are not covered by the SSN, and thus are usually purchased OOP. In its *Guidelines for Non-conventional Medicines*, the Italian National Federation of Colleges of Medical Doctors and Dentists recognized the following CAM therapies: homeopathy, phytotherapy, acupuncture, homotoxicology, traditional Chinese medicine, anthroposophic medicine, chiropraxis, osteopathy and ayurvedic medicine (FNOMCeO, 2009). The regulatory system states that CAM must be practised only by physicians who have a degree in medicine or surgery, have passed the state examination for practice and must be registered on a professional register. There is no recognized medical specialty devoted to complementary/alternative medicine. In the treatment of cancer patients the most popular remedies are homeopathy, herbal medicine and spiritual therapies. While these therapies are not covered by the SSN it is notable that Tuscany provides some under additional regional coverage.

5.14 Health care for specific populations

For over 30 years, Italy experienced large and constantly increasing international immigration. According to the most recent estimate, around 200 000 immigrants were recorded in 1980, 500 000 in 1990, 1.6 million in 2000, and currently around 4.5 million individuals (Osservasalute, 2012). These data refer to documented migrants. Immigrants represent approximately 7.5% of the national population (compared to a European average of 6.6%), mainly concentrated in the north (61.3%) and they count for 10% of the workforce (men mainly engaged in the construction and building sector and women in services to people). Most immigrants (27.4%) come from other EU Member States and their generic profile includes young and mostly female individuals (50% of the total). Minors whose parents are immigrants total about 1 million people, 70% of whom were born in Italy (Osservasalute 2012).

Considering the important economic and demographic impact of immigrants (contributing to 12% of GDP growth and doubling the country's fertility rate), integration policies for foreign residents are still inefficient and sub-optimal (Associazione di Iniziativa Parlamentare Legislativa per la Salute e Prevenzione, 2013). Nevertheless, after several years without specific regulations, legislation has now been defined to guarantee that immigrants (both documented and undocumented) are eligible to receive the same public health-care services that are available to Italian citizens (see Chapter 6). This framework (which has been ongoing since the late 1990s) has produced, over time, increased access to health services (with improvements in terms of maternal and child services indicators as well as for certain infectious disease incidence rates). Unfortunately, problems remain related to welcoming immigrants and supporting their social integration. Moreover, the heterogeneity of health policies adopted by individual regions creates inequalities in terms of the availability of services. At the level of services, in fact, there is currently little flexibility in reorganizing health-care structures to make them culturally sensitive and socially responsive to emerging priorities, particularly in the areas of preventive and public health.

Prison inmates are considered to have the same health rights as Italian citizens and so are registered in the SSN with access to the whole benefit package (Legislative Decree No. 230/1999). If such prisoners are also immigrants they are registered in the SSN as long as they are in jail. All services provided in prison have recently been assigned to the SSN and its organizations (mainly ASL and AOs) that are in charge of coordinating, supervising and providing

core services. Military personnel have additional services to those generally available to citizens and these are directly provided by military facilities financed and managed by the Ministry of Defence.

6. Principal health reforms

The National Health Service was established with a radical reform in 1978 and modified in the 1990s and early 2000s. The first reform clearly designed an NHS-type system, fully implemented in the 1980s, that guaranteed universal access to health care. With a 1992 reform, backed by the 2001 constitutional reform that redistributed powers to the regions, the National Health Service was regionalized. Now most health policies are developed and implemented by regions, with an increasing heterogeneity of institutional arrangements, provider payment rules and levels of performance in terms of the quantity and quality of care offered to citizens.

The 1992 reform also envisaged a quasi-market based on patients' choice and competition between public and private providers but this was mitigated over time with measures that give strong control to regional authorities over the allocation of resources between providers. Another priority was the 'managerialization' of health service organizations; here again, in the last decade regional authorities have centralized administrations, reduced the discretion of management and not fully supported management development in public organizations.

Overall, the last decade has been dominated by two intertwined issues: regional fragmentation and the need to maintain financial control within regional health systems. Italy's fiscal crisis has put the health system under strain; the central government has acted to control total health expenditures but performance in terms of health protection is increasingly governed at regional level, with large variations, mainly but not exclusively, between the northern and southern parts of the country.

6.1 Analysis of recent reforms

6.1.1 Establishment and 'second' reform of the SSN (1978 and 1992/93)

The SSN was established in 1978 by replacing a system based on multiple social health insurance funds. This was the first major health-care reform in the post-Second World War period. The SSN was fully implemented in the 1980s through substantial unification and harmonization of regulations, information systems and procedures that derived from several independent organizations (sickness funds and providers). However, despite full implementation, the 1980s clearly signalled some major weaknesses of the health system, namely the lack of financial control by the central government over expenditure, the over-politicization of SSN organizations, the frequent conflicts between the three political tiers of government and the lack of specific management systems and expertise to run health-care organizations (Ferrera 1995; Mapelli 1999; Fattore 1999; Borgonovi, 2001; France, Taroni & Donatini, 2005).

While reform of the SSN's founding legislation had been on the policy agenda since the mid-1980s, it was not until a critical juncture in 1992 that an opportunity to design and approve major changes (Law N. 421/92; Decree Law N. 502/92; Decree Law N. 517/93) presented itself. In 1992 the country's main governing parties collapsed under the pressure of several corruption scandals, including a major one concerning the regulation of pharmaceuticals (Fattore & Jommi, 1998). In addition, a severe economic crisis and the high level of public debt threatened Italy's ability to meet the Maastricht criteria on proposed European monetary union. Within this context a new government successfully managed to steer through the crisis, significantly reduced public expenditure in most public sectors, including health care, and regained the confidence of financial markets and European institutions. In this window of opportunity a reform of the SSN (also called the second reform) was rapidly approved. The reform included four main components: (1) regionalization; (2) managerialism; (3) quasi-market for specialist care; and (4) opting-out of the NHS (this last component was repealed in 1993) (Fattore, 1999).

(1) Regionalization

Institutional arrangements in health care were reconfigured by virtually eliminating the role of municipalities and reducing the powers of the national tier of the SSN in favour of the 19 regions and 2 autonomous provinces. While the 1992 legislation introduced the idea of 'basic benefit packages' (*Livelli Essenziali di Assistenza* – LEA), which are defined by the central government,

regions were given new competences to strengthen their fiscal autonomy (and responsibility) and the scope of their policies; they were also given new organizational powers. The model envisaged by the reform was that the national level would define the guaranteed basic benefit package and ensure that regions received adequate resources to deliver it. Conversely, regions were mandated to provide the nationally guaranteed services, and would have to use their own resources if they were unable to do so due to inefficiencies or if they wanted to provide additional services beyond those specified in the national basic package.

In addition, within a rather broad national framework regions were allowed to redesign health service supply systems and the boundaries of ASLs, detach larger and more specialized hospitals from ASLs, design new systems to pay providers, define accreditation systems for both public and private providers, and give providers guidelines on their organizational arrangements. Although regions already had several powers since the foundation of the SSN, with the 1992 reform they become the main owners of the health system. These arrangements were confirmed and enhanced, by constitutional changes approved in 2001 (Constitutional Law N. 3/2001) (see below).

(2) Managerialism

The second main area of change prompted by the reform concerned the role of management in the SSN. Appointed politicians were substituted by professional managers as heads of SSN organizations, namely the ASLs and AOs. The legislation made it compulsory to appoint general managers with a university degree and with management experience (even outside the health-care sector); they also had to be selected from a list of potential candidates identified by each region. General managers of ASLs are now employed according to fixed-term private contracts and can be dismissed by the region. General managers are responsible for appointing the Health and Administrative directors within ASLs (and in most regions, also the Directors for Social Care).

National rules on labour contracts were modified to grant more flexibility to local organizational arrangements and to allow more room for performance-based payments. Factors such as new legislation and directives, increased sensitivity of the need to develop adequate systems to run health-care organizations and a more competitive environment prompted the introduction of new management functions, such as cost accounting, budgeting, strategic planning, need assessments and quality control. In addition, the traditional financial accounting system, aimed at planning expenditure and measuring financial performance, was backed up by an accrual accounting system that allows for the measurement of organizations' economic viability and tracking

of their assets and liabilities. However, even in this respect, up to 2011 regions were given the freedom to design their own systems, and consequently there were important differences across regions' accrual accounting systems. Since 2012 uniform accounting standards apply to all public health-care organizations throughout the country. Overall, the 1990s was a period of investment in managerial systems and competences in the SSN.

(3) Quasi-market for specialist care

The reform designed a quasi-market for specialist care based on three main principles (Fattore 1999; Anessi Pessina & Cantù, 2006; France, Taroni & Donatini, 2005). Firstly, patients were given complete freedom to choose any SSN provider (even outside their region) without the need for prior authorization. Secondly, private organizations were included in this competitive arena provided that they were accredited by the region in which they operated. Therefore, the Italian SSN, at least in theory, established a fair playing field between public and private providers. Finally, a fee-for-service payment system (for outpatient care) and a DRG system (for inpatient hospital care) were introduced. By 1995 all regions were required to have an adequate information system to collect data for the attribution of each inpatient episode to Italian DRGs. In a relatively short period of time the SSN translated and adapted the US Medicare DRG system to the Italian context and produced weights and tariffs for each group on the basis of a small purposive sample of hospitals (Taroni, 1996; Fattore & Torbica, 2006). For outpatient specialist care the *Nomenclatore Tariffario*, basically a long list of possible services with their relative tariffs, was issued.

On paper, the quasi-market system designed by the reform was rather radical as it is based on the free choice of providers (including private ones) by patients and strong incentives to increase volumes, fill hospital capacity and reduce length of stay. As such, the Italian reform was different to that introduced within the British NHS under Margaret Thatcher, which was based on contractual arrangements between purchasers and providers and did not include official tariff systems. However, it should be noted that implementation of this national model varied across the regions. At one extreme was Lombardy (the largest and most prosperous region), which neatly separated hospital care from ASLs and which favoured the role of the private sector, while at the other, some southern regions greatly limited the extent of competitive forces and the use of tariff systems to fund providers (Cantù & Carbone, 2007). However, since the end of the 1990s virtually all regions have reduced the extent of quasi-markets through the introduction of a variety of measures that limit market forces, such as the

use of targets and ceilings, to directly govern the volume and revenues of both public and private providers (Jommi, Cantù & Anessi-Pessina, 2001; Cantù, Ferré & Sicilia, 2010).

(4) Opting out

A fourth element of the reform, repealed in 1993, was a vague move towards granting regions the possibility to allow patients to opt-out of the SSN. The idea behind this provision was that citizens would have continued to pay their share of taxes for the SSN but they would have been given a voucher to be spent in the private insurance market. Had it survived, this measure would have overhauled the very heart of the Italian SSN (Ferrera, 1995).

6.1.2 The 'third' SSN reform (1999)

A further reform, often labelled the third health-care reform, was approved by a centre-left government in 1999 ((Bindi) Reform Law No. 229/1999). It included a number of measures and, at a more political level, the attempt to reverse the cultural direction of the 1992 reform, especially concerning its pro-market orientation. The new legislation began by re-stating that health was a citizen's right and a collective responsibility. It also emphasized that the SSN was a universal system under government control. The government's intent in restating these principles was to limit attempts by some regions to deviate from the national model (for example, as in Lombardy) and to better control the private sector. This attempt was criticized from many quarters (Taroni, 2011) and, de facto, had a limited impact on the SSN, which in the following years, increased rather than decreased its level of decentralization.

The most controversial component of the reform was its attempt to better regulate the medical profession. It introduced a regime where salaried SSN doctors had to choose between two options for private practice (additional professional activities outside SSN funding). *Intra-moenia* doctors were authorized to have private practices but only using SSN facilities (hospitals or ASL ambulatory clinics) and under the control of their independent hospitals or ASLs. As an incentive to choose this option, the new rules stipulated that only these doctors could access senior management positions (e.g. being a department's director). The second option was for doctors to operate *extra-moenia* – meaning to practise independently – outside of SSN facilities; such doctors were prevented from having senior management positions and were paid lower salaries. These rules changed several times and are still highly debated. Currently, the two options for private practice still exist but the more

favourable career advancement conditions attached to *intra-moenia* practice are no longer in place (see section 3.7.2). The 1999 reform also put the provision of health care in prisons under the control of the SSN and its structures.

6.1.3 The legacy the 1990s' reforms

The two reforms approved in the 1990s are still debated as opinions differ about their meaning and impacts. Taroni (2011) states that quasi-markets were short lived. Indeed, regional policies have limited the extent of competition between providers through caps and targets for each provider and funding arrangements where DRG and fee-for-service reimbursement are coupled with other lines of funding, typically block grants for specific functions and activities. Interestingly, competition is stronger for patients seeking health services outside their region of residence, with significant flows of resources between regions, especially from the south to the north and the centre (Fattore, Petrarca & Torbica, 2014). Even the managerialism reforms that initially received wide support were weakened over time due to increased centralization of decision-making at regional level, which reduced the degrees of autonomy of SSN organizations, and limited use of management systems to improve their performance.

Nevertheless, compared to other sectors of the Italian public administration, the SSN – at least in the regions with stronger capacities – has been dynamic both at regional and organizational level with new management roles and systems that have helped to govern the complexity of health care. While the 1992/93 reform contained attempts to transform the SSN into a mixed system where private initiatives could have put at risk some of the health system's main principles, the overall attempt to overhaul the system was also genuinely driven by the search to modernize the system in line with other major reforms in Europe.

In the late 1990s it also became apparent that little had been done in primary care. Despite a lack of systematic reform, both the national and regional governments attempted to improve the performance of primary care doctors, mainly through two strategies. The first focused on promoting stricter relationships between GPs, and between GPs and district services such as home care, social care and public health. In the last 15 years a number of initiatives established forms of group practice, mainly based on collaboration rather than on sharing facilities, and in many regions GPs were incentivized to work with their ASLs and to establish primary care centres (see Chapter 5). Nevertheless, the basic solo-practice arrangements prevalent in primary care have not radically changed. The other strategy aimed to make GPs more accountable

for the expenditure attributable to their professional activities. Several regions implemented systems to monitor, control and often incentivize primary care physicians to contain pharmaceutical expenditure and to reduce patients' access to unnecessary specialist and emergency care.

6.1.4 Stronger regionalization and health expenditure control

In 2001, a major Constitutional reform (Constitutional Law N. 3/2001) was confirmed in a referendum by 64.2% of voters. It introduced the direct election of regional governors and redistributed legislative competences between the national government and regional governments, framing a quasi-federal arrangement for the Italian state (Table 6.1). Public policies were divided into three categories: (1) those exclusively under the jurisdiction of the national government; (2) those exclusively under the jurisdiction of regional governments; and (3) those under the joint jurisdiction of both tiers of government, granting the national government general powers and giving regions powers limited by national laws. In addition regions were allowed to enforce laws in all sectors that the Constitution did not explicitly attribute to the remit of the national government (Caravita, 2004).

The 'right to health' was assigned to the joint competence of the state and regions, while organizational matters were exclusively attributed to regions. As a result, regions gained wide legislative autonomy in the field of health, with the national government retaining the authority to define the general framework. Thus, the central government retains a set of powers revolving around health protection and also decides on the basic benefit package (LEAs) to be universally guaranteed (Maino, 2003). The scope of the reform was such that its implementation has been uncertain and remains controversial. The main concern has been that the strengthening of regionalization leads to significant regional diversities and risks fragmentation of the SSN (Pellegrino, 2005).

In the years following the Constitutional reform, agreements between the national government and regional governments, such as the three-year Pacts for Health agreed upon by the State-Regions Conference, have become the main instrument of health policy, although the agenda has been increasingly taken over by the need to better control regional health-care expenditure (see below). Over time, the reconfiguration of powers between the national and regional governments, in a context of fiscal austerity, has created a shift of power at national level from the Ministry of Health (MOH) to the Ministry of Economics and Finance (MOEF). While most policy powers are now in the hands of regions, and national policy-making has to be agreed between the

regions themselves and between them and the Ministry of Health, the need for expenditure control strengthens the role of MOEF, which now directly monitors health-care expenditure and has direct powers over regions that overrun their budgets.

In 2001, Law 405 introduced stronger responsibility in the control of health-care expenditure. In 2004, the first of a series of measures was introduced to ensure the financial recovery of regions with large health-care expenditure deficits. They include compulsory financial recovery plans, whereby regions with deficits are forced to comply with specific terms to improve their financial balances within given deadlines (Ferré, Cuccurullo & Lega, 2012). Such regions are regularly monitored by national government agencies and can be sanctioned if they fail to comply with their recovery plan's terms. Sanctions include the possible appointment of a national government-appointed commissioner to temporarily oversee the management of the region's health-care system, temporary suspension of the region's workforce turnover, as well as mandated (by the central government) tax increases. The details of these conditions have been continually redefined over the years, towards increasing controls and sanctions; for instance, the maximum accepted level for a regional health-care budget deficit was originally set at 7% but was reduced to 5% in 2009. Since 2010, steps have been taken to soften the conditions of the recovery plans; regions submitted to this regime are given more time to comply with the requirements, and the restrictions on workforce turnover have been partially loosened. In 2012, incentives were introduced for regions that introduced better budget management measures.

6.1.5 The impact of the economic crisis and cost containment

Since 2009, under pressure from the international financial crisis and amid increasing political instability, government interventions in the SSN have taken the form of either urgent decrees or entries in the annual state budget law rather than systematic reforms, and have mostly consisted of cuts to public expenditure (de Belvis et al., 2012).

Central cost containment policies use a variety of strategies. On the one hand, they strengthen control over total expenditure and make use of sanctions to ensure that regions do not overspend. On the other, they directly operate on the sources of regional spending (input costs) through measures on the payment of personnel, recruitment, standards for hospital care (e.g. minimum size of hospitals) and expenditure for goods and services. For example, a major ongoing policy to contain pharmaceutical expenditure includes measures such

as redefining the proportions of the total cost pertaining to pharmaceutical companies, wholesalers and pharmacies; a progressive reduction of the cap on regional pharmaceutical expenditure in primary and community health care; a reduction of the prices of equivalent drugs, along with other measure to promote their use; and the introduction and progressive extension of the claw-back system which requires pharmaceutical companies to pay back increasing amounts of money to regions when the nationally determined expenditure caps for pharmaceuticals are exceeded. Another example is the significant reduction in the expenditure caps on purchasing medical equipment and services by the SSN (2010 to 2013). Such measures were strengthened in 2012, with an emphasis on the identification of standard costs for all SSN contracts and a reduction of the number of hospital beds from 4 per 1000 inhabitants to 3.7 per 1000 inhabitants. In addition, the central government has impelled regions to significantly reduce expenditure on health-care personnel (see Chapter 4).

During the last months of the Berlusconi government in Autumn 2011, additional measures were adopted as part of the 2012 budget law, such as a reduction in health funding for the period 2012–2014. In the context of a general public spending review that started in 2012 under the technocratic government (led by Mario Monti), the health-care budget was reduced by €4.7 billion in the following three years (Paterlini, 2013). In addition, the budget cut was coupled with the reintroduction of co-payments for outpatient care (€10) and for non-necessary emergency admissions (€25) (see section 3.1).

Table 6.1

Major reform milestones for the Italian National Health Service (SSN)

1978	Decree 833/1978 establishes a tax-funded national health service (SSN) on the basis of universal coverage.
1992–1993	Law N. 421/92, Decree Law N. 502/92 and Decree Law N. 517/93 propel the devolution of health care to the regions. In addition, managerial autonomy is granted to local health authorities (ASLs) and hospitals (AOs) and elements of an internal market are introduced.
1999	Decree 229/1999 promotes further development of devolution; strengthens cooperation and regulation to partially reorient the internal market; establishes the tools for defining the core benefit package; introduces *intra-moenia* practice; regulates the introduction of clinical guidelines for quality in health care.
2001	Constitutional Law N. 3 modifies the second part of the Italian Constitution (Title V), giving regions more powers, including in health care.

6.2 Current and future developments

6.2.1 Fiscal federalism

The 2001 constitutional reform included the general provision of fiscal federalism, setting forth the principle that sub-national levels of government – regions, provinces and municipalities – should only spend money that they collect themselves from their own constituencies and, to a lesser degree, have access to resources that reflect their constituencies' contribution to national taxes through personal, corporate and other taxes. Thus, this significant reform entails a wholesale redesign of Italy's fiscal system to make it more decentralized and dependent on regional contexts but provides for a redistribution of resources across regions if needed in order to guarantee basic services for all citizens. Since regions are responsible for the organization and delivery of health care, the full implementation of the reform will have a significant impact on resource allocation and the funding available to their health systems. However, the 2001 legislation did not provide details on how the principle of fiscal federalism should be implemented, leaving this to subsequent legislation. Since then, progress has been piecemeal and is still incomplete.

A major step was taken in 2009 with the adoption of a framework law for fiscal federalism (Law No. 42/2009). The framework law outlined the composition of revenues for sub-national levels of government, defined the principles for redistributing resources to those with the lowest own revenues and identified the processes to ensure coordination between the different government levels. One pivotal element for the funding of health-care services is the provision to establish an Equalization Fund whereby regions with a tax income that is too low to ensure provision of a minimum standard of services (standard needs) within a broad spectrum of services (e.g. health, social services, education) would be supported by central transfers from wealthier regions and the central state.

The proposed new financing system reflects the current framework but with some significant differences. Currently, central transfers are a weighted capitation system – that is, they simply maintain a region's expenditure level from the previous year. This arrangement is claimed to cause significant inefficiencies, as different regions tend to spend different amounts of resources for the same services (i.e. they have different efficiency levels). Under the proposed new system, both the difference between the region's own revenues and the costs they have to sustain and, where this difference exists, the amount of central transfers, would be computed based on a system of standard costs,

identical for all regions. Standard costs of production should be set at the level of the average service costs of the best performing regions on health-care expenditure targets and, in future, be used for resource allocation (see section 3.3.3 for further details on the new system of standard costs of production).

So far, however, neither the Equalization Fund nor the new resource allocation framework has been operationalized. While nine enforcing decrees were approved by parliament during 2008–2013, in 2013 a special Parliamentary Commission noted that the reform was far from complete: several important aspects had either not yet been covered by decrees or had been deferred. Several political factors have played a role: firstly, the three changes of government since 2011, with the subsequent political instability, have not been conducive to reaching consensus on many of the reform's key aspects; secondly, the policy priorities imposed by the international financial crisis and the country's economic difficulties have tended to dominate; and thirdly, other concurrent reforms that clash with the principles of the fiscal federalism framework legislation (Law 42/2009), such as the possible abolition of the provinces, and continual reforms to municipal taxes, have stalled its implementation. It is unlikely that the reform will be repealed, as most political parties agree that it should be enforced. Nevertheless, uncertain future political scenarios will determine both when it will happen, and what the precise content of the reform will be. Indeed, several aspects are still open to debate, the most prominent being the definition of the standard needs of regions.

6.2.2 'Balduzzi decree' health system reforms

In 2012, an attempt was made to introduce the most comprehensive reform of the health-care system since 1999, the so-called Balduzzi decree – named after the health minister at the time. The basic benefit package (LEA) was significantly revised for the first time since 2001, with the inclusion of treatments for 110 rare diseases and other services such as epidurals during childbirth. In addition, the private professional activities of SSN doctors were addressed by introducing measures to incentivize specialists to conduct their activities within SSN facilities. It was also decided that primary care should be reorganized into teams of professionals to provide 24-hour coverage and thus ensure continuity of care (group practice), while stronger restrictions were introduced on smoking and alcohol consumption for minors. Furthermore, a series of policies to contain pharmaceutical costs was followed up by a revision of the list of reimbursable pharmaceutical products as well as the introduction of health technology assessment to negotiate their prices based on efficacy,

according to international best practices. Although the Balduzzi reform was successfully passed by parliament, as of 2014 its provisions have not been fully implemented, as the political instability following the 2013 election prevented the necessary enforcement decrees from being passed.

6.3 Conclusion

The last decade has been dominated by two intertwined issues: regional fragmentation and the need to maintain financial control within regional health systems. Backed by the reforms of the 1990s and constitutional changes, regions have gained further organizational autonomy. Some of them, due to stronger institutional capacities and more favourable socioeconomic conditions, have acted to improve their health systems while remaining financially viable; others, mostly in the south of the country, have overspent and seem unable to improve efficiency and efficacy. The financial crisis has probably exacerbated the situation. The most recent data show that current expenditure is under control in all regions (Armeni & Ferré, 2013). However, cross-regional flows of patients, satisfaction with the health system and other indicators of performance (e.g. number of hospital beds, inappropriate hospital admissions and community care) suggest that the national right to health care is not homogenously offered across regions.

7. Assessment of the health system

Italy currently spends less than the OECD average on health care in relation to its GDP (9.2% in comparison to the OECD average of 9.3%), though public spending is increasing at a faster pace than total private spending and OOP expenditure.

Despite the country's federal structure, most regions cannot fund health care with their own resources, relying on the central transfers to compensate for the differences in regional incomes. Regions also allocate their funds differently, with some southern regions still suffering large deficits and with secondary care favoured over primary and community health services.

While equitable access to health care is one of the statutory objectives of the health system, severe inequities in health status and health-care provision appear to exist across socioeconomic population groups. A significant part of these inequities stem from geographical differences: inter-regional disparities in population wealth, health-care resources and efficiency of care are especially evident between northern and southern regions. This pattern is also substantially echoed in the geographical distribution of satisfaction levels with the health-care system and its performance. Generally, however, over the last few years there has been a general decrease in satisfaction levels, and problems such as long waiting times for outpatient and diagnostic services exist across the country. The current system of specialists providing both public and private care might be contributing to waiting lists as well as favouring the wealthier over the poorer in terms of access to specialist care.

Life expectancy of Italians is one of the highest in the world, and their mortality profile is comparable to that of the other high-income countries. Prevention policies have been successful in increasing coverage for the most important vaccinations. Estimates of avoidable mortality suggest a progressive improvement and care for chronic conditions compares well at an international

level. However, the prevalence of risk factors such as overweight and obesity is significant, and health-care outcomes are inequitable across regions, genders and socioeconomic groups.

National funds are distributed to regions using formulas that aim to ensure coverage of the full scope of public health care, including primary care, hospital care and community health services; the age structure of the local population and health needs are also considered. However, the allocation formulas have been changed frequently and further reforms are currently ongoing. Despite increasing financial controls, the costs per patient treated, per service provided and per input units (e.g. costs per hospital bed) in secondary care have not decreased over the last 25 years but have actually increased and are higher than in most other OECD countries. The best explanation available for this is the disproportionately high number of hospitals of small size. The median size of Italian hospitals is one-third less than that of Germany, France and Austria, and around half that of UK hospitals. This could be due to small hospitals compensating for poor community health services such as home care and long-term care, especially in non-urban areas. Data from primary care also suggest wide geographical variations in technical efficiency. The use of generic pharmaceuticals has been increasing as a result of targets but their market penetration is still lower than in most other OECD countries. Inter-regional differences in awareness among the public and general practitioners are also a hindrance to greater use of generics.

The national policy agenda has become increasingly aware that availability of data is vital to identify problems, monitor performance and ensure accountability in the health system. Accordingly, several recent interventions have been directed at improving existing information systems and making data available to the public but their implementation has been slow in the absence of systematic monitoring.

7.1 Stated objectives of the health system

Art. 32 of the 1947 Italian Constitution states that the Republic safeguards health as a fundamental right of the individual and collective interest, and guarantees free care to the poor. Based on this principle, the founding law of the SSN (Law No. 833/1978) outlined the following objectives for the statutory health system:

- public responsibility for health protection;
- universal and equitable access to health care;
- global coverage of the care needs of all citizens;
- public financing of health care through general taxation;
- portability of rights across the country and reciprocal care between regions.

The 1992 reform (Decree 502/1992 and 421/1992) was enacted at a time of macroeconomic strain and mainly aimed to reduce costs and increase efficiency. Accordingly, it introduced decentralization, managerialism and managed competition (see Chapter 6). Regions were given full responsibility for the provision of health care, though only partial financial independence; hospitals were given semi-independent governance; and local health units were given an enterprise-like structure and re-named Local Health Authorities (ASLs). For the first time, cost constraints were accepted as a possible limitation to the provision of care.

Further reforms in the late 1990s and early 2000s (Decree 229/1999 and the Constitutional Reform of 2001) attempted to implement the principles of social solidarity and subsidiarity specified by the Constitution. In an attempt to have local health needs met by local actions, regions and ASLs received more power, including greater spending autonomy. Moreover, while it was acknowledged that financial constraints, as specified in the 1992 reform, must be considered in strategic planning and when defining the benefit package, the reforms stated directly that these considerations should not take precedence over the right to health care.

7.2 Financial protection and equity in financing

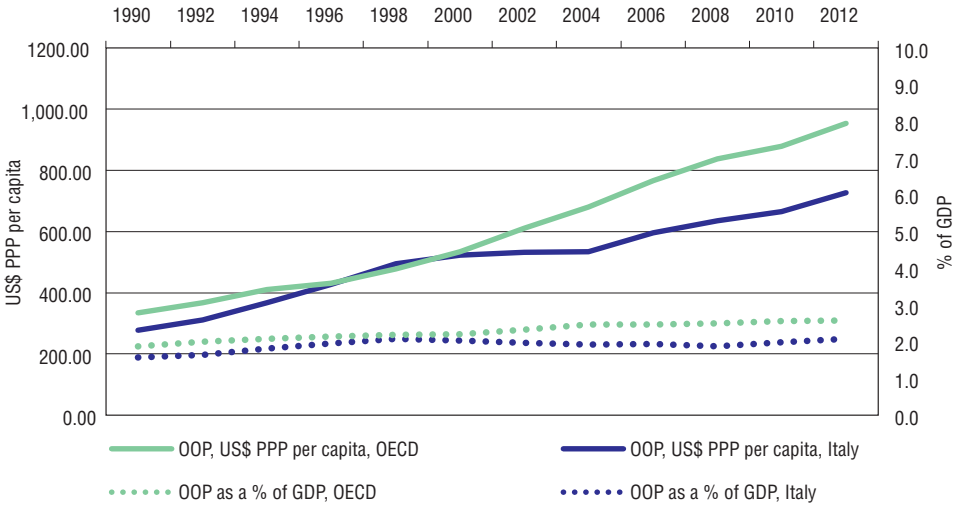
7.2.1 Financial protection

Total health expenditure in Italy in 2012 was 9.2% of GDP, of which 7.3% was covered by public sources and 1.9% by private ones (see Table 3.1). Since 2007 the growth of total health expenditure as a percentage of GDP has been slower than in other OECD countries, and currently is lower than the OECD average (see Chapter 3). Growth has been mainly driven by increased public expenditure: in 2012, total private expenditure was 19.2% of total health expenditure, marking a decline of more than 5.2% since 2000 (OECD, 2014b).

On the other hand, private health expenditure per capita calculated on the basis of PPP shows a consistently increasing trend over the last few years, reaching US$ 548 in 2012 compared to US$ 470 in 2005 (OECD, 2013). The proportion of private expenditure as a percentage of total health expenditure varies significantly across regions. Private health expenditure equals 15.8% of total health expenditure in the poorer southern regions, compared to 21.3% in the better-faring centre-northern regions but as a percentage of GDP it is higher in the south (2%) than in the north (1.7%). This is explained by the lower GDP in southern Italy (ISTAT, 2013a). Historically, OOP payments in Italy have been higher than the OECD average, both as a proportion of GDP and in absolute terms. Between 2009 and 2010 both indicators were slightly lower than the OECD average for the first time in the last 20 years (Fig. 7.1). However, it should be noted that the available OECD data do not yet cover the period from late 2011 when the new more extensive co-payment system was introduced by the regions and which is expected to increase the amount of additional private expenditure for services provided by the SSN (de Belvis et al., 2012).

Fig. 7.1

OOP payments as a % of GDP and US$PPP per capita, OECD average and Italy, 1990–2012



Source: OECD, 2014b.

Average monthly expenditure for health care by households decreased from EUR€91 to EUR€88 between 2010 and 2012 (ISTAT, 2013b). This decrease was more marked among households in central and southern Italy, which widens an

existing expenditure gap with northern households. The composition of spending shows that households in southern Italy spend more on pharmaceuticals than those in the rest of Italy, but less on most other health-related costs, such as specialist visits or diagnostic tests. The percentage of households stating in 2010 that they did not have enough money for health-related expenses is also higher in the south, among those with the lowest education levels, and among employees. However, these gaps have shown a tendency to slowly decrease over the last few years (Table 7.1) (ISTAT, 2013c).

Table 7.1
Percentage of Italian households stating that they did not have enough money for health-related expenses, 2004 and 2010

		2004	2010
Geographical location	North-western Italy	7.0	6.9
	Southern Italy	20.7	18.5
Educational level	Highest educational level (degree)	4.0	5.0
	Lower educational level (lower secondary school or no certificate)	19.3	16.9
Type of employment	Self-employed	6.3	5.8
	Employee	8.7	8.3

Sources: ISTAT, 2013c.

7.2.2 Equity in financing

All regions have a mandate to ensure the same benefit package and the same quality of services. Over the last 20 years, the tax autonomy of decentralized regional governments has increased significantly (Arachi & Zanardi, 2004). However, there are significant differences across regions in terms of economic development, tax income and, ultimately, the proportion of health-care spending that each can afford to cover with its own tax revenues. The remainder of the budget is covered by central transfers or by centrally planned transfers between regions with the specific aim of compensating for inter-regional differences in tax revenues and guarantees the same minimum level of expenditure. While the contribution of regional taxes in financing health care has been steadily increasing, the centrally managed fund is still necessary to sustain expenditure (Fattore, 1999; Cappellaro, Fattore & Torbica, 2009).

Significant geographical inequalities exist in the distribution of resources among different sectors of health care. Several regions, especially in southern Italy, devote a disproportional amount of their expenditure to secondary care, with a possible underfunding of primary care and long-term care. In

2009, beds for older people in residential care ranged from 3.6 per 1000 older residents in Campania (in southern Italy) to 47.71 per 1000 older residents in the Autonomous Province of Bolzano (in northern Italy). In 2010, only two out of the eight southern regions met the goal of providing home care to at least 3.5 older people per 100 residents, while the national average was 4.1. Moreover, several indicators for the appropriateness and efficacy of health care and patient satisfaction with hospital care, consistently point to disparities between the north and south of the country (ISTAT, 2012a).

7.3 User experience and equity of access to health care

7.3.1 User experience

In a 2012 Eurobarometer survey of EU-27 countries, Italy had one of the lowest scores in terms of citizens' perception of the quality of health-care provision, ranking 20th. In addition, it displayed the second greatest decrease (after Greece) from 2011 in the weighted version of the same indicator, and the greatest overall shift of citizens from a generally good opinion to a generally bad opinion of health-care provision (European Commission, 2012). Nationally, a 2010 survey commissioned by the Ministry of Health reported a significant geographical variability in citizens' degree of satisfaction with the health-care system (Censis, 2010). Perceived quality and satisfaction indicators for most health-care services were consistently higher in northern Italy compared with southern Italy, with central Italy displaying intermediate values (Table 7.2).

Waiting times represent a critical issue in outpatient specialist care and diagnostic services, and existing policy initiatives, in contrast with most other OECD countries, focus on these areas (Siciliani, Borowitz & Moran, 2013). Table 7.3 sets out the waiting times for diagnostic tests reported by respondents to a 2010 Ministry of Health survey, showing no significant geographical variation. National-tier interventions to reduce waiting times included the introduction of maximum waiting times as part of the benefit package in 2002, the obligation for all providers to publish waiting lists online and a National Plan for Waiting Lists Governance adopted in 2010 in which specific criteria were introduced to manage waiting lists and to give priority to patients with certain conditions (Ministero della Salute, 2010b). Policy implementation occurs at the regional level, with the creation of Central Booking Centres for appointments, the use of diagnostic and therapeutic pathways and the piloting of Homogeneous Waiting Groups for priority setting (Siciliani, Borowitz & Moran, 2013). Co-payments

Table 7.2

Perceived quality and satisfaction with a selection of public health-care services in different areas of Italy, 2010

	Perceived quality of general practitioners (% of respondents)			Perceived quality of hospital emergency services (% of respondents)			Opinion on general quality of care during hospitalization[a] (% of respondents)		
	Good	Sufficient	Poor	Good	Sufficient	Poor	Very satisfied	Rather satisfied	Little or not satisfied
North-western Italy	56.4	38.6	5.0	50.1	41.4	8.5	44.9	51.5	3.6
North-eastern Italy	52.7	40.2	7.1	45.6	39.7	14.7	59.5	39.1	1.4
Central Italy	46.3	45.0	8.7	27.7	46.8	25.5	32.5	60.3	7.2
Southern Italy	26.2	54.3	16.5	17.7	55.7	26.6	31.3	59.6	7.2
Total	43.4	48.6	8.0	33.8	47.0	19.2	39.3	54.6	6.1

Source: Censis, 2010.
Note: [a]only for citizens who had been admitted to hospital at least once in the previous 12 months.

for services could have had a containment effect on waiting times but it is more likely that broad exemption criteria could have limited this effect to the wealthier and healthier part of the population. Local experiences, such as that of the Veneto region, were successful in introducing proactive systems aimed at reducing waiting times. In Veneto, patients who were expected to wait more than three months for services are now actively monitored in ambulatory care; this measure is expected to reduce the number of patients abandoning waiting lists (de Belvis et al., 2013). It should also be noted that medical specialists might lack incentives to cooperate in reducing waiting times in public health care because these maintain demand for private practice within public structures (dual practice), with possible implications for equity (see section 7.3.2).

Table 7.3

Waiting times for diagnostic tests by geographical area, 2009

	Respondents waiting <7 days (%)	Respondents waiting 7–15 days (%)	Respondents waiting 16–30 days (%)	Respondents waiting 30–90 days (%)	Respondents waiting >90 days (%)	Average number of days
North-west Italy	20.1	19.6	22.3	24.6	13.4	51
North-east Italy	19.4	22.2	25.0	20.8	12.5	46
Centre	20.0	21.3	22.7	20.0	16.0	54
Southern Italy and islands	27.8	15.3	26.4	17.4	13.2	48
Italy	22.3	18.9	24.0	21.1	13.6	50

Source: Ministero della Salute, 2010.

7.3.2 Equity of access to health care

There is significant evidence that access to specialist and inpatient care suffers from significant inequity, with the rich being favoured over the poor (Van Doorslaer & Masseria, 2004; Van Doorslaer, Massieria & Koolman, 2006).

Recent investigations reveal that inter-regional variation in income and recourse to health care is one of the main contributors to inequity. Hospital inpatient care appears to be relatively equitable as it depends mostly on care needs. In contrast, access to general practice was found to be moderately inequitable, deviations from equity being mainly caused by income and regional variation, and access to both specialist and emergency care severely inequitable, with inequity in specialist care being a result of income, education, availability of insurance and inter-regional variation, and inequity in access to emergency care being entirely explained by inter-regional variation (Masseria & Giannoni, 2010). Variations in regional health-care supply might also play a significant role: physicians, hospital beds, occupancy rates and outpatient care indicators are disproportionately concentrated in northern and central regions (Giannoni, Rabito & Masseria, 2007). In turn, the utilization of services is heterogeneous, with evidence of emergency care being used as a surrogate for specialist care in some regions.

A second possible source of income-related differences in access could be the current regulation of private specialist care and waiting times in public health-care facilities. A recent survey compared the frequency of recourse to private care, paid OOP, for services that were also available free-of-charge from the SSN in Italy and the NHS in the UK. This practice appeared to be much more common in Italy, mainly because of waiting times in public facilities (Domenighetti et al., 2010). Italians also appeared to perceive waiting lists as a serious problem in contrast to British respondents. No comprehensive national data on waiting lists exist as yet as compliance with the obligation to publish them online is still incomplete across ASLs (AGENAS, 2010). However, data from a large consumer association suggest that waiting times might be significantly longer in Italy than in the UK (Tribunale per i diritti del malato-Cittadinanzattiva, 2006; Hurst & Siciliani, 2003). It has been suggested that dual practice (*intra-moenia*) – where specialists working in public hospitals can also work privately within public facilities – contributes adversely to this situation. Italian hospital doctors have a lower average income than most other Western countries (50% less than their British colleagues), and long waiting lists

increase their income from private specialist care[29] (Day, 2007). Political debate is ongoing as to whether a more complete separation between public and private care (making the latter less attractive for physicians than it is currently) would be desirable to reduce waiting lists and their effects on equity.

7.4 Health outcomes, health service outcomes and quality of care

7.4.1 Population health

In 2011, Italy recorded its highest mortality rate since 1980 (9.8/1000 inhabitants) (see Table 1.1). Like other western countries, the population is ageing, with the ageing index – that is, the ratio between the population aged 65 and under 15 – at 144.5% (ISTAT, 2012b). Infant mortality declined from 4.92 per 1000 male live births in 2001 to 3.79 in 2008, and from 4.21 to 3.21 for females. Significant geographical disparities persist, with composite mortality reaching 4/1000 live births in the south in 2008, compared to 3.6 in central Italy and 3 in northern Italy.

Chronic degenerative conditions have been responsible for the two most frequent causes of death for several years. In 2010, cardiovascular diseases ranked first, with a standardized mortality of 256 per 100 000 inhabitants, and cancer second with a mortality of 216 per 100 000 (OECD, 2013b). Most cancer deaths are concentrated in the more industrialized north, cardiovascular deaths in the south. In 2010, 4.9% of the population had diabetes, the peak of an upward trend over the last decade. The prevalence is highest in the south, with a value of 5.6%, followed by central Italy with 4.8% and northern Italy with 4.4%. Table 7.4 shows the most recent data on the prevalence of notable lifestyle-related risk factors for chronic diseases.

Pooled analyses of several cancer registries show that the relative five-year survival rate for breast cancers diagnosed in the three-year period 2002–2004 was 87%, having steadily increased from 81% in 1990–1991. The same indicator for cervical cancer was 67% for 2000–2004, also increasing from previous years and projected at 71% for new diagnoses in 2005–2007. For colon/rectum cancer diagnosed between 2000 and 2004, the relative five-year survival rate was 58%,

[29] The British NHS is very different on this point. In the UK, private practice within NHS facilities requires prior agreement with the employer under strict criteria and conditions (Department of Health, 2004), and private providers have agreed to open their services for NHS patients so as to decrease NHS waiting lists (Dyer, 2004), a strategy that might be successful (Jarman & Middleton, 2005; Willcox et al., 2007).

Table 7.4
Prevalence of notable risk factors in Italy, latest available year

Risk factors	Prevalence rate (%)
Smokers among people aged 14 or over, 2011	22.3
Alcohol consumers, 2010	67.3
Overweight people, 2011	35.8
Obese people, 2011	10.0

Source: Osservasalute, 2012.
Note: prevalence rate of people aged 11 or over who consume alcohol at least once a year.

up from just above 40% for diagnoses in 1999–2003. Small differences exist between genders (58% among men, 57% for women) and geographical regions (the indicator ranges from 60% in north-eastern Italy to 56% in southern Italy). The estimated five-year survival rate for patients of both genders diagnosed in 2005–2007 is 64% (AIRTUM, 2011)

Data on avoidable mortality – defined as deaths that could have been prevented with adequate disease prevention and therapy – show a decreasing trend, with the standardized amenable mortality rate estimated at 61.69/100 000 in 2009, down from 63.86 in 2006 (Osservasalute 2012). However, gender differences exist: deaths that could have been avoided by primary prevention in 2008 were 3.8% of total female deaths above 75 but 14.0% of total male deaths above 75 (Ministero della Salute, 2011a). The difference persists in deaths under age 75, with 18.5% for women and 36.9% for men. The largest component in this group is cancer (43.8%), particularly lung cancer (34.7%). Similar, albeit less striking, gender differences exist in relation to hospitalizations for causes considered avoidable by primary prevention, which mainly originate from external causes (e.g. poisoning and trauma) in women, and from heart disease and cancer in men.

7.4.2 Health service outcomes and quality of care

Table 7.5 shows the main indicators of the quality of preventive care in Italy. Coverage for all compulsory vaccinations steadily increased between 2000 and 2011, is uniform across the country and above the optimal targets set by National Health Plans. The only exception is MMR coverage, which is just above 90%, lower than the target set by WHO Europe within the plan for eradication of measles.

Table 7.5
Preventive care indicators in Italy, 2000 and 2011

	2000	2011
DT-DTP vaccination coverage (%)	95.3	96.6
MMR vaccination coverage (%)	74.1	90.8
Flu vaccination coverage, all age groups (%)	12.6[a]	17.8[b]
Flu vaccination coverage, age group 65+ season (%)	50.7[a]	62.7[b]

Sources: Osservasalute 2012; Ministero della Salute, 2014.
Notes: [a]flu season 2000–2001; [b]flu season 2011–2012.

Tables 7.6 and 7.7 show the main indicators of the quality of care for chronic conditions and the management of acute exacerbations of chronic conditions. Data on hospital admissions for chronic conditions are better than the OECD average, but they do not appear to be improving. For instance, admission rates for uncontrolled diabetes are increasing: in 2009 the rate was 33.1/100 000, compared to 28.6/100 000 in 2006 (age-sex standardized rates). Table 7.8 shows a selection of indicators on patient safety.

Table 7.6
Key indicators of quality of care for chronic conditions, Italy and OECD average, 2009

	Men		Women	
	Italy	OECD average	Italy	OECD average
Hospital admission rate for asthma	14	36	24	66
Hospital admission rate for COPD	187	251	84	154
Hospital admission rate for uncontrolled diabetes	36	54	30	46

Source: OECD, 2014b.
Note: all data are the age–sex standardized rate per 100 000 population aged 15 and over.

Table 7.7
Key indicators of quality of care for acute exacerbations of chronic conditions, Italy and OECD average, 2009

	Crude rates		Age and sex-standardized rates	
	Italy	OECD average	Italy	OECD average
In-hospital mortality rate for myocardial infarction	6.5	7.9	3.7	5.4
In-hospital mortality rate for haemorrhagic stroke	22.2	22.6	17.6	19.0
In-hospital mortality rate for ischaemic stroke	7.3	9.0	3.4	5.2

Source: OECD, 2014b.
Note: admission-based rates (same hospital) per 100 000 population aged 45 and over.

Table 7.8
Key indicators of patient safety, Italy and OECD average, 2009

	Secondary diagnosis-adjusted standardized rates		Age and sex-standardized rates	
	Italy	OECD average	Italy	OECD average
Foreign body left in during surgical procedure	3.3	5.7	2.0	5.7
Postoperative pulmonary embolism or deep vein thrombosis	536	631	215	631
Accidental puncture or laceration	114	220	13[a]	219
Obstetric trauma for vaginal delivery with instrument	2.78[b]	5.50[b]	n.a.	n.a.
Obstetric trauma for vaginal delivery without instrument	0.74[b]	1.61[b]	n.a.	n.a.

Source: OECD, 2014b.
Notes: rates per 100 000 hospital discharges; n.a., data not available; [a]The average number of secondary diagnoses is <1.5; [b]crude rates.

7.4.3 Equity of outcomes

In 2011, life expectancy was estimated at 79.4 years for men and 84.5 years for women (ISTAT, 2012b). Overall, life expectancy at birth (across both genders) was the second highest in Europe, after Switzerland. Over the last decade, the difference between genders in favour of women has been decreasing, with the advantage for women down to 5.1 years from 5.8 years in 2001. Geographically, central and northern Italy have a higher life expectancy than southern Italy, and also perform better in indicators of quality of life such as healthy life expectancy and life expectancy with no physical limitations in daily life (ISTAT/Cnel, 2013).

Mortality in Italy is significantly higher among those with a lower education level, the most common proxy of socioeconomic position. According to data from cohorts followed from 1999 to 2007 and 2011, the most disadvantaged subset of the population are women aged between 24 and 64 with the lowest education level, whose mortality rate is twice as high as same-aged women with the highest education level. Moreover, the mortality rate for all cancers is twice as high in adults aged between 25 and 64 of both genders with the lowest educational level compared with the same-aged adults with the highest educational level. Comparison with similar studies in other European countries has shown that the results observed for young women are comparable to northern Europe, while those for cancer-specific mortality among adults are similar to those observed in other southern European countries (ISTAT, 2012a). Risk factors such as being overweight or obese and smoking status are also markedly associated with education level, with a disadvantage for the youngest age groups and those with lowest education (ISTAT/Cnel, 2013).

7.5 Health system efficiency

7.5.1 Allocative efficiency

Regional health-care expenditure originates from both regional taxes and transfers from central funds. The latter are distributed based on criteria that have varied significantly over the last 20 years, and that combine geographical allocation and allocation to different health services. Table 7.9 outlines the different criteria used between 1982 and 2004.

Table 7.9
National Health Fund allocation mechanisms, 1982–2004

Period	Allocation mechanisms
1982–1984	68–78% based on past expenditure
1985–1991	85–97% based on health-care utilization by age group
1992–1996	96–98% based on resident population
1997	50% based on health-care utilization by age group and need indicators; 58% based on resident population
1998–2010	64–70% based on health utilization by age group 28–33% based on resident population
2011–	59% based on capitation 41% based on age weighted capitation

The specific proportions of the annual national health-care budget have to be allocated to three levels of care: (1) prevention; (2) primary and community health care (*district care*); and (3) secondary care (*hospital care*). In 2011, for instance, these proportions were 5%, 51% and 44%, respectively.

Different formulas are used to calculate the specific amount of each of these shares for each region. In 2011, the share for prevention activities was based on regional population; the share for hospital care was based partly on absolute population and partly on absolute population weighted by age; and, within primary and community care, the funds for family medicine and other community care were based on absolute population, those for specialist care on age-weighted population, and those for pharmaceutical care on a region-specific expenditure cap related to the absolute population. As a result, 59% of total funds were assigned to regions on a pure capitation basis, while 41% was based on variable age-weighted capitation scores.

Since 2005, when it emerged that several regions suffered from severe financial deficits due to their health-care expenditure, the allocation of funds to regions has been heavily influenced by financial recovery plans (see Chapter 3), agreed upon by the central government and the regional administrations, and which set conditions for budgetary discipline.

A far-reaching change to the allocation of health-care resources to the regions was proposed in Law Decree 68/2011 but its details are still being refined (see Chapter 3). Under this new system, all regions will have to use the same set of fixed shares for the three levels of care. Moreover, the amount transferred to each region for each sector will be determined by the average costs per capita[30] reported by the three (best-performing) regions used as benchmarks in the same sector (Caruso & Dirindin, 2011).

7.5.2 Technical efficiency

While the proportion of health-care expenditure in relation to GDP in Italy and its evolution over the last two decades are in line with the other OECD countries, it is not clear whether the same applies to efficiency.

In secondary care, several cost indicators have shown a steady decrease as a result of general reforms. In the 1990s, Italy was among the countries that introduced activity-related funding for hospital care, replacing the previous system that linked reimbursements to the length of hospital stay. As a consequence, the average length of inpatient stay decreased in the late 1990s, from 7.2 days in 1997 to 6.8 days in 2001 and has remained stable ever since. In 2012 the average was still 6.8 days, despite wide interregional variation (from 5.9 days in Campania to 8.1 days in Veneto) (Ministero della Salute, 2012e). The average preoperative bed days for patients awaiting surgery also has been decreasing – it was 2 days/patient/procedure in 2006, and 1.81 days/patient/procedure in 2012 (Ministero della Salute, 2012e) – probably as a consequence of the tight goals set by the national *Health Pacts* and regions' financial recovery plans since 2006.

At the same time, the number of inpatients treated decreased from 215/1000 inhabitants/year in 2001 to 163.5/1000 inhabitants/year in 2012, with the incidence of day care cases increasing slightly from 24.5% to 26.3%, as part of a general trend to avoid hospitalization whenever possible (Ministero della Salute, 2012e). The number of hospital beds also gradually decreased, as in most other OECD countries during the same period (see Chapter 4). The

[30] Recorded in the previous two years.

regions with the highest bed-resident ratios reduced their supply faster than others – a goal that was also accomplished by reducing the number of hospitals, thereby decreasing the pre-existing interregional variation in the availability of hospital beds (Table 7.10).

Table 7.10
Distribution of hospitals and hospital beds, and medical/nonmedical health-care personnel ratio, 2002 and 2010

		2002	2010
Number of hospitals	North	481	431
	Centre	345	302
	South	552	497
	Total Italy	1 378	1 230
Hospitals/100 000 inhabitants	North	1.88	1.60
	Centre	3.16	2.60
	South	2.69	2.40
	Total Italy	2.42	2.10
Hospital beds/1 000 inhabitants	North	4.60	3.80
	Centre	4.90	3.70
	South	3.90	3.20
	Total Italy	4.40	3.60
Ratio medical/total SSN staff	North	0.14	0.14
	Centre	0.16	0.17
	South	0.18	0.20
	Total Italy	0.16	0.17

Source: elaborated from ISTAT, 2005, 2013d, 2014; Ministero della Salute, 2002, 2011b.
Notes: medical staff refers to physicians, nurses and other clinical professionals.

Despite these changes, the costs per patient treated, per service provided and per input units (e.g. costs per hospital bed) in secondary care have not decreased over the last 25 years but have actually increased and are higher than in most other OECD countries (Iuzzolino, 2011). The differences become smaller if the number of hospital admissions or output measures is used as the denominator. The best explanation available for this is the disproportionately high number of small hospitals. The median size of Italian hospitals is one-third less than those in Germany, France and Austria, and around half of UK hospitals. This could be due to small hospitals compensating for poor community health services such as home care and long-term care, especially in non-urban areas. A consequence of the high proportion of small hospitals is the high personnel density: the ratio of hospital health-care staff per hospital bed increased in Italy from 1.8 to 3.1 between 1995 and 2005, faster than in the whole OECD in the same period (from 1.8 to 2.3) (Iuzzolino, 2011). This trend might have

been emphasized by the fact that, in the context of spending cuts, hospital beds can be reduced at a faster rate than personnel. In addition, the proportion of doctors is the same in all hospitals, irrespective of their size, while in most other OECD countries it is proportional to the size of the hospital. The ratio of medical/nonmedical staff is in fact higher in southern Italy, where the density of hospitals is higher (Table 7.10). Overall, Italy has a higher proportion of doctors than most other OECD countries – 18% of the health-care workforce – compared to less than 16% in Spain and Germany and 7.4% in France and the UK. This composition of the health-care workforce increases personnel costs per hospital bed (Iuzzolino, 2011).

The data available for technical efficiency of expenditure in primary care shows a similar geographical variability. In a recent study, technical efficiency of general practice, measured by accepted outcome indicators such as vaccination coverage and avoidable hospitalization rates, was found to vary significantly across regions, with northern regions showing better results than southern ones. The reasons for this variation remain elusive and may include different combinations of spending sources (public vs private) as well as different compositions of primary care workforce (GPs, on-call primary care physicians, and paediatricians) (Pelone et al., 2012).

Since the beginning of the marketing and distribution of generic drugs in 2002, several incentive regulations have been introduced to promote them, including mandatory price reductions and pharmacy-level substitution. The proportion of generic drugs, both in terms of total pharmaceutical consumption and expenditure, has been steadily increasing over the last few years (see section 5.6.3). However, a remarkable geographical variation exists in their market penetration, which is higher in northern than southern Italy (OSMED, 2012). Differences in the pharmaceutical policies of regions do not explain this variation: for example, Puglia and Molise, southern regions with a market penetration of generic drugs that is lower than the national average, introduced a patient co-payment for branded drugs in 2002, while the Province of Trento in northern Italy, with the highest national market share of generics, has never introduced such a measure (Casula & Tragni, 2013). The cultural preferences of doctors, patients and pharmacists might play a more significant role: a 2012 study showed that 65% of citizens in northern Italy stated that they were well informed about what generic drugs are, compared to only 44% in southern Italy (Federconsumatori, 2012). Other studies suggest that the probability of GPs prescribing a generic drug follows a similar geographical pattern (Casula & Tragni, 2013).

A series of reforms enacted between 2010 and 2012 to promote the use of generics (see Chapter 2) will probably sustain the growing trend. In particular, since August 2012 it has been mandatory for GPs to write the name of the active ingredients on their prescriptions to facilitate pharmacy-level substitution. Analysis of recent data has shown that this measure has significantly boosted generic sales in the months following its enforcement, especially in southern regions (Assogenerici, 2013).

7.6 Transparency and accountability

In 2010, the Ministry of Health produced a set of guidelines to improve online communication by health-care providers (Ministero della Salute, 2011b) but a 2012 study analysing all the 245 web sites of the country's AOs and ASLs found that overall compliance was poor (Vanzetta et. al., 2012). A second study checked the web sites of 169 hospitals for compliance with the features of patient-centredness and public participation in online services set by the Euro Health Consumer Index. Web site quality appeared to be significantly variable, with better results for public hospitals than private hospitals and for providers in northern Italy than in southern Italy (De Feo, 2013).

In 2012, the first results of a permanent programme for the evaluation of health-care outcomes – *Programma Nazionale Esiti* (PNE) (see Chapter 2) – were released to the public. They referred to 2010, and included 46 clinical outcome indicators: 32 indicators for secondary care collected from 1475 private and public hospitals and 13 indicators for primary and community health care. The results show that quality of care appears to vary significantly even between providers in the same region. While no formal sanctioning or incentive system is connected to the indicators, the programme is the first to publish provider-specific outcome data in Italy, and it represents a powerful instrument for transparency, accountability and support for provider choice by patients.

Since 1995, all health-care providers, including private accredited providers, must adopt a Health Charter (*Carta dei servizi*). The charter describes how the provider ensures fair provision of services and equal access to them, how the public receives information, the standards of quality and the methods in place to evaluate and improve them, what organized forms of protection of patients' rights exist (such as complaint procedures) and how citizens can express opinions and feedback. However, the charter has been adopted sparsely and with heterogeneous features. In 2000, its diffusion was partly accelerated by a provision specifying tools for patient participation as a condition for SSN

accreditation. The Ministry of Health is working with the regions to extend this instrument and improve standards; the National Health Plan 2011–2013 acknowledged the need for further monitoring of its implementation (Ministero della Salute, 2013c).

Through Law 190/2012, the central and regional governments have adopted several actions to prevent and address corruption in public administration, including health-care services. The activities targeted against corruption complement other recent measures dealing with transparency (e.g. the duty of hospitals and ASLs to update waiting times for ambulatory visits and hospital admissions), to ensure openness, transparency and public disclosure of information (including by health-care delivery).

8. Conclusions

Overall performance

In 2000 WHO ranked the Italian health-care system very highly due to high attainment scores in all the dimensions considered, namely health of the population, equity of finance and sensitivity to patients' expectations (WHO, 2000). These attainments were achieved with expenditure levels that were significantly lower than in many other affluent countries. The last 15 years have not been easy for Italy as the economy has been stagnant, public debt has risen and political institutions have shown structural deficiencies. But despite this rather unfavourable general scenario, the SSN is still universal, funded by general taxation, with limited co-payments and provides free access to primary care, specialized care and a variety of other public health and preventive services. Reforms have been recurrent, and despite the very difficult times for the country, the SSN appears to be rather healthy and is sufficiently valued by citizens, even though more scepticism has been manifested since the start of the economic, financial and fiscal crisis. No radical or major reforms are on the agenda.

The last five years

In the last five years the SSN has been targeted by a number of policies aimed at containing or even reducing health expenditure without reducing the provision of health services to patients. To a certain extent, these policies have been effective as expenditure is now under strict control and industrial relations within the SSN have not worsened. However, citizens' perception of the quality of services has declined slightly. Overall, the SSN is clearly strained due to the long period of cost cutbacks and there are clear signals that the economic crisis has worsened some health outcome indicators and increased demand for a variety of services. With some very specific exceptions (e.g. lower number of traffic and work injuries), the crisis has generated a double burden for the

health-care system: it has increased demand for health care and at the same time has reduced available resources due to fiscal constraints. Given current financial constraints, waiting times are on the rise and continuity of care and intermediate care for chronic diseases is increasingly difficult to ensure. While so far the SSN has been able to cope with the crisis, it is unlikely that it can keep on offering the present level of services if resources are reduced further. While efficiency improvements are always possible, it is unlikely that further cuts can be made without reducing the quantity and quality of care provided to patients.

Too much regional heterogeneity

The rich supply of indicators on the performance of regional health-care systems clearly shows that the SSN is fragmented into 21 different systems. The Italian health system is highly decentralized, with most organizational powers governed by regions and rather limited powers at national level. The state has full control over the definition of the benefit package (LEA) but there is evidence that the actual provision of these services varies greatly across regions as shown by the significant flows of patients moving from the south-central regions to central-northern ones in order to obtain care. The decentralization of the health system has allowed the stronger northern and central regions to design their own models and to fully exploit higher degrees of autonomy obtained over the last 20 years. Interestingly, these regions have followed rather different pathways, without contradicting the basic principles of the SSN, and thus they have designed rather different regional SSN models. This diversification suggests that there may be different ways to shape a universal tax-funded national health system and that important variants may be generated by different environmental factors, even within a single nation. The most salient issue with the Italian decentralization process is that it benefitted much less (if not even harmed) the southern regions of the country. Once the role of the central state was weakened, these regions, having to rely only on their own institutional capacities, found that these capacities were inadequate to cope with the new challenging tasks of governing their health-care systems. The result is a widening gap between the southern and the northern parts of the country that is mainly attributable to the lower quality of the political, managerial and professional capacities available in the southern regions.

The future

The future of the health-care system mainly depends on the future of the country's economy. If Italy overcomes the structural crisis and starts growing, cost-containment measures can be relaxed and the SSN can receive enough resources to meet the expectations of high quality and universal coverage. Overall, compared to other European countries, the SSN is already rather parsimonious; thus, longer periods of hard cost-containment policies may harm the delivery system and may induce popular calls for change.

To deal with these serious fiscal constraints, the SSN may benefit from a better definition of the specific content of the benefit package it guarantees to citizens (mainly a more detailed definition of the LEA). A narrower definition of the SSN benefit package may help to concentrate resources in the most effective and cost-effective areas, maintain high quality in these essential services and, at the same time, provide space for complementary insurance schemes.

Moving to the way the system is organized and services are delivered, three main issues deserve to be highlighted. The first concerns the relationship between politics and top management. The 1992/93 reforms limited the role of professional politicians in running SSN organizations and promoted the role of general managers. Indeed SSN organizations have experienced increasing professionalism at management level. Nevertheless, the appointment of general managers, health directors and administrative directors still appears to be mainly driven by local and political considerations. Interestingly, as general managers in the SSN tend to work almost exclusively in their region of residency, a national market for general managers has yet to materialize. Appointments based on political affiliation and without adequate consideration of professional qualities are frequent. These appointments limit the potential of general management as it makes it very difficult to manage ambitious tasks such as the closure of small hospitals, the development of new integrated systems of care or the redesign of hospitals.

A second major issue concerns primary care, which in Italy is still mainly based on solo-practice GPs or general paediatricians. This part of the SSN has been only modestly addressed by reforms and policy initiatives, mainly aimed at promoting its organizational development based on GPs, paediatricians, nurses and other professionals working together in primary care teams. There is wide agreement that such models should be widely adopted. However, they require substantial changes that need to be well promoted, incentivized and managed. It is unlikely that new legislation will suffice to make these changes

happen on the ground, also due to the lack of fresh resources to motivate professionals. More likely, regions and ASLs, adequately supported by regional and national frameworks, will be the key actors to manage changes in order to make primary care more inter-professional and collaborative than it is now. But again, different institutional and managerial capacities may result in very heterogeneous solutions across regions.

A third major issue concerns integration, de-integration and re-integration. Originally, the SSN was designed to be a very integrated system with virtually all services under the control of Local Health Units (the former name of the ASLs). Partly due to the attempt to promote a quasi-market, partly due to the desire to better recognize the role of private providers and partly because the idea of the purchaser–provider split inspired Italian policy making, from the mid-1990s the SSN was partly de-integrated, mainly by making hospitals independent of ASLs. Currently, however, most regional policies seem to have returned to integration, namely through the re-attribution of some hospitals to ASLs, the concentration of purchasing activities in regional or supra-organizational entities and the enlargement of the size of ASLs. In addition, most regions have strengthened control over their providers. Overall, in the last 10 years regional authorities have increased their grip over provider organizations, which in turn, have lost most of their organizational autonomy. This trend towards re-integration is probably due to the general conditions of austerity and the search for savings. But at the same time, it is also due to the search for better integrated care pathways that can overcome barriers deriving from the involvement of different organizations in treating the same case. It is clear that patients increasingly need a variety of providers working in a co-ordinated way and that such co-ordination is essential to ensure quality of care as well as cost-containment. But how to experiment, evaluate and disseminate good practices in this respect is more an issue of policy design developed from the bottom, rather than the results of top-down policies that reduce the number of SSN organizations by making them larger.

9. Appendices

9.1 References

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9.2 Principal legislation

Laws

Law 833/1978 Establishment of the National Health Service

Law 210/1992. Compensation for those harmed by irreversible complications due to mandatory vaccinations, blood transfusions and blood products.

Law 405/2001 as revised into the 2010–2012 Healthcare Pact (regional standard of average provision of hospital bed numbers)

Law 42/2009. Delegation to the Government on fiscal federalism, implementation of Article 119 of the Constitution.

Law 38/2010 Measures to grant access to palliative care and pain management.

Law 6/2013 Delegation to the Government for the transposition of European directives and the implementation of other European Union legislation (European delegation law 2013)

Decrees

Prime Minister's Decree, DPCM 12 October 1983. Establishment of the State-Regions Conference.

Prime Minister's Decree, DPCM 16 April 2002. Guidelines on criteria for priority access to diagnostic and therapeutic services, and waiting times.

Legislative Decree No. 502/1992. Art. 8 on free choice of GP; Art. 8, subsection 8 on free choice of provider.

Legislative Decree No. 39/1999. Palliative care and pain therapy

Legislative Decree No. 229/1999. Art. 8 on free choice of GP

Legislative Decree No. 230/1999. Reform of penal medicine, in accordance with Art. 5 of Law No. 419 of 30 November 1998

Legislative Decree No. 300/1999. Reforms on the organization of the government in accordance with Article 11 of Law No. 59, 15 March 1997 (including revisions to the functions of the Ministry of Health)

Legislative Decree No. 196/2003. Code on the protection of personal data

Legislative Decree No. 150/2009. (Brunetta Law) Implementation of Law No. 15, 4 March 2009 regarding on the optimization of public labour productivity, public sector efficiency and transparency of public administrations.

Legislative Decree No. 28/2010. Implementation of Art. 60 of Law No. 69, 18 June 2009 regarding mediation aimed at reconciling civil and commercial disputes (judicial conciliation mechanism)

Legislative Decree No.15813, September 2012, ('Balduzzi' Decree). Urgent measures to promote the development of the country through higher health protection. Coordinated with Conversion Law, No. 189, 8 November 2012.

Spending Review Decree No. 95/2012 (Art. 15) Urgent provisions for the review of public spending with no variation to services for citizens. Coordinated with Conversion Law 135/2012 .

Regional laws

Regione Emilia Romagna. Regional Law n. 29/2004. Norme generali sull'organizzazione ed il funzionamento del servizio sanitario regionale [General norms on the organization and functioning of the regional health service].

9.3 Useful web sites

National Agency for Regional Health Services:
www.agenas.it

Italian Medicines Agency (AIFA):
www.agenziafarmaco.gov.it

Ministry of Health:
www. ministerosalute.it

National Association of Pharmaceutical Companies:
www.farmindustria.it

National Association of Private Pharmacies:
www.federfarma.it

National Institute of Health:
www.iss.it

National Institute of Statistics:
www.istat.it

National Plan for Clinical Guidelines:
www.pnlg.it

9.4 HiT methodology and production process

HiTs are produced by country experts in collaboration with the Observatory's research directors and staff. They are based on a template that, revised periodically, provides detailed guidelines and specific questions, definitions, suggestions for data sources and examples needed to compile reviews. While the template offers a comprehensive set of questions, it is intended to be used in a flexible way to allow authors and editors to adapt it to their particular national context. The most recent template is available online at: http://www.euro.who.int/en/home/projects/observatory/publications/health-system-profiles-hits/hit-template-2010.

Authors draw on multiple data sources for the compilation of HiTs, ranging from national statistics, national and regional policy documents to published literature. Furthermore, international data sources may be incorporated, such as those of the OECD and the World Bank. The OECD Health Data contain over 1200 indicators for the 34 OECD countries. Data are drawn from information collected by national statistical bureaux and health ministries. The World Bank provides World Development Indicators, which also rely on official sources.

In addition to the information and data provided by the country experts, the Observatory supplies quantitative data in the form of a set of standard comparative figures for each country, drawing on the European Health for All database. The Health for All database contains more than 600 indicators defined by the WHO Regional Office for Europe for the purpose of monitoring Health in All Policies in Europe. It is updated for distribution twice a year from various sources, relying largely upon official figures provided by governments as well as health statistics collected by the technical units of the WHO Regional Office for Europe. The standard Health for All data have been officially approved by national governments. With its summer 2013 edition, the Health for All database started to take account of the enlarged EU of 28 Member States.

HiT authors are encouraged to discuss the data in the text in detail, including the standard figures prepared by the Observatory staff, especially if there are concerns about discrepancies between the data available from different sources.

A typical HiT consists of nine chapters.

1. Introduction: outlines the broader context of the health system, including geography and sociodemography, economic and political context, and population health.
2. Organization and governance: provides an overview of how the health system in the country is organized, governed, planned and regulated, as well as the historical background of the system; outlines the main actors and their decision-making powers; and describes the level of patient empowerment in the areas of information, choice, rights, complaints procedures, public participation and cross-border health care.
3. Financing: provides information on the level of expenditure and the distribution of health spending across different service areas, sources of revenue, how resources are pooled and allocated, who is covered, what benefits are covered, the extent of user charges and other out-of-pocket payments, voluntary health insurance and how providers are paid.
4. Physical and human resources: deals with the planning and distribution of capital stock and investments, infrastructure and medical equipment; the context in which information technology systems operate; and human resource input into the health system, including information on workforce trends, professional mobility, training and career paths.
5. Provision of services: concentrates on the organization and delivery of services and patient flows, addressing public health, primary care, secondary and tertiary care, day care, emergency care, pharmaceutical care, rehabilitation, long-term care, services for informal carers, palliative care, mental health care, dental care, complementary and alternative medicine, and health services for specific populations.
6. Principal health reforms: reviews reforms, policies and organizational changes; and provides an overview of future developments.
7. Assessment of the health system: provides an assessment based on the stated objectives of the health system, financial protection and equity in financing; user experience and equity of access to health care; health outcomes, health service outcomes and quality of care; health system efficiency; and transparency and accountability.
8. Conclusions: identifies key findings, highlights the lessons learned from health system changes; and summarizes remaining challenges and future prospects.
9. Appendices: includes references, useful web sites and legislation.

The quality of HiTs is of real importance since they inform policy-making and meta-analysis. HiTs are the subject of wide consultation throughout the writing and editing process, which involves multiple iterations. They are then subject to the following.

- A rigorous review process (see the following section).
- There are further efforts to ensure quality while the report is finalized that focus on copy-editing and proofreading.
- HiTs are disseminated (hard copies, electronic publication, translations and launches). The editor supports the authors throughout the production process and in close consultation with the authors ensures that all stages of the process are taken forward as effectively as possible.

One of the authors is also a member of the Observatory staff team and they are responsible for supporting the other authors throughout the writing and production process. They consult closely with each other to ensure that all stages of the process are as effective as possible and that HiTs meet the series standard and can support both national decision-making and comparisons across countries.

9.5 The review process

This consists of three stages. Initially the text of the HiT is checked, reviewed and approved by the series editors of the European Observatory. It is then sent for review to two independent academic experts, and their comments and amendments are incorporated into the text, and modifications are made accordingly. The text is then submitted to the relevant ministry of health, or appropriate authority, and policy-makers within those bodies are restricted to checking for factual errors within the HiT.

9.6 About the authors

Francesca Ferrè is a PhD candidate in Business Administration and Management at Università degli Studi di Parma and Research Fellow at the Center of Research for Health and Social Care Management (CERGAS) at Bocconi University, Milan. She is involved in several European sponsored research projects on health-care reform trends, HTA and economic evaluations. She is member of the CERGAS Observatory on Italian Healthcare Management

(OASI) that investigates the institutional arrangements, operations and policies of the Italian health-care systems. She earned a Master's double degree in Economics and Management of Public Administration from Bocconi University (Italy) and the State University of New York (SUNY) at Albany (USA). In 2013 she complemented her PhD study period with a Master of Research in Management Science at ESADE Business School (Spain).

Antonio Giulio de Belvis trained as a Medical Doctor at the Università Cattolica del Sacro Cuore in Rome, and completed postgraduate studies in Hygiene and Preventive Medicine in 2000, as well as an MSc in Epidemiology and Biostatistics in 2004. He has been Assistant Professor at the Catholic University since 2003. He was the coordinator of the university's Clinical Governance Unit in 2003–2007, the Primary Care Unit from 2008 to 2010 and from 2011 the Population Medicine Unit at the Department of Hygiene and Public Health. From 2009 to 2012 he was the Scientific Secretary of the National Observatory for the Health of the Italian Regions (OSSERVASALUTE). Since 2012 he has been the Clinical Governor of the Teaching and Research Hospital 'Agostino Gemelli' in Rome.

Luca Valerio is a PhD candidate at the Department of Public Health of the University of Amsterdam, the Netherlands. He graduated in Medicine at the Università Cattolica del Sacro Cuore in Rome where he was involved in research in health-care quality and comparative health-care systems, and worked for the European Public Health Association (EUPHA). His fields of interest are health care inequalities and population-based epidemiology of cardiovascular diseases.

Silvia Longhi was a contract researcher at the Università Cattolica del Sacro Cuore in Rome until April 2014, working as a data manager for the development and analysis of economic indicators for the National Observatory for the Health of the Italian Regions (OSSERVASALUTE). In additon to her economic background, she has developed a strong interest in health-care systems performance. She earned a Masters degree in Economics and Management of Health Care Organizations in 2005 from the Catholic University of Rome and completed her PhD in the same field in 2010.

Agnese Lazzari was a researcher at the Università Cattolica del Sacro Cuore in Rome where she worked on the development of the Research Centre for Leadership in Medicine and for the Italian Association of Medical Managers (SIMM). She has a background in Economics and Health Care Management and a PhD in Public Health Management. Her research interests are in the field of clinical governance, medical management and health-care systems. She has

been involved in various international projects and initiatives, in particular working with the Oxford Transformation Centre on the creation of value in health care.

Giovanni Fattore is full Professor and Director of the Department of Policy Analysis and Public Management at Bocconi University, Milan. He was Director of the Masters in International Healthcare Management Economics & Policy (MIHMEP) from 2002 to 2008 and is currently the Deputy Director of CERGAS (Center of Research for Health and Social Care Management). He has a degree in Economics from Bocconi University, an MSc in Health Policy and Management from Harvard University and a PhD in Social Policy from the London School of Economics and Political Science, UK. His research activities focus on health policy, applied health economics, health planning and management and economic evaluation of health-care interventions. He has worked for the OECD, WHO and the World Bank and has led several research units for projects funded by the European Commission. He is the author of approximately 100 publications in Italian or international scientific journals.

Walter Ricciardi is Professor of Hygiene and Public Health at the Università Cattolica del Sacro Cuore in Rome where he is also Director of the Department of Public Health of the Faculty of Medicine 'A. Gemelli' and Director of the local School of Public Health. In 2009 he was appointed a Board Member of the National Board of Medical Examiners of the United States of America (NBME) and in 2010 was elected President of the European Public Health Association (EUPHA) (up to 2014). In 2012 he became a Member of the WHO European Advisory Committee on Health Research (EACHR). Since May 2013 he has been a Member of the Expert Panel on effective ways of investing in Health (European Commission, DG – SANCO) and in July 2014 he was appointed Commissioner of the Italian National Institute of Health (NIH).

Anna Maresso is a Research Fellow at the European Observatory on Health Systems and Policies and Research Officer at LSE Health at the London School of Economics and Political Science. She has edited and co-authored a number of HiTs as well as other studies, including books on regulating the quality of long-term care and on the impact of the economic crisis on health systems in Europe. Anna is also the co-editor of the quarterly policy periodical *Eurohealth*. Her background is in political science, with a BA (Hons) in Government from the University of Sydney, Australia and an MSc in European Studies from the London School of Economics and Political Science, United Kingdom.

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